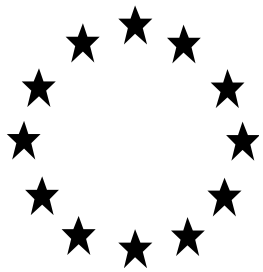
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Isopropylalkohol 70% (v/v)

Product types 1, 2, 4

Active substance: Propan-2-ol
as included in the Union list of approved active substances

Case Number in R4BP: BC-CQ025617-30

Evaluating Competent Authority: Austria

Date: 25/07/2022 (Final)

Table of Contents

1 CONCLUSION

Austria was the Competent Authority responsible for evaluation of the biocidal product Isopropylalkohol 70%(v/v). The dossier submission date 29/06/2016 is to be taken into account for relevance of (new) guidance.

The ready-to-use product Isopropylalkohol 70%(v/v) is a liquid formulation which contains 63.1% (w/w) of the active substance propan-2-ol. No substances of concern were identified.

The assessment considered:

- The conclusions and recommendations of the Assessment Report for the approval of the active substance propan-2-ol including the "elements to be taken into account by Member States when authorising products"
- The specific provisions from COMMISSION IMPLEMENTING REGULATION (EU) 2015/407 of 11 March 2015 approving propan-2-ol as an active substance for use in biocidal products for product-types 1, 2 and 4

Approval of the active substance:
The active substance propan-2-ol is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- Product type 1: The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
- Product type 2: The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
- Product type 4: The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. For biocidal products, authorisations are subject to the following conditions: (1) for products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council(3) or Regulation (EC) No 396/2005 of the European Parliament and of the Council(4) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded; (2) biocidal products containing propan-2-ol shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of propan-2-ol into food or it has been established pursuant to that Regulation that such limits are not necessary.

The fields of use are as follows:
Use # 1 – Handrub – bacteria, yeasts, enveloped viruses – professionals and non-professionals – pouring – indoor

Use # 2 – Handrub – bacteria, yeasts, enveloped viruses – non-professionals – pouring – indoor

Use # 3 – Handrub – bacteria, yeasts, enveloped viruses – professionals and non-professionals – spraying – indoor

Use # 4 – Handrub – bacteria, yeasts, enveloped viruses – non-professionals – spraying – indoor

Use # 5 – Hard surface disinfection - bacteria, yeasts, enveloped viruses – professionals and non-professionals – spraying – indoor

Use #6 – Hard surface disinfection in food processing area – bacteria, yeasts – professionals– spraying – indoor

Use #7 – Hard surface disinfection in food processing area – bacteria, yeasts – non-professionals – spraying – indoor

Identity and analytical methods were described in sufficient detail to meet the information requirements as laid down in annex III of regulation (EU) no. 528/2012. The physical-chemical properties and respective characteristics of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transport of the biocidal product.

The product is classified Flam.Liq.2, Eye Irrit.2 and STOT SE 3.

Based on the authorised use including the general directions of use and any possibly defined risk mitigation measures and provided that there will be no misuse, the following can be concluded:

- Data on the biocidal product have demonstrated sufficient efficacy against the target organisms. No resistance is expected.
- The biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups or animals, directly or through drinking water, food, feed, air, or through other indirect effects.
- Also for the environment, the risk characterisation resulted in acceptable risks for all authorised uses in all exposed environmental compartments. The assessment of secondary poisoning has shown that no adverse effects for birds and mammals are to be expected.

The product contains no active substances which are candidates for substitution.
The product has no indications for endocrine-disrupting properties.

It can be concluded that the conditions of Article 19 1)-4) and 9) of regulation (EU) no. 528/2012 are fulfilled and that the product may be authorised.

The biocidal product will be authorised for a period of 10 years in accordance with Article 17(4) of Regulation (EU) No 528/2012.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
Isopropylalkohol 70% (v/v)	RefMS (NA-APP): AT
	cMS (NA-MRP): DE, FR

[1] identifying product name from R4BP; Case no. in Austria: BC-CQ025617-30

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Aug. Hedinger GmbH & Co. KG
	Address	Heiligenwiesen 26 70327 Stuttgart Germany
Authorisation number	AT-0015774-0000	
Date of the authorisation	See authorisation letter.	
Expiry date of the authorisation	See authorisation letter.	

2.1.1.3 Manufacturer of the product

Name of manufacturer	Aug. Hedinger GmbH & Co. KG
Address of manufacturer	Heiligenwiesen 26 70327 Stuttgart Germany
Location of manufacturing sites	Heiligenwiesen 26 70327 Stuttgart Germany
	Niederlassung Sachsen-Anhalt Lange Lauchstädter Straße 47 06179 Teutschenthal Germany

2.1.1.4 Manufacturer of the active substance

Active substance	Propan-2-ol
Name of manufacturer	Shell Nederlands Chemie B.V.
Address of manufacturer	Vondelingenweg 601 3196 KK Rotterdam Netherlands
Location of manufacturing sites	Vondelingenweg 601 3196 KK Rotterdam Netherlands

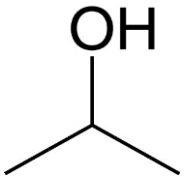
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent	
ISO name	Propan-2-ol
IUPAC or EC name	Isopropyl alcohol
EC number	200-661-7
CAS number	67-63-0
Index number in Annex VI of CLP	603-117-00-0
Minimum purity / content	99%(w/w)
Structural formula	

2.1.2.2 Candidate(s) for substitution

Not applicable.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Trade Names		**Isopropylalkohol 70%(v/v)** Isopropylalkohol 70% (V/V) API Grade/USP Isopropylalkohol 70% (V/V) G25 sterilfiltriert			
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content %(w/w)**
Propan-2-ol	Isopropyl alcohol	Active substance	67-63-0	200-661-7	63.1[1]

[1] Amount of Propan-2-ol without impurities (pure): 62.5% (w/w) based on a purity of 99%

2.1.2.4 Information on technical equivalence

Is the source of propan-2-ol the same as the one evaluated in connection with the approval for listing of the active substance on the Union list of approved active substances under Regulation (EU) No 528/2012?

Yes ☐
No ☒

The source has been subject to an assessment of technical equivalence and has been found to be **technically equivalent** based on a Tier 1 assessment (TE-APP asset number: EU-0014021-0000, Decision number: TAP-D-1208202-35-00/F).

2.1.2.5 Information on the substance(s) of concern

Not relevant, no substances of concern are contained in the biocidal product.

2.1.2.6 Type of formulation

AL – Any other liquid

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3
Hazard statement	H225 Highly flammable liquid and vapour H319 Causes serious eye irritation H336 May cause drowsiness or dizziness
Labelling	
Pictograms	 GHS02 GHS07
Signal words	Danger
Hazard statements	H225 Highly flammable liquid and vapour H319 Causes serious eye irritation H336 May cause drowsiness or dizziness
Supplemental hazard information	EUH066 Repeated exposure may cause skin dryness or cracking
Precautionary statements	P101 If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children. P103 Read carefully and follow all instructions.P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P261 Avoid breathing vapours / spray. P264 Wash hands thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P304 + P340 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a poison center or doctor if you feel unwell. P337+P313 If eye irritation persists: Get medical attention. P370+P378 In case of fire: Use alcohol-resistant foam to extinguish. P405 Store locked up. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P411+P235 Store at temperatures not exceeding 30 ºC. Keep cool. P501 Dispose of contents/container to in accordance with local and national regulations
Note	(P280 Wear eye protection/face protection.)

2.1.4 Authorised uses

2.1.4.1 Use description, use # 1

Use # 1 – Handrub – bacteria, yeasts, enveloped viruses – professionals and non-professionals – pouring – indoor

Product Type	1
Where relevant, an exact description of the authorised use	Disinfection of human skin
Target organism (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: vegetative cells Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage: not applicable
Field of use	Indoor **Field of use description:** Use # 1.1: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – professional use Use # 1.2: Hygienic handrub (PT1) by intensive care units visitors in hospitals – non-professional use
Application method(s)	Pouring: Pour the product onto hands and rub thoroughly
Application rate(s) and frequency	Application rate: 3 mL per disinfection procedure (i.e. 1/4 of the screw cap) Frequency: - Use # 1.1: 25 applications per day - Use # 1.2: 3 applications per day
Categoryies of users	Professional, non-professional
Pack sizes and packaging material	Non-professional user: Bottle (1 L, HDPE) Professional user: Bottle (1 L, HDPE) Jerry can (5 L, 10 L, HDPE)

2.1.4.2 Use-specific instructions for use

N-175 - Ready to use product for the disinfection of hands.

Apply the product only on intact human skin surface. Wash and dry your hands before using the product. Pour approximately 3 mL of the product into the hollow hand. Rub for at least 60 seconds. Application technique:

Step 1: Apply about 3 ml of disinfectant and rub into the hollow hand. Rub palm to palm to spread disinfectant over entire hands and fingers.

Step 2: Rub the back of your left hand with the palm of the right hand. Reverse and repeat action.

Step 3: Open fingers and rub the finger webs. Reverse and repeat action.

Step 4: Rub palm to palm with fingers interlocked (5 times).

Step 5: Rub thumb of each hand using a rotating movement.

Step 6: Rub the tips of the fingers against the opposite palm using circular movement. Rub wrist with both hands. Allow hands to dry completely.

Use only for children older than 6 years.

2.1.4.3 Use-specific risk mitigation measures

Use by children only under supervision of an adult.

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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2.1.4.7 Use description, use # 2

Use # 2 – Handrub – bacteria, yeasts, enveloped viruses – non-professionals – pouring – indoor

Product Type	1
Where relevant, an exact description of the authorised use	Disinfection of human skin
Target organism (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: vegetative cells Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage: not applicable
Field of use	Indoor **Field of use description:** Use #2:Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in private homes – non-professional use
Application method(s)	Pouring Pour the product onto hands and rub thoroughly
Application rate(s) and frequency	Application rate: 3 mL per disinfection procedure (i.e. 1/4 of the screw cap) Frequency: 3 applications per day
Categoryies of users	Non-professional
Pack sizes and packaging material	Bottle (1 L, HDPE)

2.1.4.8 Use-specific instructions for use

N-175 - Ready to use product for the disinfection of hands.

Apply the product only on intact human skin surface. Wash and dry your hands before using the product. Pour approximately 3 mL of the product into the hollow hand. Rub for at least 60 seconds. Application technique:

Step 1: Apply about 3 ml of disinfectant and rub into the hollow hand. Rub palm to palm to spread disinfectant over entire hands and fingers.

Step 2: Rub the back of your left hand with the palm of the right hand. Reverse and repeat action.

Step 3: Open fingers and rub the finger webs. Reverse and repeat action.

Step 4: Rub palm to palm with fingers interlocked (5 times).

Step 5: Rub thumb of each hand using a rotating movement.

Step 6: Rub the tips of the fingers against the opposite palm using circular movement. Rub wrist with both hands. Allow hands to dry completely.

N-29 Ensure adequate ventilation during the application

Use only for children older than 6 years.

2.1.4.9 Use-specific risk mitigation measures

N-220 Do not use near domestic animals.

Avoid disinfection in the presence of toddlers.

Use by children only under supervision of an adult.

2.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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2.1.4.13 Use description, use # 3

Use # 3 – Handrub – bacteria, yeasts, enveloped viruses – professionals and non-professionals – spraying – indoor

Product Type	1
Where relevant, an exact description of the authorised use	Disinfection of human skin
Target organism (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: vegetative cells Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage: not applicable
Field of use	Indoor **Field of use description:** Use # 3.1: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – professional use Use # 3.2: Hygienic handrub (PT1) by intensive care units visitors in hospitals – non-professional use
Application method(s)	Spraying Spray the product onto hands and rub thoroughly.
Application rate(s) and frequency	Application rate: 3 mL per disinfection procedure (i.e. approx. 3 spray strokes) Frequency: - Use # 3.1: 25 applications per day - Use # 3.2: 3 applications per day
Category(ies) of users	Professional, non-professional
Pack sizes and packaging material	Non-professional user: Bottle (1 L, HDPE) Professional user: Bottle (1 L, HDPE) Jerry can (5 L, 10 L, HDPE)

2.1.4.14 Use-specific instructions for use

Use the product close to the hands.

Use the product away from persons in a downward position.

N-175 - Ready to use product for the disinfection of hands.

Apply the product only on intact human skin surface. Wash and dry your hands before using the product. Spray 3 mL of the product (i.e. 3 spray strokes) onto one hand palm. Rub for at least 60 seconds. Application technique:

Step 1: Apply about 3 ml of disinfectant and rub into the hollow hand. Rub palm to palm to spread disinfectant over entire hands and fingers.

Step 2: Rub the back of your left hand with the palm of the right hand. Reverse and repeat action.

Step 3: Open fingers and rub the finger webs. Reverse and repeat action.

Step 4: Rub palm to palm with fingers interlocked (5 times).

Step 5: Rub thumb of each hand using a rotating movement.

Step 6: Rub the tips of the fingers against the opposite palm using circular movement. Rub wrist with both hands. Allow hands to dry completely.

Use only for children older than 6 years.

2.1.4.15 Use-specific risk mitigation measures

Use by children only under supervision of an adult.

2.1.4.16 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.4.17 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.4.18 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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2.1.4.19 Use description, use # 4

Use # 4 – Handrub – bacteria, yeasts, enveloped viruses – non-professionals – spraying – indoor

Product Type	1
Where relevant, an exact description of the authorised use	Disinfection of human skin
Target organism (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: vegetative cells Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage: not applicable
Field of use	Indoor **Field of use description:** Use # 4: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in private homes – non-professional use
Application method(s)	Spraying Spray the product onto hands and rub thoroughly.
Application rate(s) and frequency	Application rate: 3 mL per disinfection procedure (i.e. approx. 3 spray strokes) Frequency: 3 applications per day
Category(ies) of users	Non-professional
Pack sizes and packaging material	Bottle (1 L, HDPE)

2.1.4.20 Use-specific instructions for use

Use the product close to the hands.

Use the product away from persons in a downward position.

N-175 - Ready to use product for the disinfection of hands.

Apply the product only on intact human skin surface. Wash and dry your hands before using the product. Spray 3 mL of the product (i.e. 3 spray strokes) onto one hand palm. Rub for at least 60 seconds. Application technique:

Step 1: Apply about 3 ml of disinfectant and rub into the hollow hand. Rub palm to palm to spread disinfectant over entire hands and fingers.

Step 2: Rub the back of your left hand with the palm of the right hand. Reverse and repeat action.

Step 3: Open fingers and rub the finger webs. Reverse and repeat action.

Step 4: Rub palm to palm with fingers interlocked (5 times).

Step 5: Rub thumb of each hand using a rotating movement.

Step 6: Rub the tips of the fingers against the opposite palm using circular movement. Rub wrist with both hands. Allow hands to dry completely.

Use only for children older than 6 years.

2.1.4.21 Use-specific risk mitigation measures

N-220 Do not use near domestic animals.

Avoid disinfection in the presence of toddlers.

Use by children only under supervision of an adult.

2.1.4.22 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.4.23 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.4.24 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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2.1.4.25 Use description, use # 5

Use # 5 – Hard surface disinfection - bacteria, yeasts, enveloped viruses – professionals and non-professionals – spraying – indoor

Product Type	2
Where relevant, an exact description of the authorised use	Disinfection of surfaces which are not used for direct contact with food or feeding stuffs
Target organism (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: vegetative cells Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells Scientific name: Enveloped viruses Common name: Enveloped viruses Development stage: not applicable
Field of use	Indoor **Field of use description:** Use # 5.1: Hard surface disinfection (small surfaces), e.g. hospital – professional use Use # 5.2: Hard surface disinfection (small surfaces), e.g. working bench in laboratory, clean room, professional use Use # 5.3: Hard surface disinfection (small surfaces), e.g. in households (bathrooms) - non-professional use
Application method(s)	Spraying Low pressure spraying by hand-held trigger sprayer, followed by wiping with a dry wipe for distribution, if needed
Application rate(s) and frequency	**Application rate:** 50 mL/m² (corresponding to 25 mL/0.5 m², respectively) Discharge rate per stroke: ~ 1 mL per stroke **Frequency:** One application per disinfection procedure. - Use # 5.1: 8 applications per day - Use # 5.2: 10 applications per day - Use # 5.3: 5 applications per day
Category(ies) of users	Professional, non-professional
Pack sizes and packaging material	Non-professional user: Bottle (1 L, HDPE) Professional user: Bottle (1 L, HDPE) Jerry can (5 L, 10 L, HDPE)

2.1.4.26 Use-specific instructions for use

N-175 - Ready to use product for the disinfection of small surfaces.
N-43 - Precleaning of surfaces required before using disinfectants.

N-256 (modified) - Apply only on dry, non-porous surfaces.

Fill the undiluted product into a hand-held trigger sprayer.

N-258 - In case of an application by spraying, hold bottle upright and spray directly from a distance of 25 cm uniformly on the surface to be treated in sufficient quantity to wet the surface completely.Spray 25 spray strokes (corresponding to 25 mL) per 0.5 m².

Use the product close to the treated surface.

Use the product away from persons in a downward position.

Use the product at room temperature.

If needed, the product may be additionally distributed by wiping with a dry wipe or tissue after spraying the product onto the surface. Allow to act for 5 minutes.

Avoid the area as much as possible until the scent of the product has vanished.

When using frequently, it is recommended to wear (e.g. household) gloves.

2.1.4.27 Use-specific risk mitigation measures

N-220 Do not use near domestic animals.

Do not use for areas exceeding 0.5 m².
Do not use more than the specified number of applications per day (cf. to use frequency).

2.1.4.28 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.4.29 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.4.30 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

- - -

2.1.4.31 Use description, use # 6

Use # 6 – Hard surface disinfection in food processing area – bacteria, yeasts – professionals– spraying – indoor

Product Type	4
Where relevant, an exact description of the authorised use	Disinfection of surfaces associated with the production, transport, storage or consumption of food for humans
Target organism (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: vegetative cells Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells
Field of use	Indoor **Field of use description:** Use # 6.1: Hard surface disinfection (small surfaces), e.g. in canteens or kitchens – professional use Use # 6.2: Hard surface disinfection (small surfaces), e.g. in the food processing area – professional use
Application method(s)	Spraying Low pressure spraying by hand-held trigger sprayer, followed by wiping with a dry wipe for distribution, if needed
Application rate(s) and frequency	**Application rate:** 50 mL/m² Discharge rate per stroke: ~ 1. mL per stroke **Frequency:** One application per disinfection procedure. - Use # 6.1: 4 applications per day - Use # 6.2: 4 applications per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle (1 L, HDPE) Jerry can (5 L, 10 L, HDPE)

2.1.4.32 Use-specific instructions for use

N-175 - Ready to use product for the disinfection of small surfaces.
N-43 - Precleaning of surfaces required before using disinfectants.

N-256 (modified) - Apply only on dry, non-porous surfaces.

Fill the undiluted product into a hand-held trigger sprayer.

N-258 - In case of an application by spraying, hold bottle upright and spray directly from a distance of 25 cm uniformly on the surface to be treated in sufficient quantity to wet the surface completely.

Use the product close to the treated surface.

Use the product away from persons in a downward position.

Use the product at room temperature.Spray 50 spray strokes per m².

If needed, the product may be additionally distributed by wiping with a dry wipe or tissue after spraying the product onto the surface.

Allow to act for 5 minutes.

Avoid the area as much as possible until the scent of the product has vanished.

When using frequently, it is recommended to wear (e.g. household) gloves.

A typical size of the area to be disinfected is e.g. 1 m^2 in canteens or kitchens, 4.6 m^2 in food processing areas or 1 m^2 in kitchens in households.

2.1.4.33 Use-specific risk mitigation measures

N-57 - Do not exceed the use of 50 mL per m².

Do not use more than the specified number of applications per day (cf. to use frequency).

2.1.4.34 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.4.35 Where specific to the use, the instructions for safe disposal of the product and its packaging

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2.1.4.36 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

- - -

2.1.4.37 Use description, use # 7

Use # 7 – Hard surface disinfection in food processing area – bacteria, yeasts – non-professionals – spraying – indoor

Product Type	4
Where relevant, an exact description of the authorised use	Disinfection of surfaces associated with the production, transport, storage or consumption of food for humans
Target organism (including development stage)	Scientific name: Bacteria Common name: Bacteria Development stage: vegetative cells Scientific name: Yeasts Common name: Yeasts Development stage: vegetative cells
Field of use	Indoor **Field of use description:** Use #7: Hard surface disinfection (small surfaces), e.g. in kitchens - non-professional use
Application method(s)	Spraying Low pressure spraying by hand-held trigger sprayer, followed by wiping with a dry wipe for distribution, if needed
Application rate(s) and frequency	**Application rate:** 50 mL/m² Discharge rate per stroke: ~ 1. mL per stroke **Frequency:** One application per disinfection procedure. 1 application per day
Category(ies) of users	Non-professional
Pack sizes and packaging material	Bottle (1 L, HDPE)

2.1.4.38 Use-specific instructions for use

N-175 - Ready to use product for the disinfection of small surfaces.
N-43 - Precleaning of surfaces required before using disinfectants.

N-256 (modified) - Apply only on dry, non-porous surfaces.

Fill the undiluted product into a hand-held trigger sprayer.

N-258 - In case of an application by spraying, hold bottle upright and spray directly from a distance of 25 cm uniformly on the surface to be treated in sufficient quantity to wet the surface completely.

Use the product close to the treated surface.

Use the product away from persons in a downward position.

Use the product at room temperature.

Spray 50 spray strokes per m².

If needed, the product may be additionally distributed by wiping with a dry wipe or tissue after spraying the product onto the surface.

Allow to act for 5 minutes.

Avoid the area as much as possible until the scent of the product has vanished.

When using frequently, it is recommended to wear (e.g. household) gloves.

2.1.4.39 Use-specific risk mitigation measures

Do not use for areas exceeding 1 m² (private kitchens).

Do not use more than the specified number of applications per day (cf. to use frequency).

N-220 - Do not use near domestic animals.

Avoid disinfection in the presence of children/toddlers.

2.1.4.40 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

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2.1.4.41 Where specific to the use, the instructions for safe disposal of the product and its packaging

- - -

2.1.4.42 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

- - -

2.1.5 General directions for use

2.1.5.1 Instructions for use

N-248 - Always read the label or leaflet before use and follow all the instructions provided.

N-29 - Ensure adequate ventilation during the application.

Do not inhale vapours.

Avoid eye contact.

Do not eat, drink or smoke when using this product.
Keep containers closed when not in use.

Inform the registration holder if the treatment is ineffective.

2.1.5.2 Risk mitigation measures

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

In case the product is filled into dispensers, use only such dispensers that are capable to dose the correct amount of product.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Particulars of likely direct or indirect effects:
None.

First aid instructions:
General information
Take persons to a safe place. Observe self-protection for first aid. Take off contaminated clothing and shoes immediately. Get medical attention if symptoms occur.

If medical advice is needed, have product container or label at hand.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.

Most important symptoms and effects, both acute and delayed
Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Vapours have a narcotic effect and may cause headache, fatigue, dizziness and nausea. Coughing. Shortness of breath.

Notes for the doctor:
If ingested, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.

Emergency measures to protect the environment

N-85 -Avoid spillage of concentrates to soil, surface water or groundwater e.g. through collection pans
N-222 - Collect escaping product by means of a suitable material (e.g. earth, sand, diatomaceous earth, vermiculite, universal binding agents).
N-68 - Avoid (direct) release (of undiluted product) to the environment/sewage system.
N-133 - Do not empty into drains.
N-207 - In case of contamination of soil or water bodies notify the competent authorities.
Beware of the explosion danger.
Vapours are heavier than air and will spreadalong ground and collect in low or confined areas (sewers, basements, tanks).
Use non-sparking tools and explosion-proof equipment.
Take precautionary measures against static discharge.
Ensure electrical continuity by bonding and grounding (earthing) all equipment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents/container to a special waste collection point in accordance with local/national/international requirements.

Product residues must be collected and disposed of in accordance with the national waste disposal legislation and any regional and/or local authority requirements.

Wipes contaminated with the product / used wipes must be disposed in a closed container.

N-68 - Avoid (direct) release (of undiluted product) to the environment/sewage system.
N-133 - Do not empty into drains.
N-35 - Dilute spills with water and mop up.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Store in the original container.
Do not store at temperatures above 30°C.

Store in a well-ventilated place. Keep away from ignition sources.

Keep out of reach of children.

Shelf life: 24 months

2.1.6 Other information

Recommendation for PT2/PT4 products (professional use):
P280 Wear eye protection/face protection.

The product contains Propan-2-ol, for which an $AEC_{inhalation}$ for the professional user was agreed and used for the risk assessment of the product.

2.1.7 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Bottle	1 L	HDPE	Screw cap (HDPE or PP) or T-95-H trigger spray head (PP and LDPE)	Professional, non-professional	Yes
Jerry can[1]	5 L 10 L	HDPE	Screw cap HDPE	professional	Yes

[1] only to be used together with a dispenser that is capable of dosing the correct amount of product.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please confer to chapter 3.1 for information on data submitted on the biocidal product. For the active substance, an alternative dossier has been submitted, please cf. to chapter 2.1.8.2 for more information.

2.1.8.2 Access to documentation

A Letter of Access to the complete active substance dossier, owned by STOCKMEIER Holding GmbH, which was submitted by the ASD Consortium Alcohol for the purpose of Article 95 list inclusion is included in section 13 of the active substance IUCLID dossier. The dossier code is 015-01. The applicant, Aug. Hedinger GmbH & Co. KG, is a member of the ASD Consortium Alcohol and has full access to the complete active substance dossier.

The dossier is included in the list of alternative dossiers and has already been evaluated by DE: "The active substance dossier fulfils the requirements set out in Annex II of the BPR. DE has not identified any values in the alternative active substance dossier which are more critical compared to the values in the Assessment Report (Germany 2015 a,b,c)."

According to the document CG-17-2016-13 AP 13.1 "Evaluation of alternative dossiers during product authorisation" (ECHA 2016b) the latest LoEP, agreed by the BPC in the frame of initial or reviewed substance approval should be taken into account for the product authorisation. New available data only has to be considered if the data provided significantly alter the conclusions of the hazard or risk assessment of the active substance, which is not the case for propan-2-ol.

Therefore, the List of endpoints of the Final CAR of the approved active substance is taken into account for this assessment (cf. to Germany 2015 a,b,c)

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Use # 1 – Handrub

Product Type	1
Where relevant, an exact description of the authorised use	Use # 1.1: Hygienic handrub (PT1), e.g. in hospitals, medial practices, pharmacies, sanitary facilities of work places and industrial production areas – professional use Use #1.2: Hygienic handrub (PT1) by intensive care units visitors in hospitals – non-professional use Use # 1.3: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – non-professional use
Target organism (including development stage)	Bacteria (vegetative cells) Yeasts (vegetative cells) Enveloped viruses (development stage not applicable)
Field of use	Indoor
Application method(s)	Pouring or spraying
Application rate(s) and frequency	Amount to be applied: Hygienic handrub: 3 mL Pouring: ¼ of cap/disinfection procedure Spraying: 3 sprays per disinfection procedure Frequency: One application per disinfection procedure. - Use # 1.1: 25 applications per day (8 hour shift) - Use # 1.2: 3 applications per day - Use # 1.3: 1 applications per day
Category(ies) of users	Hygienic handrub: professional and non-professional use
Pack sizes and packaging material	Please see the relevant section.

Use # 2 – Hard surface disinfection (PT2)

Product Type	2
Where relevant, an exact description of the authorised use	Use # 2.1: Hard surface disinfection(small surfaces inPT2), e.g. working bench in laboratory, clean room, hospital – professional use Use # 2.2: Hard surface disinfection (small surfaces inPT2), e.g. in bathrooms – professional use Use # 2.3: Hard surface disinfection(small surfaces in PT2), e.g. in households - non-professional use.
Target organism (including development stage)	Bacteria (vegetative cells) Yeasts (vegetative cells)

	Enveloped viruses (development stage not applicable)
Field of use	Indoor
Application method(s)	Spraying and/or wiping
Application rate(s) and frequency	Amount to be applied: 50 mL/m² Wiping: 25 mL/ 0.5 m^2 Spraying: 25 sprays (25 mL) per 0.5 m^2 Discharge rate per stroke: ~ 1.02 ml per stroke (based on measured density:~ 0.876 g/cm^3) Spray distance and diameter: 25 cm distance and 20 cm diameter Frequency: One application per disinfection procedure. - Use # 2.1: 10 applications per day (8 hours shift) - Use # 2.2: 14 applications per day (8 hours shift) - Use # 2.3: 1 or 5 applications per day
Category(ies) of users	professional and non-professional use
Pack sizes and packaging material	Please see the relevant section.

Use # 3 – Hard surface disinfection (PT4)

Product Type	4
Where relevant, an exact description of the authorised use	Use # 3.1: Hard surface disinfection (small surfaces in PT4), e.g. in canteens or kitchens – professional use Use # 3.2: Hard surface disinfection(small surfaces inPT4), e.g. in the food processing industry – professional use Use # 3.3: Hard surface disinfection(small surfaces in PT4), e.g. in kitchens - non-professional use
Target organism (including development stage)	Bacteria (vegetative cells) Yeasts (vegetative cells)
Field of use	Indoor
Application method(s)	Spraying and/or wiping
Application rate(s) and frequency	Amount to be applied: 50 mL/m² Wiping:

	25 mL/ 0.5 m^2 50 mL/ 1 m^2 250 mL/ 5 m^2 Spraying: 25 sprays (25 mL) per 0.5 m^2 50 sprays (50 mL) per 1 m^2 Discharge rate per stroke: ~ 1.02 ml per stroke (based on measured density:~ 0.876 g/cm^3) Spray distance and diameter: 25 cm distance and 20 cm diameter Frequency: One application per disinfection procedure. - Use # 3.1: 4 applications per day (8 hour shift) - Use # 3.2: 4 applications per day (8 hour shift) - Use # 3.3: 1 application per day
Category(ies) of users	professional and non-professional use
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Test item	Results	Reference
Physical state at 20°C and 101.3 kPa	Visual inspection	Biocidal product	liquid	Anonymous 2016a
Colour at 20°C and 101.3 kPa	Visual inspection		Colourless	
Odour at 20°C and 101.3 kPa	Olfactory inspection		characteristic	
Acidity / alkalinity	Acidity: USP	Biocidal product	pH=9.3-9.5 (undiluted)	Anonymous 2016a (supplementary information)
		Biocidal product	pH=5.77 (1% dilution)	Anonymous 2018a (supplementary information)
		Active substance	pH=5.747 (1% dilution)	
	CIPAC MT 75.3		The pH value of diluted Isopropyl alcohol 70% (v/v), concentration of mixture 1%(w/v) at 23°C: pH (after 1 min) = 6.558 pH (after 2 min) = 6.510 The pH value of diluted Isopropyl alcohol 70% (v/v) batch 053781,	Anonymous 2021a (Key study)

Property	Guideline and Method	Test item	Results	Reference
			concentration of mixture 1%(w/v), is 6.5. Alkalinity: not relevant as 4< pH <10	
Relative density / bulk density	Ph. Eur. USP, in accordance with OECD 109	Biocidal product	D_{20}^{20} = 0.8771 D_{20}^{4} = 0.8760	Anonymous 2016a
Storage stability test – **accelerated storage**	-	-	As the biocidal product is classified as a flammable liquid, cat. 2, it is not recommended to store the biocidal product at temperatures above 30°C. A label phrase stating that the biocidal product must not be stored at higher temperatures will be attached to the label.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014
Storage stability test – **long term storage at ambient temperature**	-	Biocidal product	<u>IPA content (%w/w) in 1L HDPE round based bottle:</u> Start: 63.342 12 months: 63.185 (Δ=-0.25% decrease relative to start) 24 months: 63.081 (Δ= -0.41% decrease relative to start)	Anonymous 2016a

Property	Guideline and Method	Test item	Results	Reference
			Acidity (mL) in 1L HDPE round based bottle: Start: 0.13 12 months: 0.21 24 months: 0.17 IPA content (%w/w) in 1L HDPE square based bottle: Start: 63.342 12 months : 63.297 Δ=-0.07% decrease relative to start) 24 months: 63.148 Δ=-0.31% decrease relative to start) Acidity (mL) in 1L HDPE square based bottle: Start: 0.13 12 months: 0.21 24 months: 0.24 After 24 months of storage at ambient conditions (6-30°C), the test items fulfill the pass criteria for active substance content. The test item is stable during storage at room temperature for	

Property	Guideline and Method	Test item	Results	Reference
			24 months. No interaction with the packaging material was detected. The relative density of the product stayed constant over time in both packagings (0.8771). The appearance did not change. The maximum weight loss after 24 months was 0.05%	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Biocidal product	IPA content (%w/w) in 1L HDPE round based bottle: Start: 63.342 7 days: 63.237 (Δ=-0.17% decrease relative to start) IPA content (%w/w) in 1L HDPE square based bottle: Start: 63.342 7 days: 63.252 (Δ=-0.14% decrease relative to start) The test items fulfilled the requirements for active substance content acc. to LSM 053/055/057 at T0 and after 7 days.	Anonymous 2016a

Property	Guideline and Method	Test item	Results	Reference
			After 7 days of storage at low temperature (-21°C – -18°C), the test items fulfill the pass criteria for active substance content. The appearance of the product did not change during storage. The test item is stable during storage at low temperature for 7 days.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	The packaging is translucent, and thus does not provide some, but not full protection from light. A label phrase will be attached to protect the product from sunlight.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Temperature: Not applicable. As the biocidal product is classified as a flammable liquid (Cat. 2), the product should not be stored at temperatures above ambient temperature. A label phrase will be attached to indicate that the biocidal product must not be	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.

Property	Guideline and Method	Test item	Results	Reference
			stored at higher temperatures. Humidity: Since the biocidal product is a water based formulation, and since the active substance propan-2-ol is unlimitedly soluble in water and does not react with water, humidity is not expected to influence the content of active substance during storage.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	Packaging tight and in a sound condition after storage for 24 months at ambient conditions (6-30°C)	Anonymous 2016a
Wettability	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Suspensibility, spontaneity and dispersion stability	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Wet sieve analysis and dry sieve test	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A",

Property	Guideline and Method	Test item	Results	Reference
				Vers. 1.1, Nov. 2014.
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Disintegration time	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Persistent foaming	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Flowability/Pourability/Dustability	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Burning rate — smoke generators	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Burning completeness — smoke generators	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A",

Property	Guideline and Method	Test item	Results	Reference
				Vers. 1.1, Nov. 2014.
Composition of smoke — smoke generators	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Spraying pattern — aerosols	FEA 644 (analog)		The biocidal products are not applied in a manner that generates exposure to aerosols. The diameter of the spray pattern, sprayed from a distance of 25 cm, was about 20 cm. Sprayed amount per trigger sprayer operation after 12 months storage : 0.87 g – 0.90 g, with a relative standard deviation of 1.60%–2.78%. Sprayed amount per trigger sprayer operation after 24 months storage : 0.86 g–0.91 g, with a relative standard deviation of 0.73%–2.69%.	Anonymous 2016a
Other technical characteristics	-	-	Not applicable. The biocidal product is a	Data waiving according to "Guidance on the Biocidal Products

Property	Guideline and Method	Test item	Results	Reference
			ready to use liquid product. No further technical characteristics are considered relevant.	Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Physical compatibility	-	-	Not applicable. The biocidal product is a ready to use liquid product, which is not recommended to be used with other products.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Chemical compatibility	-	-	Not applicable. The biocidal product is a ready to use liquid product, which is not recommended to be used with other products.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Degree of dissolution and dilution stability	-	-	Not applicable. The biocidal product is a ready to use liquid product.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Surface tension	Ring method	Propan-2-ol in water (70%(v/v))	23.4 ± 0.02 mN/m (t=25°C)	Cheong et al., Journal of Liquid Chromatography 1987, 10, (4), 561-581.
	Wilhelmy plate principle	Propan-2-ol in water (extrapolation between 60%(w/w) and 70%(w/w))	Between 23.17-24.05 mN/m (at 20°C). Between 22.68-23.51 mN/m (at 25°C).	Vázquez et. al., J. Chem. Eng. Data 1995, 40, 611-614.
Viscosity	Capillary method	Propan-2-ol in water (extrapolation between 58.8%(w/w) and 69.0%(w/w))	3.4825 -3.7275 mPa s (at 20°C) 1.7651-1.8350 mPa s (at 40°C)	Pang et al., Proceeding of the 18th Symposium of Malaysia Chemical Engineers,

Property	Guideline and Method	Test item	Results	Reference
				2004, 1, 190-196.
	unknown	Propan-2-ol in water (70%(v/v) as read from a plot)	3.4-3.6 mPa s (at 20°C)	Kuchuk et al., Glass Physics and Chemistry, 2012, 18, 5, 460-465.

Conclusion on the physical, chemical and technical properties of the product
The biocidal product has been tested for the relevant parameters characterising its physical, chemical and technical properties. The biocidal product is stable upon storage in HDPE bottles for 24 months at ambient conditions (6-30°C), and stable upon storage in HDPE bottles for 7 days at -18 to -21°C. No interaction with the packaging material was detected.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	The biocidal product is a solution of the active substance propan-2-ol in water. As there are no chemical groups associated with explosive properties present, performing a study on explosive properties for the biocidal product is not scientifically justified, in accordance with Section 2.1.4.3 of Annex I of the CLP Regulation. Furthermore, a harmonized	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			classification for propan-2-ol already exists (Flam. Liq. 2; Eye Irrit. 2; STOT SE 3). Propan-2-ol is not classified for explosive properties.	
Flammable gases	-	-	Not applicable. The product is a water-based, liquid formulation and not gaseous.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Flammable aerosols	-	-	Not applicable. The product is not formulated as an aerosol according to the definition in Annex I of the CLP Regulation, chapter 2.3.1.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Oxidising gases	-	-	Not applicable. The product is a water-based, liquid formulation and not gaseous.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Gases under pressure	-	-	Not applicable. The product is a water-based, liquid formulation and not gaseous.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Flammable liquids	-	-	The biocidal product is a solution of the active substance propan-2-ol in water. A harmonized classification for propan-2-ol already exists	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			(Flam. Liq. 2; Eye Irrit. 2; STOT SE 3). The biocidal product contains 70%(v/v) of propan-2-ol. Based on experience, classification as Flam. Liq. 2 also applies to 70%v/v solutions of propan-2-ol. Therefore, the biocidal product has to be classified as a flammable liquid Cat. 2 and further testing is not justified.	
Flammable solids	-	-	Not applicable. The product is a water-based, liquid formulation and not a solid.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Self-reactive substances and mixtures	-	-	The biocidal product is a solution of the active substance propan-2-ol in water. No chemical groups associated with explosive or self-reactive properties are present in the product. Therefore, no testing is necessary.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Pyrophoric liquids	-	-	The biocidal product is a solution of the	Data waiving according to "Guidance on the

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			active substance propan-2-ol in water. Experience in manufacture or handling shows that propan-2-ol does not ignite spontaneously on coming into contact with air at normal temperatures. Furthermore, a harmonized classification for propan-2-ol already exists (Flam. Liq. 2; Eye Irrit. 2; STOT SE 3). Propan-2-ol is not classified for pyrophoric properties.	Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Pyrophoric solids	-	-	Not applicable. The product is a water-based, liquid formulation and not a solid.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Self-heating substances and mixtures	-	-	The biocidal product is a solution of the active substance propan-2-ol in water. A harmonized classification for propan-2-ol already exists (Flam. Liq. 2; Eye Irrit. 2; STOT SE 3). Propan-2-ol is not classified for self-	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			reactive, self-heating or auto-ignition properties.	
Substances and mixtures which in contact with water emit flammable gases	-	-	Not applicable according to Annex I, Chapter 2.12.4.1 of the CLP Regulation. The product is a solution of the active substance propan-2-ol in water. The active substance Propan-2-ol is known to be unlimitedly soluble in water to form stable mixtures.Furthermore, a harmonized classification for propan-2-ol already exists (Flam. Liq. 2; Eye Irrit. 2; STOT SE 3).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Oxidising liquids	-	-	The biocidal product is a solution of the active substance propan-2-ol in water. The molecule propan-2-ol contains an oxygen atom which is chemically bonded only to carbon and hydrogen. Thus, according to Annex I of the CLP	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Regulation, chapter 2.13.4.1, the classification procedure for the class 'oxidising liquids' does not apply.Furthermore, a harmonized classification for propan-2-ol already exists (Flam. Liq. 2; Eye Irrit. 2; STOT SE 3). Propan-2-ol is not classified for oxidising properties.	
Oxidising solids	-	-	Not applicable. The product is a water-based, liquid formulation and not a solid.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Organic peroxides	-	-	Not applicable. The biocidal product is a solution of the active substance propan-2-ol in water. Propan-2-ol does not meet the definition of an organic peroxide (see chapter 2.15.1.1 in Annex I of the CLP Regulation).	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Corrosive to metals	-	-	The biocidal product is a solution of the active substance	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A",

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			propan-2-ol in water. Based on the composition of the biocidal product and as it neither shows acidic/basic properties nor contains halogens, testing is not necessary. The product is not corrosive to metals.	Vers. 1.1, Nov. 2014.
Auto-ignition temperatures of products (liquids and gases)	-	-	The biocidal product is a solution of the active substance propan-2-ol in water. Propan-2-ol has an auto ignition temperature of 399°C to 455.6°C. These values can be considered as worst-case for the present product. Therefore, no further testing is necessary.	CRC Handbook of Chemistry and Physics (81st Ed.) Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals (14th Ed.)
Relative self-ignition temperature for solids	-	-	Not applicable. The product is a water-based, liquid formulation and not a solid.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.
Dust explosion hazard	-	-	Not applicable. The product is a water-based, liquid formulation and not a solid which may form dust.	Data waiving according to "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014.

Conclusion on the physical hazards and respective characteristics of the product
The biocidal product is a solution of the active substance propan-2-ol (70% (v/v)) in water. Its physical hazards and respective characteristics can generally be derived based on their formulation type (i.e. water-based liquid) and the intrinsic properties of the individual components. For propan-2-ol, a harmonized classification exists (Flam. Liq. 2; Eye Irrit. 2; STOT SE 3). Regarding physical hazards and respective characteristics, the biocidal product is therefore classified as a flammable liquid in cat. 2.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	GC-FID (Method MV134)*	70%, 100%, 130% 2 fold measurements	6 points Linear equation: y= 0.7073 2739 * x + 0.0003 8473 R=1	No interference	99.2 – 101.7	100.7	0.9 %	LOQ 1.400 mg/ml	Anonymous 2016j Anonymous 2016k **(Key studies)**
	*A letter of access for a direct determination method of the active substance was purchased by the applicant and submitted to RMS Austria on 27.04.2018. The method is validated according to SANCO/3030/99 rev. 4 11/07/00 and covers the direct determination of 2-propanol in the product.								
Active substance	GC-FID	10 ppm 100 ppm 250 ppm 500 ppm 750 ppm 1000 ppm (n = 6)	Correlation coefficient ≥0.995 (10 – 1000 ppm)	Complies with USP criteria (RT of active substance peak is within ± 0.2 min, run against USP system	10 – 1000 ppm (6 levels, n = 6)	100.05% – 100.07%	≤1.0% 10^{-4} %	Not relevant	Anonymous 2013a (supplementary information)

				suitability solution)					
Impurities	GC-FID		Correlation coefficient (10 – 1000 ppm)						Anonymous 2013a
Diethyl ether		10 ppm 100 ppm 1000 ppm	>0.9999	Resolution of the most critical separation was > 1.2 for each measurement, except for alpha-mesityl oxide/n-butanol in the 10 ppm standard solution (1.1)	10 – 1000 ppm (3 levels, n = 6)	97%-102%	0.6%-1.3%	LoD/ppm = 2.19 LoQ/ppm = 6.62	
Diisopropyl ether			>0.9999			97%-102%	0.5%-1.2%	LoD/ppm = 1.89 LoQ/ppm = 5.74	
Cyclohexane			>0.9999			99%-100%	0.6%-1.3%	LoD/ppm = 13.82 LoQ/ppm = 41.88	
Acetone			0.9996			88%-121%	0.5%-1.1%	LoD/ppm = 41.29 LoQ/ppm = 125.13	
Methanol			>0.9999			92%-106%	0.5%-1.5%	LoD/ppm = 4.17 LoQ/ppm = 12.62	
Methyl isobutyl ketone			>0.9999			98%-103%	0.6%-1.5%	LoD/ppm = 4.52 LoQ/ppm = 13.70	
2-Butanol			>0.9999			100%-101%	0.6%-1.3%	LoD/ppm = 6.90 LoQ/ppm = 20.90	
n-Propanol			>0.9999			96%-100%	0.6%-1.3%	LoD/ppm = 13.71 LoQ/ppm = 41.55	
beta-Mesityl oxide			>0.9999			98%-104%	0.6%-3.0%	LoD/ppm = 1.99 LoQ/ppm = 6.02	
Ethylbenzene			>0.9999			87%-101%	0.6%-1.3%	LoD/ppm = 8.24 LoQ/ppm = 24.96	

alpha-Mesityl oxide			>0.9999			96%-109%	0.6%-1.4%	LoD/ppm = 16.09 LoQ/ppm = 48.75	
n-Butanol			0.9997			92%-104%	0.6%-1.4%	LoD/ppm = 33.56 LoQ/ppm = 101.70	
Methyl isobutyl carbinol			>0.9999			99%-104%	0.6%-1.3%	LoD/ppm = 5.71 LoQ/ppm = 17.29	
Diisobutyl ketone			>0.9999			94%-116%	0.7%-1.3%	LoD/ppm = 12.97 LoQ/ppm = 39.29	
4,6-Dimethyl-2-heptanone			0.9980			88%-120%	0.6%-2.0%	LoD/ppm = 24.52 LoQ/ppm = 74.30	
Diacetone alcohol			0.9995			91%-143%	0.7%-2.8%	LoD/ppm = 51.36 LoQ/ppm = 156.21	
Water (indirect determination of active substance)	Karl-Fischer Titration	Ph. Eur. methods are validated and can be used without further validation.							Ph. Eur. (8th Ed., 2014, method 2.5.12) (Supplementary information)

Analytical methods for soil
Please refer to the CAR of the active substance Isopropanol

Analytical methods for air
Please refer to the CAR of the active substance Isopropanol. Furthermore, a method to determine propan-2-ol in air is available through ISO 16017-1:2000 "Innenraumluft, Außenluft und Luft am Arbeitsplatz - Probenahme und Analyse flüchtiger organischer Verbindungen durch Sorptionsröhrchen/thermische

Desorption/Kapillar-Gaschromatographie" which provides a lower limit of quantification of 0.5 µg/m3.

Analytical methods for water
Please refer to the CAR of the active substance Isopropanol.

Analytical methods for animal and human body fluids and tissues
Analytical methods for the determination of propan-2-ol in animal and human body fluids and tissues are not required. According to the "Guidance on the Biocidal Products Regulation, Volume I, Part A", Vers. 1.1, Nov. 2014, this data is only required if the active substance is classified as toxic or very toxic.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
Methods for analysis of residues of the active substance in food or feeding stuffs are not required for several reasons: After application of propan-2-ol as disinfectant, the active ingredient will evaporate without leaving any relevant residues. Also,short-chain alcohols are already present in low amounts in a variety of food, drinks and feeding stuffs, hence no differentiation can be made between natural occurring alcohols and minimum amounts of residues of alcohols derived from their use as disinfectant.

Conclusion on the methods for detection and identification of the product
An analytical method was provided to determine the content of the active substance in the product specifically, linearly, precisely, accurately, and reproducibly. For monitoring methods for the determination of residues in soil, air and water, please refer to the CAR of the active substance Isopropanol. Further analytical methods for the determination of propan-2-ol in animal and human body fluids and tissues as well as in food or feeding stuffs are not required.

2.2.5 Efficacy against target organisms

This chapter was evaluated according to ECHA (2018d).

2.2.5.1 Function and field of use

Use #1 to Use #4:
The biocidal product is based on the active substance propan-2-ol. The product is a ready-to-use product with an intended use concentration of 70% (v/v) propan-2-ol. The product belongs to Product Type 1 (Human hygiene biocidal products) as it shall be used for hygienic handrub by professional and non-professional users. It is applied by spraying or pouring.

Use #5:
The biocidal product is based on the active substance propan-2-ol. The product belongs to Product Type 2 (Private area and public health area disinfectants and other biocidal products) as it shall be used for hard surface disinfection. The product is a ready-to-use product with an intended use concentration of 70%(v/v) propan-2-ol. The product is intended to be used for hard surface disinfection in industry, institutions, private homes and medical areas by professional and non-professional users. It is applied by spraying.

Use #6 and Use #7:
The biocidal product is based on the active substance propan-2-ol. The product belongs to Product Type 4 (Food and Feed area and other biocidal products) as it shall be used for hard surface disinfection. The product is a ready-to-use product with an intended use concentration of 70% (v/v) propan-2-ol. The product is intended to be used for hard surface disinfection in kitchens, canteens and the food processing industry, by professional and non-professional users. It is applied by spraying.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

Use #1 to Use #4:
The biocidal product reduces the number of vegetative cells of microorganisms such as gram-positive and gram-negative bacteria as well as yeasts and enveloped viruses that occur on human skin and therefore are to be controlled with the biocidal product. The product is applied in order to increase the hygienic status. Man is indirectly protected.

Use #5:
The biocidal product reduces the number of vegetative cells of microorganisms such as gram-positive and gram-negative bacteria as well as yeasts and enveloped viruses that occur on surfaces. The product is applied in order to increase the hygienic status. Man is indirectly protected.

Use #6 and Use #7:
The biocidal product reduces the number of vegetative cells of microorganisms such as gram-positive and gram-negative bacteria as well as yeasts that occur on surfaces. The product is applied in order to increase the hygienic status. Man is indirectly protected.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Use #1 to Use #4:
The biocidal product has been shown to have a biocidal effect on bacteria and yeasts, when applied as hygienic handrub. This has been demonstrated according to the international guidelines EN 13727, EN 13624 and EN 1500. Additionally, according to EN standard

procedure DIN EN 14476, it had been shown to have a biocidal effect on the Modified Vaccinia Virus, strain Ankara. It therefore showed bactericidal, yeasticidal and virucidal activity against enveloped viruses.

Use #5:
The biocidal product has been shown to have a biocidal effect on bacteria and yeasts when applied on hard surfaces (medical area). This has been demonstrated according to the international guidelines EN 13727, EN 13624 and EN 13697. The virucidal activity of the product against enveloped viruses has been demonstrated according to EN standard procedures EN 14476 and EN 16777 with the Modified Vaccinia Virus, strain Ankara (MVA)

Use #6 and Use #7:
The biocidal product has been shown to have a biocidal effect on bacteria and yeasts when applied on hard surfaces (food and feed area). This has been demonstrated according to the international guidelines EN 1276, EN 1650 and EN 13697.

2.2.5.4 Mode of action, including time delay

Propan-2-ol exhibits an unspecific mechanism of effect. It affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm's proteins. It similarly interacts with corresponding viral structures. This process (referred to as denaturation) and the enzymes' coagulation leads to a loss of cellular activity resulting in the cell's death. [Germany 2015 a,b,c]. Due to the fast mode of action, a time delay is not relevant.

2.2.5.5 Efficacy data

Use #1 to Use #4:
The bactericidal and yeasticidal efficacy of the product was tested according to the international standards EN 13727, EN 13624 and EN 1500 under test conditions defined for hand disinfection. Laboratory studies were performed in suspension tests (EN 13727 (phase 2, step 1) and EN 13624 (phase 2, step 1)) as well as in handrub tests (EN 1500 (phase 2, step 2)). The virucidal activity against enveloped viruses was determined in suspension tests (phase 2, step 1) under obligatory test conditions according to EN14476.

The table "Experimental data on the efficacy of the biocidal product against target organism(s)" below provides an overview of the efficacy.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT01, bactericidal	Hygenic handrub	Isopropyl-alkohol 70% (v/v)	*Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Enterococcus hirae*	EN 13727 (phase 2, step 1)	Quantitative suspension test Interfering substance: 0.3 g/L bovine albumin (low level soiling conditions)	The bactericidal activity determined under obligatory test conditions according to EN 13727 was reduced by a factor of ≥5 lg (99.999%) at a minimum concentration of 80% (v/v).	Anonymous 2016b

					Test temperature: 20°C Contact time: 30 seconds Test concentrations: 10%(v/v), 50%(v/v), 80%(v/v) Reduction factor: ≥5 lg	The results comply with the requirements for hand disinfection.	
PT01, bactericidal	Hygenic handrub	Isopropyl-alkohol 70% (v/v)	*Escherichia coli*	EN 1500 (phase 2, step 2)	Quantitative surface test Interfering substance: the product is directly applied on human skin Test temperature: skin or body temperature Contact time: 30 seconds Test concentrations: 100%(v/v) Reduction factor: ≥reference product propan-2-ol (60%)	The bactericidal activity determined under obligatory test conditions according to EN 1500 showed a higher log reduction compared to the reference product propan-2-ol (60%). The results comply with the requirements for hand disinfection.	Anonymous 2016d
PT01, yeasticidal	Hygenic handrub	Isopropyl-alkohol 70% (v/v)	*Candida albicans*	EN 13624 (phase 2, step 1)	Quantitative suspension test Interfering substance: 0.3 g/L bovine albumin (low level soiling conditions) Test temperature: 20°C Contact time: 30 seconds Test concentrations:	The yeasticidal activity determined under obligatory test conditions according to EN 13624 was reduced by a factor of ≥4 lg (99.99%) at a minimum concentration of 80%(v/v). The results comply with the requirements for hand disinfection.	Anonymous 2016c

					10%(v/v), 50%(v/v), 80%(v/v) 97%(v/v) Reduction factor: ≥4 lg		
PT 01, virucidal against enveloped viruses	Hygenic handrub	Isopropyl-alkohol 70% (v/v)	Modified Vaccinia Virus, strain Ankara	EN 14476 (phase 2, step 1)	Quantitative suspension test Interfering substance: 0.3 g/l bovine albumin (low level soiling conditions) Test temperature: 20°C Contact time: 60 seconds, 120 seconds Test concentrations: 10%(v/v), 50%(v/v), 80%(v/v) Reduction factor: ≥4 lg	The virucidal activity against enveloped viruses was determined under obligatory test conditions according to EN14476 :2013+A1:2015/prA2 :2016. The results showed that the test organism was reduced by a factor of ≥4 lg (99.99%) at a minimum concentration of 80%(v/v) and a contact time of 60 seconds. The results comply with the requirements for hand disinfection.	Anonymous 2017a

Use #5:
The bactericidal and yeasticidal efficacy of the product was tested according to the international standards EN 13727, EN 13624 and EN 13697 under test conditions defined for hard surface disinfection of PT2.
Laboratory studies were performed in suspension tests (EN 13727 (phase 2, step 1) and EN 13624 (phase 2, step 1)) as well as in surface tests (EN 13697 (phase 2, step 2)).

In addition, a test on virucidal activity against enveloped viruses according to EN 14476 (P2S1) using the Modified Vaccinia Virus, strain Ankara (MVA) has been performed. The results have demonstrated a virucidal activity against enveloped viruses. The same was shown for the undiluted product, performing the phase 2, step 2 test according to EN 16777.

The table "Experimental data on the efficacy of the biocidal product against target organism(s)" below provides an overview of the efficacy.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT02, bactericidal	Hard surface disinfection	Isopropyl-alkohol 70% (v/v)	*Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae*	EN 13727 (phase 2, step 1)	Quantitative suspension test Interfering substance: 0.3 g/L bovine albumin (low level soiling conditions) Test temperature: 20°C Contact time: 5 minutes Test concentrations: 10%(v/v), 50%(v/v), 80%(v/v) Reduction factor: ≥5 lg	The bactericidal activity determined under obligatory test conditions according to EN 13727 was reduced by a factor of ≥5 lg (99.99%) at a minimum concentration of 50%(v/v). The results comply with the requirements for hard surface disinfection.	Anonymous 2016e
PT02, yeasticidal	Hard surface disinfection	Isopropyl-alkohol 70% (v/v)	*Candida albicans*	EN 13624 (phase 2, step 1)	Quantitative surface test Interfering substance: 0.3 g/L bovine albumin (low level soiling conditions) Test temperature: 20°C	The yeasticidal activity determined under obligatory test conditions according to EN 13624 was	Anonymous 2016f

					Contact time: 5 minutes Test concentrations: 10%(v/v), 50%(v/v), 80%(v/v), 97%(v/v) Reduction factor: ≥4 lg	reduced by a factor of ≥4 lg (99.99%) at a minimum concentration of 80%(v/v). The results comply with the requirements for hard surface disinfection.	
PT 02, bactericidal and yeasticidal	Hard surface disinfection	Isopropyl-alkohol 70% (v/v)	*Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Enterococcus hirae, Candida albicans*	EN 13697 (phase 2, step 2)	Quantitative surface test Interfering substance: 0.3 g/L bovine albumin (low level soiling conditions), for *P. aeruginosa*: 8.5 g/L skimmed milk (low level soiling conditions) Test temperature: 20°C Contact time: 5 minutes Test concentrations: 10%(v/v), 50%(v/v), 100%(v/v) Reduction factor: ≥4 lg (bacteria) Reduction factor: ≥3 lg (yeast)	The bactericidal and yeasticidal activity determined under obligatory test conditions according to EN 13697 was reduced by a factor of ≥4 lg (99.99%) for bacteria at a minimum concentration of 50%(v/v) and a factor of ≥3 lg (99.9%) for *C. albicans* at a minimu	Anonymous 2016g

						m concentration of 100% (v/v). The results comply with the requirements for hard surface disinfection.	
PT02, virucidal against enveloped viruses	Hard surface disinfection	Isopropyl-alkohol 70% (v/v)	Modified Vaccinia Virus, strain Ankara	EN 14476 (phase 2, step 1)	Quantitative suspension test Interfering substance: 0.3 g/L bovine albumin (low level soiling conditions) Test temperature: 20°C Contact time: 60 seconds, 120 seconds Test concentrations: 10%(v/v), 50%(v/v), 80%(v/v), Reduction factor: ≥4 lg	The virucidal activity against enveloped viruses was determined under obligatory test conditions according to EN14476:2013+A1:2015/prA2:2016. The results showed that the test organism was reduced by a factor of ≥4 lg (99.99%) at a minimum concentration of 80%(v/v) and a contact time of 60 seconds.	Anonymous 2017a

						The results comply with the requirements for hard surface disinfection.	
PT02, virucidal against enveloped viruses	Hard surface disinfection	Isopropyl-alkohol 70% (v/v)	Modified Vaccinia Virus, strain Ankara	EN 16777 (phase 2, step 2)	Quantitative surface test Interfering substance: 0.3 g/L bovine albumin (low level soiling conditions) Test temperature: 18°C–25°C Contact time: 5 minutes, 10 minutes Test concentrations: 20%(v/v), 40%(v/v), 100%(w/w) (undiluted) Reduction factor: ≥4 lg	The virucidal activity against enveloped viruses was determined under obligatory test conditions according to EN16777:2018 The results showed that the test organism was reduced by a factor of ≥4 lg (99.99%) at a minimum concentration of 100% (undiluted) product and a contact time of 5 minutes under clean conditions. The results	Anonymous 2020a

						comply with the requirements for hard surface disinfection.	

Use #6 and Use #7:
The bactericidal and yeasticidal efficacy of the product was tested according to the international standards EN 1276, EN 1650 and EN 13697 under test conditions defined for hard surface disinfection of PT4.
Laboratory studies were performed in suspension tests (EN 1276 (phase 2, step 1) and EN 1650 (phase 2, step 1)) as well as in surface tests (EN 13697 (phase 2, step 2)).

The table "Experimental data on the efficacy of the biocidal product against target organism(s)" below provides an overview of the efficacy.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT04, bactericidal	Hard surface disinfection	Isopropyl-alkohol 70% (v/v)	*Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae, Escherichia coli*	EN 1276 (phase 2, step 1)	Quantitative suspension test Interfering substance: 0.3 g/L bovine albumin (low level soiling conditions) Test temperature: 20°C Contact time: 5 minutes Test concentrations: 10%(v/v), 50%(v/v), 80%(v/v) Reduction factor: ≥5 lg	The bactericidal activity determined under obligatory test conditions according to EN 1276 was reduced by a factor of ≥5 lg (99.999 %) at a minimum concentration of 50%(v/v). The results comply with the requirements for hard surface	Anonymous 2016h

						disinfection.	
PT04, yeasticidal	Hard surface disinfection	Isopropyl-alkohol 70% (v/v)	*Candida albicans*	EN 1650 (phase 2, step 1)	Quantitative surface test Interfering substance: 0.3 g/L bovine albumin (low level soiling conditions) Test temperature: 20°C Contact time: 5 minutes Test concentrations: 10%(v/v), 50%(v/v), 80%(v/v) Reduction factor: ≥ 4 lg	The yeasticidal activity determined under obligatory test conditions according to EN 1650 was reduced by a factor of ≥4 lg (99.99%) at a minimum concentration of 50%(v/v). The results comply with the requirements for hard surface disinfection.	Anonymous 2016i
PT04, bactericidal and yeasticidal	Hard surface disinfection	Isopropyl-alkohol 70% (v/v)	*Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Enterococcus hirae, Candida albicans*	EN 13697 (phase 2, step 2)	Quantitative surface test Interfering substance: 0.3 g/L bovine albumin (low level soiling conditions), for *P. aeruginosa*: 8.5 g/L skimmed milk (low level soiling conditions) Test temperature: 20°C Contact time: 5 minutes	The bactericidal and yeasticidal activity determined under obligatory test conditions according to EN 13697 was reduced by a factor of ≥4 lg (99.99%) for bacteria at a minimum	Anonymous 2016g

					Test concentrations: 10%(v/v), 50%(v/v), 100%(v/v) Reduction factor: ≥4 lg (bacteria) Reduction factor: ≥3 lg (yeast)	concentration of 50%(v/v) and a factor of ≥3 lg (99.9%) for *C. albicans* at a minimum concentration of 100%(v/v). The results comply with the requirements for surface disinfection.	

Conclusion on the efficacy of the product

Use #1 to Use #4:

The propan-2-ol based disinfectant, Isopropylalkohol 70% (v/v) is intended to be used for hand disinfection by manual handrub.

The results showed a bactericidal and yeasticidal efficacy according to the international standards EN 13727, EN 13624 and EN 1500 under the defined test conditions.

A test on virucidal activity against enveloped viruses according to EN 14476 showed that the product is also effective against the Modified Vaccinia Virus, strain Ankara (MVA). The results have demonstrated a virucidal activity against enveloped viruses.

Use #5:

The propan-2-ol based disinfectant, Isopropylalkohol 70% (v/v) is intended to be used for surface disinfection by spraying only or, if needed, by spraying followed by wiping with a dry tissue or wipe to distribute the product more evenly on the surface.

The results showed a bactericidal and yeasticidal efficacy according to the international standards EN 13727, EN 13624 and EN 13697 under the defined test conditions. In addition, a test on virucidal activity against enveloped viruses according to EN 14476 using the Modified Vaccinia Virus, strain Ankara (MVA) has been performed. The results have demonstrated a virucidal activity against enveloped viruses.

Use #6 and Use #7:

The propan-2-ol based disinfectant, Isopropylalkohol 70% (v/v), is intended to be used for hard surface disinfection by spraying only or, if needed, by spraying followed by wiping with a dry tissue or wipe to distribute the product more evenly on the surface.

The results showed a bactericidal and yeasticidal efficacy according to the international standards EN 1276, EN 1650 and EN 13697 under the defined test conditions.

2.2.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of propan-2-ol, the development of resistance is not expected and not reported. A natural resistance against sporulated bacteria is known where propan-2-ol is ineffective at any concentration. Likewise, propan-2-ol is more effective against enveloped viruses compared to non-enveloped viruses. This is mainly due to the second layer of the enveloped viruses, which can be easily destroyed by alcoholic solutions leading to inactivation of the virus. The non-enveloped viruses have one protein-layer (capsid) which shows a pronounced natural resistance against chemical and physical disinfection methods [Germany 2015a, b, c].

2.2.5.7 Known limitations and observations on undesireable or unintended side effects

No limitations and no undesirable or unintended side-effects have been observed during the studies on the efficacy against the target organisms of the product.

2.2.5.8 Evaluation of the label claims

Use #1 to Use #4:
The label of the ready-to-use product Isopropylalkohol 70% (v/v) contains use instructions. The contact time needed for the respective use is provided on the label, in order to ensure sufficient time for the bactericidal, yeasticidal and virucidal activity against enveloped viruses. Thus, it can be concluded that a sufficient efficacy is ensured by following the use instructions on the label.

Use #5:
The label of the ready-to-use product Isopropylalkohol 70% (v/v) contains use instructions. The contact time needed for the respective use is provided on the label, in order to ensure sufficient time for the bactericidal, yeasticidal and virucidal activity against enveloped viruses under clean conditions. Thus, it can be concluded that a sufficient efficacy is ensured by following the use instructions on the label.

Use #6 and Use #7:
The label of the ready-to-use product Isopropylalkohol 70% (v/v) contains use instructions. The contact time needed for the respective use is provided on the label, in order to ensure sufficient time for the bactericidal and yeasticidal. Thus, it can be concluded that a sufficient efficacy is ensured by following the use instructions on the label.

2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

Not applicable. The product is not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not corrosive or irritating to skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product *Isopropylalkohol 70% (v/v).*
Classification of the product according to CLP and DSD	No classification required. Supplemental hazard statement: EUH066 (Repeated exposure may cause skin dryness or cracking)

Data waiving	
Information requirement	Annex III of BPR, point 8.1 "Skin corrosion or skin irritation".
Justification	Studies on potential skin corrosive or skin irritating properties of the biocidal product *Isopropylalkohol 70% (v/v)* are not required. According to Annex III, Title 1, point 8.1. of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.1 "Skin corrosion or skin irritation" of ECHA 2018c, "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." According to the CLP principles, the biocidal product *Isopropylalkohol 70% (v/v)* does not need to be classified with respect to local effects on the skin. However, according to the third party dossier for propan-2-ol local skin reactions have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions. According to these observations an appropriate labelling is indicated.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causing eye irritation.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product *Isopropylalkohol 70% (v/v).*
Classification of the product according to CLP and DSD	Eye Irrit. 2, H319 Causes serious eye irritation

Data waiving	
Information requirement	Annex III of BPR, point 8.2 "Eye irritation".
Justification	Studies on potential eye damaging or eye irritating properties of the biocidal product *Isopropylalkohol 70% (v/v)* are not required. According to Annex III, Title 1, point 8.2. of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.2 "Eye irritation" of ECHA 2018c, "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." According to the CLP principles, the biocidal product *Isopropylalkohol 70% (v/v)* needs to be classified with respect to local effects on the eyes, with Eye Irrit. 2, H319 Causes serious eye irritation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Based on intrinsic properties of individual components of the biocidal product *Isopropylalkohol 70% (v/v).*
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.7.1, "other endpoints"
Justification	There are no testing requirements for respiratory irritation under the BPR. Studies on potential respiratory tract irritation properties of the biocidal product *Isopropylalkohol 70% (v/v)* are not required. There are no testing requirements for respiratory irritation under the BPR (see point "Respiratory irritation" under chapter II, section 2.1.2. "Eye irritation" of ECHA 2018c. Nevertheless, Annex I, chapter 3.8.3.4.5 of Regulation (EC) No 1272/2008 (CLP) allows for extrapolation of the toxicity of a mixture that contains substances classified with respect to specific target organ toxicity after single exposure category 3 (STOT SE, Cat. 3; H335) based on valid data on all components in the mixtures classified with STOT SE, Cat. 3; H336: May cause drowsiness or dizziness. According to the CLP principles, the biocidal product *Isopropylalkohol 70% (v/v)* does not need to be classified with respect to respiratory tract irritation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to skin.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product *Isopropylalkohol 70% (v/v).*
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.3 "Skin sensitisation".
Justification	Studies on potential skin sensitization properties of the biocidal product *Isopropylalkohol 70% (v/v)* are not required. According to Annex III, Title 1, point 8.3. of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.3. "Skin sensitization" of ECHA 2018c, "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." According to the CLP principles, the biocidal product *Isopropylalkohol 70% (v/v)* does not need to be classified with respect to skin sensitization.

Respiratory sensitisation (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product *Isopropylalkohol 70% (v/v).*
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.4 "Respiratory sensitisation" (ADS)
Justification	Currently no standard tests and no OECD test guidelines are available for respiratory sensitisation. Studies on potential respiratory sensitization properties of the biocidal product *Isopropylalkohol 70% (v/v)* are not required. According to Annex III, Title 1, point 8.4. of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.4. "Respiratory sensitisation" of ECHA 2018c, "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." According to the CLP principles, the biocidal product *Isopropylalkohol 70% (v/v)* does not need to be classified with respect to respiratory sensitisation.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not acutely toxic via the oral route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal product *Isopropylalkohol 70% (v/v).*
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.1 "Acute toxicity by oral route"
Justification	Studies on the potential acute oral toxicity of the biocidal product *Isopropylalkohol 70% (v/v)* are not required. According to Annex III, Title 1, point 8.5.1. of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.5. "Acute toxicity" of ECHA 2018c, "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." According to the CLP principles, the biocidal product *Isopropylalkohol 70% (v/v)* does not need to be classified with respect to acute oral toxicity.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic via the inhalation route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal product *Isopropylalkohol 70% (v/v).*
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.2 "Acute toxicity by inhalation"
Justification	Studies on the potential acute inhalation toxicity of the biocidal product *Isopropylalkohol 70% (v/v)* are not required. According to Annex III, Title 1, point 8.5.2. of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.5 "Acute toxicity" of ECHA 2018c, "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." According to the CLP principles, the biocidal product *Isopropylalkohol 70% (v/v)* does not need to be classified with respect to acute inhalation toxicity.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic via the dermal route.
Justification for the selected value	Based on intrinsic properties of individual components of the biocidal product *Isopropylalkohol 70% (v/v).*
Classification of the product according to CLP and DSD	No classification required.

Data waiving	
Information requirement	Annex III of BPR, point 8.5.3 "Acute toxicity by dermal route"
Justification	Studies on the potential acute dermal toxicity of the biocidal product *Isopropylalkohol 70% (v/v)* are not required. According to Annex III, Title 1, point 8.5.3. of the BPR (Regulation (EU) 528/2012) and chapter III, section 3.1.5. "Acute toxicity" of ECHA 2018c, "testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected." According to the CLP principles, the biocidal product *Isopropylalkohol 70% (v/v)* does not need to be classified with respect to acute dermal toxicity.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Propan-2-ol
Value(s)	Transdermal flux: 0.85 mg/cm^2/h
Justification for the selected value(s)	In the propan-2-ol Assessment Reports (AR) for PT1, 2 and 4 (PT1, 2, 4; Germany 2015a, b, c, p.12), it is proposed to use a dermal absorption (transdermal flux) rate of 0.85 mg/cm^2/h for risk characterization of propan-2-ol.

Data waiving	
Information requirement	Annex III of BPR, point 8.6 "Dermal absorption"
Justification	Studies on the dermal absorption of propan-2-ol from *Isopropylalkohol 70% (v/v)* are not required. According to chapter III, section 3.1.6. "Information on dermal absorption" of ECHA 2018c, dermal absorption can be estimated by extrapolation of experimental data obtained with a similar formulation. For the biocidal product *Isopropylalkohol 70% (v/v)*, dermal absorption can be assessed by read-across to a dermal absorption study evaluated in the context of the active substance dossier on propan-2-ol (Boatman et al. 1998, for details see AR of propan-2-ol (PT 1, 2, 4; Germany 2015a, b, c). This study has been performed with a 70% (w/w) propan-2-ol in aqueous solution under occlusive conditions and a dermal absorption (transdermal flux) rate of 0.85 mg/cm^2/h derived for this product. Since the composition of *Isopropylalkohol 70% (v/v)* is similar to the tested product reported in the AR of propan-2-ol (PT 1, 2, 4; Germany 2015a, b, c, p. 12), the dermal absorption (transdermal flux) rate of 0.85 mg/cm^2/h is used throughout the human health exposure and risk assessment. The biocidal product does not contain any other coformulants which are likely to cause higher surfactant or solvent properties of the product compared to the tested active substance of the assessment report. This indicates that propan-2-ol is likely to be the most capable ingredient in the formulation affecting dermal penetration. Due to the fast evaporating properties of the active substance it can be assumed that steady state conditions on the skin which would provide the transdermal flux won't be reached.

Available toxicological data relating to

Other endpoints

According to the CLP principles, the biocidal product *Isopropylalkohol 70% (v/v)* needs to be classified with respect to specific target organ toxicity — single exposure, category 3, with STOT SE, H336: May cause drowsiness or dizziness, based on the high active substance concentration in the biocidal product (> 60%).

STO SE 3, H336 classicication is required for the biocidal product, since the content of the active substance is higher as the recommended generic concentration limit of 20%.

Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

No substances of concern (SoCs) have been identified for the biocidal product *Isopropylalkohol 70% (v/v)*.

Available toxicological data relating to a mixture

The biocidal product does not contain mixtures that a substance of concern is a component of.

Other

Food and feedingstuffs studies

Food and feedingstuffs studies in livestock animals are not required as the biocidal product is not intended for applications where contact with feedingstuffs may arise. Consequently, the transfer of potential residues of the biocidal products to food of animal origin *via* feedingstuffs is not relevant.

Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product

In line with the AR of propan-2-ol (PT1, 2, 4; Germany 2015a, b, c; p. 27/p. 28), residues in food or feed from intended use of propan-2-ol biocidal products in PT2 and PT4 are not expected, as no direct or indirect contact with food or feed is intended. For further Information please refer to chapter 2.2.8.2. ‘Dietary exposure’.

Other test(s) related to the exposure to humans

Other tests related to the exposure of humans are not required for the biocidal product.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a	Yes	Yes	n.a	Yes	Yes	No
Dermal	n.a	Yes	Yes	n.a	No	No	No
Oral	n.a	No	No	n.a	No	No	No

Explanatory note:

The exposure assessments are based on model calculations using generic models, models and default values from the Biocides Human Health Exposure Methodology (vers. 1, October 2015), HEAdhoc recommendations and HEEG opinions. Justifications for deviations from the CAR (Germany 2015 a,b,c) are provided in the respective description of the scenarios, e.g. in cases where detailed applicant information is available.

Exposure assessments are performed for all individual scenarios (uses including sub-uses) which are relevant for PT01/PT02 and PT04 (see table "List of scenarios" below) considering the relevant propan-2-ol concentration.

List of scenarios

Summary table: scenarios			
Scenario / Use #	**Scenario** (e.g. mixing/loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
[1]	PT1: Refilling of bottles (primary exposure)	Primary exposure: The RTU product is transfered from a large packaging into a container with a suitable dosing head. (PT1)	Professionals
[2]	PT1: Hand disinfection by hand rub in hospital room (application method: pouring / spraying)	Primary exposure: The RTU product is applied on cleaned and dried hands, then hands are rubbed intensively. The disinfectant is left on the skin until it evaporates completely. (PT1)	Professionals (professional bystander covered)
[3]	PT1: Hand disinfection by hand rub in hospital room (application method: pouring / spraying)	Secondary exposure: Inhalation exposure of professional bystanders in rooms where hygienic hand disinfection is performed according to scenario [2].	General public (patients toddler)
[4]	PT1: Hand disinfection by hand rub at intensive care units (application method: pouring / spraying)	Primary exposure: The RTU product is applied on cleaned and dried hands, then hands are rubbed intensively. The disinfectant is left on the skin until it evaporates completely. (PT1)	Non-professionals (Child)
[5]	PT1: Hand disinfection by hand rub at home for dialysis (application method: pouring / spraying)	Primary exposure: The RTU product is applied on cleaned and dried hands, then hands are rubbed intensively. The disinfectant is left on the skin until it evaporates completely. (PT1)	Non-professionals (child)
[6]	PT1: Hand disinfection by hand rub at home for dialysis (application method: pouring / spraying)	Secondary exposure: Inhalation exposure of non-professional bystanders in rooms where hygienic hand disinfection is performed according to scenario [5].	General public (toddler)
[7]	PT 2/4: Refilling of bottles (primary exposure)	Primary exposure: The RTU product is transfered from a large packaging into a container with a suitable dosing head. (PT2)	Professionals
[8]	PT2: Hard surface disinfection of small surfaces in hospitals (application method: spraying/wiping)	Primary exposure: The RTU product is either sprayed onto a surface and left to dry, or a (paper) tissue is wetted with the product (by pouring or spraying) and the surface is wiped and left to dry. (PT2)	Professionals (professional bystander covered)

Scenario / Use #	**Scenario** (e.g. mixing/loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
[9]	PT2: Hard surface disinfection of small surfaces in hospitals (application method: spraying/wiping)	Secondary exposure: Inhalation exposure of Non-professional bystander after surface disinfection according to scenario [8].	General public (Patients, toddler)
[10]	PT2: Hard surface disinfection (small surfaces in PT2), e.g. in bathrooms – professional use (primary exposure) - spraying and/or wiping	Primary exposure: The RTU product is either sprayed onto a surface (and maybe wiped over) and left to dry, or a (paper) tissue is wetted with the product (by pouring or spraying) and the surface is wiped and left to dry. (PT2)	Professionals
[11]	PT2: Hard surface disinfection of small surfaces in laboratory/clean room (application method: spraying/wiping)	Primary exposure: The RTU product is either sprayed onto a surface and left to dry, or a (paper) tissue is wetted with the product (by pouring or spraying) and the surface is wiped and left to dry. (PT2)	Professionals (professional bystander covered)
[12]	PT2: Hard surface disinfection of small surfaces in private bathroom (application method: spraying/wiping)	Primary exposure: The RTU product is either sprayed onto a surface and left to dry, or a (paper) tissue is wetted with the product (by pouring or spraying) and the surface is wiped and left to dry. (PT2)	Non-professionals
[13]	PT2: Hard surface disinfection of small surfaces in private bathroom (application method: spraying/wiping)	Secondary exposure: Inhalation exposure of non-professional bystander after surface disinfection according to scenario [12] .	General public (toddler)
[14]	PT4: Hard surface disinfection of small surfaces in canteens or kitchens (application method: spraying/wiping)	Primary exposure: The RTU product is sprayed onto a surface and left to dry, or a (paper) tissue is wetted with the product (by pouring or spraying) and the surface is wiped and left to dry. (PT4)	Professionals (professional bystander covered)
[15]	PT4: Hard surface disinfection of small surfaces in food processing industry (application method: spraying/wiping)	Primary exposure: The RTU product is sprayed onto a surface and left to dry, or a (paper) tissue is wetted with the product (by pouring or spraying) and the surface is wiped and left to dry. (PT4)	Professionals (professional bystander covered)
Scenario / Use #	**Scenario** (e.g. mixing/loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)

[16]	PT4: Hard surface disinfection of small surfaces in private kitchen (application method: spraying/wiping)	Primary exposure: The RTU product is sprayed onto a surface and left to dry, or a (paper) tissue is wetted with the product (by pouring or spraying) and the surface is wiped and left to dry. (PT4)	Non-professionals
[17]	PT4: Hard surface disinfection of small surfaces in private kitchen (application method: spraying/wiping)	Secondary exposure: Inhalation exposure of non-professional bystander (children) after surface disinfection according to scenario [18].	General public (children)

Industrial exposure

For the biocidal product "Isopropylalkohol 70% (v/v)", no industrial applications are intended by the applicant.

Professional and/or non-professional exposure

2.2.6.2.1 Scenario [1]: Refilling of bottles (primary exposure)

Description of Scenario [1]: Refilling of bottles (primary exposure)
Applicant's statement: "In general, 150 mL–1000 mL bottles are not intended for refilling. However, according to the applicant's experience most users do not pour the product directly from the original packaging into their hands, but transfer the product into a container with a suitable dosing head." Hence, a refilling scenario is considered accordingly. This scenario is however covered by the loading scenario as added for jerry cans sized 2–10 L in the PT2 section below. For details on the used model and relevant input parameters please refer to scenario [7] in section 2.2.8.4.

Calculations for Scenario [1]: *Refilling of bottles (primary exposure)*

As the potential refilling step is relevant for the combined exposure, results from scenario [7] are also presented here for the sake of clarity.
The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[7]	Tier 1 / None	not relevant	0.00099	0.005	0.006

Further information and considerations on scenario [1]: *Refilling of bottles (primary exposure)*

No further information and considerations on scenario [1] are relevant.

2.2.6.2.2 Scenario [2]: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – professional use (primary exposure)

Description of Scenario [2]: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – professional use (primary exposure)
On previously cleaned and dried hands, 3 mL of the biocidal product are applied to the hand (either by pouring into the screwing cap (1/4 of the cap corrsensponds to 3 mL) or by spraying (3 strokes)). (Follow application technique as given in the use instructions). The complete surface of both hands is moistened and let to dry. According to the HEAdhoc recommendation no. 9 and 1, 25 hand disinfections are performed during an 8 h-shift. Dermal exposure: To assess dermal exposure, a generic model considering the transdermal flux (0.85 mg/cm^2/h) is used. The total exposure duration for one hand disinfection depends on the evaporation time of 3 mL disinfectant at 30°C body temperature (i.e. 1.61 min). Inhalation exposure (vapour): To assess the inhalation exposure to vapour, the air concentration of propan-2-ol is calculated with Tier 1 approach according to HEadHoc recommend. 9 with ConsExpoWeb (Inhalation model; exposure to vapour: instantenous release. Therefore it is assumed that a health care worker performs 25 hand disinfection per daily shift. For worst case scenario is presumed that the desinfections are done in one single room consecutetively without break. Since combined scenario calculation led to a refinement of the modell Tier 2 was calculated according to HeadHoc recommend.9 with ConsExpo Web (Inhalation model, exposure to vapour: constant rate) for one application. Since propan-2-ol is volatile, it evaporates completely during the application. Consequently, the input parameter "release duration" in ConsExpo is triggered by the evaporation time of the applied propan-2-ol amount (1.61 min for 3 mL at 30°C), whereas the "exposure duration" is triggered by the total time the nurse stays in the room (during and after disinfection, i.e. 10 min). The air concentration of propan-2-ol has its maximum shortly after complete evaporation and then declines due to the air exchange in the room. During this decline phase the second hand rub is performed. Therefore, the air concentration released by the second hand disinfection is increased by the remaining air concentration from the first application. This is done in Excel after exporting data from ConsExpo for one hand rub (see Excel file from HEAdhoc recommendation no. 9, Annex 2). The third hand rub, performed in the same room, is calculated in the same manner. After 240 min, the nurse enters again the first patient room and performs 3 new hand disinfections. The remaining air concentration in this room after 240 min has to be considered for the calculations of the subsequent applications.

The resulting air concentration for 3 hand disinfections in 4 different rooms (under consideration of the remaining air concentration) corresponds to the 8 h time weighted-average (8 h-TWA). As the nurse is identified to be the worst case professional bystander as e.g. doctors, who visit patients during the shift in every 4 rooms are covered by this scenario.

Inhalation exposure (aerosol): not considered relevant, based on the intrinsic properties of propan-2-ol and the application method. Propan-2-ol has a vapour pressure > 1 x 10-2 Pa at 20°C. According to ECHA (2020) (HEAdHoc recommend 6 footnote 1 page 48) the high vapour pressure of the very volatile substance Propan-2-ol as well as the form of spraying device shows that the formation of aerosol is negligible for inhalative exposure calculation (please cf. to ECHA (2018a) for harmonised calculation for inhalative exposure for trigger spray application). The product is intended to be handled away from the body close to the hand or surface which should be in contact. As Propanol has a higher molecular weight compared to ambient air it is expected that droplets sink immediately. Nevertheless the exposure assessment calculations are performed very conservative: It is assumed that 100% of the substance will be inhaled by the consumer by vapour, taking into account 100% inhalative absorption. Therefore the total amount of substance is assumed to be systemically taken up.

	Parameters	**Value**
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Adults: 60 kg
	Inhalation rate[3] (shortterm)	Adults: 1.25 m^3/h (~0.021 m^3/min)
	Dermal absorption [transdermal flux][6]	0.85 mg/cm^2/h
	Frequency of application[4]	25 times
	Exposure duration[4] (dermal value calculated acc. to HEAdhoc recommendation no.9)	25 x 1 min (inhalative) 1.04 min (dermal)
	Area in contact with disinfectant[3,5]	820 cm^2 (both hands)
	Room volume[4]	80 m^3
	Ventilation rate[4]	1.5/h
	Applied product amount[4]	3 mL (= 2.63 g)
	Vapour pressure (25°C)[7]	5780 Pa
	Release duration[4] (calculated acc. to calculated in ConsExpo Web acc. to HEAdhoc recommendation no.9)	1.04 min
Tier 2	Frequency of application[4]	25 times per 8 h-shift
	Exposure duration[4] (dermal value calculated in ConsExpo Web acc. to HEAdhoc recommendation no.9)	1.04 min (dermal) 10 min (inhalation)

[1] Please refer to section 2.1.2.1 of this document
[2] Please refer to section 2.2.2 of this document
[3] ECHA 2017, Recommendation No. 14
[4] ECHA 2016a, Recommendation No. 9
[5] ECHA 2015a, page 15, Table 1
[6] Germany 2015a, chapter 3, page 46
[7] Germany 2015a, chapter 1, page 43

Calculations for Scenario [2]:

$$Evaporation\ Time\ t\ [s] = \frac{m \times R\ \times T}{M\ \times\ \beta\ \times p\ \times A} \times K$$

m…mass [kg]
R…gas constant [J x K-1 x mol-1]
T…temperature [K]
M…molar mass [g/mol]
ß…coefficient of mass transfer in the vapour phase [m/h]
p…vapour pressure of the pure substance [Pa]
A…area [cm²]
K…conversion factor [s]

$$Systemic\ dermal\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = \frac{evaporation\ time\ [min] * cycles\ per\ day\ [d^{-1}]}{60\ min} \times transdermal\ flux\ \left[\frac{mg}{cm^2\ h}\right] \times Area\ in\ contact\ [cm^2] \div bodyweight\ [kg]$$

$$Systemic\ inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times inhalation\ rate\ \left[\frac{m^3}{h}\right] \times exposure\ duration\ [h] \times exposure\ per\ day\ [d^{-1}] \div body\ weight\ adult\ [kg] \times inhalation\ absorption\ [\%] \div 100$$

In the following, estimated exposure is provided for scenario [2]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[2]	Tier 1 / None	Not relevant	3.73	4.90	8.63
[2]	Tier 2 / None	Not relevant	1.55	4.90	6.46

Further information and considerations on scenario [2]: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – professional use (primary exposure)

No further information and considerations on scenario [2] are relevant.

2.2.6.2.3 Scenario [3]: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – general public (secondary exposure)

Description of Scenario [3]: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – general public (secondary exposure)
Secondary exposure may occur the general public (visitors/patients) in the room where hygienic hand disinfection is performed. As worst case a toddler as patient was calculated who is exposed to 3 applications of hand disinfection performed by the nurse twice a day as modelled in HeadHoc recommend. 9. Visitors are covered by this scenario due to the lower exposure during one day. Dermal exposure: Direct contact to the disinfectant is not conceivable. Thus, dermal exposure is generally considered negligible. Inhalation exposure (vapour): As a worst-case it is assumed that inhalation exposure towards vapour will be in maximum in the same range as for the professional who performs 6 hand disinfections in one patient room per day and that the toddler lies next to the nurse inhaling the vapour. For details on the used model and relevant input parameter please refer to scenario [2] Tier 1 in section 2.2.6.2. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation. **For details on primary inhalation exposure towards vapour, see scenario [1].**

	Parameters	Value
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Toddler: 10 kg
	Inhalation rate[3] (longterm)	Toddler: 0.333 m³/h
	Frequency of application[4]	6 times per day
	Exposure duration[4]	6 x 1 min (inhalation)
	Room volume[4]	80 m³
	Ventilation rate[4]	1.5/h
	Applied product amount[4]	3 mL (= 2.63 g)
	Release duration[4] (calculated acc. to calculated in ConsExpo Web acc. to HEAdhoc recommendation no.9)	1.61 min
	No PPE	0% protection
Tier 2	Not performed	

[1] Please refer to section 2.1.2.1 of this document
[2] Please refer to section 2.2.2 of this document
[3] ECHA 2017, HEAdhoc Recommendation no. 14
[4] ECHA 2016a, HEAdhoc Recommendation no. 9

Calculations for Scenario [3]: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – general public (secondary exposure)

$$Evaporation\ Time\ t\ [s] = \frac{m \times R\ \times T}{M\ \times\ \beta\ \times p\ \times A} \times K$$

m…mass [kg]
R…gas constant [J x K-1 x mol-1]
T…temperature [K]
M…molar mass [g/mol]
β…coefficient of mass transfer in the vapour phase [m/h]
p…vapour pressure of the pure substance [Pa]
A…area [cm²]
K…conversion factor [s]

$$Systemic\ dermal\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = \frac{evaporation\ time\ [min] * cycles\ per\ day\ [d^{-1}]}{60\ min} \times transdermal\ flux\ \left[\frac{mg}{cm^2\ h}\right] \times Area\ in\ contact\ [cm^2] \div bodyweight\ [kg]$$

$$Systemic\ inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times inhalation\ rate\ \left[\frac{m^3}{h}\right] \times exposure\ duration\ [h] \times exposure\ per\ day\ [d^{-1}] \div body\ weight\ adult\ [kg] \times inhalation\ absorption\ [\%] \div 100$$

The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[3] Toddler	Tier 1/ None	negligible	0.40	negligible	0.40

Further information and considerations on scenario [3]: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – general public (secondary exposure)

No further information and considerations on scenario [3] are relevant.

2.2.6.2.4 Scenario [4]: Hygienic handrub (PT1) by intensive care units visitors in hospitals – non-professional use (primary exposure)

Description of Scenario [4]: Hygienic handrub (PT1) by intensive care units visitors in hospitals – non-professional use (primary exposure)
On previously cleaned and dried hands, 3 mL of the biocidal product are applied to the hand (either by pouring into the screwing cap (1/4 of the cap corresponds to 3 mL) or by spraying (3 strokes). (Follow application technique as given in the use instructions). The complete surface of both hands is moistened and left to dry. According to the AR of propan-2-ol[1], up to 3 applications are performed per day by visitors of intensive care units. Dermal exposure: To assess dermal exposure, a generic model considering the transdermal flux (0.85 mg/cm^2/h) is used. The total exposure duration for one hygienic hand disinfection depends on the evaporation time of 3 mL disinfectant at 30°C according to the calculation of evaporation time of ECHA 2015a and HeadHoc recommend.9 for professional disinfection in hospitals (i.e. 1.61 min). The visitor (child) is covering both hands (427.8 cm²) with one application of disinfection product. Inhalation exposure (vapour): Since propan-2-ol is volatile, it evaporates completely during the assumed time of 2.5 h for one application. It is presumed that the applicant is exposed to 3 applications. The air changing rate of 3h^{-1} is considered to be higher than at normal patient room in hospital. The air concentration of propan-2-ol has its maximum shortly after complete evaporation and then rapidly declines due to the air exchange in the room. The scenario was calculated according in line with CAR. A child as visitor of an ICU was also calculated as worst case. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation.

	Parameters	**Value**
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Child: 23.9 kg
	Inhalation rate[4] (shortterm))	Child: 1.32 m³/h (0.022 m³/min)
	Dermal absorption [transdermal flux][5]	0.85 mg/cm²/h
	Frequency of application[6]	3 times per day
	Exposure duration[7]	1.04 min (dermal) 10 min (inhalation)
	Area in contact with disinfectant[3]	427.8 cm² (both hands)
	Room volume[5]	25 m³
	Ventilation rate[5]	3/h
	Applied product amount[7]	3 mL (= 2.63 g)
	Release duration[7]	1.04 min
	No PPE	0% protection
Tier 2	Not performed	

[1] correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3] ECHA 2015a, page 15, Table 1
[4] ECHA 2015a, page 15, Table 2
[5]Germany 2015a, chapter 1, page 43
[6]Germany 2015a, chapter 1, page 26
[7]ECHA 2016a, Recommendation no. 9

Calculations for Scenario [4]: Hygienic handrub (PT1) by intensive care units visitors in hospitals – non-professional use (primary exposure)

$$Evaporation\ Time\ t\ [s] = \frac{m \times R\ \times T}{M\ \times\ \beta\ \times p\ \times A} \times K$$

m…mass [kg]
R…gas constant [J x K-1 x mol-1]
T…temperature [K]
M…molar mass [g/mol]
β…coefficient of mass transfer in the vapour phase [m/h]
p…vapour pressure of the pure substance [Pa]
A…area [cm²]
K…conversion factor [s]

$$Systemic\ dermal\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = \frac{evaporation\ time\ [min] * cycles\ per\ day\ [d^{-1}]}{60\ min} \times transdermal\ flux\ \left[\frac{mg}{cm^2\ h}\right] \times Area\ in\ contact\ [cm^2] \div bodyweight\ [kg]$$

$$Systemic\ inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times inhalation\ rate\ \left[\frac{m^3}{h}\right] \times exposure\ duration\ [h] \times exposure\ per\ day\ [d^{-1}] \div body\ weight\ child\ [kg] \times inhalation\ absorption\ [\%] \div 100$$

In the following, estimated exposure for 3 hand disinfections per day is provided for scenario [4]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[4] Child	Tier 1/ None	not relevant	3.65	1.48	5.13

Further information and considerations on scenario [4]: Hygienic handrub (PT1) by intensive care units visitors in hospitals – non-professional use (primary exposure)

No further information and considerations on scenario [4] are relevant.

2.2.6.2.5 Scenario [5]: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – non-professional use (primary exposure)

Description of Scenario [5]: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – non-professional use (primary exposure)
On previously cleaned and dried hands, 3 mL of the biocidal product are applied to the hand (either by pouring into the screwing cap (1/4 of the cap corrsensponds to 3 mL) or by spraying (3 strokes). (Follow application technique as given in the use instructions). The complete surface of both hands is moistened and left to dry. According to the AR of propan-2-ol (PT1, Germany 2015a, p. 26), application per day seems to be realistic scenario. It can be assumed that non-professionals will perform more than one application during practicing home dialysis. Due to the instructions at hospital site it is realistic that the non-professional will be trained according to the '5 Moments for Hand Hygiene' approach by WHO, which is commonly used at hospitals (Pittet et.al.). Disinfection before touching the patient, before performing a clean/aseptic procedure (e.g. changing catheder/connection tubes, helping with medical equipment) and after body fluid contact/patient contact seems to be realistic procedure steps. Therefore 3 applications in maximum area are assumed as worst case scenario. A child who routinely perfoms home dialysis is chosen for worst-case. Adults which are more common to perform home dialysis are covered by the child. Dermal exposure: To assess dermal exposure, a generic model considering the transdermal flux (0.85 mg/cm^2/h) is used. The total exposure duration for one hygienic hand disinfection depends on the evaporation time of 3 mL disinfectant at 30 °C according to Human Exposure Guidance Methodology (ECHA 2015a). Inhalation exposure (vapour): To assess the inhalation exposure to vapour, the air concentration of propan-2-ol is calculated with ConsExpo Web (Inhalation model, exposure to vapour: instantenous rate) for one application. It is assumed that the threefold amount of disinfection is realeased at once for 3 application scenario as worst case assumption. The air concentration of propan-2-ol has its maximum shortly after complete evaporation and then declines due to the air exchange in the room. The scenario was calculated in line with CAR. It is presumed that the non-professional stays in the same room for 10h. Due to the assumption that the the non-professional only performs light exercises at home he/she has a lower ventilation rate while staying at home. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation.

	Parameters	**Value**
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Child: 23.9 kg
	Inhalation rate (longterm, resting)[4]	Children: 0.5m³/h
	Dermal absorption [transdermal flux][5]	0.85 mg/cm²/h
	Frequency of application[6]	3 times per day
	Exposure duration[7]	1.04 min (dermal) 10 h (inhalation)
	Area in contact with disinfectant[3,8]	427.8 cm² (both hands)
	Room volume[6]	25 m³
	Ventilation rate[5]	0.6/h
	Applied product amount[7]	3 mL (= 2.63 g)
	Release duration[7] (calculated acc. to calculated in ConsExpo Web acc. to HEAdhoc recommendation no.9)	1.04 min
	No PPE	0% protection
Tier 2	Not performed	

[1]correspond to Chapter 2.1.2.3.
[2]correspond to Chapter 2.2.2.
[3]ECHA 2015a, page 15, Table 1
[4] ECHA 2015a, page 15, Table 2
[5] Germany 2015a, chapter 1, page 46
[6]Germany 2015a, chapter 1, page 26
[7]ECHA 2016a, Recommendation no. 9
[8] ECHA 2017, Recommendation no. 14

Calculations for Scenario [5]: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – non-professional use (primary exposure)

$$Evaporation\ Time\ t\ [s] = \frac{m \times R\ \times T}{M\ \times\ \beta\ \times p\ \times A} \times K$$

m…mass [kg]
R…gas constant [J x K-1 x mol-1]
T…temperature [K]
M…molar mass [g/mol]
β…coefficient of mass transfer in the vapour phase [m/h]
p…vapour pressure of the pure substance [Pa]
A…area [cm²]
K…conversion factor [s]

$$Systemic\ dermal\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = \frac{evaporation\ time\ [min] * cycles\ per\ day\ [d^{-1}]}{60\ min} \times transdermal\ flux\ \left[\frac{mg}{cm^2\ h}\right] \times Area\ in\ contact\ [cm^2] \div bodyweight\ [kg]$$

$$Systemic\ inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times inhalation\ rate\ \left[\frac{m^3}{h}\right] \times exposure\ duration\ [h] \times exposure\ per\ day\ [d^{-1}] \div body\ weight\ adult\ [kg] \times inhalation\ absorption\ [\%] \div 100$$

In the following, estimated exposure for one hand disinfections per day is provided for scenario [5]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[5] Child	Tier 1/none	Not relevant	6.90	1.48	8.38

Further information and considerations on scenario [5]: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – non-professional use (primary exposure)

No further information and considerations on scenario [5] are relevant.

2.2.6.2.6 Scenario [6]: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – general public (secondary exposure)

Description of Scenario [6]: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – general public (secondary exposure)		
Secondary exposure may occur to non-professional bystanders (adults, children, toddler) in rooms where hygienic hand disinfection is performed and are living together. Dermal exposure: Direct contact to to the disinfectant is not conceivable. Thus, dermal exposure is generally considered negligible. Inhalation exposure (vapour): As a worst-case it is assumed that inhalation exposure towards vapour will be in maximum in the same range as for the person who performs the hand disinfection and that the bystander stays in the room for 10 h. A Toddler is calculated as worst case who are staying in the same room. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for the reasoning. For details on primary inhalation exposure towards vapour, see scenario [5].		
	Parameters	Value
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Toddler: 10 kg
	Inhalation rate (long-term, resting)[4]	Toddler: 0.33 m³/h (0.00556 m³/min)
	Frequency of application[5]	3 times per day
	Exposure duration[5]	600 min (inhalation)
	Room volume[5]	25 m³
	Ventilation rate[5]	0.6/h
	Applied product amount[2]	3 mL (= 2.63 g)
	Release duration[6]	1.04 min
	No PPE	0% protection
Tier 2	Not performed	

[1]correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3]ECHA 2015a, page 15, Table 1
[4] ECHA 2015a, page 15, Table 2
[5]Germany 2015a, chapter 1, page 26
[6]ECHA 2016a, Recommendation no. 9

Calculations for Scenario [6]: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – bystander (secondary exposure)

$$Evaporation\ Time\ t\ [s] = \frac{m \times R\ \times T}{M\ \times\ \beta\ \times p\ \times A} \times K$$

m…mass [kg]
R…gas constant [J x K-1 x mol-1]
T…temperature [K]
M…molar mass [g/mol]
β…coefficient of mass transfer in the vapour phase [m/h]
p…vapour pressure of the pure substance [Pa]
A…area [cm²]
K…conversion factor [s]

$$Systemic\ dermal\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = \frac{evaporation\ time\ [min] * cycles\ per\ day\ [d^{-1}]}{60\ min} \times transdermal\ flux\ \left[\frac{mg}{cm^2\ h}\right] \times Area\ in\ contact\ [cm^2] \div bodyweight\ [kg]$$

$$Systemic\ inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times inhalation\ rate\ \left[\frac{m^3}{h}\right] \times exposure\ duration\ [h] \times exposure\ per\ day\ [d^{-1}] \div body\ weight\ adult\ [kg] \times inhalation\ absorption\ [\%] \div 100$$

In the following, estimated secondary exposure for one hand disinfection per day is provided for scenario [6]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[6] Toddler	Tier 1 / None	not relevant	10.99	negligible	10.99

Further information and considerations on scenario [6]: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – general public (secondary exposure)

No further information and considerations on scenario [6] are relevant.

2.2.6.2.7 Scenario [7]: Manual loading of the biocidal product (primary exposure)

Description of Scenario [7]: Manual loading of the biocidal product (primary exposure)		
The RTU product is loaded from a jerry can (2–10 L) into a smaller vessel for further utilisation. It is presumed, that a professional user will load a suitable vessel one time at the beginning of the shift. The professional lifts the jerry can using both hands and closes the screw cap after filling. The exposure of both hands by spitting of the liquid product is assumed as worst-case scenario. Inhalation exposure (vapour) and Dermal exposure: The calculation of dermal is determined using default values of EUROPOEM II database User guidance p.24 as recommended by HEEG, 2008 Opinion 1 mixing&loading and HeadHoc recommend. 6 based on a simple loading procedure for 1 container per day. As a worst-case a 10 L jerry can is chosen for calculation. To assess dermal exposure, a generic model considering the transdermal flux (0.85 mg/cm^2/h) is used. The inhalative exposure was calculated with ConsExpo Web and the parameters of RIVM (2018) (Cleaning products fact sheet) based on the model 'Generic exposure scenario for loading undiluted liquids' p36. Therefore ConsExpo model inhalation–exposure to vapour–evaporation–constant release area was chosen. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for the reasoning.		
	Parameters	Value
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3,4]	Adults: 60 kg
	Dermal absorption[5]	0.85 mg/cm^2/h
	Frequency of application	1 time per 8 h-shift
	Indicative exposure, dermal[6,7] (both hands)	8 mg/kg a.s. per operation
	Applied product amount (packaging size)	10 L (8.771 kg)
	Exposed skin area[4] (both hands)	820 cm²
	No PPE	0% protection
	Parameters for ConsExpo Web (inhalative exposure)	
	Exposure duration[8]	0.75 min
	Molecular weight matrix[8]	18 g/mol
	Product amount[8] (hald of the amount of 10 L according to RIVM (2018)	4385.5g

	Room volume[8]	1 m³
	Ventilation rate[8]	0.5 /h
	Inhalation rate[3]	1.25 m³/h
	Mass transfer coefficient[8]	10 m/hr
	Release area	20 cm²
	Emission duration	0.3 min
Tier 2	Not performed	

[1] correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3] ECHA 2017, Recommendation no. 14
[4] ECHA 2015a, page 15, Table 1
[5] Germany 2015, chapter 1, page 43
[6] EC, HEEG 2008, opinion 1, page 5
[7] ECHA 2020, recommendation no.6, page 11
[8]RIVM (2018)

Calculations for Scenario [7]: Manual loading of the biocidal product (primary exposure)

$$Evaporation\ Time\ t\ [s] = \frac{m \times R\ \times T}{M\ \times\ \beta\ \times p\ \times A} \times K$$

m…mass [kg]
R…gas constant [J x K-1 x mol-1]
T…temperature [K]
M…molar mass [g/mol]
β…coefficient of mass transfer in the vapour phase [m/h]
p…vapour pressure of the pure substance [Pa]
A…area [cm²]
K…conversion factor [s]

$$\boldsymbol{indicative\ value\ product}\ \left[\frac{\boldsymbol{mg}}{\boldsymbol{kg\ product}}\right] = \frac{\boldsymbol{indicative\ value\ a.s.}\left[\frac{\boldsymbol{mg}}{\boldsymbol{kg\ a.s.}}\right] \times\ \boldsymbol{weight\ fraction}\ [\%]}{\boldsymbol{100}}$$

$$Systemic\ inhalative\ exposure\ \left[\frac{mg}{kg\ bw\ day}\right] = indicative\ value\ \left[\frac{mg}{m^3}\right] \times inhalation\ rate\ \left[\frac{m^3}{h}\right] \times exposure\ duration\ [h] \times exposure\ per\ day\ [d^{-1}] \div body\ weight\ adult\ [kg] \times inhalation\ absorption\ [\%] \div 100$$

$$\boldsymbol{Systemic\ dermal\ exposure}\ \left[\frac{\boldsymbol{mg}}{\boldsymbol{kg\ bw\ day}}\right] = \frac{\boldsymbol{evaporation\ time\ [min] \times cycles\ per\ day\ [d^{-1}]}}{\boldsymbol{60\ min}} \times \boldsymbol{transdermal\ flux}\ \left[\frac{\boldsymbol{mg}}{\boldsymbol{cm^2\ h}}\right] \times \boldsymbol{Area\ in\ contact}\ [\boldsymbol{cm^2}] \div \boldsymbol{bodyweight}\ [\boldsymbol{kg}]$$

In the following, estimated exposure for 1 loading per 8 h-shift is provided for scenario [7]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[7]	Tier 1 / None	not relevant	0.00099	0.005	0.006

Further information and considerations on scenario [7]: Manual loading of the biocidal product (primary exposure)

No further information and considerations on scenario [7] are relevant.

2.2.6.2.8 Scenario [**8**]: Hard surface disinfection (small surfaces in PT2), e.g. hospital rooms – professional use (primary exposure) - spraying

Description of scenario [8]: Hard surface disinfection (small surfaces in PT2), e.g. in hospital – professional use (primary exposure) - spraying
25 strokes of the undiluted product (RTU) are sprayed onto a small surface (0.5 m³) to be treated within a short distance between 20-25 cm. The liquid has to completely cover the surface. The product shall act for 5 min. Afterwards crude residues are wiped over with (paper) tissue or subsequently left to dry. Due to the very short distance of spraying the product onto the surface the main exposure is expected from product evaporation on the small surface. Based on the fact that the user will hold the spray away from her/his body and down to the small surface an eye contact can be excluded by intended use. Additionally due to the fast evaporation of propan-2-ol it can be excluded that small traces on hands/arms are transported to the eyes. According to AR of propan-2-ol (PT2, Germany 2015b, p. 26) exposure by spraying is expected to be higher or equal to wiping application. Therefore no additional scenario was calculated for wiping application. Based on recommendation 15, a professional is expected to enter 4 ventilated rooms per working day. The professional performs one surface disinfection of 0.5 m² in each room during staying 20 minutes in the room and is assumed to repeat their visit and disinfection in each room after the first round. In total, the staff person carries out 8 surface disinfections in 4 different rooms per day. Professional bystanders (e.g. doctors, therapists) are covered by this scenario. Dermal exposure: To assess dermal exposure, a generic model considering the transdermal flux (0.85 mg/cm²/h) is used. For worst case dermal exposure BEAT model for small scale surface wiping (Hughson et. al (2004) "Determination of dermal exposures during mixing, spraying and wiping activities") is taken into account for hands only. The 75th percentile value from literature (214 µL/min) was assumed to be sufficient (6 records, uncertainty factor: 5.0). The professional uses a paper wipe for distribution of the disinfection holding in one hand or wiping off residues after residence time. The total dermal area exposed to disinfect is expected be one palm. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation. Inhalation exposure (vapour): According to HeadHoc recommend.15, to assess the inhalation exposure to vapour, the air concentration of propan-2-ol is calculated with ConsExpo Web (Inhalation model, exposure to vapour: evaporation, Realease area: Increasing). Since propan-2-ol is volatile, it evaporates completely during the application. For extrapolation of remaining air concentration when the professional enters the first room the second time after 240 min Excel sheet of HeadHoc recommend 15 'recom_9_annex_inhalation_exposure_calc_en_2017.xls' was used.

	Parameters	**Value**
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Adults: 60 kg
	Inhalation rate (shortterm)[3]	Adults: 1.25 m^3/h (0.021 m^3/min)
	Dermal absorption[4]	0.85 mg/cm^2/h
	Frequency of application[5]	8 times per 8 h-shift
	Exposure duration	20 min/ room stay
	Application duration[5]	1 min/0.5m²
	Area in contact with disinfectant[3]	205 cm^2 (one hand palm) = ¼ both hands
	Room volume[5,6]	80 m^3
	Ventilation rate[5,6]	1.5/h
	Area to be disinfected[5]	0.5 m^2
	Applied product amount[7]	21.9275 g (25 mL)
	Vapour pressure (25°C)[8]	5780 Pa
	Release duration[6]	2.37 min
	No PPE	0% protection
Tier 2	Not performed	

[1] correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3] ECHA 2017, Recommendation no. 14
[4] Germany 2015b, PT2, chapter 2, page 30
[5] ECHA 2017, Recommendation no. 15
[6] ECHA 2016a, Recommendation no. 9
[7] correspond to Chapter 2.1.4.
[8] Germany 2015b, PT2, chapter 1, page 43

Calculations for scenario [8]: Hard surface disinfection (small surfaces in PT2), e.g. working bench in laboratory, clean room, hospital – professional use (primary exposure) - spraying and/or wiping

$$\boldsymbol{inhalative\ exposure}\ [\boldsymbol{mg}]$$
$$= \boldsymbol{4\ rooms}\ (\boldsymbol{1st\ treatment}) \times \boldsymbol{mean\ air\ concentration}\ \left[\frac{\boldsymbol{mg}}{\boldsymbol{m^3}}\right] \times \boldsymbol{20min}$$
$$\times \boldsymbol{inhalation\ rate}\ \left[\frac{\boldsymbol{m^3}}{\boldsymbol{h}}\right] + \boldsymbol{4\ rooms}\ (\boldsymbol{2nd\ treatment})$$
$$\times (\boldsymbol{mean\ air\ concentration}\ \left[\frac{\boldsymbol{mg}}{\boldsymbol{m^3}}\right] + \boldsymbol{residual\ air\ concentration}[\frac{\boldsymbol{mg}}{\boldsymbol{m^3}}] \times \boldsymbol{20\ min}$$
$$\times \boldsymbol{inhalation\ rate}\ [\frac{\boldsymbol{m^3}}{\boldsymbol{h}}]$$

$$\boldsymbol{systemic\ inhalative\ exposure} = \frac{\boldsymbol{inhalative\ exposure}\ [mg] * \boldsymbol{inhalation\ absorption}[\%] * \boldsymbol{frequency\ per\ day}\ [d^{-1}]}{\boldsymbol{body\ weight}\ [kg\ bw] * 100}$$

$$\boldsymbol{Systemic\ dermal\ exposure}\ \left[\frac{mg}{kg\ bw\ day}\right] = \frac{\boldsymbol{evaporation\ time}\ [min] * \boldsymbol{cycles\ per\ day}\ [d^{-1}]}{60\ min} \times \boldsymbol{transdermal\ flux}\ \left[\frac{mg}{cm^2\ h}\right] \times \boldsymbol{Area\ in\ contact}\ [cm^2] \div \boldsymbol{bodyweight}\ [kg]$$

In the following, estimated exposure for 8 applications per 8 h-shift is provided for scenario [8]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[8]	Tier 1 / None	negligible	6.50	0.90	7.39

Further information and considerations on scenario [8] - Hard surface disinfection (small surfaces in PT2), e.g. working bench in laboratory, clean room, hospital – professional use (primary exposure) - spraying and/or wiping

No further information and considerations on scenario [8] are relevant.

2.2.6.2.9 Scenario [**9**]: Hard surface disinfection (small surfaces in PT2), e.g. hospital rooms – general public (secondary exposure) - spraying and/or wiping

Description of scenario [9]: Hard surface disinfection (small surfaces in PT2), e.g. hospital rooms – general public (secondary exposure) - spraying and/or wiping		
Secondary exposure may occur to the general public (visitors/patients) in areas where surface disinfection in hospital rooms is performed. A toddler as patient is considered to be the worst-case Dermal exposure: Direct contact to freshly disinfected surfaces may only happen casually. In the unlikely case of dermal contact, exposure is considered to be of short duration only. Thus, dermal exposure is generally considered negligible. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for explanation. Inhalation exposure (aerosol and vapour): As a worst-case it is assumed that inhalation exposure towards vapour will be in the same range as for the professional who disinfects the surfaces in 1 room. The non-professional stays in the room for 24 h. The exposure duration for 1 application is assumed to be 240 min afterwards 2 application occurs. According to HeadHoc recommend. 15 children and toddler are calculated as worst case. Due to low activity the ventilation rate for long term exposure was chosen.		
	Parameters	Value
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Toddler: 10 kg
	Inhalation rate (longterm)[3]	Toddler: 0.333 m³/h
	Frequency of application[5]	2 times per 8 h-shift
	Application duration[5]	1 min/0.5m²
	Room volume[5,6]	80 m³
	Ventilation rate[5,6]	1.5/h
	Area to be disinfected[5]	0.5 m²
	Applied product amount[7]	21.9275 g (25 mL)
	Vapour pressure (25°C)[8]	5780 Pa
	Release duration[6]	2.19 min
	No PPE	0% protection
	Time exposed to vapour[5]	240 min per event

[1] correspond to Chapter 2.1.2.3.

[2] correspond to Chapter 2.2.2.

[3] ECHA 2017, Recommendation no. 14

[4] Germany 2015b, PT2, chapter 2, page 30

[5] ECHA 2017, Recommendation no. 15

[6] ECHA 2016a, Recommendation no. 9
[7] correspond to Chapter 2.1.4.
[8] Germany 2015b, PT2, chapter 1, page 43

Calculations for scenario [9]: Hard surface disinfection (small surfaces in PT2), e.g. working bench in laboratory, clean room, hospital – general public (secondary exposure) - spraying and/or wiping

$$\boldsymbol{inhalative\ exposure}\ [\boldsymbol{mg}] = (\boldsymbol{mean\ air\ concentration}\ \left[\frac{\boldsymbol{mg}}{\boldsymbol{m^3}}\right] + \boldsymbol{residual\ air\ concentration}\left[\frac{\boldsymbol{mg}}{\boldsymbol{m^3}}\right]) \times \boldsymbol{4h} \times \boldsymbol{inhalation\ rate}\ [\frac{\boldsymbol{m^3}}{\boldsymbol{h}}]$$

$$\boldsymbol{systemic\ inhalative\ exposure} = \frac{\boldsymbol{inhalative\ exposure}\ [\boldsymbol{mg}] * \boldsymbol{inhalation\ absorption}[\%] * \boldsymbol{frequency\ per\ day}\ [\boldsymbol{d^{-1}}]}{\boldsymbol{body\ weight}\ [\boldsymbol{kg\ bw}] * \boldsymbol{100}}$$

$$\boldsymbol{Systemic\ dermal\ exposure}\ \left[\frac{\boldsymbol{mg}}{\boldsymbol{kg\ bw\ day}}\right] = \frac{\boldsymbol{evaporation\ time}\ [\boldsymbol{min}] * \boldsymbol{cycles\ per\ day}\ [\boldsymbol{d^{-1}}]}{\boldsymbol{60\ min}} \times \boldsymbol{transdermal\ flux}\ \left[\frac{\boldsymbol{mg}}{\boldsymbol{cm^2\ h}}\right] \times \boldsymbol{Area\ in\ contact}\ [\boldsymbol{cm^2}] \div \boldsymbol{bodyweight}\ [\boldsymbol{kg}]$$

In the following, estimated exposure for 8 applications per 8 h-shift is provided for scenario [9]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from general public					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[9] Toddler	Tier 1 / None	negligible	8.43	negligible	8.43

Further information and considerations on scenario [9] - Hard surface disinfection (small surfaces in PT2), e.g. working bench in laboratory, clean room, hospital – general public (secondary exposure) - spraying and/or wiping

No further information and considerations on scenario [9] are relevant.

2.2.6.2.10 Scenario [10]: Hard surface disinfection (small surfaces in PT2), e.g. in bathrooms – professional use (primary exposure) - spraying and/or wiping

Description of scenario [10]: Hard surface disinfection (small surfaces in PT2), e.g. in bathrooms – professional use (primary exposure) - spraying

25 strokes of the undiluted product (RTU) are sprayed onto a small surface (0.5 m³) to be treated within a short distance between 25 cm. The liquid has to completely cover the surface. The product shall act for 5 min. Afterwards crude residues are wiped over with (paper) tissue or subsequently left to dry.

The assumptions made for scenario [10] are based on the scenario "Surface disinfection in bathrooms" described for non-professionals in the AR of propan-2-ol (PT2, Germany 2015b) as these are also considered relevant for the professional user. Different to the non-professional user who only performs up to 5 applications per day, the professional user is expected to perform up to 19 applications per 8 h working shift.
It is further assumed that one disinfection lasts 5 min and that the person leaves the (bath)room directly after application (i.e. after 5 min).

Due to the very short distance of spraying the product onto the surface the main exposure is expected to come from product evaporation on the small surface. Based on the fact that the user will hold the spray away from her/his body and down to the small surface an eye contact can be excluded by intended use. Additionally due to the fast evaporation of propan-2-ol it can be excluded that small traces on hands/arms are transported to the eyes. According to AR of propan-2-ol (PT2, Germany 2015b, p. 26) exposure by spraying is expected to be higher or equal to wiping application. Therefore no additional scenario was calculated for wiping application.

Dermal exposure: To assess dermal exposure, a generic model considering the transdermal flux (0.85 mg/cm²/h) is used. A total exposure duration of 5 min for hand contact during or after spraying and/or wiping is assumed.

Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation.

Inhalation exposure (vapour): To assess the inhalation exposure to vapour, the air concentration of propan-2-ol is calculated with ConsExpo 4.1 (Inhalation model, exposure to vapour: evaporation) for one application. Since propan-2-ol is volatile, it evaporates completely during the application. It is assumed that the non-professional leaves the bathroom after use of 5 min duration. As a worst case scenario 19 applications per day are taken into account.

Tier 2: Assessment Tier 1 lead to a total exposure of 19.47 mg/kg bw/day. An exceedance of the AEL is already achieved by inhalative exposure only. Assuming that a hotel cleaning stuff is exposed to the substance in small guest bathrooms it cannot be ensured that any kind of additional ventilation can be achieved. The hotel bath room cleaning will be the task of the professional, the number of applications cannot be reduced. Therefore an RPE shall be taken into account. As Propan-2-ol is a small molecule the RPE which should be applied is a combination for gases and particle filter: A-P2 (AUVA 2021). This corresponds to a a half or quarter mask with filter which has the same APF of 10 for both filter types, P2 and gases.

	Parameters	**Value**
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Adults: 60 kg
	Inhalation rate[3] (shortterm)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Dermal absorption[4]	0.85 mg/cm^2/h
	Frequency of application[5]	19 times per 8 h-shift
	Exposure duration[6]	5 min per application
	Area in contact with disinfectant[3]	205 cm^2 (one hand palm) = ¼ both hands
	Room volume[7]	10 m^3
	Ventilation rate[8]	2/h
	Area to be disinfected[6]	0.5 m^2
	Applied product amount[9] (application rate acc. to applicant information: 40-50 mL/m^2)	21.9275 g (25 mL)
	Release duration[10]	2.194 min
	Vapour pressure (25°C)[11]	5780 Pa
	No PPE	0% protection
Tier 2	RPE	10 (APF)

[1] correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3] ECHA 2017, Recommendation no. 14
[4]Germany 2015b, PT2, chapter 2, page 30
[5]Aguilar-Escobar et al. 2021: 645-660
[6]Germany 2015b, PT2, chapter 2, page 26
[7]RIVM report 2014 General Fact, chapter 3.1.3., page 23
[8]RIVM report 2014 General Fact, chapter 3.2.3., page 29
[9]correspond to Chapter 2.1.4.
[10]ECHA 2015a, page 15, page 255
[11]Germany 2015, chapter 1, page 43

Calculations for scenario [10]: Hard surface disinfection (small surfaces in PT2), e.g. in bathrooms – professional use (primary exposure) - spraying and/or wiping

$$Evaporation\ Time\ t\ [s] = \frac{m \times R\ \times T}{M\ \times\ \beta\ \times p\ \times A} \times K$$

m…mass [kg]
R…gas constant [J x K-1 x mol-1]
T…temperature [K]
M…molar mass [g/mol]
β…coefficient of mass transfer in the vapour phase [m/h]

p…vapour pressure of the pure substance [Pa]
A…area [cm²]
K…conversion factor [s]
Tier 1:

$$\textbf{systemic inhalative exposure} = \frac{\textbf{inhalative exposure}\ [mg] * \textbf{inhalation absorption}[\%] * \textbf{frequency per day}\ [d^{-1}]}{\textbf{body weight}\ [\textbf{kg bw}] * 100}$$

$$\textbf{Systemic dermal exposure}\ \left[\frac{mg}{\textbf{kg bw day}}\right] = \frac{\textbf{evaporation time}\ [min] * \textbf{cycles per day}\ [d^{-1}]}{60\ min} \times \textbf{transdermal flux}\ \left[\frac{mg}{cm^2\ h}\right] \times \textbf{Area in contact}\ [cm^2] \div \textbf{bodyweight}\ [kg]$$

Tier 2:

$$\textbf{systemic inhalative exposure} = \frac{\left(\frac{\textbf{inhalative exposure}\ [mg] * \textbf{inhalation absorption}[\%] * \textbf{frequency per day}\ [d^{-1}]}{\textbf{body weight}\ [\textbf{kg bw}] * 100}\right)}{APF(RPE)}$$

In the following, estimated exposure for 19 applications per 8 h-shift is provided for scenario [10]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[10]	Tier 1 / None	negligible	18.14	1.33	19.47
	Tier 2/ RPE (APF 10)	negligible	1.81	1.33	3.14

Further information and considerations on scenario [10] - Hard surface disinfection (small surfaces in PT2), e.g. in bathrooms – professional use (primary exposure) - spraying and/or wiping

For further information and considerations please refer to chapter '2.2.7. Risk characterization for human health'.

2.2.6.2.11 Scenario [11]: Hard surface disinfection (small surfaces in PT2), e.g. working bench in laboratory, clean room – professional use (primary exposure) - spraying and/or wiping

Description of scenario [11]: Hard surface disinfection (small surfaces in PT2), e.g. working bench in laboratory, clean room– professional use (primary exposure) - spraying

25 strokes of the undiluted product (RTU) are sprayed onto a small surface (0.5 m³) to be treated within a short distance between 20-25 cm. The liquid has to completely cover the surface. The product shall act for 5 min. Afterwards crude residues are wiped over with (paper) tissue or subsequently left to dry.

Due to the very short distance of spraying the product onto the surface the main exposure is expected from product evaporation on the small surface. Based on the fact that the user will hold the spray away from her/his body and down to the small surface an eye contact can be excluded by intended use. Additionally due to the fast evaporation of propan-2-ol it can be excluded that small traces on hands/arms are transported to the eyes. According to AR of propan-2-ol (PT2, Germany 2015b, p. 26) exposure by spraying is expected to be higher or equal to wiping application. Therefore no additional scenario was calculated for wiping application. It is assumed that the professional cleans her/his working bench every 45 min during 8 hour shift. Due to the assumption that professional bystander are only exposed by inhalative exposure this group is covered by this scenario. For worst case scenario a small room (25m²) with ventilation rate of 8/h is adopted from HeadHoc recommend. 15. Due to clean room have similar default values as laboratory except bigger room volume the clean room is covered by this scenario.

Dermal exposure: To assess dermal exposure, a generic model considering the transdermal flux (0.85 mg/cm²/h) is used. For worst case dermal exposure 1 min per 0.5m² was assumed. The professional uses a paper wipe for distribution of the disinfection holding in one hand. The total dermal area exposed to disinfect is expected be one palm.

Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation.

Inhalation exposure (vapour): According to HeadHoc recommend.15, to assess the inhalation exposure to vapour, the air concentration of propan-2-ol is calculated with ConsExpo Web (Inhalation model, exposure to vapour: evaporation, Realease area: Increasing). Since propan-2-ol is volatile, it evaporates completely during the application, has its maximum shortly after complete evaporation and then rapidly declines due to the air exchange in the room.

	Parameters	**Value**
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Adults: 60 kg
	Inhalation rate[3] (shortterm)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Dermal absorption[4]	0.85 mg/cm^2/h
	Frequency of application[5]	10 times per 8 h-shift
	Exposure duration[6]	1 min per application
	Area in contact with disinfectant[3]	205 cm^2 (one hand palm) = ¼ both hands
	Room volume[7]	25 m^3
	Ventilation rate[8]	8/h
	Area to be disinfected[5]	0.5 m^2
	Applied product amount[9] (application rate acc. to applicant information: 40-50 mL/m^2)	21.9275 g (25 mL)
	Release duration[10]	2.194 min
	Vapour pressure (25°C)[11]	5780 Pa
	No PPE	0% protection
Tier 2	Not performed	

[1] correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3] ECHA 2017, Recommendation no. 14
[4]Germany 2015b, PT2, chapter 2, page 30
[5] ECHA 2017, Recommendation no. 15
[6]Germany 2015b, DocII-Evaluation report PT2, page 106
[7]RIVM report 2014 General Fact, chapter 3.1.3., page 23
[8]RIVM report 2014 General Fact, chapter 3.2.3., page 29
[9]correspond to Chapter 2.1.4.
[10]ECHA 2015a, page 15, page 255
[11]Germany 2015, chapter 1, page 43

Calculations for scenario [11]: Hard surface disinfection (small surfaces in PT2), e.g. in bathrooms – professional use (primary exposure) - spraying

$$\boldsymbol{systemic\ inhalative\ exposure} = \frac{\boldsymbol{inhalative\ exposure}\ [mg] * \boldsymbol{inhalation\ absorption}[\%] * \boldsymbol{frequency\ per\ day}\ [d^{-1}]}{\boldsymbol{body\ weight}\ [kg\ bw] * 100}$$

$$\boldsymbol{Systemic\ dermal\ exposure}\ \left[\frac{mg}{kg\ bw\ day}\right] = \frac{\boldsymbol{evaporation\ time}\ [min] * \boldsymbol{cycles\ per\ day}\ [d^{-1}]}{60\ min} \times \boldsymbol{transdermal\ flux}\ \left[\frac{mg}{cm^2\ h}\right] \times \boldsymbol{Area\ in\ contact}\ [cm^2] \div \boldsymbol{bodyweight}\ [kg]$$

In the following, estimated exposure for 14 applications per 8 h-shift is provided for scenario [11]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[11]	Tier 1 / None	negligible	14.22	1.40	15.62

Further information and considerations on scenario [11] - Hard surface disinfection (small surfaces in PT2), e.g. in bathrooms – professional use (primary exposure) - spraying

No further information and considerations on scenario [11] are relevant.

2.2.6.2.12 Scenario [12]: Hard surface disinfection (small surfaces in PT2), e.g. in households - non-professional use (primary exposure) - spraying

Description of scenario [12]: Hard surface disinfection (small surfaces in PT2), e.g. in households - non-professional use (primary exposure) - spraying
25 strokes of the undiluted product (RTU) are sprayed onto a small surface (0.5 m^3) to be treated within a short distance between 20-25 cm. The liquid has to completely cover the surface. The product shall act for 5 min. Afterwards crude residues are wiped over with (paper) tissue or subsequently left to dry. Due to the very short distance of spraying the product onto the surface the main exposure is expected from product evaporation on the small surface. Based on the fact that the user will hold the spray away from her/his body and down to the small surface an eye contact can be excluded by intended use. Additionally due to the fast evaporation of propan-2-ol it can be excluded that small traces on hands/arms are transported to the eyes. According to AR of propan-2-ol (PT2, Germany 2015b, p. 26) exposure by spraying is expected to be higher or equal to wiping application. One disinfection lasts 5 min in total and is performed once per day. In case of an infectious disease in a household, 5 disinfections à 5 min may are assumed to be performed in maximum per day. Furthermore it is assumed that the person leaves the (bath)room directly after application (i.e. after 5 min). Dermal exposure: To assess dermal exposure, a generic model considering the transdermal flux (0.85 $mg/cm^2/h$) was used. According to AR of propan-2-ol (PT2, Germany 2025b) it is assumed that during the cleaning process the non-professional coveres both hands with product during spraying and wiping process for a very short time until the whole product is evaporated. Due to fast evaporation time dermal contact to the treated surface is considered to be negligible. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation. Inhalation exposure (vapour): To assess the inhalation exposure to vapour, the air concentration of propan-2-ol is calculated with ConsExpo 4.1 (Inhalation model, exposure to vapour: evaporation) for one application. Since propan-2-ol is volatile, it evaporates completely during the application. It is assumed that the non-professional leaves the bathroom after use of 5 min duration in a daily routine. As a worst case scenario an 5 applications per day are taken into account in case of infectious disease at the household.

	Parameters	**Value**
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Adults: 60 kg
	Inhalation rate[3] (shortterm)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Dermal absorption[4]	0.85 mg/cm^2/h
	Frequency of application[5]	5 times per day
	Exposure duration[5]	5 x 5 min
	Area in contact with disinfectant[3]	820 cm^2
	Room volume[6]	10 m^3
	Ventilation rate[7]	2/h
	Area to be disinfected[8]	0.5 m^2
	Applied product amount[9]	21.9275 g (25 mL)
	Vapour pressure (25°C)[10]	5780 Pa
	Thickness of layer of product in contact with skin[11]	0.01 cm
	No PPE	0% protection
Tier 2	Not performed	

[1] correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3] ECHA 2017, Recommendation no. 14
[4] Germany 2015b, PT2, chapter 2, page 12
[5] Germany 2015b, PT2, chapter 2, page 26
[6]ConsExpo General Fact Sheet 2006, page 14
[7]ConsExpo General Fact Sheet 2006, page 19
[8]ECHA 2017, Recommendation no. 15
[9]correspond to Chapter 2.1.4.
[10] Germany 2015b, PT2, chapter 1, page 43
[11]ECHA 2015, chapter 7.2, page 255

Calculations for scenario [12]: Hard surface disinfection (small surfaces in PT2), e.g. in households - non-professional use (primary exposure) - spraying and/or wiping

Dermal:

$$\text{Mass of compound [g]} = \frac{\text{Area of skin [cm}^2\text{]} \times \text{thickness of layer [cm]} \times \text{density of product } \left[\frac{\text{g}}{\text{mL}}\right] \times \text{weight of fraction [\%]}}{100}$$

$$\text{Evaporation Time t [s]} = \frac{m \times R \times T}{M \times \beta \times p \times A} \times K$$

m…mass [kg]

R…gas constant [J x K-1 x mol-1]
T…temperature [K]
M…molar mass [g/mol]
β…coefficient of mass transfer in the vapour phase [m/h]
p…vapour pressure of the pure substance [Pa]
A…area [cm²]
K…conversion factor [s]

$$\text{Systemic dermal exposure } \left[\frac{\text{mg}}{\text{kg bw day}}\right] = \frac{\text{evaporation time [min]} * \text{cycles per day [d}^{-1}\text{]} \times \text{ transdermal flux } \left[\frac{\text{mg}}{\text{cm}^2\,\text{h}}\right] \times \text{Area in contact [cm}^2\text{]}}{60\ \text{min} \times \text{bodyweight [kg]}}$$

Inhalative:

$$\text{systemic inhalative exposure} = \frac{\text{inhalative exposure [mg/m}^3\text{]} \times \text{exposure duration [h]} \times \text{inhalation rate } \left[\frac{\text{m}^3}{\text{h}}\right] \times \text{inhalation absorption[\%]} \times \text{frequency per day [d}^{-1}\text{]}}{\text{body weight [kg bw]} * 100}$$

In the following, estimated exposure per day is provided for scenario [13]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[12]	Tier 1 / None	negligible	4.77	1.74	6.51

Further information and considerations on scenario [12]: Hard surface disinfection (small surfaces in PT2), e.g. in households - non-professional use (primary exposure) - spraying

No further information and considerations on scenario [12] are relevant.

2.2.6.2.13 Scenario [13]: Hard surface disinfection (small surfaces in PT2), e.g. in households – general public (secondary exposure) - spraying

Description of scenario [13]: Hard surface disinfection (small surfaces in PT2), e.g. in households - general public (secondary exposure) - spraying
Secondary exposure may occur to non-professional bystanders (adults, children or toddler) in areas where surface disinfection is performed. This is expected for only one application per day. Inhalative exposure of adults is assumed to be the same as in scenario [13]. As a worst case Scenario [14] was calculated for children and toddler who are standing next to the non-professional who performs surface disinfection. Dermal exposure: Direct contact to freshly disinfected surfaces may only happen occasionally for a very short time until the whole product is evaporated. Due to fast evaporation time dermal contact to the treated surface is considered to be negligible. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation. Inhalation exposure (vapour): As a worst-case it is assumed that inhalation exposure towards vapour will be in maximum in the same range as for the person who disinfects the surfaces and that the bystander stays in the room for the duration of one application (i.e. 5 min). The air concentration of propan-2-ol is calculated with ConsExpo 4.1 (Inhalation model, exposure to vapour: evaporation) for one application. Since propan-2-ol is volatile, it evaporates completely during the application.

	Parameters	**Value**
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Toddler: 10 kg
	Inhalation rate[3] (shortterm)	Toddler: 1.26 m^3/h (0.021 m^3/min)
	Dermal absorption[4]	0.85 mg/cm^2/h
	Frequency of application[5]	once per day
	Exposure duration[5]	5 min
	Room volume[6]	10 m^3
	Ventilation rate[7]	2/h
	Area to be disinfected[8]	0.5 m^2
	Applied product amount[9]	21.9275 g (25 mL)
	Area in contact with disinfectant[3]	820 cm^2
	Vapour pressure (25°C)[10]	5780 Pa
	Thickness of layer of product in contact with skin[11]	0.01 cm
	No PPE	0% protection
Tier 2	Not performed	

[1] correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3] ECHA 2017, Recommendation no. 14
[4] Germany 2015b, PT2, chapter 2, page 12
[5] Germany 2015b, PT2, chapter 2, page 26
[6]ConsExpo General Fact Sheet 2006, page 14
[7]ConsExpo General Fact Sheet 2006, page 19
[8]ECHA 2017, Recommendation no. 15
[9] correspond to Chapter 2.1.4.
[10] Germany 2015b, PT2, chapter 1, page 43
[11]ECHA 2015, chapter 7.2, page 255

Calculations for scenario [13]: Hard surface disinfection (small surfaces in PT2), e.g. in households - general public (secondary exposure) - spraying

Inhalative:

$$\text{systemic inhalative exposure} = \frac{\text{inhalative exposure } [\text{mg/m}^3] \times \text{exposure duration } [\text{h}] \times \text{inhalation rate } \left[\frac{\text{m}^3}{\text{h}}\right] \times \text{inhalation absorption}[\%] \times \text{frequency per day } [\text{d}^{-1}]}{\text{body weight } [\text{kg bw}] * 100}$$

In the following, estimated secondary exposure for 1 application per day is provided for scenario [13]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment". The exposure of adults form scenario [13] is presented for the sake of completeness.

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[13] Toddler	Tier 1 / None	negligible	5.78	negligible	5.78

Further information and considerations on scenario [13]: Hard surface disinfection (small surfaces in PT2), e.g. in households - general public (secondary exposure) - spraying

No further information and considerations on scenario [13] are relevant.

2.2.6.2.14 Scenario [14]: Hard surface disinfection (small surfaces in PT4), e.g. in canteens or kitchens – professional use (primary exposure) - spraying

Description of scenario [14]: Hard surface disinfection (small surfaces in PT4), e.g. in canteens or kitchens – professional use (primary exposure) - spraying
The undiluted product (RTU) is sprayed onto a small-surfaces in food processing industry to be treated within a distance between 20-25 cm. The liquid has to completely cover the surface. The product shall act for 5 min. Afterwards crude residues are wiped over with (paper) tissue or subsequently left to dry. According to the AR of propan-2-ol (PT4, Germany, 2015c, p. 26), one disinfection lasts 2 min in total and is performed 4 times per day (i.e. every 2 h during a 8 h-shift). As a worst case, it is assumed that the person does not leave the room and is exposed for 8 h daily (120 min per application). Professional bystanders are covered by this scenario due to the assumption, that a bystanders is only exposed by inhalative exposure in the same amount as the professional. Dermal exposure: To assess dermal exposure, a generic model considering the transdermal flux (0.85 mg/cm^2/h) is used. For worst case dermal exposure BEAT model for small scale surface wiping (Hughson et. al (2004) "Determination of dermal exposures during mixing, spraying and wiping activities") is taken into account for hands only. The 75th percentile value from literature (214 µL/min) was assumed to be sufficient (6 records, uncertainty factor: 5.0). The professional uses a paper wipe for distribution of the disinfection holding in one hand or wiping off residues after residence time. The total dermal area exposed to disinfect is expected be one palm. A total exposure duration of 2 min for hand contact during or after spraying and/or wiping is assumed. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation. Inhalation exposure (vapour): To assess the inhalation exposure to vapour, the air concentration of propan-2-ol is calculated with ConsExpo 4.1 (Inhalation model, exposure to vapour: evaporation) for one application. The "exposure duration" is triggered by the total time the worker stays in the room (during and after disinfection, i.e. 120 min). The ventilation rate is assumed to be 15 m³/h. Due to its physico-chemical properties Propa-2-ol fully evaporates during the exposure duration.

	Parameters	**Value**
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Adults: 60 kg
	Inhalation rate (shortterm)[3]	Adults: 1.25 m^3/h (0.021 m^3/h)
	Dermal absorption[4]	0.85 mg/cm^2/h
	Frequency of application[5]	4 times per 8 h-shift
	Exposure duration[5]	2 min per application (dermal) 120 min (inhalation vapour)
	Area in contact with disinfectant[5]	205 cm^2 (one hand palm)
	Room volume[5]	25 m^3
	Ventilation rate[5]	15/h
	Area to be disinfected[5]	1 m^2
	Applied product amount[6]	43.855 g (50 mL)
	Application time[5]	2 min
	Vapour pressure[5] (25°C)	5780 Pa
	No PPE	0% protection
Tier 2	Not performed	

[1] correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3] ECHA 2017, Recommendation no. 14
[4] Germany 2015c, PT4, chapter 2, page 13
[5] Germany 2015c, PT4, chapter 2, page 26
[6] correspond to Chapter 2.1.4.

Calculations for scenario [14]: Hard surface disinfection (small surfaces in PT4), e.g. in canteens or kitchens – professional use (primary exposure) - spraying

$$\text{systemic inhalative exposure} = \frac{\text{inhalative exposure [mg/m}^3\text{]} \times \text{exposure duration [h]} \times \text{inhalation rate} \left[\frac{\text{m}^3}{\text{h}}\right] \times \text{inhalation absorption[\%]} \times \text{frequency per day [d}^{-1}\text{]}}{\text{body weight [kg bw]} * 100}$$

In the following, estimated exposure for 4 applications per 8 h-shift is provided for scenario [14]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[14]	Tier 1 / None	negligible	6.17	0.11	6.28

Further information and considerations on scenario [14] - Hard surface disinfection (small surfaces in PT4), e.g. in canteens or kitchens – professional use (primary exposure) - spraying

No further information and considerations on scenario [14] are relevant.

2.2.6.2.15 Scenario [15]: Hard surface disinfection (small surfaces in PT4), e.g. in the food processing industry – professional use (primary exposure) - spraying

Description of scenario [15]: Hard surface disinfection (small surfaces in PT4), e.g. in the food processing industry – professional use (primary exposure) - spraying

The undiluted product (RTU) is sprayed onto a small-surfaces in food processing industry to be treated within a distance between 20-25 cm so as to the liquid completely cover the surface. The product shall act for 5 min. Afterwards crude residues are wiped over with (paper) tissue or subsequently left to dry.

According to the AR of propan-2-ol (PT4, Germany, 2015c, p. 26), the application time of spraying is 2min/m² and is performed 4 times per day (i.e. every 2 h during a 8 h-shift). As a worst case, it is assumed that the person does not leave the room and is exposed for 8 h daily. Professional bystanders are covered by this scenario due to the assumption, that a bystanders is only exposed by inhalative exposure in the same amount as the professional.

Dermal exposure: To assess dermal exposure, a generic model considering the transdermal flux (0.85 mg/cm^2/h) is used. For worst case dermal exposure BEAT model for small scale surface wiping (Hughson et. al (2004) "Determination of dermal exposures during mixing, spraying and wiping activities") is taken into account for hands only. The 75th percentile value from literature (214 µL/min) was assumed to be sufficient (6 records, uncertainty factor: 5.0). The professional uses a paper wipe for distribution of the disinfection holding in one hand or wiping off residues after residence time. The total dermal area exposed to disinfect is expected be one palm. A total exposure duration of 5 min for each application for hand contact during or after spraying and/or wiping is assumed.

Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation.
Inhalation exposure (vapour): To assess the inhalation exposure to vapour, the air concentration of propan-2-ol is calculated with ConsExpo 4.1 (Inhalation model, exposure to vapour: evaporation) for one application. According to AR of propan-2-ol (PT4, Germany 2015c, p. 26) it is assumed that the disinfection of cutting machine and packaging machinery with a total area of 4.6 m² are taken into account[5,7]. Since propan-2-ol is volatile, it evaporates completely during the application. The "exposure duration" is triggered by the total time the worker stays in the room for one application (during and after disinfection, i.e. 120 min). As worst case a room volume the nearest space volumne in a production hall around the disinfected machines 300 m³ was assumed according to the assumption of the AR of propan-2-ol. Due to the possibility that disinfection could also be performed in food processing industry of brewery and bakeries 20°C where assumed differing from AR propan-2-ol.

	Parameters	Value
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Adults: 60 kg
	Inhalation rate[3] (shortterm)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Dermal absorption[4]	0.85 mg/cm^2/h
	Frequency of application[5]	4 times per 8 h-shift
	Exposure duration[5]	5 min (dermal) 120 min (inhalation vapour)
	Area in contact with disinfectant[5]	410 cm^2 (both palms)
	Room volume[7] (acc. to applicant information)	300 m^3
	Ventilation rate[5]	20/h
	Area to be disinfected[7]	4.6 m^2
	Applied product amount[6]	201.733 g (230 mL)
	No PPE	0% protection
Tier 2	Not performed	

[1] correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3] ECHA 2017, Recommendation no. 14
[4] Germany 2015c, PT4, chapter 2, page 13
[5] Germany 2015c, PT4, chapter 2, page 26
[6] correspond to Chapter 2.1.4.
[7] Germany, 2014, Doc II Evaluation Report

Calculations for scenario [15]: Hard surface disinfection (small surfaces in PT4), e.g. in the food processing industry – professional use (primary exposure) - spraying

In the following, estimated exposure for 4 applications per 8 h-shift is provided for scenario [15]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[15]	Tier 1 / None	negligible	1.83	0.14	1.97

Further information and considerations on scenario [15] - Hard surface disinfection (small surfaces in PT4), e.g. in the food processing industry – professional use (primary exposure) - spraying

Due to the assumption that disinfection of kitchen and canteens is performed in professional areas where food is processed and not at guest rooms an exposure of guest visiting the restaurants can be excluded.

2.2.6.2.16 Scenario [16]: Hard surface disinfection (small surfaces in PT4), e.g. in kitchens - non-professional use (primary exposure) - spraying

Description of scenario [16]: Hard surface disinfection (small surfaces in PT4), e.g. in kitchens - non-professional use (primary exposure) - spraying
The undiluted product (RTU) is sprayed onto a small-surface (1 m²) to be treated within a distance between 20-25 cm so as to the liquid completely cover the surface. The product shall act for 5 min. Afterwards crude residues are wiped over with (paper) tissue or subsequently left to dry. According to the AR of propan-2-ol (PT2, Germany, 2015b), one disinfection lasts 5 min in total and is performed once per week. For worst-case it is assumed that disinfection procedure is performed once each day. It is assumed that the person leaves the kitchen 15 min after cleaning as disinfection is assumed to be the final step after preparation of a meal. Wiping is expected to cause lower exposure than spraying. Therefore no separate wiping scenario is taken into account. Dermal exposure: To assess dermal exposure, a generic model considering the transdermal flux (0.85 mg/cm^2/h) was used. According to AR of propan-2-ol (PT4, Germany 2015c) it is assumed that during the cleaning process both hands are covered with product during spraying and wiping process for a very short time until the whole product is evaporated. Due to fast evaporation time dermal contact to the treated surface is considered to be negligible. Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation. Inhalation exposure (vapour): To assess the inhalation exposure to vapour, the air concentration of propan-2-ol is calculated with ConsExpo 4.1 (Inhalation model, exposure to vapour: evaporation) for one application. Since propan-2-ol is volatile, it evaporates completely during the application. The application time is 5 min on a 1m² area. The maximum amount of 50mL product is chosen as worst-case amount.

	Parameters	**Value**
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Adults: 60 kg
	Inhalation rate[3] (shortterm)	Adults: 1.25 m^3/h (0.021 m^3/min)
	Dermal absorption[4]	0.85 mg/cm^2/h
	Frequency of application[5]	once per day
	Area in contact with disinfectant[3,5]	820 cm^2 (both hands)
	Applied product amount on both hands[6] (820 cm^2 x 0.01 cm (layer on skin))	7.19222 g (8.2 mL)
	Evaporation time[6]	1.839203874 min
	Exposure duration[5,6]	1.839203874 min (dermal) 15 min (inhalation vapour)
	Room volume[7]	15 m^3
	Ventilation rate[7]	2.5/h
	Area to be disinfected[9]	1 m^2
	Applied product amount[8,9]	43.9 g (50 mL)
	No PPE	0% protection
Tier 2	Not performed	

[1] correspond to Chapter 2.1.2.3.
[2] correspond to Chapter 2.2.2.
[3] ECHA 2017, Recommendation no. 14
[4] Germany 2015c, PT4, chapter 2, page 13
[5] Germany 2015c, PT4, chapter 2, page 27
[6]ECHA 2015, chapter 7.2, page 255
[7]ConsExpo, 2006, General Fact Sheet, chapter 3
[8] ECHA 2018a, Recommendation no. 15
[9] correspond to Chapter 2.1.4.

Calculations for scenario [16]: Hard surface disinfection (small surfaces in PT4), e.g. in kitchens - non-professional use (primary exposure) - spraying

Dermal:

$$\text{Mass of compound [g]} = \frac{\text{Area of skin [cm}^2\text{]} \times \text{thickness of layer [cm]} \times \text{density of product } \left[\frac{\text{g}}{\text{mL}}\right] \times \text{weight of fraction [\%]}}{100}$$

$$\text{Evaporation Time t [s]} = \frac{\text{m} \times \text{R} \times \text{T}}{\text{M} \times \beta \times \text{p} \times \text{A}} \times \text{K}$$

m…mass [kg]
R…gas constant [J x K-1 x mol-1]
T…temperature [K]
M…molar mass [g/mol]
β…coefficient of mass transfer in the vapour phase [m/h]
p…vapour pressure of the pure substance [Pa]
A…area [cm²]
K…conversion factor [s]

$$\text{Systemic dermal exposure } \left[\frac{\text{mg}}{\text{kg bw day}}\right] = \frac{\text{evaporation time [min]} * \text{cycles per day [d}^{-1}\text{]} \times \text{ transdermal flux } \left[\frac{\text{mg}}{\text{cm}^2\,\text{h}}\right] \times \text{Area in contact [cm}^2\text{]}}{60\ \text{min} \times \text{bodyweight [kg]}}$$

Inhalative:

$$\text{systemic inhalative exposure} = \frac{\text{inhalative exposure [mg/m}^3\text{]} \times \text{exposure duration [h]} \times \text{inhalation rate } \left[\frac{\text{m}^3}{\text{h}}\right] \times \text{inhalation absorption[\%]} \times \text{frequency per day [d}^{-1}\text{]}}{\text{body weight [kg bw]} * 100}$$

In the following, estimated exposure for one application per day is provided for scenario [16]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[16]	Tier 1 / None	negligible	4.95	0.34	5.29

Further information and considerations on scenario [16] - Hard surface disinfection (small surfaces in PT4), e.g. in kitchens - non-professional use (primary exposure) - spraying and/or wiping

No further information and considerations on scenario [16] are relevant.

2.2.6.2.17 Scenario [17]: Hard surface disinfection (small surfaces in PT4), e.g. in kitchens - general public (secondary exposure) - spraying and/or wiping

Description of scenario [17]: Hard surface disinfection (small surfaces in PT4), e.g. in kitchens - general public (secondary exposure) - spraying

Secondary exposure may occur to non-professional bystanders (adults, children or toddler) in areas where surface disinfection is performed. This is expected for only one application per day. Inhalative exposure of adults is assumed to be the same as in scenario [16]. As a worst case Scenario [17] was calculated for children who are standing/playing around next to the non-professional who performs surface disinfection.

Dermal exposure: Direct contact to freshly disinfected surfaces may only happen occasionally for a very short time until the whole product is evaporated. Due to fast evaporation time dermal contact to the treated surface is considered to be negligible.

Inhalation exposure (aerosol): not considered relevant. Please refer to scenario [2] for further explanation.

Inhalation exposure (vapour): As a worst-case it is assumed that inhalation exposure towards vapour will be in maximum in the same range as for the person who disinfects the surfaces and that the bystander stays in the room for the duration of one application (i.e. 5 min). The air concentration of propan-2-ol is calculated with ConsExpo 4.1 (Inhalation model, exposure to vapour: evaporation) for one application. Since propan-2-ol is volatile, it evaporates completely during the application.

	Parameters	Value
Tier 1	Weight fraction of compound[1]	63.1%(w/w)
	Density[2]	0.8771 g/mL
	Body weight[3]	Children: 23.9 kg
	Inhalation rate[3]	Children (shortterm): 1.32 m3/h (0.008 m3/min)
	Frequency of application[4]	once per day
	Exposure duration[4,5]	15 min (inhalation vapour)
	Room volume[6]	15 m^3
	Ventilation rate[6]	2.5/h
	Area to be disinfected[8]	1 m^2
	Applied product amount[8]	43.9 g (50 mL)
	No PPE	0% protection
Tier 2	Not performed	

[1] correspond to Chapter 2.1.2.3.

[2] correspond to Chapter 2.2.2.

[3] ECHA 2017, Recommendation no. 14
[4] Germany 2015c, PT4, chapter 2, page 27
[5]ECHA 2015, chapter 7.2, page 255
[6]ConsExpo, 2006, General Fact Sheet, chapter 3
[7] ECHA 2018a, Recommendation no. 15
[8] correspond to Chapter 2.1.4.

Calculations for scenario [17]: Hard surface disinfection (small surfaces in PT4), e.g. in kitchens - general public (secondary exposure) - spraying and/or wiping

$$\text{systemic inhalative exposure} = \frac{\text{inhalative exposure [mg/m}^3\text{]} \times \text{exposure duration [h]} \times \text{inhalation rate} \left[\frac{\text{m}^3}{\text{h}}\right] \times \text{inhalation absorption[\%]} \times \text{frequency per day [d}^{-1}\text{]}}{\text{body weight [kg bw]} * 100}$$

In the following, estimated secondary exposure for one application per day is provided for scenario [17]. The calculation sheets are provided in Annex 3.2, section I "Human Health Risk Assessment".

Summary table: estimated exposure from non-professional uses					
Exposure scenario	**Tier / PPE**	**Estimated inhalation uptake (aerosol) [mg/kg bw/d]**	**Estimated inhalation uptake (vapour) [mg/kg bw/d]**	**Estimated dermal uptake [mg/kg bw/d]**	**Estimated total uptake [mg/kg bw/d]**
[17] Children	Tier 1 / None	negligible	13.12	negligible	13.12

Further information and considerations on scenario [17] - Hard surface disinfection (small surfaces in PT4), e.g. in kitchens - general public (secondary exposure) - spraying

No further information and considerations on scenario [17] are relevant.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario / Use #	**Exposed group (e.g. professionals, non-professionals, general public)**	**Tier / PPE**	**Estimated total uptake [mg/kg bw/d]**
[1]	Professionals	Tier 1 (Scenario [7]) / none	0.006
[2]	Professionals	Tier 2 / None	6.46
[3]	General public toddler	Tier 1 / None	0.40
[4]	Non-professional child	Tier 1 / None	5.13
[5]	Non-professionals child	Tier 1 / None	8.38
[6]	General public toddler	Tier 1 / None	10.99
[8]	Professionals	Tier 1 / none	7.39
[9]	General public toddler	Tier 1 / none	8.43
[10]	Professionals	Tier 1/ none Tier 2 / RPE (APF 10)	19.47 3.14
[11]	Professionals	Tier 1 / none	15.62
[12]	Non-professionals	Tier 1 / none	6.51
[13]	General public toddler	Tier 1 / none	5.78
[14]	Professionals	Tier 1 / none	6.28
[15]	Professionals	Tier 1 / none	1.97
[16]	Non-Professionals	Tier 1 / none	5.29
[17]	General public Child	Tier 1 / none	13.12

COMBINED SCENARIOS

Explanatory note:

Since the biocidal product is intended to be used in PT1, PT2 and PT4, cumulative exposure cannot be excluded. Primary and secondary exposure of professionals and non-professionals needs to be considered.

According to the AR of propan-2-ol (PT1, 2, 4; Germany 2015a, b, c), it can be assumed for professional users that cumulative exposure to propan-2-ol from biocidal products of different product types is limited to specific professions (e.g. a nurse cannot be exposed to professional exposure in food industry). However, in some few cases, professionals may be exposed to biocidal products from different product types e.g. PT1 and PT2. It is assumed to be realistic, that a nurse perfoms disinfection of hands and a small surface in hospitals rooms during her working shift. The worst case scenario is calculated together with refilling of disinfectant. Therefore the combined scenario is listed for professional exposure. An accumulation of professional exposure to non-professional and secondary exposure is not considered reasonable. Compared to total exposure, where professional exposure is a very regular frequent event, the fraction of non-professional exposure is small, particularly if also the frequency is taken into account but often performed with worse ventilation conditions. Professional secondary exposure is covered by the primary professional exposure.

Combined exposure estimates for non-professional uses in PT1 are considered to be unlikely. For non-professionals using the product for PT2 and PT4 the single scenarios has been considered only. A combination of Scenario [-12] and [16] seems to be a very rare event. A combination of a disinfection procedure of bathroom 5 times a day and once for the kitchen is unlikely to happen. Furthermore scenario [16] of PT2 covers 5 applications at one day at the domestic bathroom in case of a high risk of infection. The amount of product, the sum of disinfected area and the lower ventilation rate compared to a kitchen covers a combination of kitchen and bathroom disinfection once a day.
Non-professional secondary exposure of adults does not need to be accumulated to the non-professional primary exposure estimates, since this is already integrated in the primary exposure assessment. Cumulative secondary exposure has to be considered for children and toddlers which are unaccounted for primary exposure. The combined exposure estimates were identified for general public in PT1/2 for patients in hospital who are exposed to hand and small surface exposure performed by the professional.

Based on the considerations above, the following cumulative exposure estimates have been identified for professionals and non-professionals in PT1, PT2 and PT4.

The following combined exposure estimates were identified for professional uses in PT1/2/4.

Combined Scenarios and values to be used in risk assessment			
Scenario / Use #	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier / PPE**	**Estimated total uptake [mg/kg bw/d]**
[1] + [2]	Professionals	Tier 1 + Tier 2/ none	6.47
[1] + [2] + [8]	Professionals	Tier 1 + Tier 2 + Tier 1/ none	13.86
[7] + [10] Tier 1 Tier 2	Professionals	Tier 1 + Tier 1/none Tier 1 + Tier 2/ RPE (APF 10)	19.48 3.15
[7] + [11]	Professionals	Tier 1 + Tier 1 / none	15.63
[7] + [14]	Professionals	Tier 1 + Tier 1/ none	6.29
[7] + [15]	Professionals	Tier 1 + Tier 1/ none	1.98
[3] + [9] Toddler	General public Toddler	Tier 1 + Tier 1 /None	8.83

Exposure of the general public

Cf. to chapter "Professional an/or non-professional exposure".

Monitoring data

Concerning human exposure, no monitoring data are available.

Dietary exposure

In line with the AR of propan-2-ol (PT1, PT2 and PT4; Germany 2015a, b, c), residues in food or feed from intended use of propan-2-ol biocidal products in PT1, PT2 and PT4 are not expected, as due to fast evaporation of the constitutent no direct or indirect contact with food or feed is intended. The *Isopropylalkohol 70% (v/v)* is an aqueous solution containing 63.1% (w/w) propan-2-ol and is applied in the same manner as the representative biocidal product in the respective AR containing 70% (w/w) propan-2-ol. Both products, the representative product as well as the *Isopropylalkohol 70% (v/v)*, are not used directly on food or feed. Nevertheless, use as a non-professional hand disinfectant or as surface disinfectant in food or feed processing areas could potentially lead to transfer of residues onto food. However, due to its high vapour pressure, the active substance propan-2-ol evaporates completely within the time of application of the biocidal product so that transfer from treated surfaces to food should not occur. In the unlikely case that residue transfer does occur, the active substance will evaporate from the food before it is eaten. Therefore,

dietary exposure to humans from the use of propan-2-ol as a biocide of PT1, PT2 and PT4 can be excluded.

Information of non-biocidal use of the active substance

As stated in the AR of propan-2-ol (PT1, 2, 4; Germany, 2015a, b, c), propan-2-ol may also occur in other biocidal product types as non-active substance. It is also used by consumers and workers in other fields that are not covered by biocide regulation (e.g. solvent in household cleaners or coatings).
As a respective methodology is not available yet, aggregated exposure cannot be comprehensively assessed for the time being.
Despite the lack of clear guidance on aggregated exposure assessment, calculated cumulative exposure for PT1, PT2 and PT4 might serve as a first estimate or even surrogate for aggregated exposure based on the following considerations:

- The concentration of propan-2-ol when present as a non-active substance in other PTs or used e.g. as solvent in (household) cleaners or coatings is considered to be lower than in the representative *Isopropylalkohol 70% (v/v)* which contains 63.1% (w/w) propan-2-ol.
- Intended uses of e.g. cleaners and disinfectants are expected similar.
- Primary and secondary exposure for the intended biocidal uses in PT1, PT2 and PT4 are estimated using worst-case assumptions such as maximum application rates, duration and frequency.
- It seems very unlikely that a professional and/or non-professional extensively uses propan-2-ol containing biocidal and non-biocidal products on the same day and, at the same time, at high application rates and durations each. In this respect it has to be noted that respective assumptions have already been made for the cumulative assessment in the ARs for propan-2-ol (PT 1, 2, 4, Germany, 2015).

Therefore, it can be concluded that exposure from non-biocidal sources is likely to be covered by the cumulative risk assessment performed for the intended uses in PT1, PT2 and PT4.

For cumulated exposure from the biocidal use of the *Isopropylalkohol 70% (v/v)* in PT1, PT2 and PT4, please refer to section "Cumulative exposure" within "Use #3 – Disinfection of small surfaces in product type 04".

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Livestock exposure to the active substance used in the biocidal product *Isopropylalkohol 70% (v/v)* is not expected due to the expected field of use.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not required. For more information, please refer to chapter "dietary exposure" above.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not required. For more information, please refer to chapter "dietary exposure" above.

Exposure associated with production, formulation and disposal of the biocidal product

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR. It is assumed that the production is performed in conformity with national and European occupational safety and health regulations.
In addition, production or formulation of biocidal products are already covered by REACH legislation, where the registrants (manufacturers/importers) of substances are obliged to consider human hazard and exposure and to provide RMMs/exposure scenarios for ensuring safe use (e.g. via SDS in the supply chain). Moreover, it is assumed that industrial production sites are subject to permit for installation. Therefore, it is not considered relevant to perform an additional exposure assessment under the biocide regime.

For instructions for disposal, cf. to chapter 2.1.5.4.

Moreover, the applicant provided the following information:

"The production of the biocidal product is done in accordance with local and national occupational health and safety regulations.
The formulation of the product takes place in a closed system. The raw materials are fed sequentially, using adequate dosing equipment, into a closed mixing vessel equipped with an air exhaust duct to prevent emission into the working environment.
For working steps, where exposure of workers cannot be excluded, such as connecting lines, manual dosing of starting materials or quality control, the workers use adequate PPE (gloves, safety goggles completed by respiratory protection if required). The staff are trained workers.
From the vessels, the finished product is pumped to a filling station. The filling process is done manually under exhaust ventilation. As occupational health and safety regulations are observed (e.g. through regular measurements of air concentrations), exposure of industrial workers towards the finished product is minimal."

Aggregated exposure

Not applicable.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation, according to the AR of propan-2-ol (PT1, 2, 4, Germany 2015a, b, c)

Reference	Study	NOAEC [ppm]	AF	Correction for oral absorption	Value [mg/kg bw/d]
$AEL_{acute/medium-term/long-term}$ Professionals	Human volunteer study	200	3.8	Not relevant	17.9
$AEL_{acute/medium-term/long-term}$ General population	Human volunteer study	200	6.4	Not relevant	10.7
ARfD	Not necessary, no residues in food expected				
ADI	Not necessary, no residues in food expected				

Maximum residue limits or equivalent

Default MRL of 0.01 mg/kg applies according to Art 18(1)(b) Reg 396 / 2005.
For further explanation please refer to explanation above in chapter 2.2.6.2. 'Dietary exposure'.

Risk for industrial users

Due to no scenario for industrial user were submitted by the applicant this chapter has no relevance for the risk assessment.

Risk for professional users

Based on the exposure assessment, the risk for the individual scenarios is calculated as provided in the following table.

Systemic effects

Scenario / Use #	Tier / PPE	AEL [mg/kg bw/d]	Estimated uptake [mg/kg bw/d]	Estimated uptake/ AEL [%]	Acceptable (yes/no)
[1] / [7]	Tier 1 / none	17.9	0.006	0.0335	yes
[2]	Tier 2 / None	17.9	6.46	36.09	yes
[8]	Tier 1 / none	17.9	7.39	41.29	yes
[10]	Tier 1 /none	17.9	19.47	108.77	no
[11]	Tier 1 /none	17.9	15.62	87.26	yes
[14]	Tier 1/ none	17.9	6.28	35.08	yes
[15]	Tier 1 /none	17.9	1.97	11.01	yes

Scenario [10] represents the estimated total exposure of a professional working in a hotel who cleans 19 bathrooms per day in a 8h-workshift. The calculated risk ratio at Tier 1 exceeds 100%. The risk is not caused by dermal contact to the product but inhalative exposure already exceeds the AEL of 17.9 mg/kg bw/day for professionals. As bathrooms are already calculated with higher ventilation rate (compared to living rooms) no further refinement on ventilation conditions can be performed. Additional ventilation by opening windows can not be assumed by default. Therefore a Tier 2 model for refinement using an RPE was applied at exposure assessment. Tier 2 shows that the risk would be acceptable by application of an appropriate RPE. As Propan-2-ol is a small molecule the RPE which should be applied is at least an A-P2 which is a combination filter for gases and particles (AUVA 2021). This corresponds to a half or quarter mask with P2 and gas filter combination. A quarter mask is not a common type of mask (e.g. FFP2) which should not be applied to professionals who are not trained for such equipment and are expected to work at hotels. Bathroom disinfection should be possible to be performed without special training conditions for certain products. A quarter mask of the proposed type would cause difficulties in normal breathing if it is used correctly and would lead to the setting of a physically burdensome risk reduction. Furthermore at a hotel a high number of bathrooms has to be treated per day under this conditions. Based on this argumentation and the decision of BPC-43 taken to a related case the use of RPE at Tier 2 is not applicable therefore the risk is not acceptable.

Combined scenarios

Scenarios combined	Tier	AEL [mg/kg bw/d]	Estimated uptake [mg/kg bw/d]	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1] + [2]	Tier 1 + Tier 2/ None	17.9	6.47	36.15	yes
[1] + [2] + [8]	Tier 1 + Tier 2 + Tier 1/ None	17.9	13.86	77.43	yes
[7] + [10]	Tier 1 / None	17.9	19.48	108.83	no
[7] + [11]	Tier 1 / None	17.9	15.63	55.53	yes
[7] + [15]	Tier 1 / None	17.9	6.29	35.14	yes
[7] + [16]	Tier 1 / None	17.9	1.98	11.06	yes

For further information to combined Scenario [7] and [10] please refer to ‘systemic effects’ above.

Local effects

Local effects are evaluated for propan-2-ol according to ECHA Guidance on BPR: Volume III Parts B+C (ECHA 2017b). Due to the eye irritating effects of propan-2-ol, Isopropan-2-ol 70% (v/v) is classified with H319 (causes serious eye irritation). Additionally the biocidal product has to be labelled with EUH066 (repeated exposure may cause skin dryness or cracking). According to ECHA Guidance on BPR: Volume III Parts B+C a qualitative risk assessment on both hazard effects has to be performed. In general this hazard statements for skin dryness and eye irritating effects are categorized to cause low hazard (ECHA 2017b, table 24, page 246). The performed local risk assessment is shown in the table below by evaluating the frequency and duration of contact time, the degree of potential exposure under best practice conditions as well as the application of relevant RMM.
All intended uses of PT 1/2/4 require an application duration of a few minutes. In case of the refilling task an eye contact is only expected by incidence. All other uses are not expected to cause a contact of propan-2-ol to the eyes. With the proposed protection measures the reduction of dermal and eye contact minimize the anticipated health risk to an acceptable level.

PT	Tasks, uses, processes	Concentration b.p. (max.) in application solution	Local effects in terms of C&L	Hazard category	Frequency and duration of potential exposure [per day]	Potential degree of exposure	Relevant RMM & Instructions for use	Acceptability
1/2/4	Refilling	RTU (64.73% (w/w) a.s.)	H319 EUH066	Low	1 application per day, about 1 min per task	Incidental eye contact expected, dermal exposure expected	Labelling: 'Avoid contact to eyes.' Regular cleaning of equipment and work area. Good standard of occupational hygiene. Instructions for use. Washing of face/eye after accidental exposure.	Yes
1	Hygienic Hand disinfection	RTU (64.73% (w/w) a.s.)	H319 EUH066	Low	25 applications, duration per application: about 1 min per task	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard	Yes

							of occupational hygiene.	
1	Hygienic Hand disinfection – domestic	RTU (64.73% (w/w) a.s.)	H319 EUH066	Low	3 applications, duration per application: about 1 min per task	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	Yes
2	Small surface disinfection – hospital room	RTU (64.73% (w/w) a.s.)	H319 EUH066	Low	8 applications, duration per application: about 2 min per task	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	Yes
2	Small surface disinfection – hotel room	RTU (64.73% (w/w) a.s.)	H319 EUH066	Low	19 applications, duration per application: about 2 min per day	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard	Yes

							of occupational hygiene.	
2	Small surface disinfection – laboratory	RTU (64.73% (w/w) a.s.)	H319 EUH066	Low	10 applications, duration per application: about 2 min	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	Yes
4	Small surfaces – kitchen and canteens	RTU (64.73% (w/w) a.s.)	H319 EUH066	Low	4 applications, duration per application: about 2 min	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard of occupational hygiene.	Yes
4	Small surfaces – food processing machinery	RTU (64.73% (w/w) a.s.)	H319 EUH066	Low	4 applications; duration per application about 5 min	eye contact not expected, dermal exposure expected	Labelling: "Avoid contact to eyes." Regular cleaning of equipment and work area. Good standard	Yes

							of occupational hygiene.	

Conclusion

The performed risk assessment on systemic effects demonstrates that no unacceptable risk at worst case scenario level and combined scenario level is achieved in most cases. However, part of the use #5 has to be restricted (PT2, professionals, hotel room disinfection) based on the high inhalative exposure for professionals which cause a risk for systemic effects and the decision that a sufficient RPE at Tier 2 is not applicable in this case. Due to exceeded risk ratio for hotel cleaning staff this use is not authorized.

Additionally for PT2 Use 5 the RMM 'Do not use for areas exceeding 0.5 m².' is set.

The local risk assessment does not raise concern for the user. P 280 is recommended for professional use for labelling, however this is set in parenthesis since a general use instruction 'Avoid contact to eyes' is set for professional and non-professionals. No other PPE has to be set for other systemic or local effects. Based on the performed risk assessment of local and systemic effects low risk for professionals was identified under the defined conditions.

Risk for non-professional users

Systemic effects

Scenario / Use #	Tier / PPE	AEL [mg/kg bw/d]	Estimated uptake [mg/kg bw/d]	Estimated uptake/ AEL [%]	Acceptable (yes/no)
[4] Child	Tier 1/ None	10.7	5.13	47.94	yes
[5] Child	Tier 1/ None	10.7	8.38	78.32	yes
[12]	Tier 1 / None	10.7	6.51	60.84	yes
[16]	Tier 1 / None	10.7	5.29	49.44	yes

Combined scenarios

Not required. For further information please refer to chapter 2.2.6.2. 'Combined scenarios'

Local effects

Isopropan-2-ol is classified as Eye Irrit. 2 (H319) and EUH066 (Repeated exposure may cause skin dryness). According to ECHA Guidance on BPR: Volume III Parts B+C a qualitative risk assessment on both hazard effects has to be performed.
Non-professionals experience dermal exposure at hygienic hand disinfection and small surface disinfection in domestic area only. In general eye contact is not expected due to the kind of application, and physico-chemical properties of the product. The contact to eyes is only expected by accident (e.g. rubbing eyes immediately after hand disinfection). For the label H319 (Causes serious eye irritation) 'P 280 Wear eye protection/face protection' is recommended. However for non-professionals no PPE should be prescribed. Therefore, in the general use instructions the label 'Avoid contact to eyes' is provided. Furthermore labelling with P305, P351, P338 as well as P337+P313 is needed.

For non-professionals the application frequency and the amount of product which comes into contact with skin is lower than dermal exposure of professionals without the usage of PPE. Based on the fact that only small amounts of product are applied and accidential contact is expected to be low there is no concern on the safe use of the product. Therefore the non-professional user is covered by the local risk assessment of the professional. The risk assessment for non-professionals is therefore covered by professionals. For further information please refer to local risk assessment for professional user.

Conclusion

The performed risk assessment on systemic effects raise no concern for risk at worst case scenario level and combined scenario level for non-professionals using the intended application frequency and amount of product. The local risk assessment showed an acceptable risk. For non-professional use the general labelling 'Avoid contact to eyes' is recommendend to avoid accidential contact.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[3] Toddler	Tier 1 / none	10.7	0.40	3.74	yes
[6] Toddler	Tier 1 / None	10.7	10.99	102.71	no
[9] Toddler	Tier 2 / None	10.7	8.43	78.79	yes
[13] Toddler	Tier 1 / None	10.7	5.78	54.02	yes
[17] Children	Tier 1 / None	10.7	13.12	122.62	no

Combined scenarios

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[3] + [9] Toddler	Tier 1 + Tier 2 / None	10.7	8.83	82.52	Yes

Local effects

Local effects for general public are not identified by intended uses of the product performed by the professional or non-professional applicant. The main route of exposition is expected via inhaling vapour during application. The identified tasks do not indicate eye or dermal contact of the general public.

Conclusion

The performed risk assessment on systemic effects raise concern for the risk at worst case scenario level for some uses for children and toddlers as bystanders. Scenario [6] and Scenario [17] showed that the application of the product in domestic area lead to an unacceptable risk for systemic effects by inhalative exposure. At domestic areas like living rooms and kitchens a sufficient high ventilation cannot be assumed (no refinement possible). Therefore, an unacceptable risk for the use of product for children and toddler as bystanders in domestic area is identified. The RMM to protect children and toddlers 'Avoid' disinfection in the presence of children/toddlers is set for Use 2 and Use 4 and 7. Additionally for PT2 Use 5 the RMM 'Do not use for areas exceeding 0.5 m².' is set. Additionally for PT4 Use 7 the RMMs 'Do not use for areas exceeding 1 m² (private kitchens).' and 'Do not use more than the specified number of applications per day (cf. to use frequency).' are set.

Risk for consumers via residues in food

Not relevant, since no residues in food are expected. Please refer to chapter 'dietary exposure' for further information.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant, since neither additional active substances nor substances of concern are contained in the *Isopropylalkohol 70% (v/v)*.

2.2.7 Risk assessment for animal health

There is no information available demonstrating that pets or domestic animals are more susceptible to the active substance or the biocidal product. Therefore, it is assumed that secondary exposure and risk assessment for the general public can be considered for these animals. A risk for small children was identified in domestic area. Therefore the RMM 'N-220 Do not use near domestic animals.' should be applied

2.2.8 Risk assessment for the environment

Isopropylalkohol 70% (v/v) is a ready-to-use disinfectant which contains the active substance propan-2-ol. The product has not been tested for toxicity on aquatic and terrestrial organisms. Valid data are available for the active substance propan-2-ol which are sufficient for classification and labeling of the product and the environmental exposure and risk assessment.

2.2.8.1 Effects assessment on the environment

The PNEC values for the active substance propan-2-ol are deduced from the propan-2-ol Assessment Reports for PT1, 2 and 4 (Germany, 2015a, b, c). These values are used in the environmental exposure and risk assessment.

$PNEC_{water}$ [mg/L]	**$PNEC_{sed}$ [mg/kg_{wwt}]**	**$PNEC_{STP}$ [mg/L]**	**$PNEC_{soil}$ [mg/kg_{wwt}]**
2.82	2.41	10	0.496

Neither $PNEC_{bird}$ nor $PNEC_{small\ mammal}$ have been determined due to the low estimated BCF of propan-2-ol and associated low potential of accumulation in the environment.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

The biocidal product is a ready-to-use (RTU) formulation containing the active substance propan-2-ol.

The biocidal product is a dilution of the active substance propan-2-ol in water and does not contain any substance which has to be classified regarding environmental hazard. Therefore, the biocidal product is not classified with respect to the environment. Synergistic effects between the components are not expected. For the active substance propan-2-ol valid data are available, which are sufficient to perform the risk assessments.

Further Ecotoxicological studies

Not relevant

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Not relevant
No testing on other-non target organisms is required since the product is only used indoors.

Supervised trials to assess risks to non-target organisms under field conditions

Not relevant.
No testing on other-non target organisms is required since the product is only used indoors.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Not relevant
The biocidal product is not used in the form of a bait or granules.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant.
No testing on other-non target organisms is required since the product is only used indoors. A treatment of a specific habitat type is not the intended use. Studies are therefore not required.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Foreseeable routes of entry of the active substance propan-2-ol into the environment are described in the PAR on the basis of the "Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1)", (EUBEE 2004), the "Emission Scenario Document for Product Type 2: Private and public health area disinfectants and other biocidal products (EU 2011a)" and the "Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas (EU 2011b)". These ESDs adequately reflect the use of the product in PT1, 2 and 4. The information on how the active substance is released into the environment and the calculated PEC-values in the different compartments are provided in the PAR Chapter 2.2.8 "Risk assessment for the environment".

Further studies on fate and behaviour in the environment (ADS)

According to the "Guidance on the Biocidal Products Regulation, Volume IV: Environment, Part A (ECHA 2018b)" further studies may be required for "products that are used outside, with direct emission to soil, water or surfaces, the components in the product may influence the fate and behaviour (and ecotoxicity) of the active substance."
Since the biocidal product is solely to be used indoor, no further studies on fate and behaviour in the environment are required.
Furthermore, since the active substance is classified as readily biodegradable and no other substances are of concern, no further studies on fate and behaviour in the environment are necessary.

Leaching behaviour (ADS)

The leaching behaviour of the biocidal product Isopropylalkohol 70% (v/v) is not relevant since no leaching from treated articles occurs.

Testing for distribution and dissipation in soil (ADS)

Not relevant
Further testing is not required since the product is only used indoors.

Testing for distribution and dissipation in water and sediment (ADS)

Not relevant
Further testing is not required since the product is only used indoors.

Testing for distribution and dissipation in air (ADS)

Not relevant
Further testing is not required since the product is only used indoors.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

An outdoor spray application of Isopropylalkohol 70% (v/v) is not intended in either of the uses envisaged. Thus, no overspray study is required.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Since an outdoor spray application of Isopropylalkohol 70% (v/v) is not intended in either of the uses envisaged no data on overspray behaviour are required.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 1
Assessed scenarios	Scenario 1: Disinfection of skin and hand in hospitals (professional use) Scenario 2: Disinfection in human hygiene (non-professional use)
ESD(s) used	Emission Scenario Document for Product Type 1: EUBEES; Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1) (EUBEES 2004), Technical Agreements for Biocides (ECHA 2021)
Approach	Scenario 1: tonnage/average consumption Scenario 2: tonnage/average consumption
Distribution in the environment	Calculated based on ECHA-Guidance BPR, Vol. IV, ENV – Part B + C (ECHA 2017c) and in agreement with the assessment report on propan-2-ol (Germany 2015a, b, c).
Groundwater simulation	n.a.
Confidential Annexes	YES: In the confidential Annex 3.6.4. the tonnage based scenarios 1a and 2a are provided
Life cycle steps assessed	Scenario 1 and 2: Production: no Formulation: no Use: yes Service life: not relevant: no service-life after application
Remarks	non

Assessed PT	PT 2
Assessed scenarios	Scenario 3: Hard surface disinfection (small surfaces) in institutional areas (e.g. hospitals, hotels) (professional) Scenario 4: Hard surface disinfection (small surfaces) in industrial areas/premises Scenario 5: Hard surface disinfection in the sanitary sector (non-professional)
ESD(s) used	Emission Scenario Document for Product Type 2: JRC; Emission Scenario Document for Private and public health area disinfectants and other biocidal products (ECHA 2011a) Emission Scenario Document for Product Type 2: RIVM; Emission Scenarios Document for Private and public health area disinfectants and other biocidal products (sanitary and medical sector (EUBEES 2001), Technical Agreements for Biocides (ECHA 2021)
Approach	Scenario 3: tonnage based/ consumption based Scenario 4: consumption based Scenario 5: tonnage based/ consumption based

Distribution in the environment	Calculated based on ECHA-Guidance (ECHA 2017c) and in agreement with the Assessment Report on propan-2-ol (Germany 2015a, b, c).
Groundwater simulation	n.a.
Confidential Annexes	YES: In the confidential Annex 3.6.4. the tonnage based approaches 3a and 5a are provided
Life cycle steps assessed	Scenario 3, 4 and 5: Production: No Formulation: No Use: Yes Service life: not assessed, not relevant: no service-life after application
Remarks	non

General information

Assessed PT	PT 4
Assessed scenarios	Scenario 6: Disinfection in entire plants Scenario 7: Disinfection in large scale catering kitchens Scenario 8: Disinfection in private kitchens
ESD(s) used	Emission Scenario Document for Product Type 4: JRC; Emission Scenario Document for Disinfectants used in food and feed areas (ECHA 2011b), Technical agreement for biocides (ECHA 2021)
Approach	Scenario 6: average consumption Scenario 7: average consumption Scenario 8: average consumption
Distribution in the environment	Calculated based on ECHA-Guidance BPR, Vol. IV, ENV – Part B + C (ECHA 2017c) and in agreement with the assessment report on propan-2-ol (Germany 2015a, b, c).
Groundwater simulation	n.a.
Confidential Annexes	NO
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No, not relevant: no service-life after application
Remarks	non

Emission estimation

Scenarios for the use of the biocidal product were calculated both, consumption based and tonnage based (where appropriate) (EUBEES 2004, EUBEES 2001). Since the local emissions for the consumption based approach are higher than the emissions calculated with the tonnage based approach, the emission values of the consumption based approach are used for PEC calculation and risk assessment. Calculation tables for the tonnage based approaches 1a, 2a, 3a and 5a are given in the confidential Annex 3.6.4..

Use #1 - #4: Scenario 1b – Hand disinfection (professional use) – consumption based approach[1)]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Fraction released to wastewater	0.1	[-]	Germany 2015a, b, c
Fraction released to air	0.9	[-]	Germany 2015a, b, c
Efficient dose rate of the hand disinfectant	0.003	[L/event]	
Fraction of active substance in the hand disinfectant	0.631	[-]	
Number of applications	25	[-]	
Density of the product	0.8771	[kg/L]	
Qsubst,occup.bed	0.0831	[kg/bed*d]	

[1)]calculation according to ESD PT1, table 3.7, p. 13 (ECHA 2004)

Calculations for Scenario 1

Resulting local emission to relevant environmental compartments	
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**
STP	2.49
Air	22.4

Use #1 - #4: Scenario 2b – Hand disinfection (non-professional use) – consumption based approach[2)]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Number of applications	3	[-]	set value
Number of inhabitants feeding one STP	10000	[-]	Default value
Fraction of inhabitants using product	0.5	[-]	Worst case assumption

Active substance in product	631	[g/kg]	Data provided by costumer
Consumption per application	1.66	[g a.s.]	
Fraction released to wastewater	0.1	[-]	Germany 2015a, b, c
Fraction released to air	0.9	[-]	Germany 2015a, b, c
Specific density of the product	0.8771	kg/L	Set value
Market share of disinfectant	0.5	[-]	Default value

[2)]calculation according to ESD PT1, table 3.4, p. 10 (ECHA 2004)

Calculations for Scenario 2

Resulting local emission to relevant environmental compartments	
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**
STP	1.25
Air	11.2

Use #5.1: Scenario 3a Hard surface disinfection (small surfaces) in institutional areas – tonnage based approach

The calculation and results of the tonnage based approach are given in the confidential Annex 3.6.4.. Default values and calculations are based on ESD PT2 (EU 2011a), Section 2.1.4.2, Table 3.

Use #5.1: Scenario 3b Hard surface disinfection (small surfaces) in institutional areas– consumption based approach[1)]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Concentration at which the active substance is used	0.631	kg/L	applicant information

[1)]calculation according to ESD PT2, table 4, p. 16 (EU 2011a)

Calculations for Scenario 3b

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	2.21E+00	Sum of general purpose and lavatory
Air	1.99E+01	

Use #5.2: Scenario 4 - Disinfection in industrial areas (consumption based)[1)]

Since the default value for RTU products for small scale application refers to a certain number of applications, normally the default value of 1 application is used for the assessment and does not need to be changed (ECHA 2021). Due to more specific application rates given by the applicant for the use in the industrial area, the default value is set to 2 applications considering a more realistic worst case scenario (ECHA 2021, WG ENV VII 2018 6.3-5).

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Application rate of biocidal product	0.05	[L/m²]	applicant information
Concentration of active substance in the product	631	[g/L]	applicant information
Surface area to be disinfected	25	m^2	ECHA 2021
Fraction released to wastewater	0.1	[-]	Germany 2015a, b, c
Fraction released to air	0.9	[-]	Germany 2015a, b, c
Number of applications	2	[-]	Set value

[1)]calculation according to the calculation formula ESD PT2, table 2, p.12 (EU 2011a)

Calculations for Scenario 4

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.58E-01	Daily emission to the sewer system
Air	1.42E+00	

Use #5.3: Scenario 5a – Hard surface disinfection for sanitary purposes – non-professional (tonnage based)

Disinfection used for sanitary purposes (tonnage based)[1)]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Relevant tonnage in the EU for this application	--	[t/yr]	Confidential information
Fraction for the region	0.1	[-]	

[1)]calculation according to ESD PT2, table 2.1, p. 9 (EUBEES 2001)

Results of the calculation are given in the conf. Annex 3.6.4.

Use #5.3: Scenario 5b – Hard surface disinfection for sanitary purposes – non-professional (consumption based)[2)]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Fraction released to wastewater	0.1	[-]	Germany 2015a, b, c
Fraction released to air	0.9	[-]	Germany 2015a, b, c
Concentration at which active substance is used	0.631	[kg/L]	applicant information
Consumption per capita	0.007	[L/cap*d]	
Fraction of substance disintegrated during or after application (before release to the sewage system)	0	[-]	

[2)]calculation according to ESD PT2, table 2.2, p. 10 (EUBEES 2001)

Calculations for Scenario 5b

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	2.21E+00	SUM (General + Lavatory), daily emission to the sewer system
Air	1.99E+01	

Use #6: Scenario 6 - Disinfection in entire plants – professional user[1)]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Amount of biocidal active substance used per year in the local plant	143	[kg/year]	Pick value
Fraction released to wastewater	0.1	[-]	Germany 2015a, b, c
Fraction released to air	0.9	[-]	Germany 2015a, b, c

[1)]calculation according to ESD PT 4, table 5, p. 15 (EU 2011)

Calculations for Scenario 6

Resulting local emission to relevant environmental compartments			
Compartment		**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP[2)]	On-site STP	4.8E-03	Daily emission to on-site STP
	Off-site STP	6.2E-02	Daily emission to off-site STP
Air[3)]		0.557	

[2)] $E_{local,water}$ (on-site STP) was calculated using the calculation excel sheet for PT4 and inserting the values of $C_{local,water}$ into equations 35 and 36, respectively, of the Guidance on the BPR, Volume IV ENV, (Parts B + C) (ECHA 2017c)
[3)] Local emission to air was calculated by the formula: Elocal(air)=(Qai/Temission)*Fair

Use #6: Scenario 7 - Disinfection in large scale catering kitchens (small scale application) – professional user[1)]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Application rate of the active substance	27.7	[g/m^2]	applicant information
Fraction released to wastewater	0.1	[-]	Germany 2015a, b, c
Fraction released to air	0.9		Germany 2015a, b, c
Area to be disinfected	50	[m^2]	ECHA 2021

[1)]calculation according to ESD PT4, table 10, p.24 (EU 2011)

Calculations for Scenario 7

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission (Elocal$_{compartment}$) [kg/d]**	**Remarks**
STP	0.139	Daily emission to the sewer system
Air	1.247	

Use #7: Scenario 8 - Disinfection in private kitchens – non-professional user[2)]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Application rate of the biocidal product	43.85	[g/m^2]	applicant information
Concentration of the active substance in the biocidal product	0.631	[g/g]	applicant information
Fraction released to wastewater	0.1	[-]	Germany 2015a, b, c
Fraction released to air	0.9	[-]	Germany 2015a, b, c

[2)]calculation according to TAB ENV 70 (ECHA 2021)

Calculations for Scenario 8

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.107	Daily emission to the sewer system
Air	9.961	

Fate and distribution in exposed environmental compartments

The fate and distribution in exposed environmental compartments is covered by the active substance data on propan-2-ol (Germany 2015a, b, c).

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	yes	yes	n.r.	n.r.	yes	yes	yes	yes	n.r.
Scenario 2	yes	yes	n.r.	n.r.	yes	yes	yes	yes	n.r.
Scenario 3	yes	yes	n.r.	n.r.	yes	yes	yes	yes	n.r.
Scenario 4	yes	yes	n.r.	n.r.	yes	yes	yes	yes	n.r.
Scenario 5	yes	yes	n.r.	n.r.	yes	yes	yes	yes	n.r.
Scenario 6	yes	yes	n.r.	n.r.	yes	yes	yes	yes	n.r.
Scenario 7	yes	yes	n.r.	n.r.	yes	yes	yes	yes	n.r.
Scenario 8	yes	yes	n.r.	n.r.	yes	yes	yes	yes	n.r.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	60.09	g/mol	Germany 2015a, b, c
Melting point	-89.5	°C	Germany 2015a, b, c
Boiling point (1013 hPa)	82.5	°C	Germany 2015a, b, c
Vapour pressure (at 25 °C)	5780	Pa	Germany 2015a, b, c
Relative density (at 20 °C)	0.78505	g/kg	Germany 2015a, b, c
Water solubility (at 25 °C)	1000000	mg/L	Germany 2015a, b, c
Henry´s Law constant (at 25 °C)	0.80	Pa x m^3/mol	Germany 2015a, b, c

Organic carbon/water partition coefficient (Koc)	3.31	L/kg	Germany 2015a, b, c
Octanol water partition coefficient	0.05	[-]	Germany 2015a, b, c
Solids-water partitioning coefficient of suspended matter	0.331	L/kg	Calculated with EUSES 2.2.0
Suspended matter-water partitioning coefficient	0.983	L/kg	Calculated with EUSES 2.2.0
Soil-water partitioning coefficient	0.299	L/kg	Calculated with EUSES 2.2.0
Biodegradability	Readily biodegradable		Germany 2015a, b, c
DT_{50} for degradation in soil (at 12ºC)	30	d	default

Calculated fate and distribution in the STP	
Compartment	**Percentage [%]**
Fraction of emission emitted to air by STP	0.181
Fraction of emission emitted to water by STP	7.98
Fraction of emission via primary settler	0.0299
Fraction of emission via surplus sludge[1)]	1.04E-03
Fraction of emission degraded in STP	91.8

[1)]The fraction of emission to the sludge that is applied on agricultural soil ($F_{STP\text{-}soil}$) is calculated as the sum of the fraction of emission in the primary settler and the fraction of emission in the surplus sludge.

The distribution of propan-2-ol in the STP was calculated with EUSES 2.2.0 and Simple Treat 4.0, respectively, based on the physical-chemical properties of the active substance.

In the following the calculated PEC-values for each scenario of the relevant PTs are presented.

Calculated PEC values

Summary table on calculated PEC values						
		PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}[1]**
		[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
PT1	Scenario 1	9.9E-02	9.9E-03	8.5E-03	1.3E-03	4.07
PT1	Scenario 2	5.0E-02	4.9E-03	4.3E-03	6.5E-04	2.04
PT2	Scenario 3	8.8E-02	8.8E-03	7.5E-03	9.9E-04	2.7
	Scenario 4b	6.3E-03	6.3E-04	5.4E-04	7.4E-05	0.22
	Scenario 5b	8.8E-02	8.8E-03	7.5E-03	1.1E-03	3.5

PT4	Scenario 6	On-site[1)]	5.5E-01	3.4E-03	2.9E-03	2.9E-05	0.09
		Off-site	2.5E-03	2.5E-04	2.1E-04		
	Scenario 7		5.5E-03	5.5E-04	4.7E-04	6.5E-05	0.19
	Scenario 8		4.4E-02	4.4E-03	3.8E-03	5.6e-04	1.76
	[1)] PEC_{sed} and PEC_{STP} for scenario 6 (on-site STP) were calculated by following the Guidance on BPR, Vol. VI ENV Part B&C, Equation 53 (PEC_{sed}) (ECHA 2017c) and by applying the dilution factor of 160 given by the ESD PT4 (EU 2011b) on PEC_{water}, respectively, since PEC_{water} = $Clocal_{eff}$ is already given by the calculation of the scenario.						

Primary and secondary poisoning

Primary poisoning

Considering the proposed uses of the propan-2-ol a primary poisoning of birds or mammals is not anticipated.

Secondary poisoning

A $logK_{ow}$ of 0.05 was determined for propan-2-ol, which is below the relevant trigger value of 3 as stated in the Guidance on BPR, Vol.IV ENV, Part B + C (ECHA 2017c). The calculation of the bioconcentration factors based on $logK_{ow}$ of 0.05 according to the BPR guidance mentioned before results in a $BCF_{earthworm}$ of 0.853 L/kg_{wwt} and BCF_{fish} of 0.22 L/kg_{wwt}. The results show that propan-2-ol does have no evidence to bioaccumulate. Thus, there is no concern with respect to secondary poisoning (Germany 2015a, b, c).

2.2.8.3 Risk characterisation

Atmosphere

Conclusion:
It was concluded in the assessment report that due to the intended uses of propan-2-ol and the available substance information the environmental risk of propan-2-ol for the atmosphere can be assumed as low (Germany 2015a, b, c).

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values		
		PEC/PNEC$_{STP}$
PT1	Scenario 1	9.9E-03
	Scenario 2	5.0E-03
PT2	Scenario 3	8.8E-03
	Scenario 4b	6.3E-04
	Scenario 5b	8.8E-03
PT4	Scenario 6 - onsite	5.5E-02
	Scenario 6 - offsite	2.5E-04
	Scenario 7	5.5E-04
	Scenario 8	4.4E-03

Conclusion:
The individual PEC/PNEC ratios for the STP scenarios for propan-2-ol within the different PTs are below the trigger value of 1. Therefore it is concluded that there is no unacceptable risk for this environmental compartment.

Aquatic compartment

Summary table on calculated PEC/PNEC values			
		PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
PT1	Scenario 1	3.5E-03	3.5E-03
	Scenario 2	1.7E-03	1.8E-03
PT2	Scenario 3	3.1E-03	3.1E-03
	Scenario 4b	2.2E-04	2.2E-04
	Scenario 5b	3.1E-03	3.1E-03
PT4	Scenario 6 - onsite	1.2E-03	1.2E-03
	Scenario 6 - offsite	8.8E-05	8.8E-05
	Scenario 7	1.9E-04	1.9E-04
	Scenario 8	1.6E-03	1.6E-03

Conclusion: For the emission pathway via STP, the PEC/PNEC values for the aquatic compartment are below 1 for propan-2-ol within the assessed PTs. Therefore it is concluded that there is no unacceptable risk for the environment for the aquatic compartment.

Terrestrial compartment

Calculated PEC/PNEC values		
		PEC/PNEC$_{soil}$
PT1	Scenario 1	2.6E-03
	Scenario 2	1.3E-03
PT2	Scenario 3	1.9E-03
	Scenario 4b	1.5E-04
	Scenario 5b	2.2E-03
PT4	Scenario 6	6.0E-05
	Scenario 7	1.3E-04
	Scenario 8	1.1E-03

Conclusion:
For the emission pathway via STP, the individual PEC/PNEC ratios for propan-2-ol are below 1 for the terrestrial compartment. Therefore it is concluded that there is no unacceptable risk for the environment for the terrestrial compartment.

Groundwater

For groundwater, exceedances of the groundwater trigger value of 0.1 µg/L of the EU Drinking Water Directive (Council Directive 98/83/EC) were calculated for most of the scenarios.
There are two different release pathways to groundwater, via air (90% for propan-2-ol) and via sludge application ($F_{STP\text{-}sludge}$ = 0.031% of 10% emission to wastewater for propan-2-ol). According to the TAB ENV 188 (ECHA 2021), is was concluded, that for products containing very volatile substances, there is no need to conduct a risk assessment for subsequent environmental compartments following the release pathway via air. This conclusion is applicable for propan-2-ol, since it is a volatile alcohol. This conclusion also concerns all relevant PTs, which are PT 1, 2 and 4 for propan-2-ol. Therefore, no risk assessment was conducted for groundwater exposure from outdoor air deposition.
For the release pathway via STP, no unacceptable risk was calculated for soil due to sludge application. Nevertheless, the groundwater trigger value of 0.1 µg/L was exceeded for some of the scenarios.
According to the conclusion and final minutes of the WG-VII-ENV-2018, when FOCUS PEARL is used for the groundwater assessment of volatile compounds, the model might not be suitable, since it overestimates the leaching rate to groundwater. It is further stated that in general, for very volatile substances "[…]no assessment of the groundwater compartment is needed. The exceedance of the groundwater trigger value is not likely and the FOCUS PEARL model is unlikely to provide realistic concentrations."
Whilst the discussion was relating to PT2 use, the CA of AT is of the opinion that losses of propan-2-ol from other applications in PT1 and PT4 behave in exactly the same way and can be handled identically in the risk assessment.

In conclusion, based on expert judgement and the physical and chemical properties of propan-2-ol (high volatility, weak adsorption properties, low $DT50_{soil}$), the trigger value of 0.1 µg/L is not expected to be realistically exceeded.

No unacceptable risk to the groundwater compartment is expected.

Primary and secondary poisoning

Conclusion:
There is no unacceptable risk of primary and secondary poisoning during application and/or service life of Isopropylalkohol 70% (v/v).

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

Hand disinfection / small surface disinfection: Emission pathways
- via STP

Screening Step 2: Identification of relevant substances

According to the "Transitional Guidance on mixture toxicity assessment for the environment (May 2014)" the following substances need to be considered as relevant for the mixture assessment:

1. active substance
2. substances of concern (SoC)
3. active substances from other PTs
4. other ingredients

Only one active substance and no substances of concern are contained in the product. In addition, no active substances from other PTs and no other ingredients that need consideration are contained.

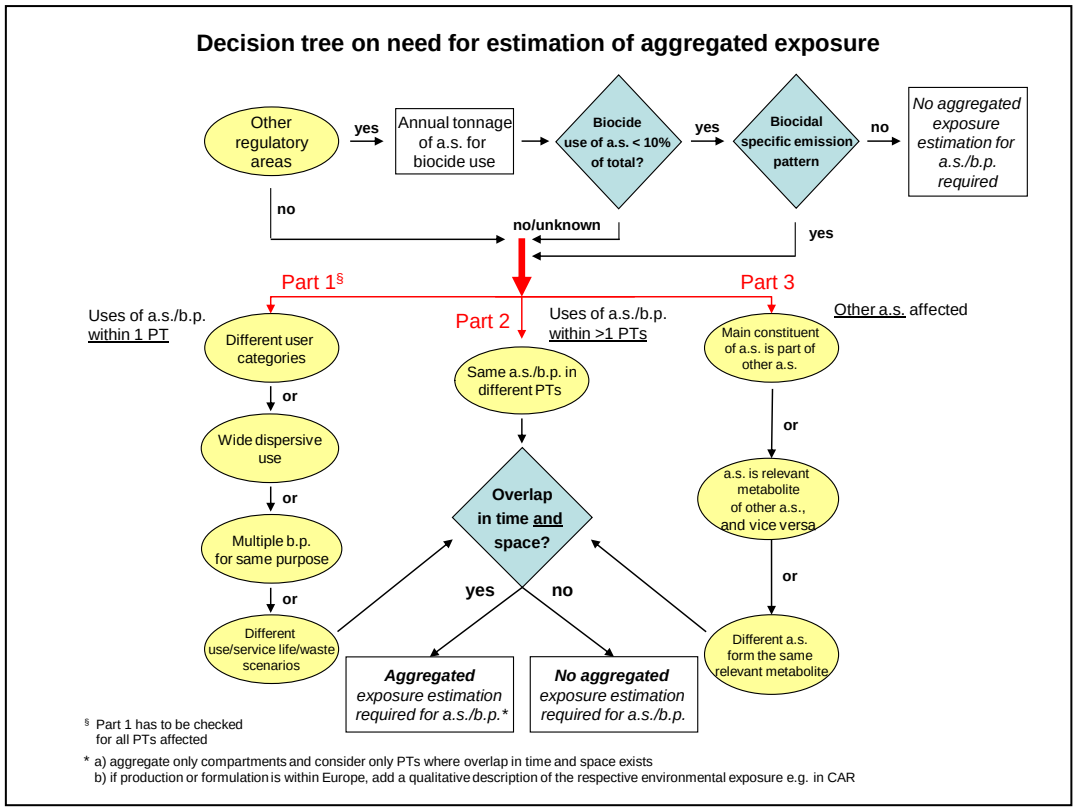
Screening Step 3: Screen on synergistic interactions

Not applicable, since only one relevant substance is contained in products.

Screening step		
1	Significant exposure of environmental compartments?	**Yes**
2	Number of relevant substances >1?	**No**
3	Indication for synergistic effects for the product or its constituents in the literature?	**No**

Conclusion:
No assessment of mixture toxicity needed according to the criteria defined in the above table.

Aggregated exposure (combined for relevant emmission sources)



Conclusion:

It is concluded in the assessment report that no aggregated exposure assessment is required since the tonnage for biocidal purposes is less than 10% of the total tonnage produced. Furthermore, no specific biocidal use pattern could be identified (Germany 2015a, b, c).

Overall conclusion on the risk assessment for the environment of the product
The results of the environmental risk assessment show that there is no unacceptable risk for the environment from the authorised use of the product Isopropylalkohol 70% v/v.

2.2.9 Measures to protect man, animals and the environment

Measures to prevent fire:
Electrostatic discharge may cause fire. Ensure electrical continuity by bonding and grounding (earthing) all equipment. Avoid splash filling. Do NOT use compressed air for filling, discharging, or handling operations.
Extinguish any naked flames. Do not smoke. Remove ignition sources. Avoid sparks. Containers, even those that have been emptied, can contain explosive vapours. Do not cut, drill, grind, weld or performsimilar operations on or near containers.

Methods and precautions concerning transport
Land transport ADR/RID and GGVSEB, Inland water ways transport (ADN):
Class: 3
UN-No.: 1219
Packing group: II
Hazard identification no.: 33
Hazard label(s): 3
Tunnel restriction code: (D/E)
Proper Shipping Name: ISOPROPANOL

Sea transport (IMDG):
Class: 3
UN-No.: 1219
Packing group: II
Hazard label(s): 3
EMS number: F-E, S-D
Marine pollutant: No
Proper Shipping Name: ISOPROPANOL

Air transport (ICAO-TI / IATA-DGR):
Class: 3
UN-No.: 1219
Packing group: II
Hazard label(s): 3
Proper Shipping Name: ISOPROPANOL

Methods and precautions concerning fire
Extinguishing media
Suitable extinguishing media: Carbon dioxide (CO_2), alcohol resistant foam, dry extinguishing powder, water spray jet. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: Full water jet.

Special hazards arising from the substance or mixture: Highly flammable liquid and vapour. Solvent vapours may form explosive mixtures with air. Solvent vapours may form explosive mixtures with air. The vapour is heavier than air, spreads along the ground and distant ignition is possible. Vapours may be ignited by a spark, a hot surface or an ember. In case of fire may be liberated: hazardous combustion products: At low oxygen level: corrosive substances; carbon monoxide and carbon dioxide.

Information for fire-fighting
In case of fire: Use respiratory protection independent of recirculated air and protective fire-fighting clothing.
If protective equipment is not available or not used, fight fire from an protected location or safe distance. Keep adjacent containers cool by spraying with water. Use appropriate containment (of product and fire fighting water) to avoid environmental contamination. Prevent from spreading or entering drains, ditches or rivers.

Possibility of neutralization of effects
The biocidal effects of the biocidal product may be neutralised by dilution with water.

Conditions for controlled discharge and incineration
Controlled discharge or incineration of the product is not foreseen. Regarding incineration, the biocidal product is highly flammable.

Possibility of destruction or decontamination following release in the air
In case of evaporation of large amounts of the biocidal product, ensure adequate ventilation and keep away sources of ignition.

Possibility of destruction or decontamination following release in water, including drinking water
The biocidal product is miscible in water and readily biodegradable, decontamination is not possible.

Possibility of destruction or decontamination following release in or on soil
Decontamination of soil is not necessary due to volatilisation and ready biodegradability.

Specify any repellents or poison control measures included in the preparation that are present to prevent action against non-target organisms
Not applicable; no control measures or repellents required

Please refer to chapters 2.1.3, 2.1.4 and 2.1.5. and 2.2.5, 2.2.6 as well as 2.2.8 for additional information.

2.2.10 Assessment of a combination of biocidal products

Not relevant, product is not recommended to be used in combination with other biocidal products.

2.2.11 Comparative assessment

Since the active substance propan-2ol has not been identified as a candidate for substitution a comparative assessment is not needed.

2.2.12 ED Assessment

According to the CAR for propan-2-ol (cf. to Germany 2015 a,b,c), there is no indication for endocrine disrupting properties of the active substance. Additionally, there is no indication for endocrine disrupting properties of the co-formulants of the biocidal product.
In summary, there is no indication for endocrine disrupting properties of the biocidal product.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data owner
3.1 3.2 3.3 3.4.1.2 3.5.12	Anonymous	2016a	Bericht des Stabilitätstests für die Stabilitätsuntersuchung der Biozid-Produkte Isopropylalkohol 70% (v/v), Isopropylalkohol 70% (v/v) API grade/USP, Isopropylalkohol 70% (v/v) G25 sterilfiltriert	Aug. Hedinger GmbH & Co. KG, Qualitätskontrolle, Stuttgart, Germany		No (Laboratory is GMP certified)	Yes	Aug. Hedinger GmbH & Co. KG
3.2	Anonymous	2018a	pH-value of a 1 % aqueous dilution	Aug. Hedinger GmbH, Germany		No (Laboratory is GMP certified)	Yes	Aug. Hedinger GmbH & Co. KG
3.2	Anonymous	2021a	Determination of pH value according to CIPAC MT 75.3	Aug. Hedinger GmbH, Germany		No (Laboratory is GMP certified)	Yes	Aug. Hedinger GmbH & Co. KG

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data owner
5.1	Anonymous	2013a	Determination of "Volatile Impurities" in Isopropyl Alcohol and the "Assay" of Isopropyl Alcohol via GC - Validation Report	Aug. Hedinger GmbH & Co. KG	IPA-CW20.M	No	Yes	Aug. Hedinger GmbH & Co. KG
5.1	Anonymous	2016j	Validation of Method: MV134 - BG: GC-Determination of Ethanol, 1-Propanol and 2-Propanol in Formulations	BioGenius GmbH TechnologiePark, Friedrich-Ebert-Strasse, 51429 Bergisch Gladbach, Germany	Mo5421	yes	yes	BioGenius GmbH
5.1	Anonymous	2016k	MV134 BG GC-Determination of Ethanol, 1-Propanol and 2-Propanol in Formulations	BioGenius GmbH TechnologiePark, Friedrich-Ebert-Strasse, 51429 Bergisch Gladbach, Germany	MV134	yes	yes	BioGenius GmbH

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data owner
6.7	Anonymous	2016b	Bactericidal Activity of Isopropylalkohol 70% (V/V) in the quantitative suspension test according to DIN EN 13727:2015 (Phase 2, Step 1).	Dr. Brill + Partner GmbH - Institute for Hygiene und Microbiology, Hamburg; Gemany	L16/0113.6	Not specified	Yes	Aug. Hedinger GmbH & Co. KG, Stuttgart; Germany
6.7	Anonymous	2016c	Yeasticidal Activity of Isopropylalkohol 70% (V/V) in the quantitative suspension test according to DIN EN 13624:2013 (Phase 2, Step 1).	Dr. Brill + Partner GmbH - Institute for Hygiene und Microbiology, Hamburg; Gemany	L16/113.2	Not specified	Yes	Aug. Hedinger GmbH & Co. KG, Stuttgart; Germany
6.7	Anonymous	2016d	Suitability of Isopropylalkohol 70% (V/V) for hygienic handrub in the practice-like trial with test persons according to DIN EN 1500:2013 (Phase 2, Step2).	Dr. Brill + Partner GmbH - Institute for Hygiene und Microbiology, Hamburg; Gemany	L16/113.7	Not specified	Yes	Aug. Hedinger GmbH & Co. KG, Stuttgart; Germany

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data owner
6.7	Anonymous	2016e	Bactericidal Activity of Isopropylalkohol 70% (V/V) in the quantitative suspension test according to DIN EN 13727:2015 (Phase 2, Step 1).	Dr. Brill + Partner GmbH - Institute for Hygiene und Microbiology, Hamburg; Gemany	L16/0113.5	Not specified	Yes	Aug. Hedinger GmbH & Co. KG, Stuttgart; Germany
6.7	Anonymous	2016f	Yeasticidal Activity of Isopropylalkohol 70% (V/V) in the quantitative suspension test according to DIN EN 13624:2013 (Phase 2, Step 1).	Dr. Brill + Partner GmbH - Institute for Hygiene und Microbiology, Hamburg; Gemany	L16/0113.12	Not specified	Yes	Aug. Hedinger GmbH & Co. KG, Stuttgart; Germany
6.7	Anonymous	2016g	Bactericidal and Yeasticidal Activity of Isopropylalkohol 70% (V/V) in the quantitative surface test according to DIN EN 13697:2015 (Phase 2, Step 2).	Dr. Brill + Partner GmbH - Institute for Hygiene und Microbiology, Hamburg; Gemany	L16/0113.13	Not specified	Yes	Aug. Hedinger GmbH & Co. KG, Stuttgart; Germany

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data owner
6.7	Anonymous	2016h	Bactericidal Activity of Isopropylalkohol 70% (V/V) in the quantitative suspension test according to DIN EN 1276:2009 (Phase 2, Step 1).	Dr. Brill + Partner GmbH - Institute for Hygiene und Microbiology, Hamburg; Gemany	L16/0113.4	Not specified	Yes	Aug. Hedinger GmbH & Co. KG, Stuttgart; Germany
6.7	Anonymous	2016i	Yeasticidal Activity of Isopropylalkohol 70% (V/V) in the quantitative suspension test according to DIN EN 1650:2013 (Phase 2, Step 1).	Dr. Brill + Partner GmbH - Institute for Hygiene und Microbiology, Hamburg; Gemany	L16/0113.11	Not specified	Yes	Aug. Hedinger GmbH & Co. KG, Stuttgart; Germany
6.7	Anonymous	2017a	Expert Opinion on the efficacy of Isopropylalkohol 70% v/v against Modified Vaccinia Virus Ankara (MVA)	Labor Prof. Dr. G. Enders MVZ GbR, Rosenbergstraße 85, 70193 Stuttgart, Germany	LI-017-149	Not specified	Yes	Aug. Hedinger GmbH & Co. KG, Stuttgart; Germany

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data owner
6.7	Anonymous	2020a	Expert Opinion/ Test report on the efficacy of Isopropyl alcohol 70% against the Modified vaccinia virus Ankara (MVA) according to EN 16777	Labor Prof. Dr. G. Enders MVZ GbR, Rosenbergstraße 85, 70193 Stuttgart, Germany	LI-020-376	Not specified	Yes	Aug. Hedinger GmbH & Co. KG, Stuttgart; Germany

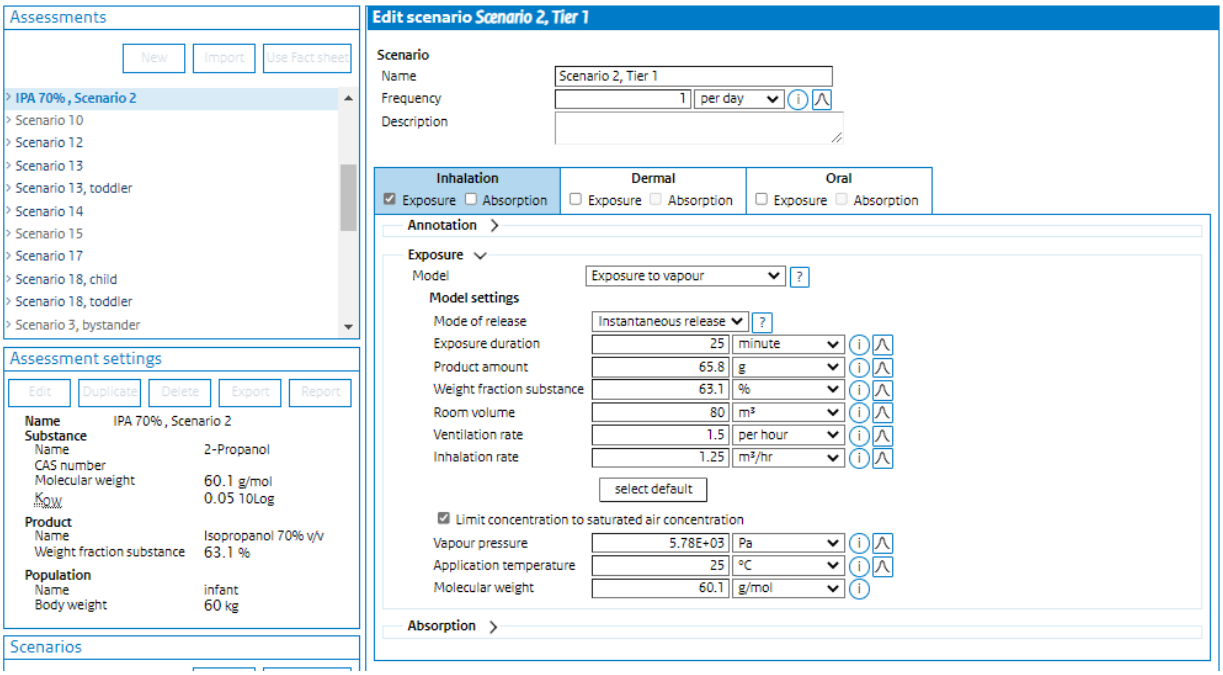
3.2 Output tables from exposure assessment tools

HUMAN HEALTH RISK ASSESSMENT

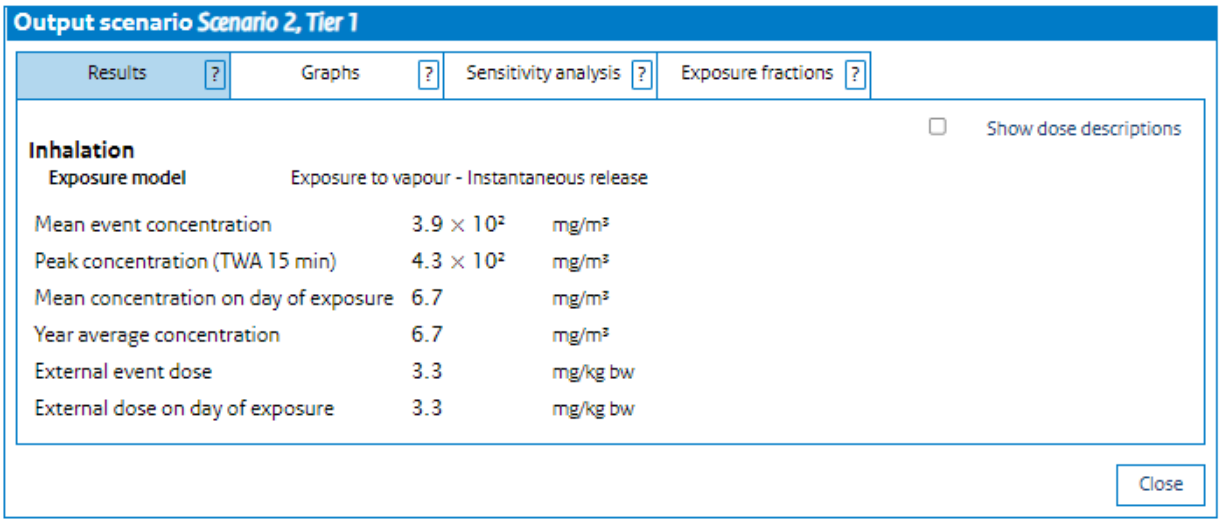
3.2.1 Scenario [2]: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – professional use (primary exposure)

Calculation ConsExpo Web

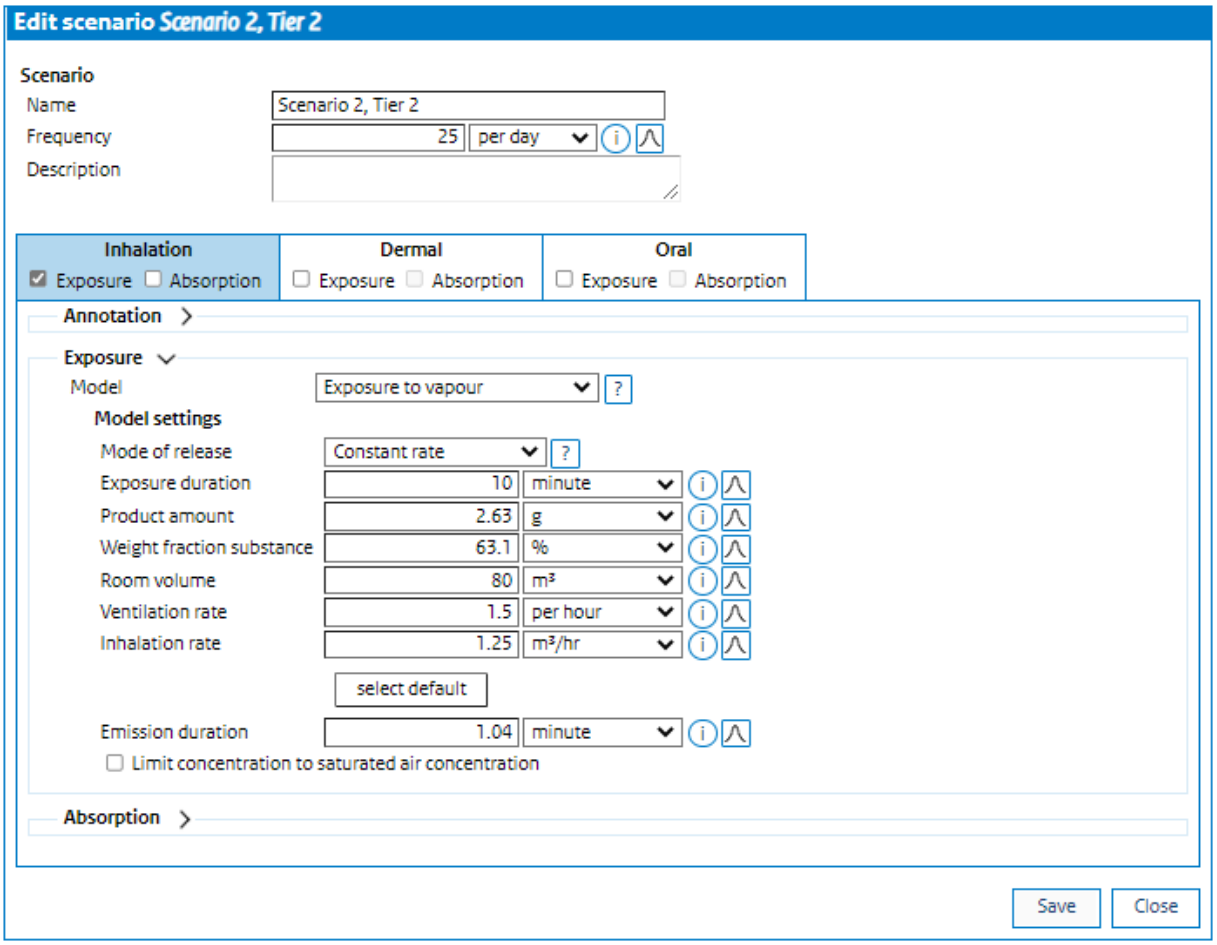
Tier 1 inhalative exposure



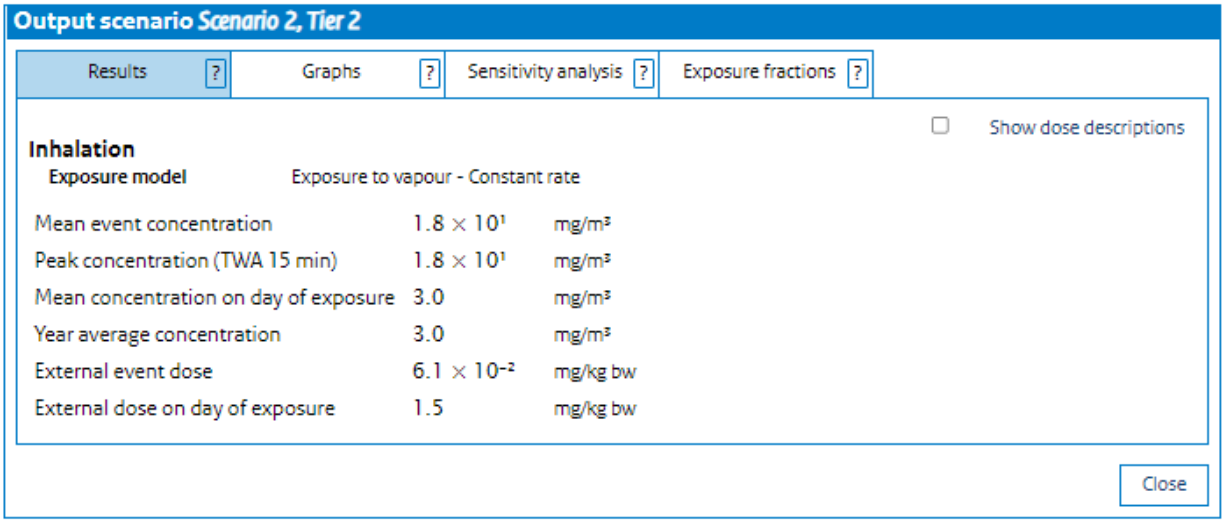
Tier 1 Results



Tier 2 inhalative exposure



Tier 2 Results



Calculation model for Tier 2 inhalative exposure, raw data

Time (min)	Air concentration
0,00	0,00
0,10	1,99
0,20	3,98
0,30	5,96
0,40	7,94
0,50	9,91
0,60	11,90
0,70	13,80
0,80	15,80
0,90	17,80
1,00	19,70
1,10	20,40
1,20	20,40
1,30	20,30
1,40	20,30
1,50	20,20
1,60	20,20
1,70	20,10
1,80	20,10
1,90	20,00
2,00	20,00
2,10	19,90
2,20	19,90
2,30	19,80

2,40	19,80
2,50	19,70
2,60	19,70
2,70	19,60
2,80	19,60
2,90	19,50
3,00	19,50
3,10	19,40
3,20	19,40
3,30	19,40
3,40	19,30
3,50	19,30
3,60	19,20
3,70	19,20
3,80	19,10
3,90	19,10
4,00	19,00
4,10	19,00
4,20	18,90
4,30	18,90
4,40	18,80
4,50	18,80
4,60	18,70
4,70	18,70
4,80	18,60
4,90	18,60
5,00	18,50
5,10	18,50
5,20	18,50
5,30	18,40
5,40	18,40
5,50	18,30
5,60	18,30
5,70	18,20
5,80	18,20
5,90	18,10
6,00	18,10
6,10	18,00
6,20	18,00
6,30	18,00
6,40	17,90
6,50	17,90
6,60	17,80
6,70	17,80

6,80	17,70
6,90	17,70
7,00	17,60
7,10	17,60
7,20	17,60
7,30	17,50
7,40	17,50
7,50	17,40
7,60	17,40
7,70	17,30
7,80	17,30
7,90	17,20
8,00	17,20
8,10	17,20
8,20	17,10
8,30	17,10
8,40	17,00
8,50	17,00
8,60	17,00
8,70	16,90
8,80	16,90
8,90	16,80
9,00	16,80
9,10	16,70
9,20	16,70
9,30	16,70
9,40	16,60
9,50	16,60
9,60	16,50
9,70	16,50
9,80	16,40
9,90	16,40
10,00	16,40

Calculation according to ECHA 2016a, Recommendation no. 9 of the BPC Ad hoc Working Group on Human Exposure Annex 2: Inhalation exposure calculation with ConsExpo Excel file

mean concentration (1 disinfection)		
17,46	**mg/m3**	
mean concentration (3 disinfections)		
26,72	**mg/m3**	
remaining air concentration (240 min)		
0,26	**mg/m3**	

ConsExpo Parameter

exposure duration:	10	min (default)
product amount:	2,631	g
weight fraction:	0,647	
room volume:	80	m3 (default)
ventilation rate:	1,5	/h (default)
emission duration:	1,61	min
duration - 1 event	10	min
duration - 3 events	20	min
different rooms	4	

Result

Calculation 8 h TWA for 3 hand disinfections in 4 different rooms (**with remaining**)

(mean event conc. (3 disinfections)*20 min*4 rooms + (mean event conc. (3 disinfections) + remaining conc.)*20 min*4 rooms + mean event conc. (1 disinfection)*10 min)/480 min = 8h TWA

8h TWA = 9,31 mg/m3

Calculations for systemic exposure

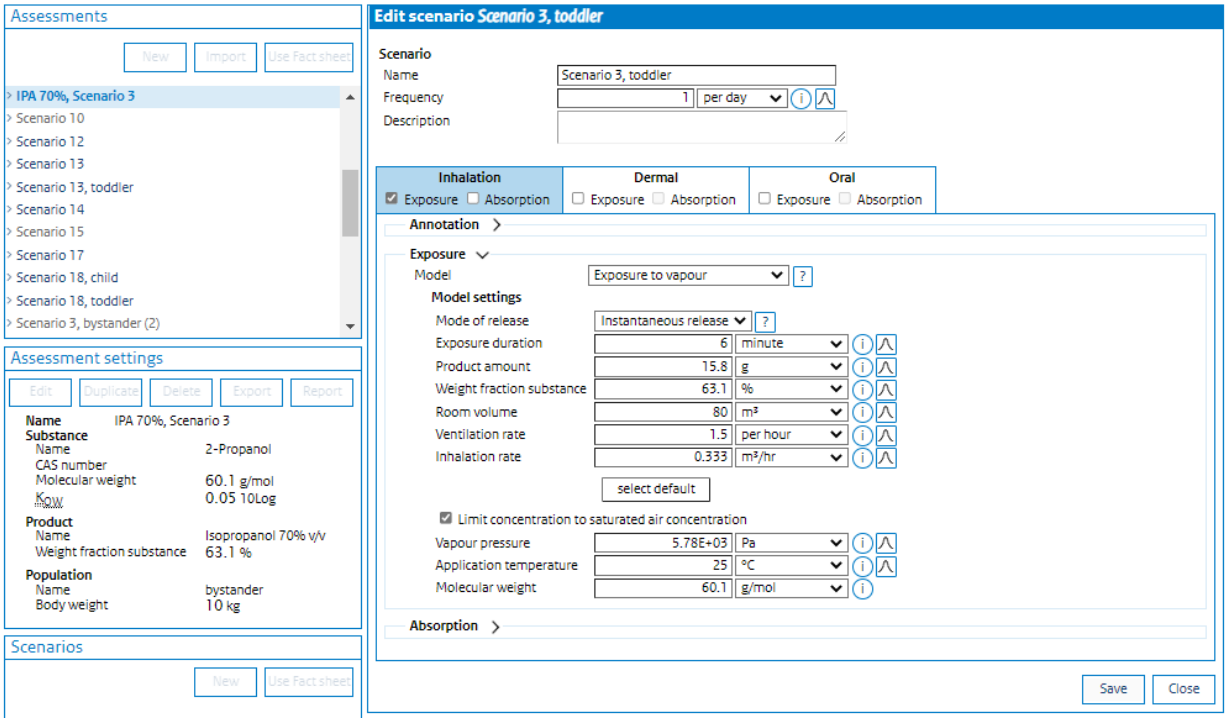
Tier 1	**Inhalative exposure calculation (instantenous rate)**			
	Peak concentration (TWA 15 min) (Consexpo)	430	mg/m³	CONSEXPO WEB
	Inhalation rate	1,25	m³/h	Methodology
	exposure duration	0,4166	h	Headhoc 9
	exposure per day	1	1/day	Headhoc 9
	body weight adult	60	kg	Methodology
	inhalation absorption	100	%	Tox Wert
	inhalation exposure	**3,73**	**mg/kg bw/day**	

Evaporation time	**Value**	**Unit**	**Reference**
mass	1660,3503	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9
skin temperature	303,15	K	Headhoc 9
molar mass	60,09	g/mol	Headhoc 9
coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9
vapour pressure of the pure substance	5780	Pa	Germany 2015

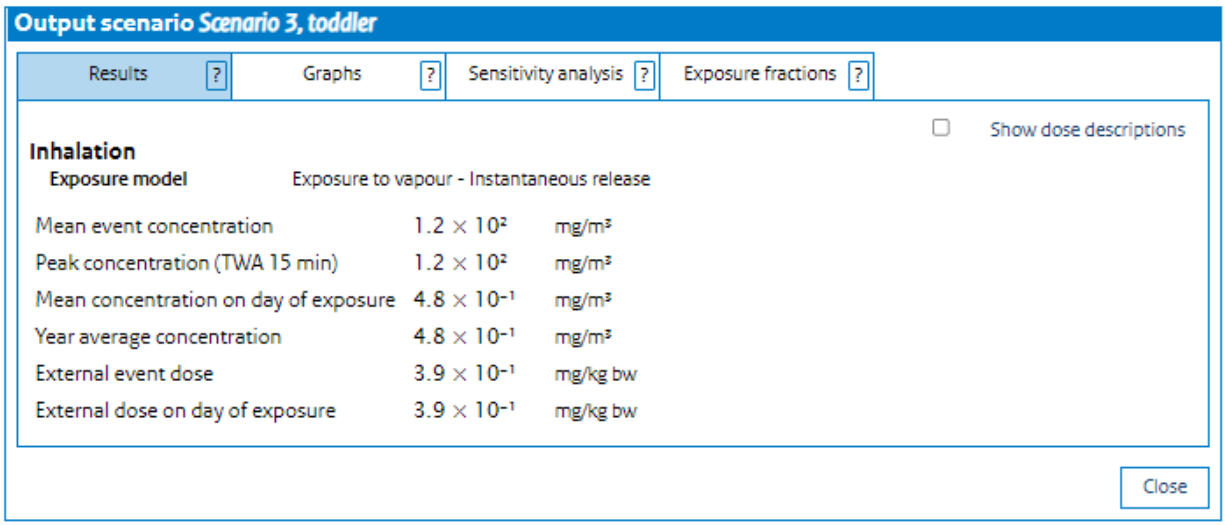
	area	820	cm²	Headhoc 9
	conversion factor	36000	s	Headhoc 9
	evaporation time	**60,80043284**	**s**	
		1,013340547	**min**	
Tier 2	**Inhalative exposure calculation (constant rate)**			
	Indicatice value (Consexpo)	9,312873333	mg/m³	CONSEXPO WEB
	Inhalation rate	1,25	m³/h	Methodology
	exposure duration	8	h	Headhoc 9
	exposure per day	1	1/day	Headhoc 9
	body weight adult	60	kg	Methodology
	inhalation absorption	100	%	Tox Wert
	inhalation exposure	**1,55**	**mg/kg bw/day**	
	Dermal exposure calculation			
	evaporation time	1,013340547	min	HeadHoc 9
	Number of cycles per day	25	per day	HeadHoc 9
	Dermal absorption	0,85	mg/cm²/h	Germany 2015
	Area (palms and backs of both hands)	820	cm²	Methodology
	Body weight adult	60	kg	Methodology
	systemic dermal exposure	**4,904849733**	**mg/kg bw/day**	
	Total systemic exposure	**6,46**	**mg/kg bw/day**	
	AEL (professionals)	**17,9**	**mg/kg bw/day**	

3.2.2 Scenario [3]: Hygienic handrub (PT1), e.g. in hospitals, medical practices, pharmacies, sanitary facilities of work places and industrial production areas – general public (secondary exposure)

Calculation ConsExpo Web



Results



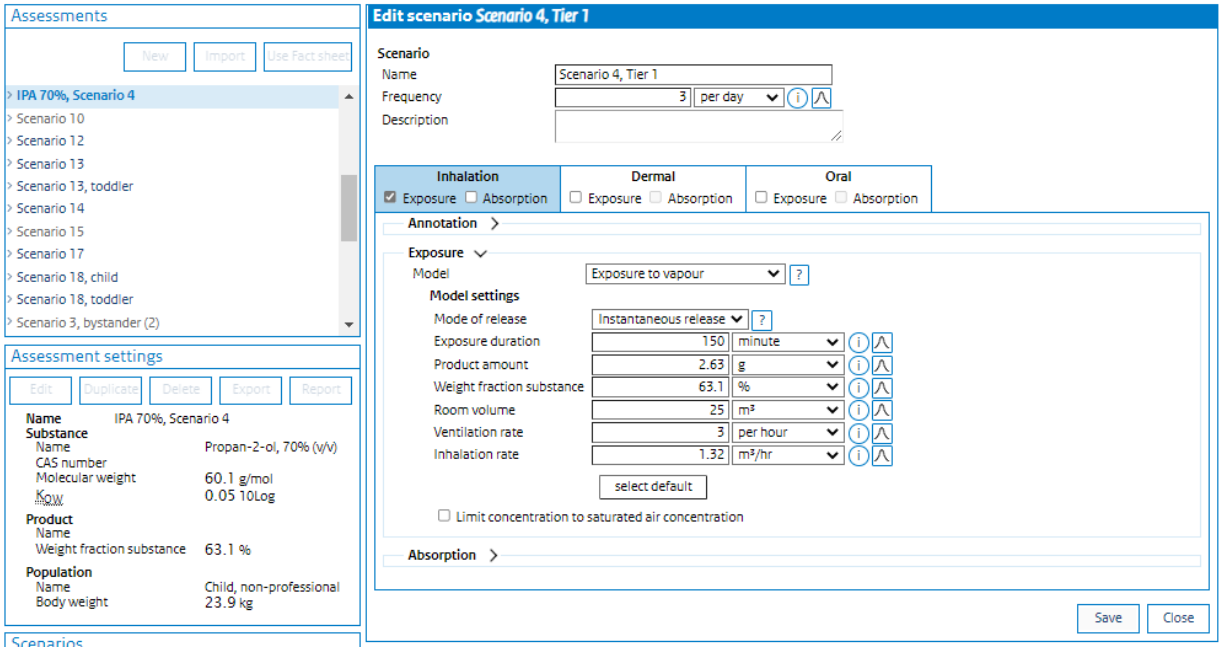
Calculations for systemic exposure

Tier 1	**Toddler in 1 room staying next to nurse for 6 applications (ConsExpo Web instanteneous rate)**			
	Inhalative exposure calculation	**Value**	**Unit**	**Reference**
	Peak concentration (TWA 15 min) (Consexpo)	**120**	**mg/m³**	**CONSEXPO**
	Inhalation rate	**0,333**	**m³/h**	**Methodology**
	exposure duration	**0,1**	**h**	**Headhoc 9**
	exposure per day	**1**	**1/day**	**Headhoc 9**
	body weight toddler	**10**	**kg**	**Methodology**
	inhalation absorption	**100**	**%**	**default value**
	inhalation exposure	**0,40**	**mg/kg bw/day**	

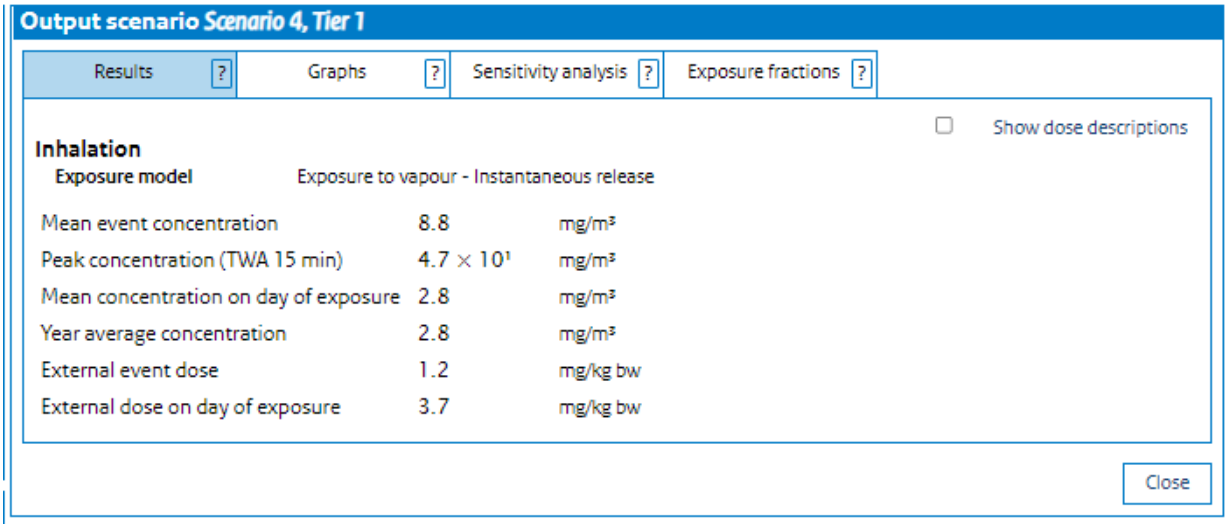
3.2.3 Scenario [4]: Hygienic handrub (PT1) by intensive care units visitors in hospitals – non-professional use (primary exposure)

Calculation ConsExpo Web

Child, inhalative exposure



Child, Result



Calculations for systemic exposure

Evaporation time	Value	Unit	Reference
mass	1660,3503	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9
skin temperature	303,15	K	Headhoc 9
molar mass	60,09	g/mol	Headhoc 9
coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9
vapour pressure of the pure substance	5780	Pa	Germany 2015
area	427,8	cm^2	Headhoc 9
conversion factor	36000	s	Headhoc 9
evaporation time	116,541269	s	
	1,94235449	min	

Tier 1

Child
Inhalative exposure calculation

	Value	Unit	Reference
Mean event concentration	8,80	mg/m^3	CONSEXPO
exposure duration	2,50	h	
Inhalation rate	1,32	m^3/h	Human Exposure Methodology
exposure per day	3,00	1/day	Headhoc 9
body weight child	23,90	kg	Methodology
inhalation absorption	100,00	%	default value
inhalation exposure	3,65	mg/kg bw/day	

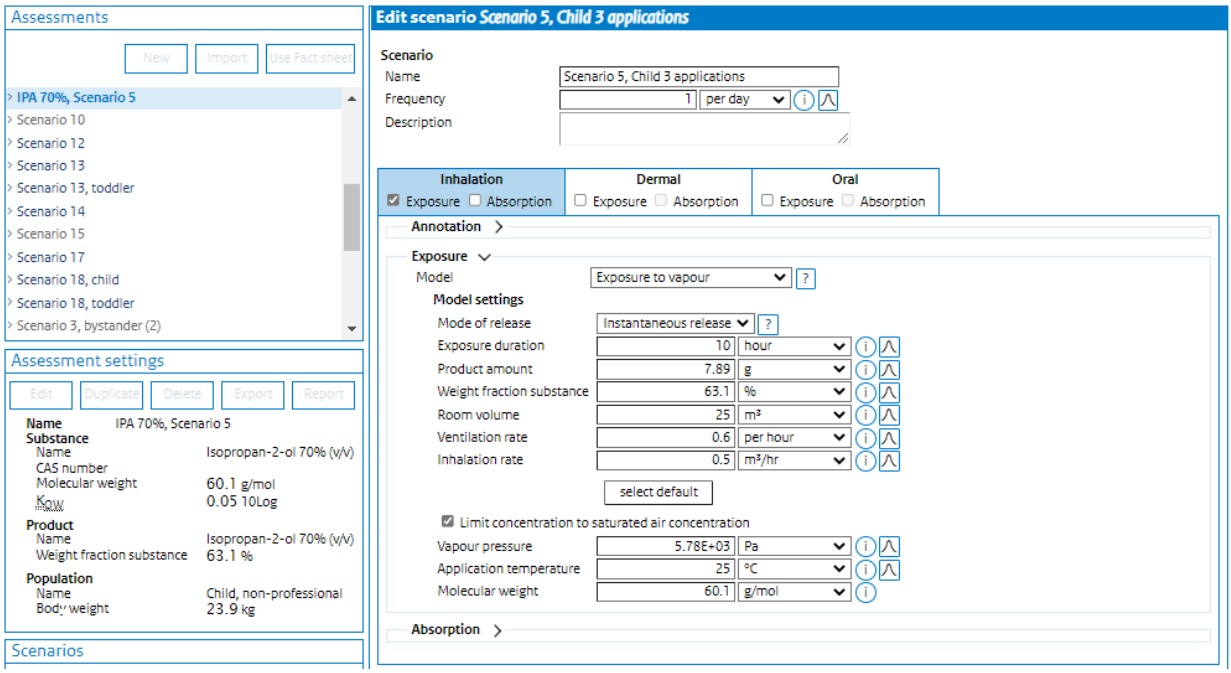
Dermal exposure calculation

	Value	Unit	Reference
evaporation time	1,94235449	min	HeadHoc 9
exposure per day	3	per day	
Dermal absorption	0,85	$mg/cm^2/h$	Germany 2015
Area (palms and backs of both hands)	427,8	cm^2	Human Exposure Methodology
Body weight child	23,9	kg	Human Exposure Methodology
systemic dermal exposure	1,47761163	mg/kg bw/day	

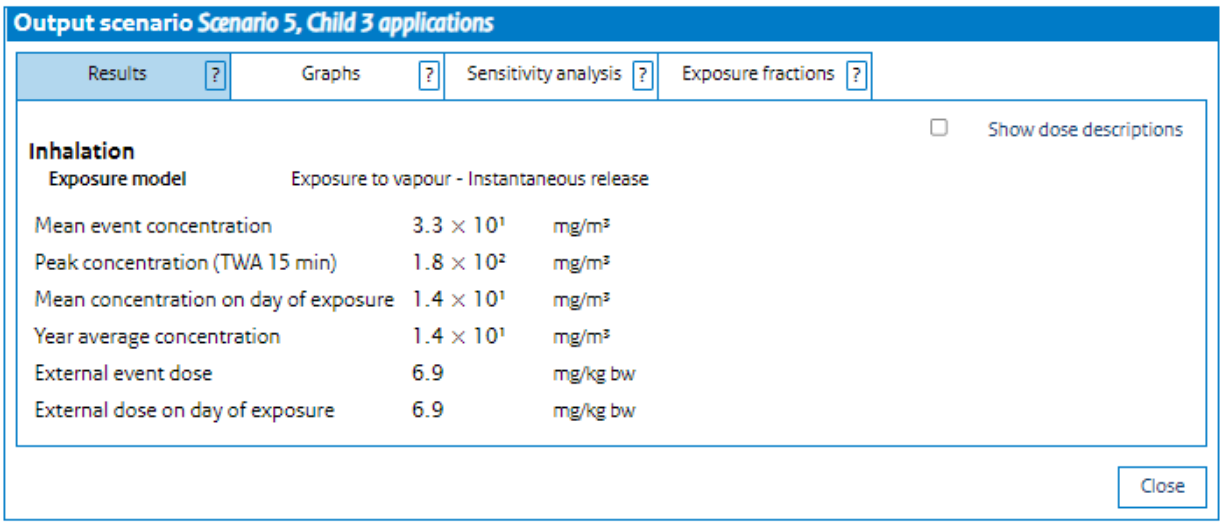
Total systemic exposure	**5,12**	**mg/kg bw/day**
AEL (professionals)	**17,9**	**mg/kg bw/day**
AEL (General population)	**10,7**	**mg/kg bw/day**

3.2.4 Scenario [5]: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – non-professional use (primary exposure)

Calculation ConsExpo Web



Results



Calculations

Children

Evaporation time

	Value	Unit	Reference

mass	1660,3503	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9
skin temperature	303,15	K	Headhoc 9
molar mass	60,09	g/mol	Headhoc 9
coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9
vapour pressure of the pure substance	5780	Pa	Germany 2015a
area	427,8	cm²	Headhoc 9
conversion factor	36000	s	Headhoc 9
evaporation time	116,5412691	s	
	1,942354485	min	

3 applications

Inhalative exposure calculation

	Value	**Unit**	**Reference**
mean event concentration	33	mg/m³	ConsExpoWeb
exposure duration	10	h	ConsExpoWeb
Inhalation rate	0,5	m³/h	ECHA 2015a
exposure per day	1	1/day	Headhoc 9
body weight adult	23,9	kg	ECHA 2015a
inhalation absorption	100	%	
inhalation exposure	6,90376569	mg/kg bw/day	

Dermal exposure calculation

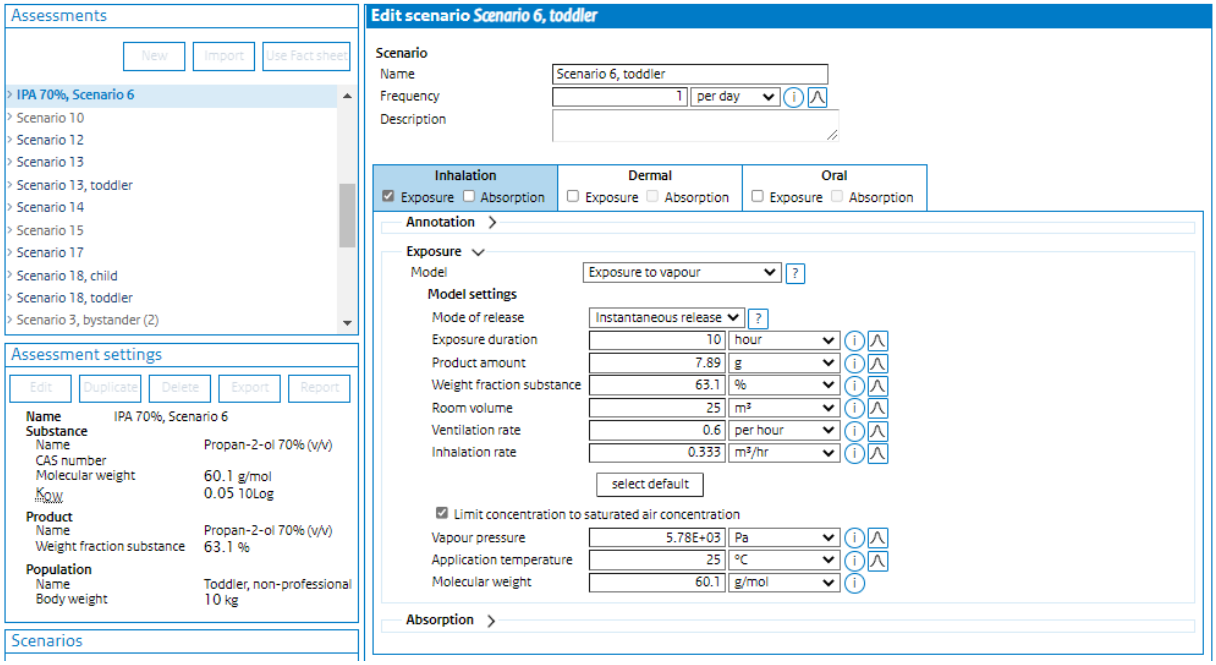
	Value	**Unit**	**Reference**
evaporation time	**1,942354485**	**min**	**HeadHoc 9**
Cycles per Day	3		
Dermal absorption	0,85	mg/cm²/h	Germany 2015a
Area (palms and backs of both hands)	427,8	cm²	ECHA 2015a
Body weight adult	23,9	kg	ECHA 2015a
systemic dermal exposure	1,477611635	mg/kg bw/day	

Total systemic exposure	**8,381377325**	**mg/kg bw/day**
AEL (professionals)	**17,9**	**mg/kg bw/day**
AEL (General population)	**10,7**	**mg/kg bw/day**

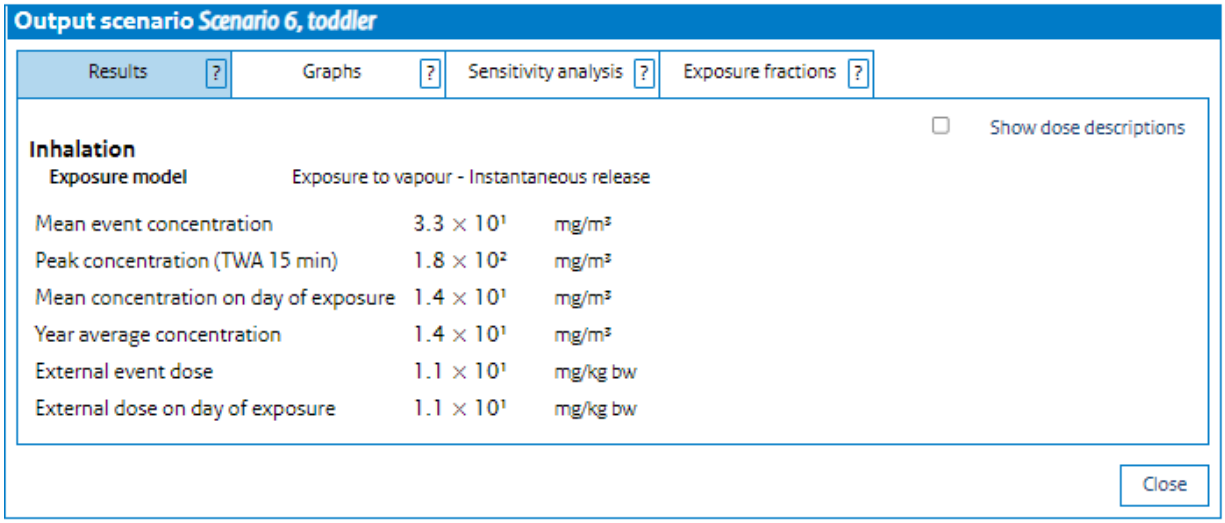
3.2.5 Scenario [6]: Hygienic handrub (PT1), e.g. in home dialysis and sanitary facilities in homes – general public (secondary exposure)

Calculation ConsExpo Web

Toddler, 3 applications, inhalative exposure



Toddler, 3 applications, results



Calculation of systemic exposure

Toddler

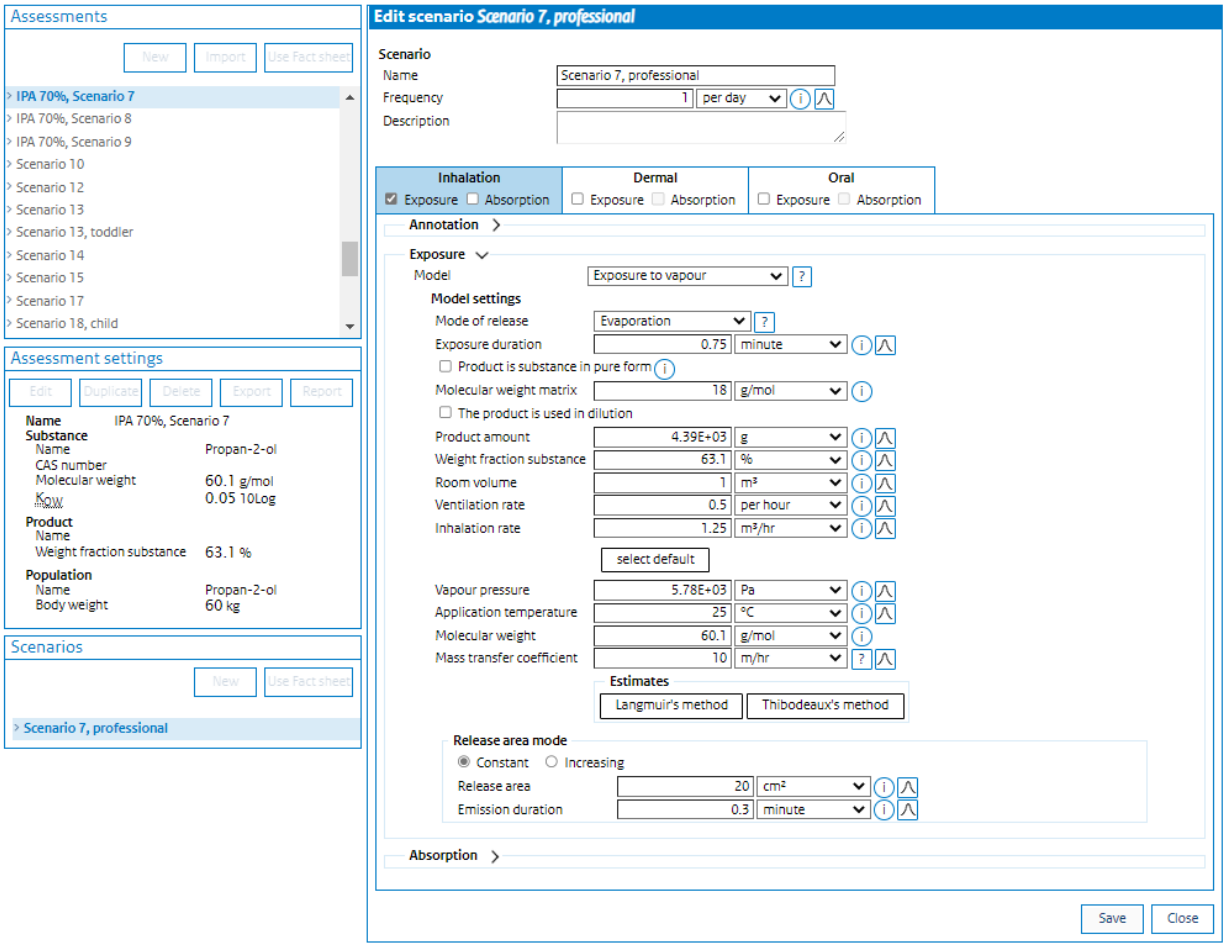
3 applications

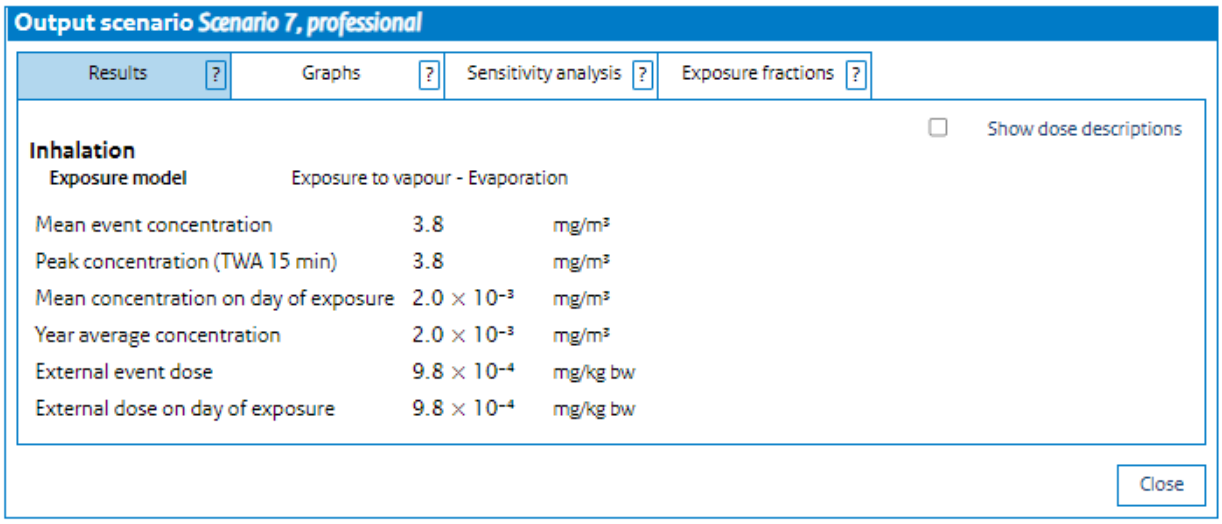
Inhalative exposure calculation

	Value	Unit	Reference
mean event concentration	33,00	mg/m³	ConsExpoWeb
exposure duration	10,00	h	ConsExpoWeb
Inhalation rate	0,33	m³/h	ECHA 2015a
exposure per day	1,00	1/day	Headhoc 9
body weight adult	10,00	kg	ECHA 2015a
inhalation absorption	100,00	%	default value
inhalation exposure	**10,99**	**mg/kg bw/day**	

3.2.6 Scenario [7]: Manual loading of the biocidal product (primary exposure)

Calculation ConsExpo Web





Calculation of systemic exposure

Inhalative exposure Jerry Can	**Value**	**Unit**	**Reference**
Product amount (half of the amount at bottle [10L])	5	L	RIVM (2018)
density	0,8771	g/mL	
Masse produkt	4385,5	g	
	4,3855	kg	

Inhalative exposure calculation (constant rate)			**Reference**
Indicatice value (Consexpo)	3,8	mg/m³	CONSEXPO WEB
Inhalation rate	1,25	m³/h	Methodology
exposure duration	0,0125	h	Headhoc 9
exposure per day	1	1/day	Headhoc 9
body weight adult	60	kg	Methodology
inhalation absorption	100	%	Tox Wert
inhalation exposure	**0,0009895833**	**mg/kg bw/day**	

Dermal exposure

Jerry Can	**Value**	**Unit**	**Reference**
Mass	10	L	
Density	0,8771	g/mL	
Product mass	8771	g	
	8,771	kg	
weight fraction	63,1	%	
Mass a.s.	5,534501	kg	

Dermal exposure mass calculation	**Value**	**Unit**	**Reference**
indicative value	8	mg/kg a.s. per operation	EUROPOEM II
Mass product container	5,534501	kg a.s.	
exposure per day	1	per day	
contact mass per day	44,276008	mg/day	

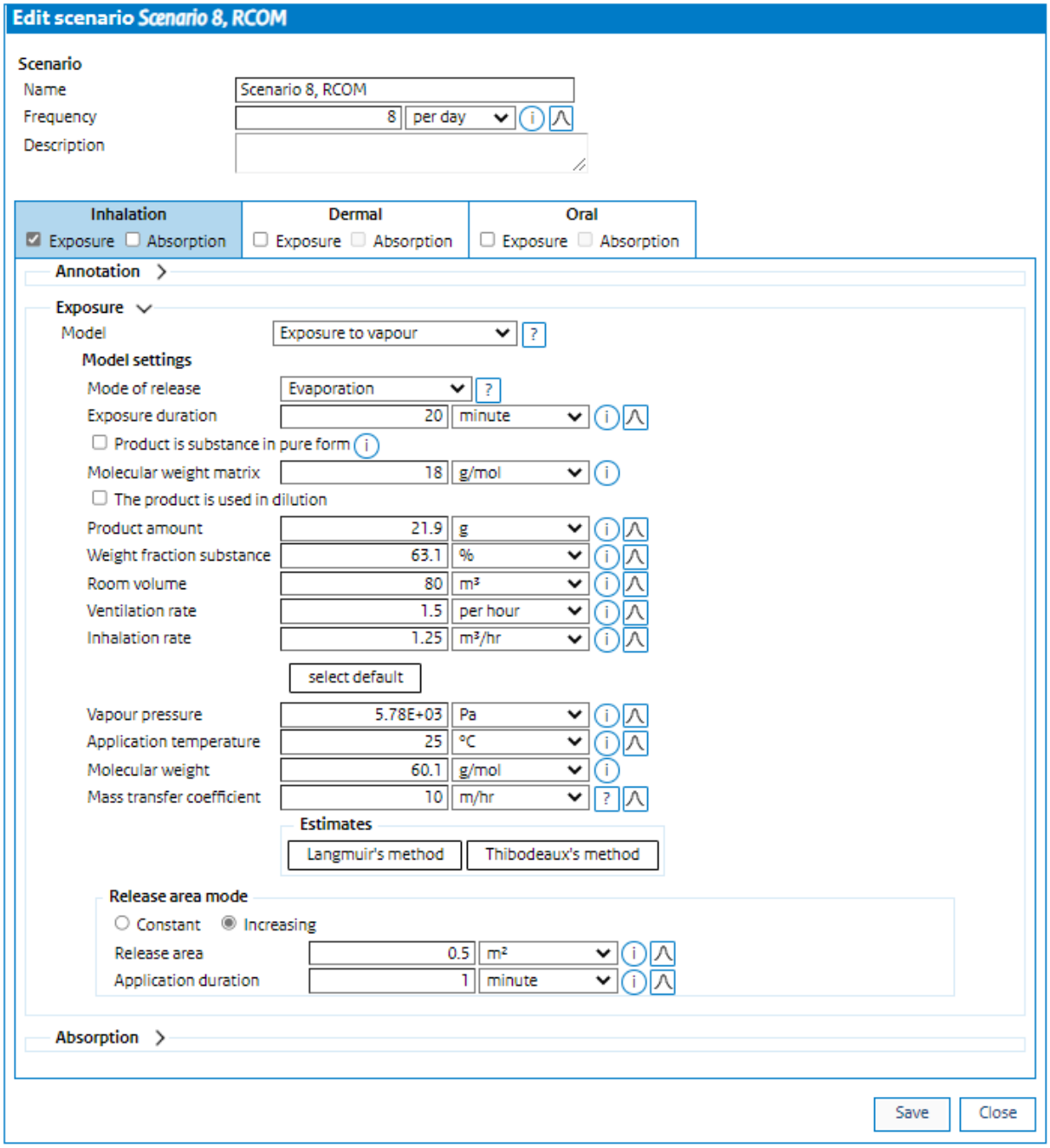
Evaporation time	**Value**	**Unit**	**Reference**
contact mass per day	44,276008	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9
skin temperature	303,15	K	Headhoc 9
molar mass	60,09	g/mol	Headhoc 9
coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9
vapour pressure of the pure substance	5780	Pa	Germany 2015
area	820	cm^2	Headhoc 9
conversion factor	36000	s	Headhoc 9
evaporation time	1,621344876	s	
	0,027022415	min	

Dermal exposure calculation	**Value**	**Unit**	**Reference**
evaporation time	**0,027**	min	HeadHoc 9
Number of cycles per day	1,000	day^{-1}	HeadHoc 9
Dermal absorption	0,850	$mg/cm^2/h$	Germany 2015
Area (palms and backs of both hands)	820,000	cm^2	Methodology
Body weight adult	60,000	kg	Methodology
systemic dermal exposure	**0,0052318**	**mg/kg bw/day**	

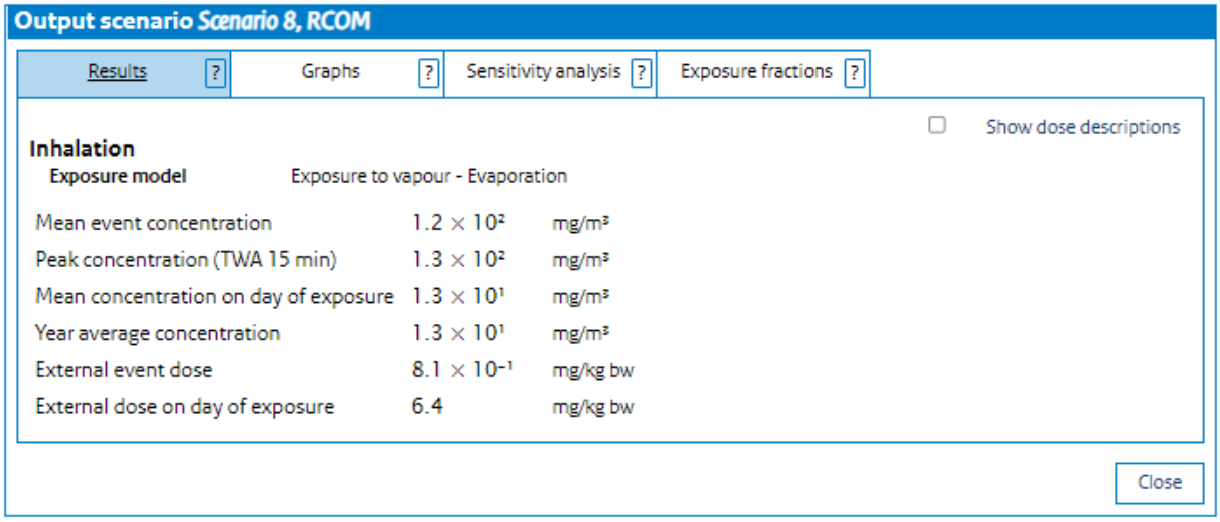
Total systemic exposure	**0,006**	**mg/kg bw/day**	
AEL (professionals)	**17,900**	**mg/kg bw/day**	

3.2.7 Scenario [8]: Hard surface disinfection (small surfaces in PT2), e.g. working bench in laboratory, clean room, hospital – professional use (primary exposure) - spraying and/or wiping

Calculation ConsExpo Web



ConsExpo Results



Rohdaten Modell ConsExpo Web

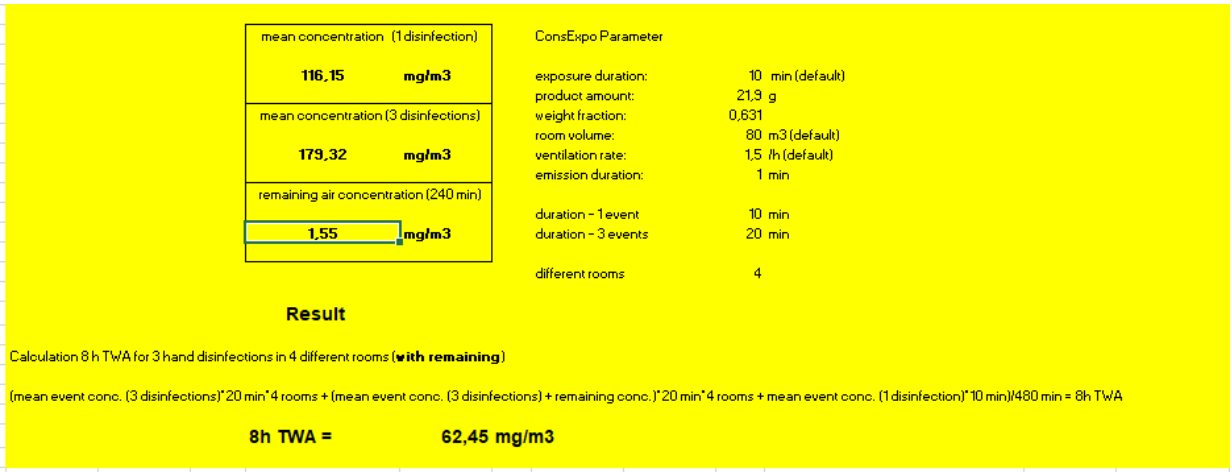
Time (min)	Air concentration
0,00	0,00
0,20	0,98
0,40	3,84
0,60	8,52
0,80	14,90
1,00	23,00
1,20	31,60
1,40	39,80

1,60	47,70
1,80	55,10
2,00	62,10
2,20	68,70
2,40	75,00
2,60	80,90
2,80	86,40
3,00	91,60
3,20	96,40
3,40	101,00
3,60	105,00
3,80	109,00
4,00	113,00
4,20	116,00
4,40	119,00
4,60	122,00
4,80	124,00
5,00	127,00
5,20	129,00
5,40	131,00
5,60	133,00
5,80	134,00
6,00	136,00
6,20	137,00
6,40	138,00
6,60	139,00
6,80	140,00
7,00	140,00
7,20	141,00
7,40	141,00
7,60	142,00
7,80	142,00
8,00	142,00
8,20	143,00
8,40	143,00
8,60	143,00
8,80	143,00
9,00	143,00
9,20	143,00
9,40	142,00
9,60	142,00
9,80	142,00
10,00	142,00
10,20	141,00

10,40	141,00
10,60	140,00
10,80	140,00
11,00	140,00
11,20	139,00
11,40	139,00
11,60	138,00
11,80	138,00
12,00	137,00
12,20	137,00
12,40	136,00
12,60	136,00
12,80	135,00
13,00	135,00
13,20	134,00
13,40	133,00
13,60	133,00
13,80	132,00
14,00	132,00
14,20	131,00
14,40	131,00
14,60	130,00
14,80	129,00
15,00	129,00
15,20	128,00
15,40	128,00
15,60	127,00
15,80	126,00
16,00	126,00
16,20	125,00
16,40	125,00
16,60	124,00
16,80	123,00
17,00	123,00
17,20	122,00
17,40	122,00
17,60	121,00
17,80	120,00
18,00	120,00
18,20	119,00
18,40	119,00
18,60	118,00
18,80	118,00
19,00	117,00

19,20	116,00
19,40	116,00
19,60	115,00
19,80	115,00
20,00	114,00

Calcutaion Excel HeadHoc recommend 15



mean concentration (1 disinfection)	
116,15	**mg/m3**
mean concentration (3 disinfections)	
179,32	**mg/m3**
remaining air concentration (240 min)	
1,55	**mg/m3**

Result

Calculation 8 h TWA for 3 hand disinfections in 4 different rooms (**with remaining**)

(mean event conc. (3 disinfections)*20 min*4 rooms + (mean event conc. (3 disinfections) + remaining conc.)*20 min*4 rooms + mean event conc. (1 disinfection)*10 min)/480 min = 8h TWA

8h TWA = 62,45 mg/m3

ConsExpo Parameter

exposure duration:	10	min (default)
product amount:	21,9	g
weight fraction:	0,631	
room volume:	80	m3 (default)
ventilation rate:	1,5	/h (default)
emission duration:	1	min
duration - 1 event	10	min
duration - 3 events	20	min
different rooms	4	

Calculation of systemic exposure

Calculation Inhalative exposure

	Value	**Unit**	**Reference**
rooms	4		HeadHoc 9
Mean Air concentration	116,1514583	mg/m³	HeadHoc 9 Excel
time exposure in 1 room	0,3333	h	HeadHoc 9
Inhalative exposure calculation			
	Value	Unit	Reference
Inhalation Rate	1,25	m³/h	ECHA 2015a
Remaining Air concentration (240min)	1,554339314	mg/m³	HeadHoc 9 Excel
Inhalative exposure	**389,7231171**	**mg**	
Body weight	**60**	**kg**	**ECHA 2015a**

event per day	**1**	**per day**
inhalative absorption	**100**	**%**
systemic inhalative exposure	**6,495385285**	**mg/kg bw/day**

Dermal exposure calculation

	Value	Unit	Reference
BEAT Model 75th percentile	214	µl/min	BEAT Hughson et. al (2004)
weight fraction	63,1	%	
Daily exposure	8	min	Germany 2015a
Dichte	0,8771	mg/µL	see Chapter 2.2.2.
product	**947,5065712**	**mg**	

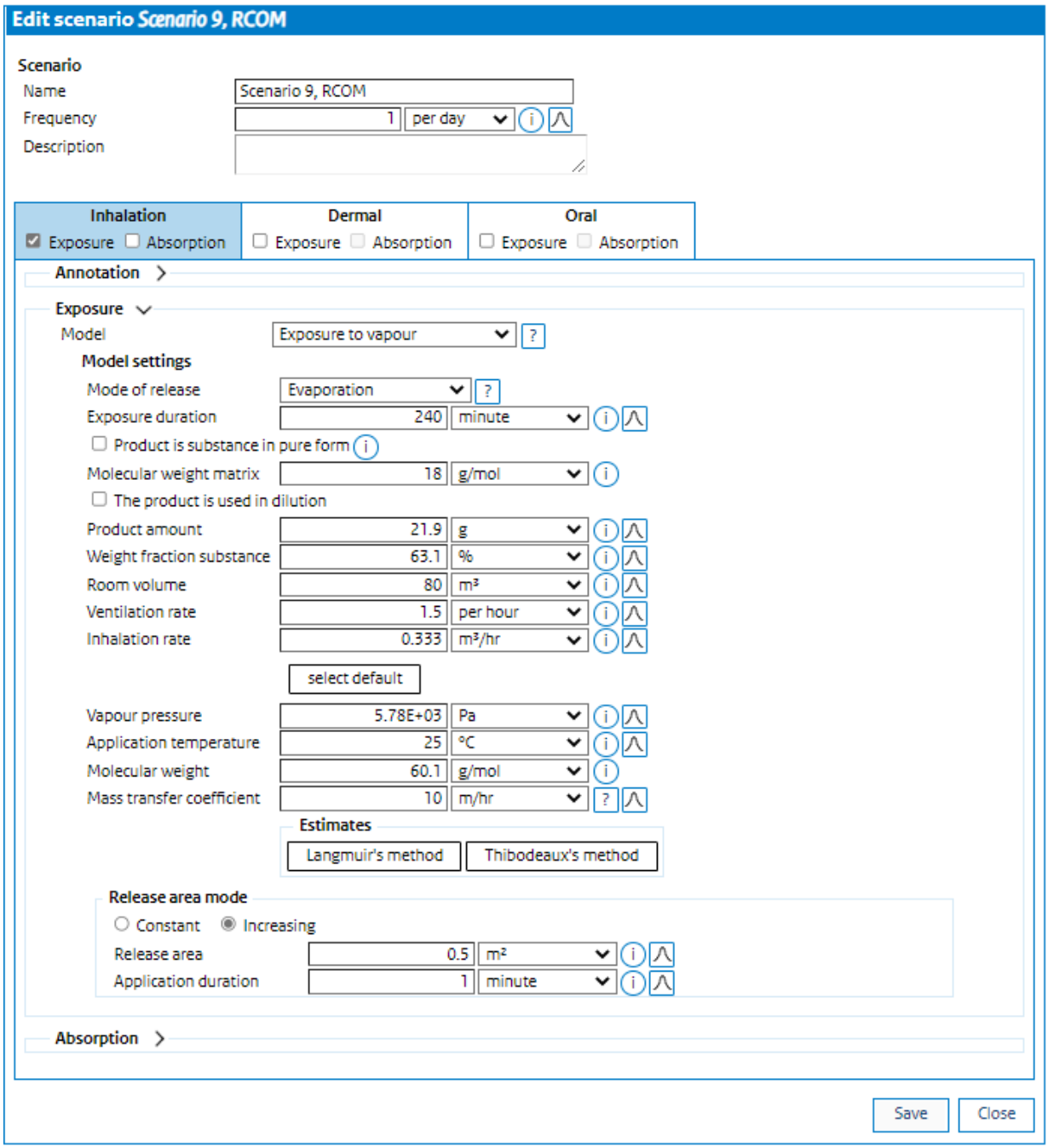
Evaporation time	**Value**	**Unit**	**Reference**
mass	947,5065712	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9
skin temperature	303,15	K	Headhoc 9
molar mass	60,09	g/mol	Headhoc 9
coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9
vapour pressure of the pure substance	5780	Pa	Germany 2015
area	205	cm²	Headhoc 9
conversion factor	36000	s	Headhoc 9
evaporation time	**138,7871214**	**s**	
	2,313118689	**min**	

Dermal exposure calculation

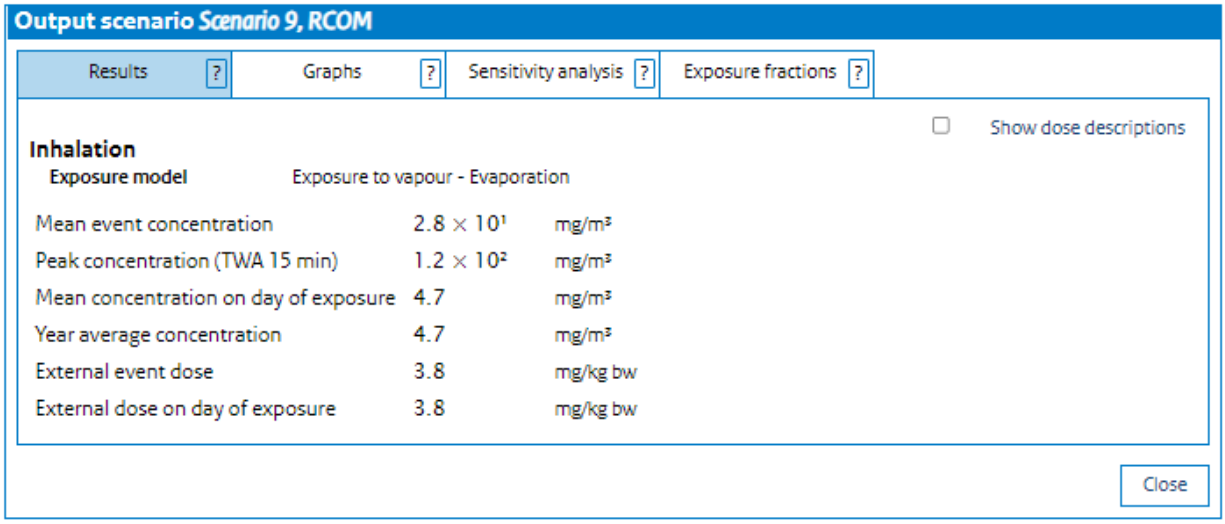
	Value	Unit	Reference
Contact time	2,313118689	min	HeadHoc 9
Cycles per Day	8	per day	
Dermal absorption	0,85	mg/cm²/h	Germany 2015a
Area (palms and backs of both hands)	205	cm²	ECHA 2015a
Body weight adult	60	kg	ECHA 2015a
systemic dermal exposure	**0,895690959**	**mg/kg bw/day**	

Total systemic exposure	**7,39**	**mg/kg bw/day**
AEL (professionals)	**17,9**	**mg/kg bw/day**
AEL (General population)	**10,7**	**mg/kg bw/day**

3.2.8 Scenario [9]: Hard surface disinfection (small surfaces in PT2), e.g. working bench in laboratory, clean room, hospital – general public (secondary exposure) - spraying



ConsExpo Results



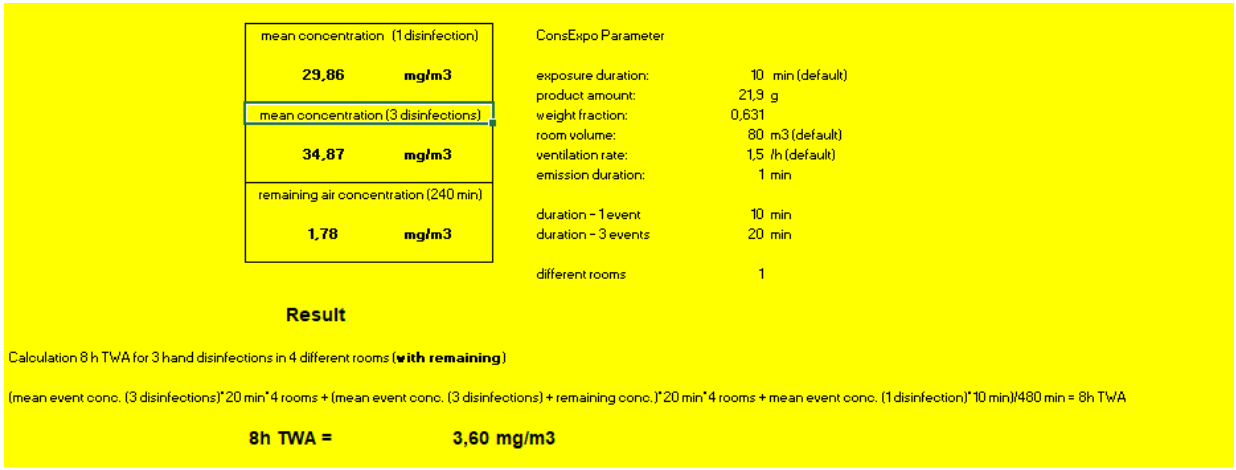
Rohdaten

Time (min)	Air concentration
0,00	0,00
2,40	75,00
4,80	124,00
7,20	141,00
9,60	142,00
12,00	137,00
14,40	131,00
16,80	123,00
19,20	116,00
21,60	110,00
24,00	103,00
26,40	97,30
28,80	91,70
31,20	86,30
33,60	81,30
36,00	76,60
38,40	72,20
40,80	68,00
43,20	64,00
45,60	60,30
48,00	56,80
50,40	53,50
52,80	50,40
55,20	47,50
57,60	44,70
60,00	42,10

62,40	39,70
64,80	37,40
67,20	35,20
69,60	33,10
72,00	31,20
74,40	29,40
76,80	27,70
79,20	26,10
81,60	24,60
84,00	23,10
86,40	21,80
88,80	20,50
91,20	19,30
93,60	18,20
96,00	17,20
98,40	16,20
100,80	15,20
103,20	14,30
105,60	13,50
108,00	12,70
110,40	12,00
112,80	11,30
115,20	10,60
117,60	10,00
120,00	9,43
122,40	8,88
124,80	8,37
127,20	7,88
129,60	7,42
132,00	6,99
134,40	6,59
136,80	6,20
139,20	5,84
141,60	5,50
144,00	5,18
146,40	4,88
148,80	4,60
151,20	4,33
153,60	4,08
156,00	3,84
158,40	3,62
160,80	3,41
163,20	3,21
165,60	3,02

168,00	2,85
170,40	2,68
172,80	2,53
175,20	2,38
177,60	2,24
180,00	2,11
182,40	1,99
184,80	1,87
187,20	1,77
189,60	1,66
192,00	1,57
194,40	1,48
196,80	1,39
199,20	1,31
201,60	1,23
204,00	1,16
206,40	1,09
208,80	1,03
211,20	0,97
213,60	0,91
216,00	0,86
218,40	0,81
220,80	0,76
223,20	0,72
225,60	0,68
228,00	0,64
230,40	0,60
232,80	0,57
235,20	0,53
237,60	0,50
240,00	0,47

Calcutaion Excel HeadHoc recommend 15



mean concentration (1 disinfection)	
29,86	mg/m3
mean concentration (3 disinfections)	
34,87	mg/m3
remaining air concentration (240 min)	
1,78	mg/m3

ConsExpo Parameter

exposure duration:	10	min (default)
product amount:	21,9	g
weight fraction:	0,631	
room volume:	80	m3 (default)
ventilation rate:	1,5	/h (default)
emission duration:	1	min
duration - 1 event	10	min
duration - 3 events	20	min
different rooms	1	

Result

Calculation 8 h TWA for 3 hand disinfections in 4 different rooms (**with remaining**)

(mean event conc. (3 disinfections)*20 min*4 rooms + (mean event conc. (3 disinfections) + remaining conc.)*20 min*4 rooms + mean event conc. (1 disinfection)*10 min)/480 min = 8h TWA

8h TWA = 3,60 mg/m3

Calcutaion Excel HeadHoc recommend 15

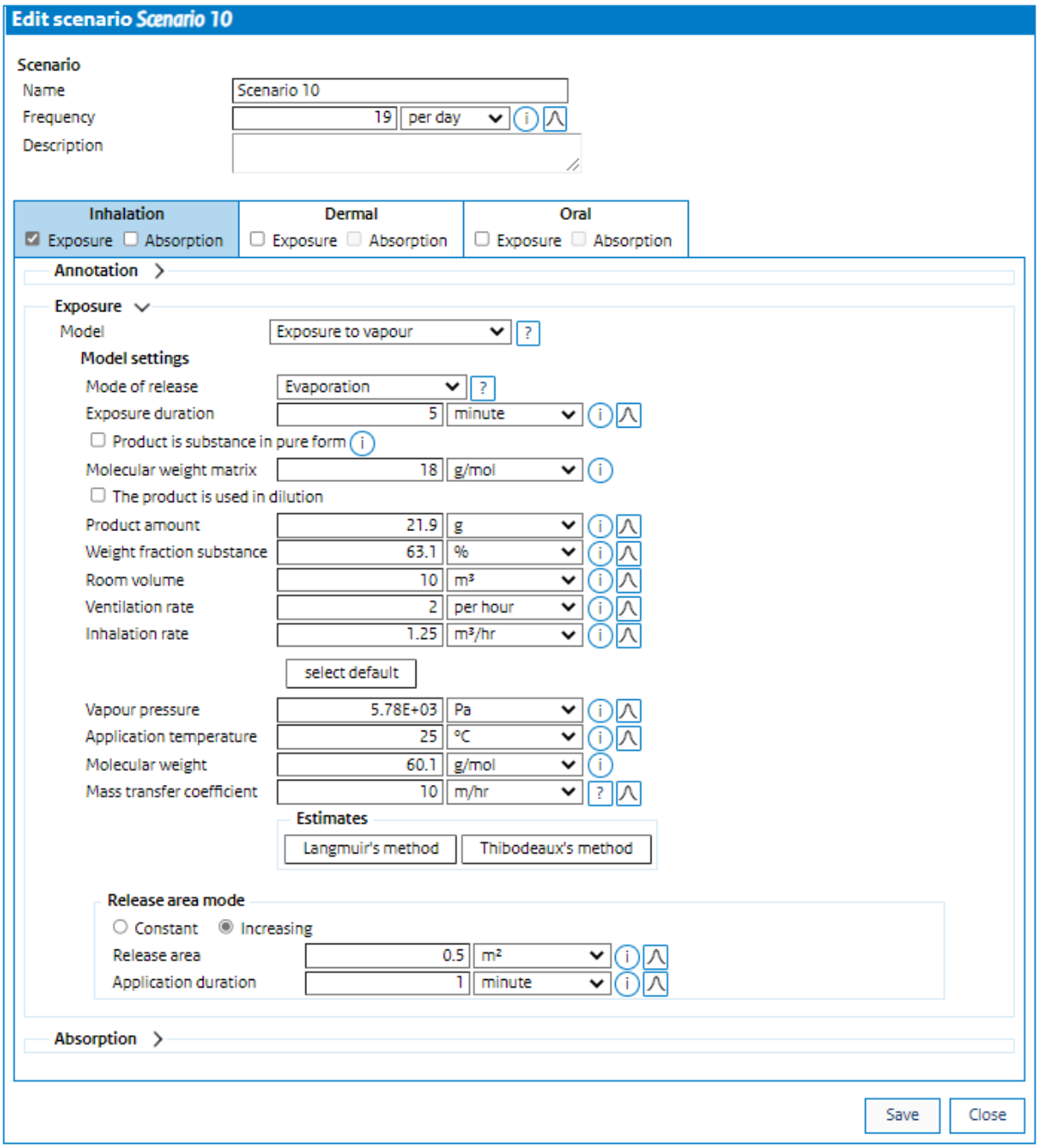
Toddler

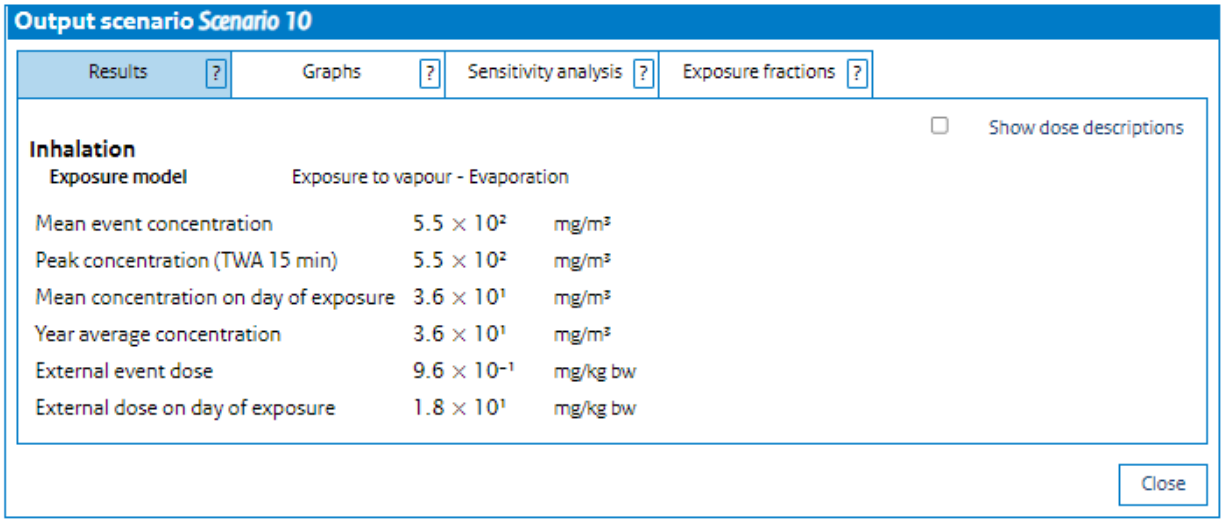
Calculation Inhalative exposure

			Reference
rooms	1		HeadHoc 9
Mean Air concentration	29,86	mg/m³	HeadHoc 9 Excel
time exposure in 1 room	4	h	HeadHoc 9
Inhalation Rate	0,333	m³/h	Methodology
Remaining Air concentration (240min)	1,78	mg/m³	HeadHoc 9 Excel
Inhalative exposure	42,14448	mg	
Body weight	10	kg	Methodology
event per day	2	per day	
inhalative absorption	100	%	default value
systemic inhalative exposure	**8,428896**	**mg/kg bw/day**	
Total systemic exposure	**8,43**	**mg/kg bw/day**	
AEL (professionals)	**17,9**	**mg/kg bw/day**	
AEL (General population)	**10,7**	**mg/kg bw/day**	

3.2.9 Scenario [10]: Hard surface disinfection (small surfaces in PT2), e.g. in bathrooms – professional use (primary exposure) - spraying and/or wiping

Calculation ConsExpo Web


Edit scenario Scenario 10
Scenario
Name
Scenario 10
Frequency
19
per day
Description
Inhalation
Exposure
Absorption
Dermal
Exposure
Absorption
Oral
Exposure
Absorption
Annotation
Exposure
Model
Exposure to vapour
Model settings
Mode of release
Evaporation
Exposure duration
5
minute
Product is substance in pure form
Molecular weight matrix
18
g/mol
The product is used in dilution
Product amount
21.9
g
Weight fraction substance
63.1
%
Room volume
10
m³
Ventilation rate
2
per hour
Inhalation rate
1.25
m³/hr
select default
Vapour pressure
5.78E+03
Pa
Application temperature
25
°C
Molecular weight
60.1
g/mol
Mass transfer coefficient
10
m/hr
Estimates
Langmuir's method
Thibodeaux's method
Release area mode
Constant
Increasing
Release area
0.5
m²
Application duration
1
minute
Absorption
Save
Close


Output scenario Scenario 10
Results
Graphs
Sensitivity analysis
Exposure fractions
Show dose descriptions
Inhalation
Exposure model
Exposure to vapour - Evaporation
Mean event concentration
5.5 × 10²
mg/m³
Peak concentration (TWA 15 min)
5.5 × 10²
mg/m³
Mean concentration on day of exposure
3.6 × 10¹
mg/m³
Year average concentration
3.6 × 10¹
mg/m³
External event dose
9.6 × 10⁻¹
mg/kg bw
External dose on day of exposure
1.8 × 10¹
mg/kg bw
Close

Tier 1

Adult

Inhalative exposure calculation

	Value	Unit	Reference
Peak concentration (TWA 15 min)	550,00	mg/m³	ConsExpoWeb
exposure duration	0,08	h	ConsExpoWeb
Inhalation rate	1,25	m³/h	ECHA 2015a
exposure per day	19,00	1/day	Headhoc 9
body weight adult	60,00	kg	ECHA 2015a
inhalation absorption	100,00	%	
inhalation exposure	**18,14**	**mg/kg bw/day**	

Dermal exposure calculation

	Value	Unit	Reference
BEAT Model 75th percentile	135,034	µl/min	BEAT Hughson et. al (2004)
Daily exposure	5	min	Germany 2015a
Dichte	0,8771	mg/µL	see Chapter 2.2.2.
product	592,191607	mg	

Evaporation time

	Value	Unit	Reference
mass	592,191607	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9
skin temperature	303,15	K	Headhoc 9
molar mass	60,09	g/mol	Headhoc 9
coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9

vapour pressure of the pure substance	5780	Pa	Germany 2015a
area	205	cm²	Headhoc 9
conversion factor	36000	s	Headhoc 9
evaporation time	**86,7419509**	**s**	
	1,44569918	**min**	

Dermal exposure calculation

	Value	**Unit**	**Reference**
Contact time	1,44569918	min	HeadHoc 9
Cycles per Day	19	per day	
Dermal absorption	0,85	mg/cm²/h	Germany 2015a
Area (palms and backs of both hands)	205	cm²	ECHA 2015a
Body weight adult	60	kg	ECHA 2015a
systemic dermal exposure	**1,32954127**	**mg/kg bw/day**	

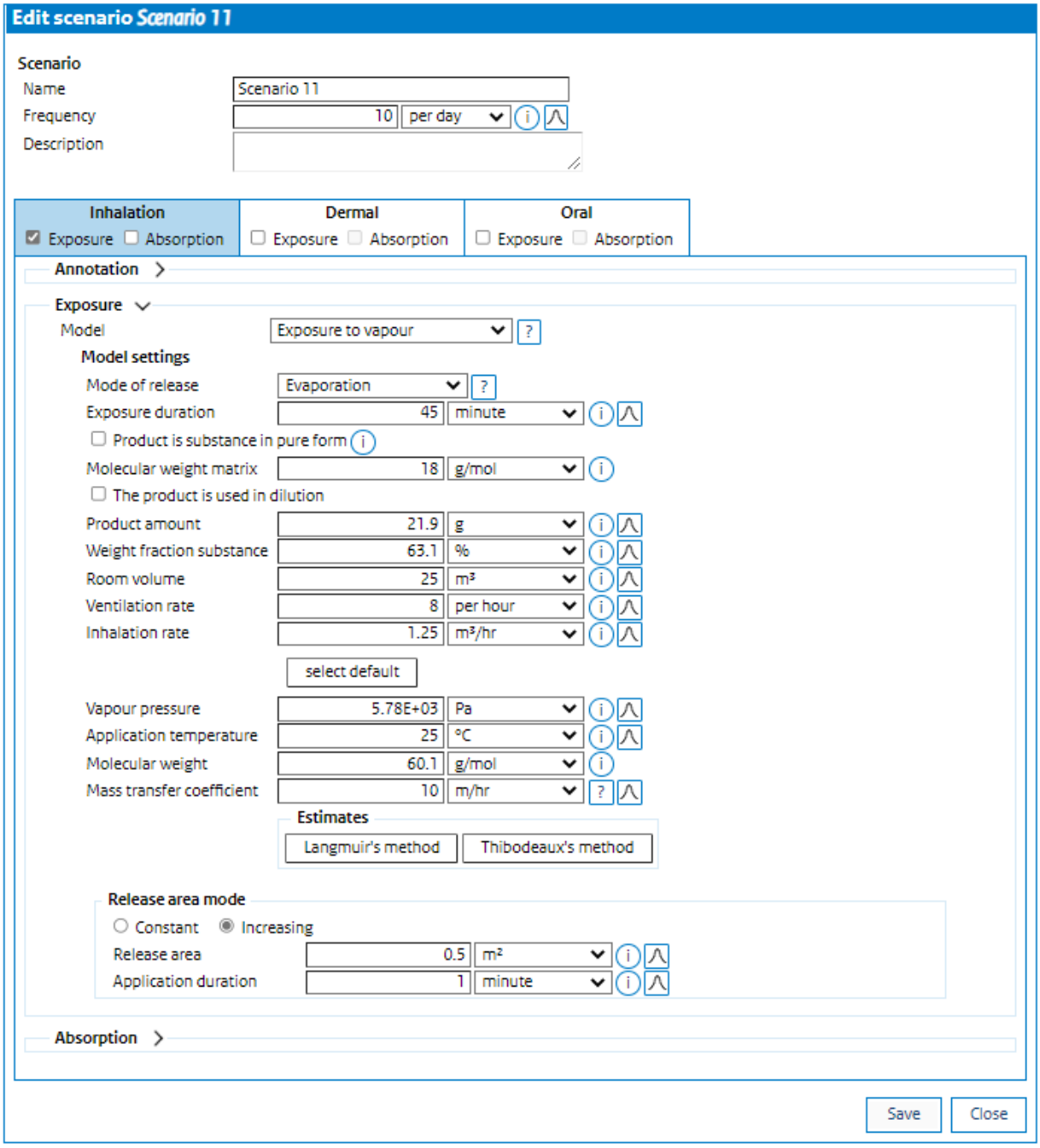
Tier 2

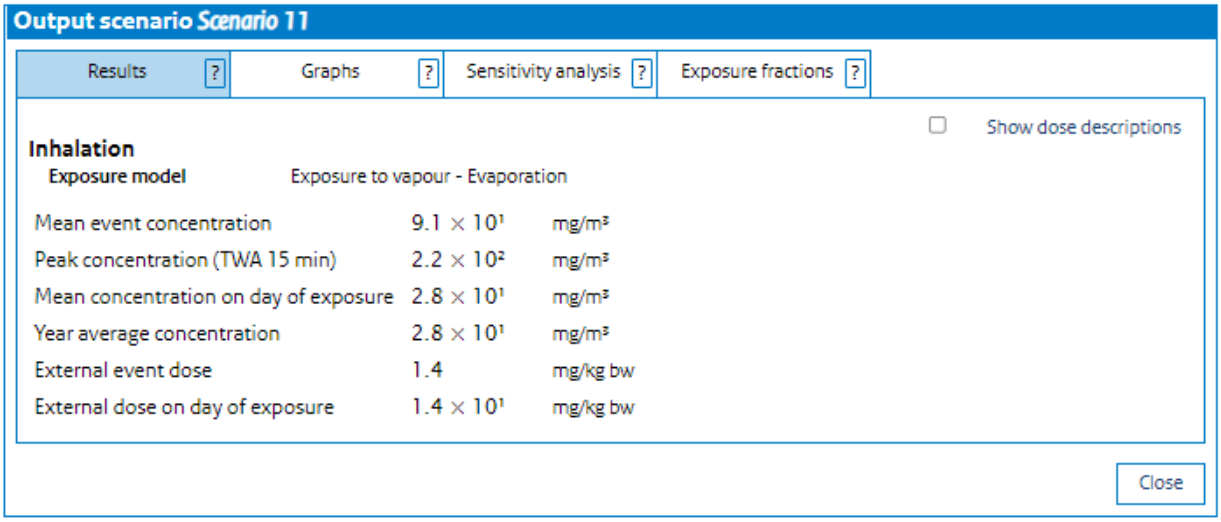
Inhalative exposure calculation

	Value	**Unit**	**Referenz**
Peak concentration (TWA 15 min)	550,00	mg/m³	ConsExpoWeb
exposure duration	0,08	h	ConsExpoWeb
Inhalation rate	1,25	m³/h	ECHA 2015a
exposure per day	19,00	1/day	Headhoc 9
body weight adult	60,00	kg	ECHA 2015a
inhalation absorption	100,00	%	
RPE AF	10,00		
inhalation exposure	**1,81**	**mg/kg bw/day**	
Total systemic exposure	**3,14**	**mg/kg bw/day**	
AEL (professionals)	**17,9**	**mg/kg bw/day**	
AEL (General population)	**10,7**	**mg/kg bw/day**	

3.2.10 Scenario [11]: Hard surface disinfection (small surfaces in PT2), e.g. working bench in laboratory, clean room, hospital – professional use (primary exposure) - spraying

Calculation ConsExpo Web





Calculation of systemic exposure

Adult

Inhalative exposure calculation

Peak concentration (TWA 15 min)	**Value** **91,00**	**Unit** **mg/m³**	**Reference** **ConsExpoWeb**
exposure duration	0,75	h	ConsExpoWeb
Inhalation rate	1,25	m³/h	ECHA 2015a
exposure per day	10,00	1/day	Headhoc 9
body weight adult	60,00	kg	ECHA 2015a
inhalation absorption	100,00	%	
inhalation exposure	14,22	mg/kg bw/day	

Dermal exposure calculation

	Value	**Unit**	**Reference**
BEAT Model 75th percentile	214	µl/min	BEAT Hughson et. al (200
Weight fraction	63,1	%	
Daily exposure	10	min	Germany 2015a
Dichte	0,8771	mg/µL	see Chapter 2.2.2.
product	1184,38321	mg	

Evaporation time

	Value	**Unit**	**Reference**
mass	1184,38321	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9
skin temperature	303,15	K	Headhoc 9
molar mass	60,09	g/mol	Headhoc 9
coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9
vapour pressure of the pure substance	5780	Pa	Germany 2015a

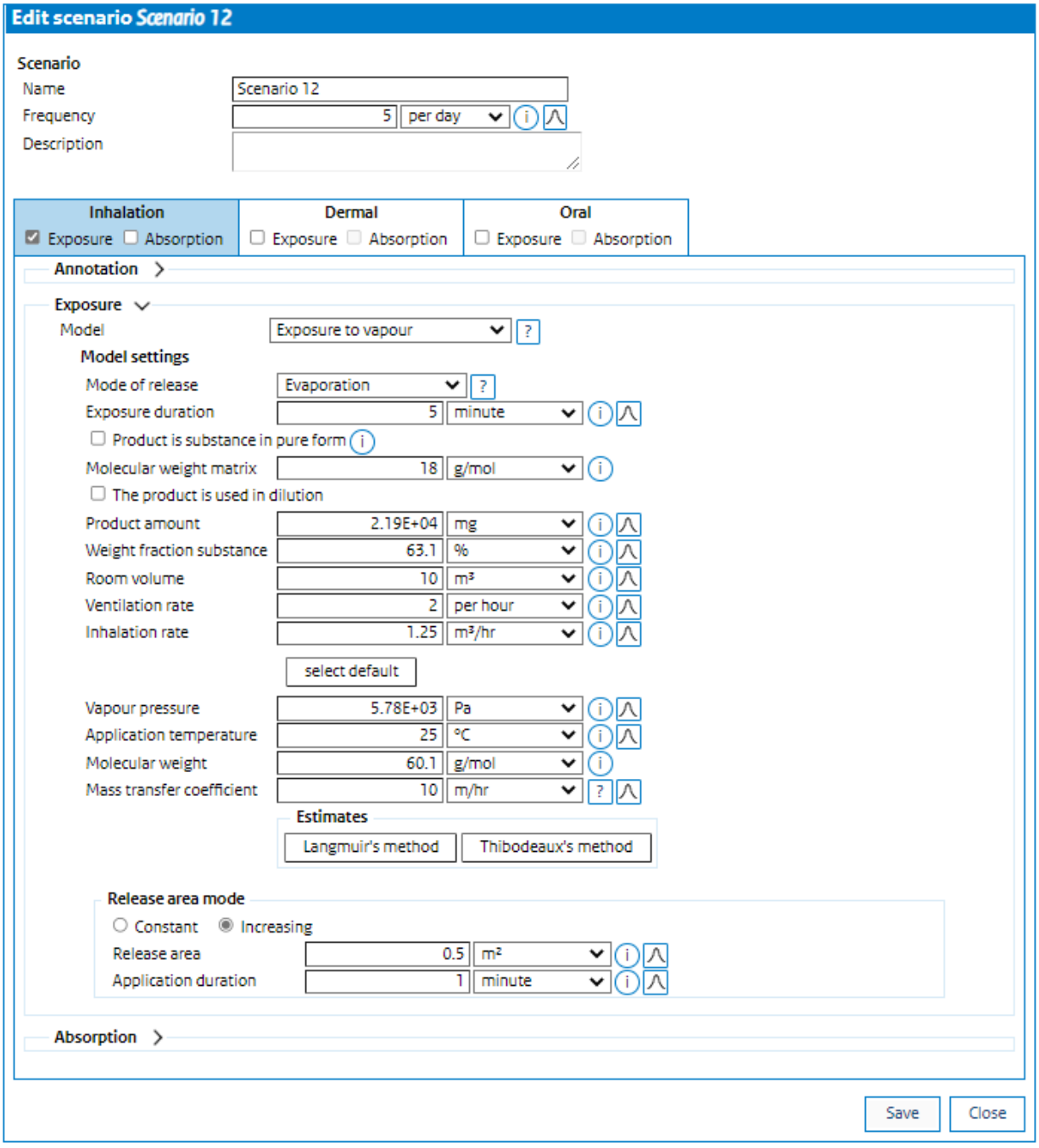
area	205	cm²	Headhoc 9
conversion factor	36000	s	Headhoc 9
evaporation time	173,483902	s	
	2,89139836	min	

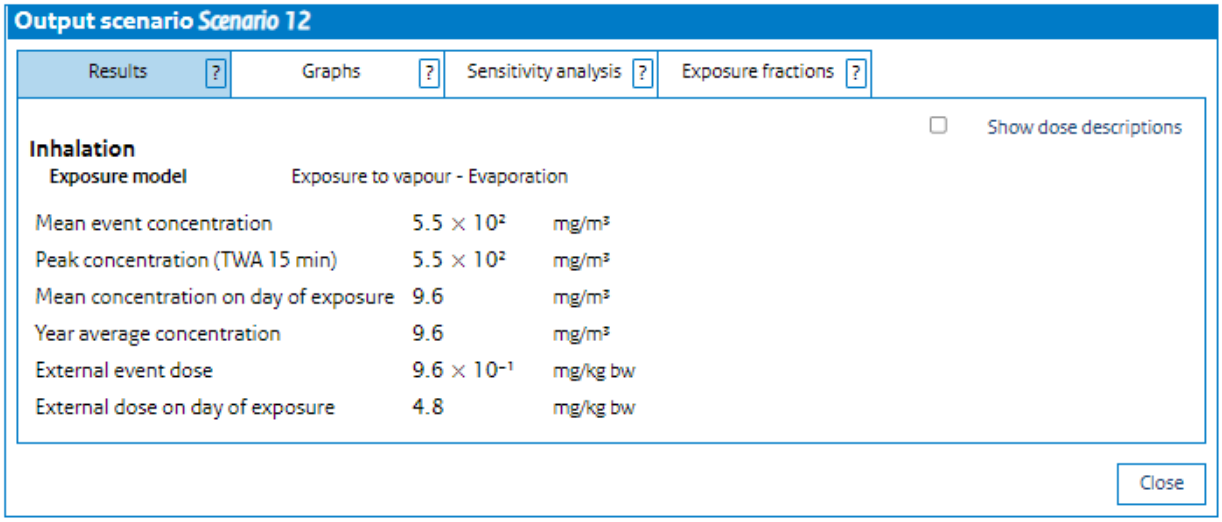
Dermal exposure calculation

	Value	**Unit**	**Reference**
Contact time	2,89139836	min	HeadHoc 9
Cycles per Day	10	per day	
Dermal absorption	0,85	mg/cm²/h	Germany 2015a
Area (palms and backs of both hands)	205	cm²	ECHA 2015a
Body weight adult	60	kg	ECHA 2015a
systemic dermal exposure	1,39951712	mg/kg bw/day	
Total systemic exposure	**15,62**	**mg/kg bw/day**	
AEL (professionals)	**17,9**	**mg/kg bw/day**	
AEL (General population)	**10,7**	**mg/kg bw/day**	

3.2.11 Scenario [12]: Hard surface disinfection (small surfaces in PT2), e.g. in households - non-professional use (primary exposure) - spraying

Calculation ConsExpo Web





Calculation of systemic exposure

5 application maximum for acute infections in household

Area of skin	820	cm²	ECHA 2015a
Thickness of layer of product in contact with skin	0,01	cm	ECHA 2015a, chapter 7.2
Volume of product	8,2	cm³ = mL	
density of product	0,8771	g/mL	see chapter 2.2.2.
mass of product	7,19222	g	
weight fraction of compound	64,73	%	see chapter 2.1.2.3.
mass of compound	4,65552401	g	

5 applications per day

Evaporation time	**Value**	**Unit**	**Referenz**
mass	2937,63565	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9
skin temperature	303,15	K	Headhoc 9
molar mass	60,09	g/mol	Headhoc 9
coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9
vapour pressure of the pure substance	5780	Pa	Germany 2015b
area	820	cm²	Headhoc 9
conversion factor	36000	s	Headhoc 9
evaporation time	107,573395	s	
	1,79288992	min	

Calculation Inhalative exposure

	Value	**Unit**	**Reference**
Mean Air concentration	550	mg/m³	Germany 2015b

exposure duration	0,08333333	h	Germany 2015b
exposure duratioin on 1 day	5	per day	HeadHoc 15
Inhalation Rate	1,25	m³/h	ECHA 2015a
Body weight	60	kg	ECHA 2015a
Inhalative absorption	100	%	
	4,77430556	mg/kg bw/day	

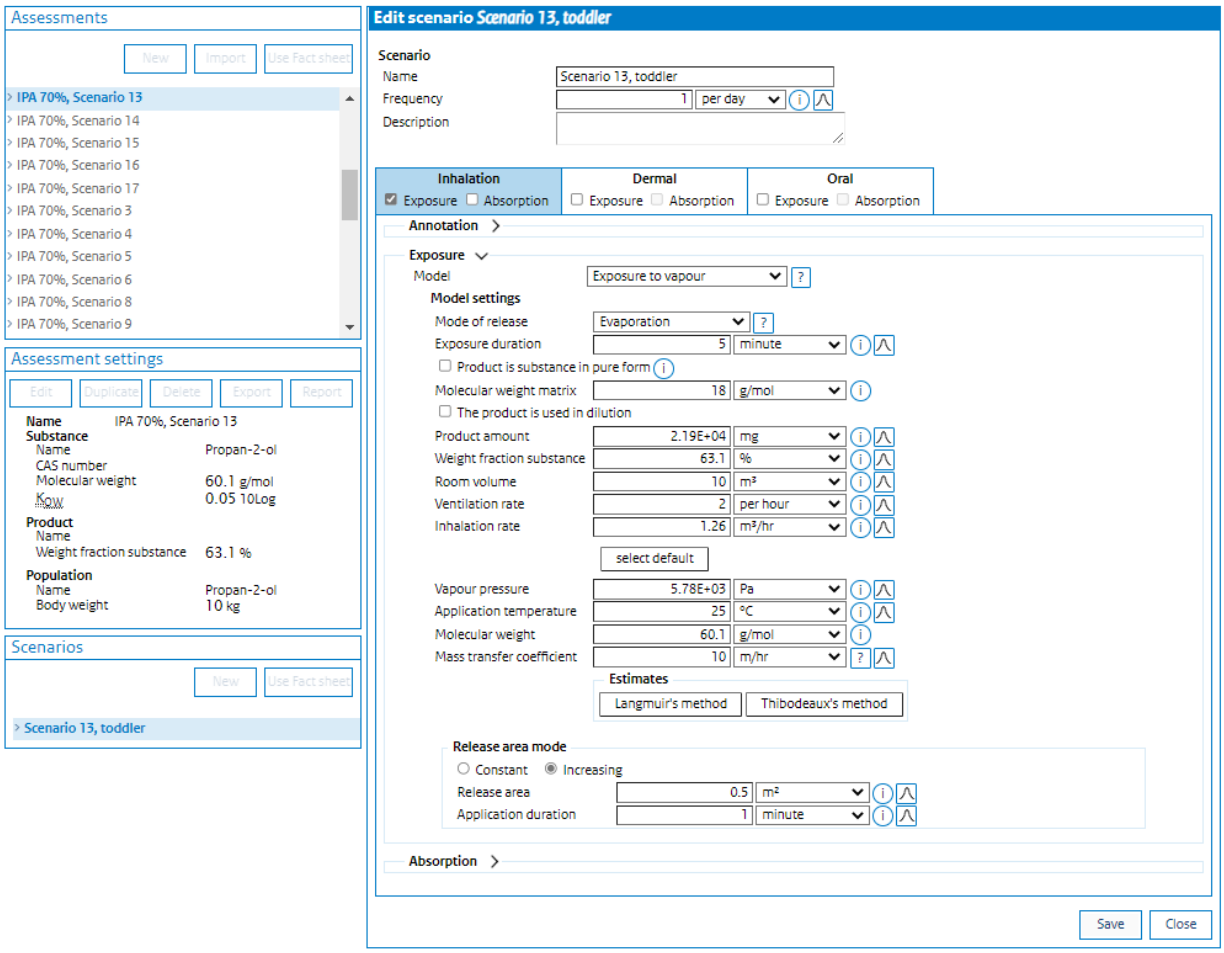
Dermal exposure calculation

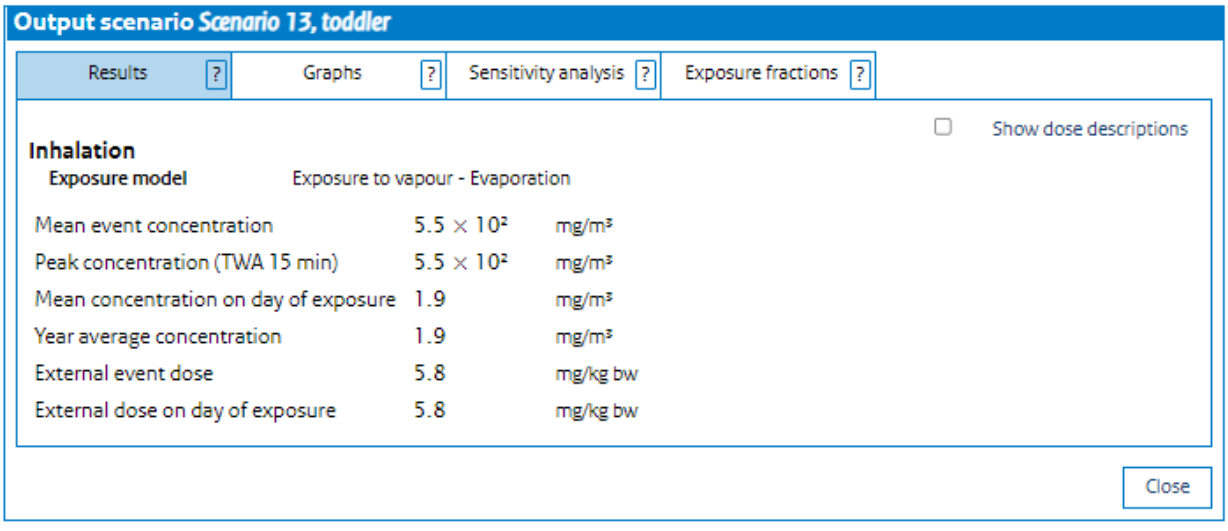
	Value	**Unit**	**Referenz**
Contact time	1,79288992	min	HeadHoc 9
Cycles per Day	5	per day	Germany 2015a
Dermal absorption	0,85	mg/cm²/h	Germany 2015a
Area (palms and backs of both hands)	820	cm²	ECHA 2015a
Body weight adult	60	kg	ECHA 2015a
systemic dermal exposure	1,73561705	mg/kg bw/day	
Total systemic exposure	**6,51**	**mg/kg bw/day**	
AEL (professionals)	**17,9**	**mg/kg bw/day**	
AEL (General population)	**10,7**	**mg/kg bw/day**	

3.2.12 Scenario [13]: Hard surface disinfection (small surfaces in PT2), e.g. in households - general public (secondary exposure) - spraying

Calculation ConsExpo Web

Toddler





Calculation of systemic exposure

Toddler

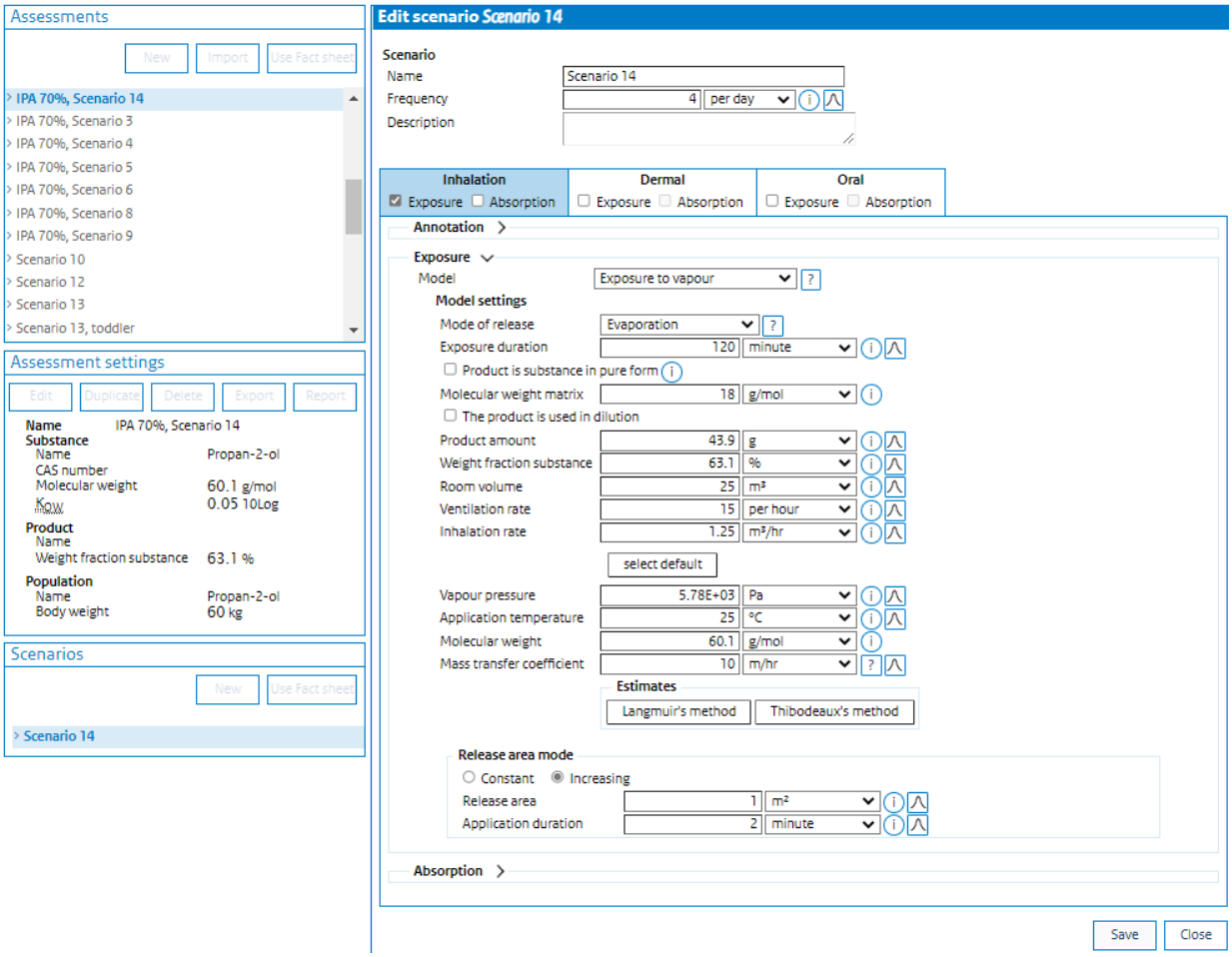
1 application maximum daily routine use

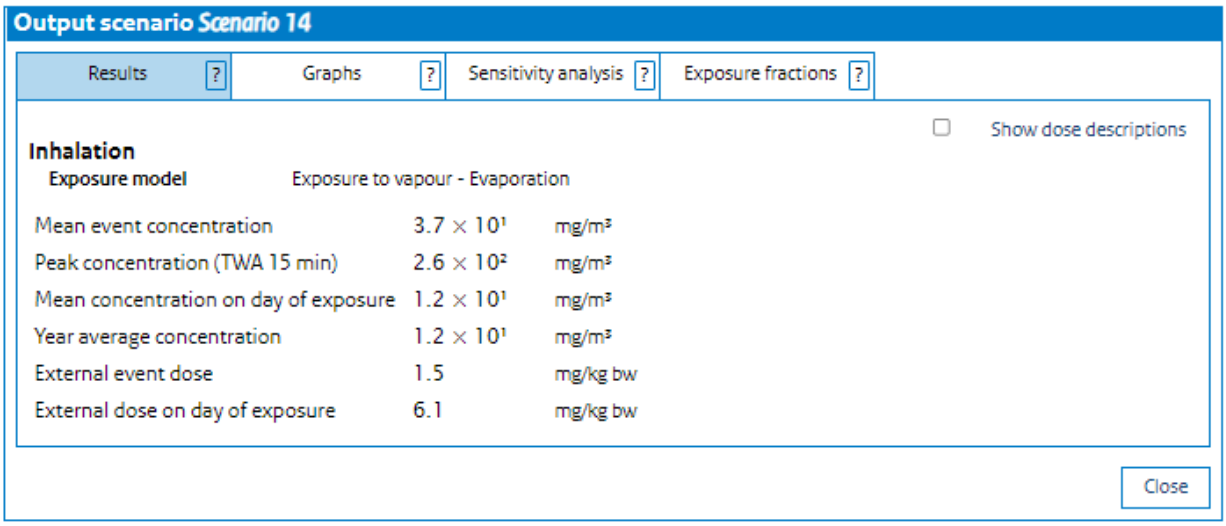
Calculation Inhalative exposure

	Value	Unit	Reference
Mean Air concentration	550	mg/m³	HeadHoc 9 Excel
exposure duration	0,08333333	h	Germany 2015
exposure duratioin on 1 day	1	per day	HeadHoc 15
Inhalation Rate	1,26	m³/h	Methodology
Body weight	10	kg	Methodology
Inhalative absorption	100	%	
	5,775	mg/kg bw/day	
Total systemic exposure	5,78	mg/kg bw/day	
AEL (professionals)	**17,9**	**mg/kg bw/day**	
AEL (General population)	**10,7**	**mg/kg bw/day**	

3.2.13 Scenario [14]: Hard surface disinfection (small surfaces in PT4), e.g. in canteens or kitchens – professional use (primary exposure) - spraying and/or wiping

Calculation ConsExpo Web





Calculation of systemic exposure

Adult

Calculation Inhalative exposure

	Value	Unit	Reference
mean event concentration	37	mg/m³	
exposure duration	2	h	
exposure duration on 1 day	4	per day	HeadHoc 15 (default)
Inhalation Rate	1,25	m³/h	ECHA 2015 Methodology
Body weight	60	kg	ECHA 2015 Methodology
Inhalative absorption	100	%	
systemic inhalative exposure	6,16666667	mg/kg bw/day	

Dermal exposure calculation

	Value	Unit	Reference
BEAT Model 75th percentile	214	µl/min	BEAT Hughson et. al (2004)
Weight fraction	63,1	%	
Daily exposure	2	min	
Dichte	0,8771	mg/µL	see Chapter 2.2.2.
product	236,8766	mg	

Evaporation time

	Value	Unit	Reference
mass	236,8766	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9 (default)
skin temperature	303,15	K	Headhoc 9 (default)
molar mass	60,09	g/mol	

coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9 (default)
vapour pressure of the pure substance	5780	Pa	
area	205	cm²	Headhoc 9 (default)
conversion factor	36000	s	Headhoc 9 (default)
evaporation time	34,69678	s	
	0,57828	min	

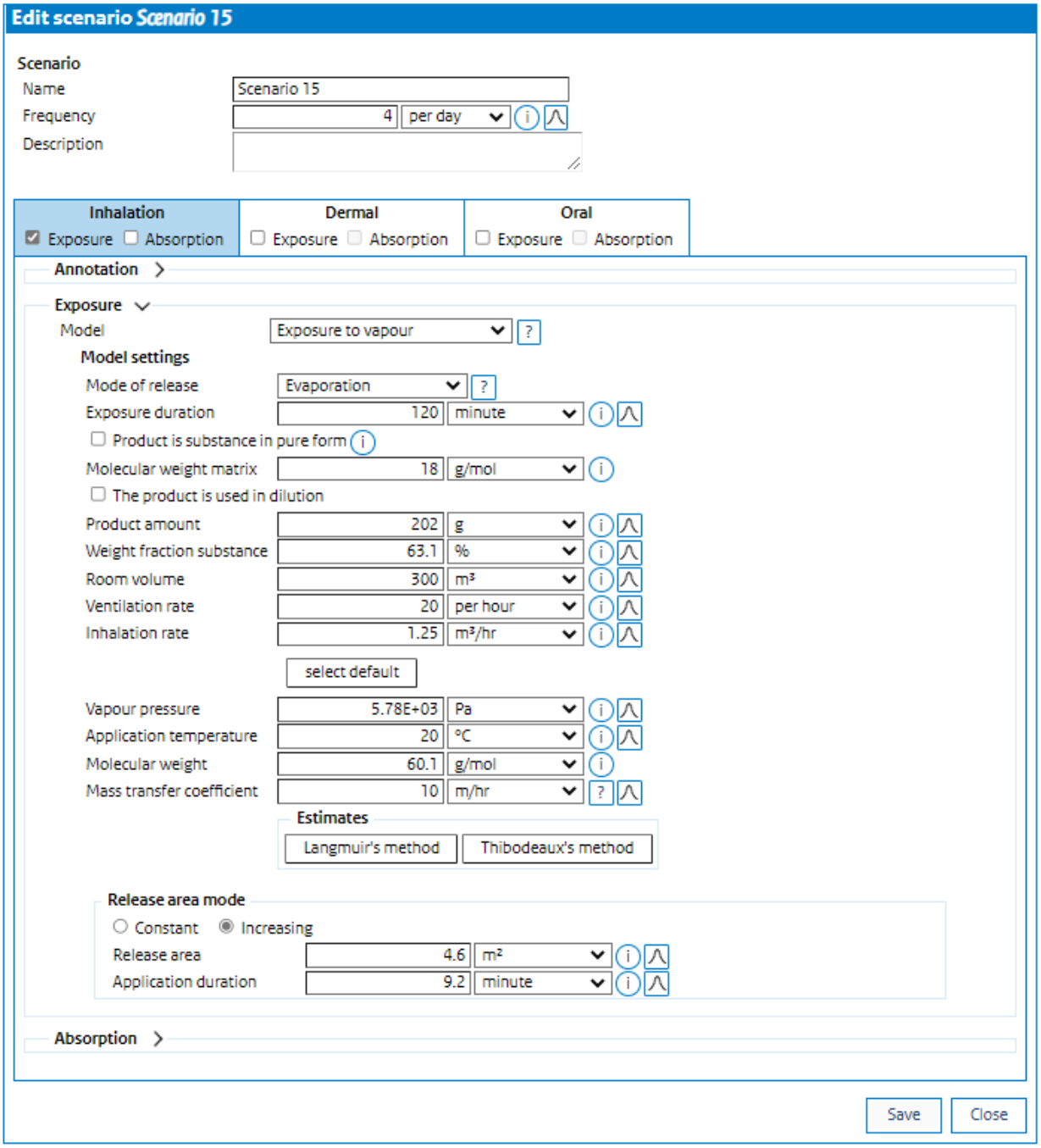
Dermal exposure

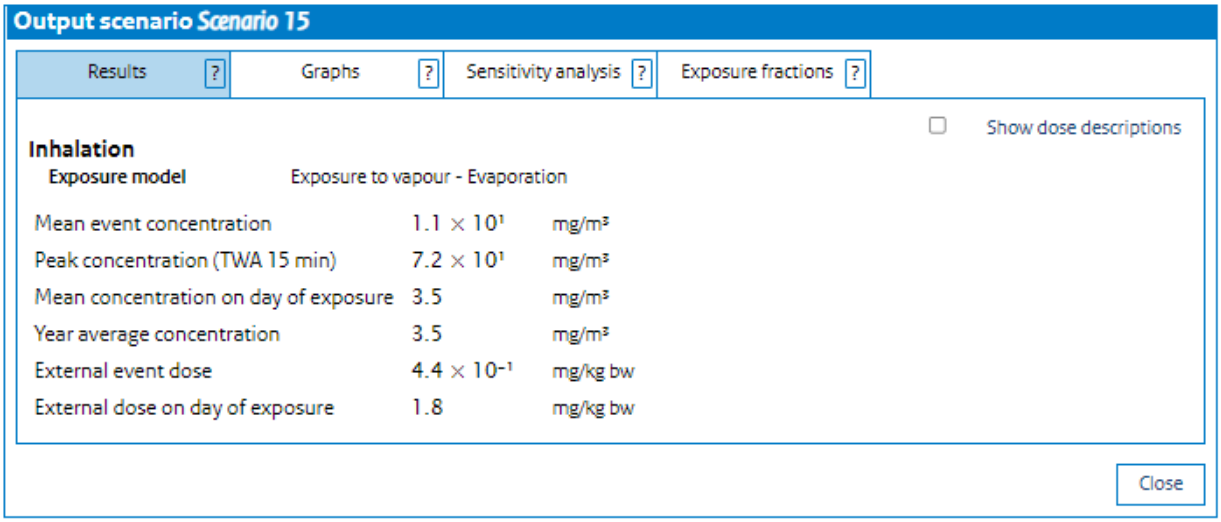
	Value	Unit	Reference
Contact time	0,57828	min	HeadHoc 9 (default)
Cycles per Day	4	per day	
Dermal absorption	0,85	mg/cm²/h	
Area (palms and backs of both hands)	205	cm²	ECHA 2015 Methodology
Body weight adult	60	kg	ECHA 2015 Methodology
systemic dermal exposure	0,111961	mg/kg bw/day	

Total systemic exposure	**6,28**	**mg/kg bw/day**
AEL (professionals)	**17,9**	**mg/kg bw/day**
AEL (General population)	**10,7**	**mg/kg bw/day**

3.2.14 Scenario [15]: Hard surface disinfection (small surfaces in PT4), e.g. in the food processing industry – professional use (primary exposure) - spraying

Calculation ConsExpo Web


Edit scenario Scenario 15
Scenario
Name
Scenario 15
Frequency
4
per day
Description
Inhalation
Exposure
Absorption
Dermal
Exposure
Absorption
Oral
Exposure
Absorption
Annotation
Exposure
Model
Exposure to vapour
Model settings
Mode of release
Evaporation
Exposure duration
120
minute
Product is substance in pure form
Molecular weight matrix
18
g/mol
The product is used in dilution
Product amount
202
g
Weight fraction substance
63.1
%
Room volume
300
m³
Ventilation rate
20
per hour
Inhalation rate
1.25
m³/hr
select default
Vapour pressure
5.78E+03
Pa
Application temperature
20
°C
Molecular weight
60.1
g/mol
Mass transfer coefficient
10
m/hr
Estimates
Langmuir's method
Thibodeaux's method
Release area mode
Constant
Increasing
Release area
4.6
m²
Application duration
9.2
minute
Absorption
Save
Close



Calculation of systemic exposure

Adult

Calculation Inhalative exposure

	Value	Unit	Reference
mean event concentration	11	mg/m³	HeadHoc 9 Excel
exposure duration	2	h	Germany 2015a
exposure duratioin on 1 day	4	per day	HeadHoc 15
Inhalation Rate	1,25	m³/h	ECHA 2015a
Body weight	60	kg	ECHA 2015a
Inhalative absorption	100	%	
systemic inhalative exposure	1,83333333	mg/kg bw/day	

Dermal exposure calculation

	Value	Unit	Reference
BEAT Model 75th percentile	214	µl/min	BEAT Hughson et. al (2004
Weight fraction	63,1	%	
Daily exposure	5	min	Germany 2015a
Dichte	0,8771	mg/µL	see Chapter 2.2.2.
product	592,1916	mg	

Evaporation time	**Value**	**Unit**	**Reference**
mass	592,1916	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9
skin temperature	303,15	K	Headhoc 9
molar mass	60,09	g/mol	Headhoc 9
coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9
vapour pressure of the pure substance	5780	Pa	Germany 2015
area	410	cm²	Headhoc 9

conversion factor	36000	s	Headhoc 9
evaporation time	43,37098	s	
	0,72285	min	

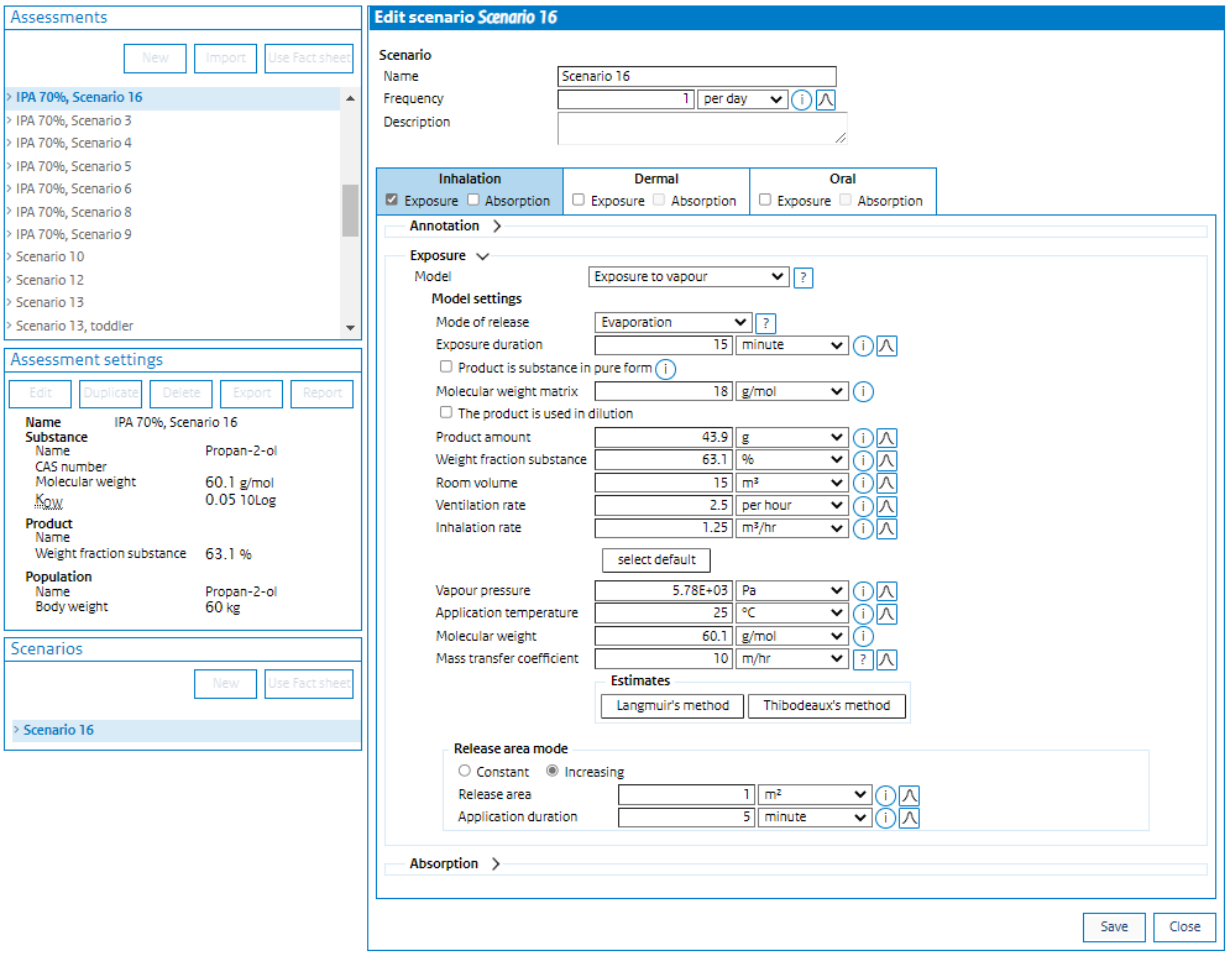
Dermal exposure calculation

	Value	**Unit**	**Reference**
Contact time	0,72285	min	HeadHoc 9
Cycles per Day	4	per day	
Dermal absorption	0,85	mg/cm²/h	Germany 2015a
Area (palms and backs of both hands)	205	cm²	ECHA 2015a
Body weight adult	60	kg	ECHA 2015a
systemic dermal exposure	0,139952	mg/kg bw/day	

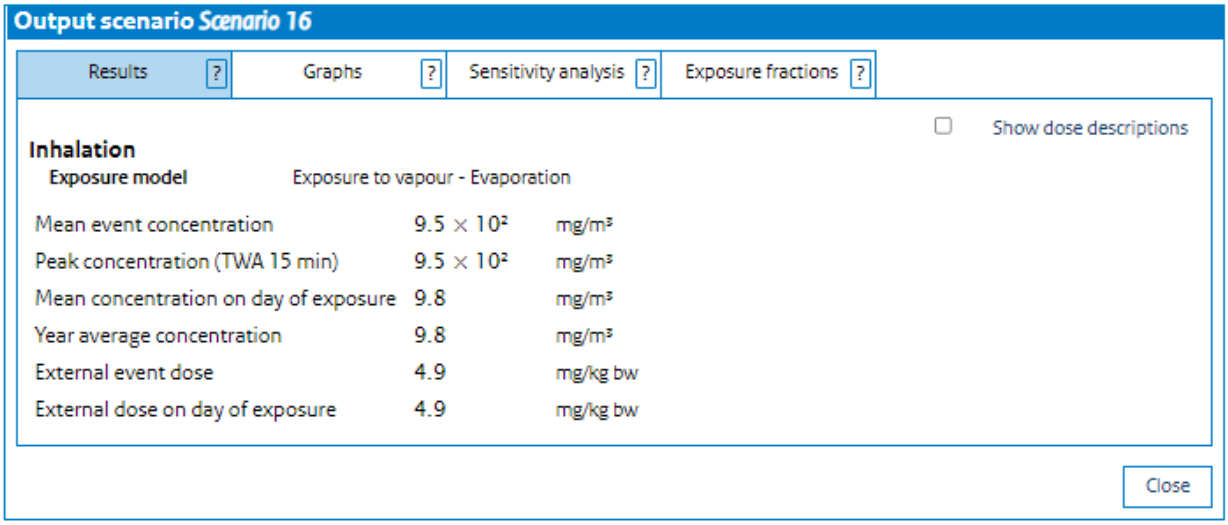
Total systemic exposure	**1,97**	**mg/kg bw/day**
AEL (professionals)	**17,9**	**mg/kg bw/day**
AEL (General population)	**10,7**	**mg/kg bw/day**

3.2.15 Scenario [16]: Hard surface disinfection (small surfaces in PT4), e.g. in kitchens - non-professional use (primary exposure) - spraying and/or wiping

Calculation ConsExpo Web



Results



Calculation of systemic exposure

Adult

1 application per day

	Value	Unit	Reference
Area of skin	820	cm²	HeadHoc 14
Thickness of layer of product in contact with skin	0,01	cm	Methodology chapter 7.2
Volume of product	8,2	cm³ = mL	
density of product	0,8771	g/mL	PAR chapter 2.2.2.
mass of product	7,19222	g	
weight fraction of compound	63,10	%	PAR chapter 2.1.2.3.
mass of compound	4,53829082	g	

Evaporation time	**Value**	**Unit**	**Reference**
mass	2863,66151	mg	see Chapter 2.2.2.
gas constant	8,314	J x K-1 x mol-1	Headhoc 9
skin temperature	303,15	K	Headhoc 9
molar mass	60,09	g/mol	Headhoc 9
coefficient of mass transfer in the vapour phase	8,7	m/h	Headhoc 9
vapour pressure of the pure substance	5780	Pa	Germany 2015
area	820	cm²	Headhoc 9
conversion factor	36000	s	Headhoc 9
evaporation time	104,864533	s	
	1,74774222	min	

Calculation Inhalative exposure

	Value	Unit	Reference
mean event concentration	950	mg/m³	HeadHoc 9 Excel
exposure duration	0,25	h	Germany 2015
exposure duratioin on 1 day	1	per day	HeadHoc 15
Inhalation Rate	1,25	m³/h	Methodology
Body weight	60	kg	Methodology
Inhalative absorption	100	%	
systemic inhalative exposure	4,94791667	mg/kg bw/day	

Dermal exposure calculation

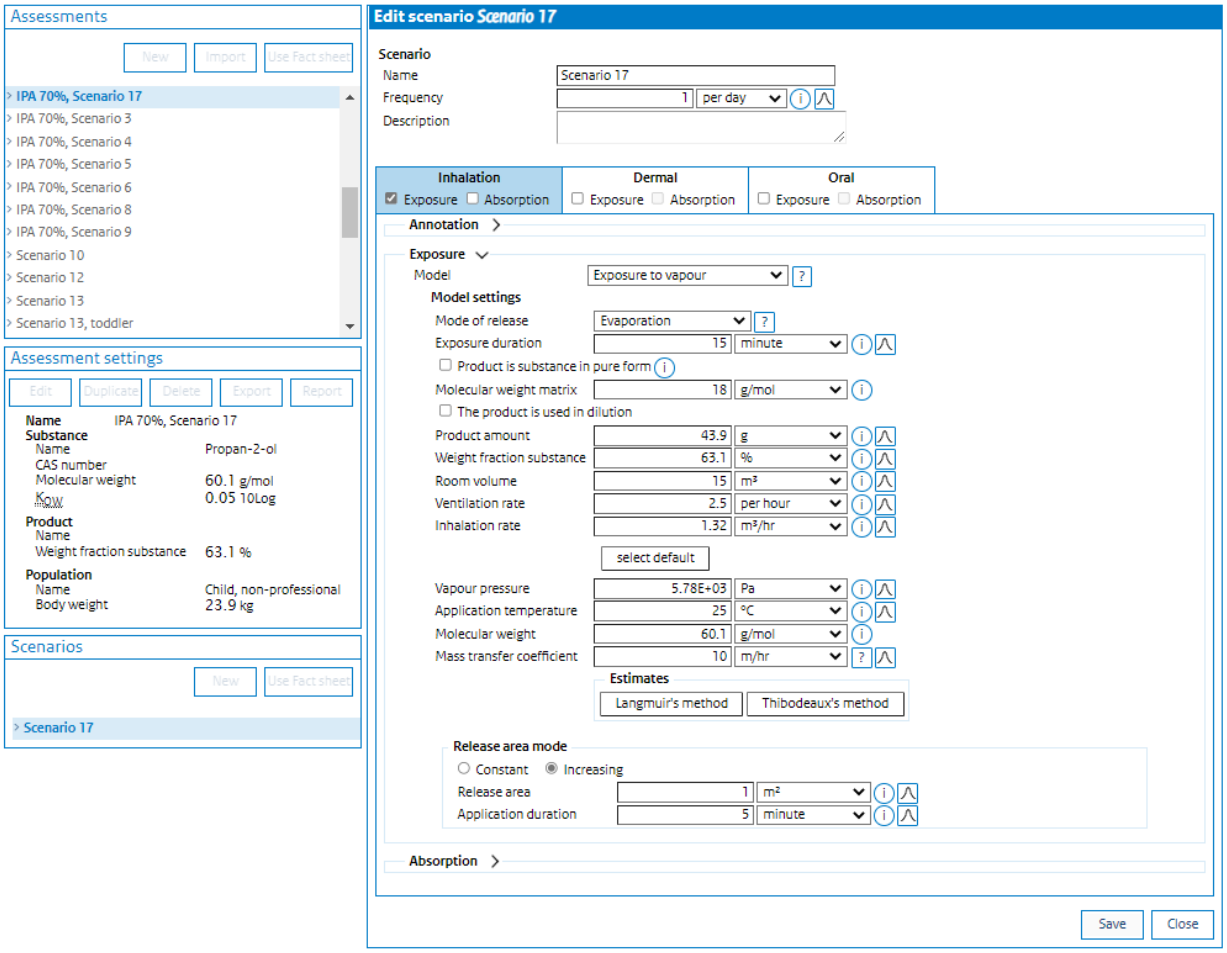
	Value	Unit	Reference
Contact time	1,74774222	min	HeadHoc 9
Cycles per Day	1	per day	Germany 2015
Dermal absorption	0,85	mg/cm²/h	Germany 2015
Area (palms and backs of both hands)	820	cm²	Methodology
Body weight adult	60	kg	Methodology
systemic dermal exposure	0,33838231	mg/kg bw/day	

Total systemic exposure	**5,29**	**mg/kg bw/day**
AEL (professionals)	**17,9**	**mg/kg bw/day**
AEL (General population)	**10,7**	**mg/kg bw/day**

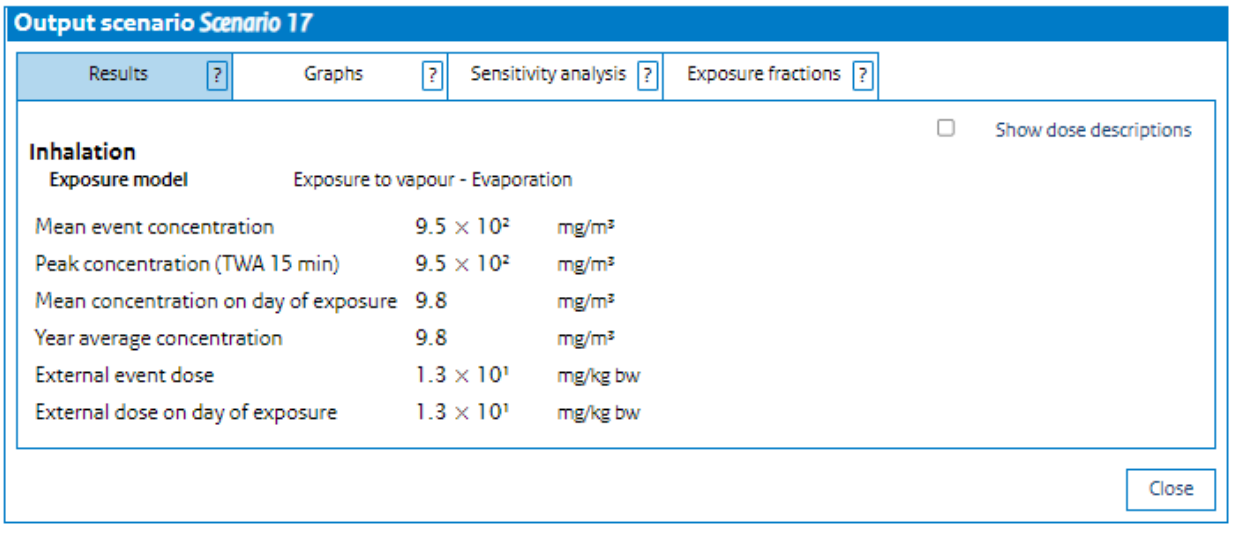
3.2.16 Scenario [17]: Hard surface disinfection (small surfaces in PT4), e.g. in kitchens - general public (secondary exposure) - spraying

Calculation ConsExpo Web

Child:



Results



Calculation of systemic exposure

Child

1 application per day

Calculation Inhalative exposure

	Value	**Unit**	**Reference**
mean event concentration	950	mg/m³	HeadHoc 9 Excel
exposure duration	0,25	h	Germany 2015
exposure duratioin on 1 day	1	per day	HeadHoc 15
Inhalation Rate	1,32	m³/h	Methodology
Body weight	23,9	kg	Methodology
Inhalative absorption	100	%	
systemic inhalative exposure	13,1171548	mg/kg bw/day	

Total systemic exposure	**13,12**	**mg/kg bw/day**
AEL (professionals)	**17,9**	**mg/kg bw/day**
AEL (General population)	**10,7**	**mg/kg bw/day**

3.3 New information on the active substance

No new relevant information on the acitive substance has been submitted. Please cf. to chapter 2.1.8.2 for further information.

3.4 Residue behaviour

No data available.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Not relevant. Please cf. to chapter 2.2.5. and IUCLID.

3.6 Confidential annex

Please cf. to separate document.

3.7 Other

3.7.1 Reference list (excluding list of studies. cf. to chapter 3.1)

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