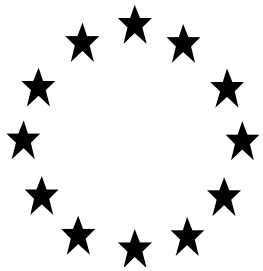
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR UNION AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Pal IPA Product Family

Product type(s) 2 & 4

Propan-2-ol

Case Number in R4BP: BC-DY025578-07

Evaluating Competent Authority: UK CA

Date: 22/03/2019

Table of Contents

Changes history table

Application type	refMS/ eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
UA-APP	UK	BC-DY025578-07	19.12.2019	Authorisation	
	DE		02.03.2022	Post Authorisation Requirements: long-term storage stability	chapter 1.3, p. 6; chapter 2.2.2, p. 22-23 +25; chapter 3.1, p.111

1 CONCLUSION

The outcome of the assessment for Pal IPA Product Family is specified in the BPC opinion following discussions at the BPC-29 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

1.1 Summary of decisions and restrictions

It is concluded after evaluation that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product subject to the following conditions:

1.1.1 Usage area

User	Usage Area
Professional	Indoor disinfectant for use against bacteria, mycobacteria and yeast on hard, non-porous surfaces in cleanrooms for biotechnology, pharmaceutical, manufacture of non-invasive medical devices, healthcare industries and other critical life science applications; industrial food and feed preparation areas

1.1.2 Pest and application rate

Authorisation is granted for use against bacteria, mycobacteria and yeast.

Application rate: One wipe per 1 – 1.5 m^2 of surface ensuring a 1-minute contact time.

1.1.3 Active substance details

The concentration of the active substance propan-2-ol in the biocidal product is 70 % v/v (62.9 % w/w).

The minimum purity of the active substance propan-2-ol is 99 % w/w.

The sources of propan-2-ol (Brenntag GmbH (ExxonMobil Petroleum & Chemical B.V.B.A) and Brenntag GmbH (Shell Chemicals Europe B.V.)) [redacted].

The source of propan-2-ol manufactured by Brenntag GmbH (ExxonMobil Petroleum & Chemical B.V.B.A) [redacted].

[redacted].

The source of propan-2-ol manufactured by Brenntag GmbH (Shell Chemicals Europe B.V.) [redacted].

[redacted].

[redacted].

[redacted].

1.1.4 Comparative assessment and authorisation

A comparative assessment is not required since propan-2-ol is not considered a candidate for exclusion in accordance with Article 5(1) or substitution in accordance with Article 10(1) of EU Regulation 528/2012.

1.2 Necessary issues accounted for in the product label

Wash hands and exposed skin before meals and after use.

Avoid contact with eyes

Used wipes must be disposed in a closed container

When performing disinfection in areas where members of the public may be present, persons should be prevented from entering the room until the room has been well ventilated.

1.3 Requirement for further information

Storage stability data:

Data showing satisfactory chemical and physical properties for the product family and their retention after ambient storage in the commercial packaging (PET/Foil/PE sachet and HDPE canister wipe packs) for the required shelf life must be provided. The specification proposed and properties tested should be in accordance with "Guidance on information requirements" (ECHA, Nov. 2014). All relevant properties should be determined prior to and after storage.

Addendum:
The required data on long-term storage stability for the product family have been submitted and assessed. The study was considered acceptable.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier	**Country (if relevant)**
Pal IPA Product Family	EU

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Pal International Limited
	Address	Bilton Way, Lutterworth, Leicestershire, LE17 4JA, England
Pre-submission phase started on	22nd December 2015	
Pre-submission phase concluded on	18th February 2016	
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Pal International Limited
Address of manufacturer	Bilton Way, Lutterworth, Leicestershire, LE17 4JA, England
Location of manufacturing sites	Bilton Way, Lutterworth, Leicestershire, LE17 4JA, England

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Propan-2-ol
Name of supplier	Brenntag GmbH
Address of supplier	Stinnes Platz 1 45472 – Mülheim an der Ruhr Germany
Name of manufacturer	ExxonMobil Petroleum & Chemical B.V.B.A.
Address of manufacturer	Polderdijkweg 3B, B-2030 Antwerpen, Belgium
Location of manufacturing sites	Baton Rouge Chemical Plant (BRCP), Exxon Mobil Chemical Plant, 4999 Scenic Highway, Baton Rouge, Louisiana, 70897, USA

Active substance	Propan-2-ol
Name of supplier	Brenntag GmbH
Address of supplier	Stinnes Platz 1 45472 – Mülheim an der Ruhr Germany
Name of manufacturer	Shell Chemicals Europe B.V.
Address of manufacturer	PO Box 2334, 3000 CH, Rotterdam, Netherlands
Location of manufacturing sites	Haven 3222, Vondelingenweg 601, 3196 KK, Vondelingenplaat, Netherlands

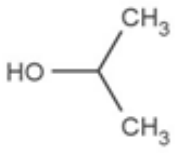
2.1.2 Product family composition and formulation

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 ☒ This was a dummy product therefore new data have been submitted.
No ☐

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Propan-2-ol
IUPAC or EC name	Propan-2-ol
EC number	200-661-7
CAS number	67-63-0
Index number in Annex VI of CLP	603-117-00-0
Minimum purity / content	990 g/kg
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance is not a candidate for substitution.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% v/v)**		**Content (% w/w)**	
					Min	**Max**	**Min**	**Max**
Propan-2-ol	Propan-2-ol	Active substance	67-63-0	200-661-7	70 (pure)	70 (pure)	62.9* (pure)	62.9* (pure)

*Technical material added to product = 62.9~~4~~ to 63.5~~4.65~~% (Water content adjusted)

The full formulation composition details are contained within the Confidential Annex Section 3.6.1.

2.1.2.4 Information on technical equivalence

The sources of propan-2-ol (Brenntag GmbH (ExxonMobil Petroleum & Chemical B.V.B.A) and Brenntag GmbH (Shell Chemicals Europe B.V.)) [redacted].

The source of propan-2-ol manufactured by Brenntag GmbH (ExxonMobil Petroleum & Chemical B.V.B.A) [redacted].

The source of propan-2-ol manufactured by Brenntag GmbH (Shell Chemicals Europe B.V.) [redacted]

2.1.2.5 Information on the substance(s) of concern

No substances of concern have been identified in the product family.

2.1.2.6 Type of formulation

meta SPC 1: AL (any other liquid) - RTU wipe

2.1.3 Hazard and precautionary statements[1]

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

Classification	
Hazard category	Flam. Liquid 2 Eye Irritant 2 STOT SE 3
Hazard statement	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H336: May cause drowsiness or dizziness.
Labelling	
Signal words	Danger
Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation H336: May cause drowsiness or dizziness
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P210: Keep away from heat/sparks/open flames/hot surfaces. – No smoking. P233: keep container tightly closed. P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling.

[1] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

	P271: use only outdoors or in a well-ventilated area. P280: Wear protective gloves/eye protection/face protection P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P304+P340: IF INHALED: Remove person to fresh air and keep 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 CENTRE/ doctor/…/if you feel unwell. P337 + P313 If eye irritation persists: Get medical advice/attention P370+P378: In case of fire: Use alcohol-resistant foam to extinguish. P403+P235: Store in a well-ventilated place. Keep cool. P405: Store locked up P501: Dispose of contents/container in accordance with local regulations.
Note	Supplementary Hazard Information EUH066: Repeated exposure may cause skin dryness or cracking. Both the assessment report and the Biocidal Products Committee (BPC) opinion on propan-2-ol propose this additional label phrase based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions. As propan-2-ol is present at a concentration of 70 % in the formulation, it is the opinion of the UK CA that the additional labelling phrase should be applied as a precautionary measure. The wipe itself is an inert polymer matrix and does not affect the classification. The user will be exposed directly to the liquid on the inert matrix. P240, P241, P242, and P243 are not considered necessary as the products are not so volatile as to generate a hazardous atmosphere. See Section 2.2.3.

2.1.4 Authorised use(s)

2.1.4.1 Meta SPC 1 – Pal IPA Product Family Wipes

2.1.4.1.1 Use description

Table 1. Use # 1 – Professional use

Product Type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals PT04 – Food and feed area
Where relevant, an exact description of the authorised use	Indoor disinfectant for use against bacteria, mycobacteria and yeast on hard, non-porous surfaces in cleanrooms for biotechnology, pharmaceutical, manufacture of non-invasive medical devices, healthcare industries and other critical life science applications; industrial food and feed preparation areas Acceptable use temperature: room temperature (20±2°C)
Target organism (including development stage)	Bacteria Mycobacteria Yeast
Field of use	Indoor
Application method(s)	Wiping
Application rate(s) and frequency	One wipe per 1 – 1.5 m^2 of surface. 1 minute contact time for bacteria and myobacteria 3 minute contact time for yeast
Category(ies) of users	Professional
Pack sizes and packaging material	Impregnated100 % polypropylene wipes in: - HDPE canister with PP lid – 150 wipes (0.5 L), 200 wipes (2 L), 240 wipes (2 L) - PP bucket with PP lid cap – 500 wipes (8 L), 1000 wipes (8 L), 1500 wipes (8 L) Impregnated 100 % polyester wipes in: - Laminate flow wrap packet sealed with PET/PE – 25, 50 or 100 wipes - Aluminium foil single sachet– 1 wipe

1

2

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2.1.4.1.1.1 Use-specific instructions for use

Do not use on surfaces sensitive to alcohol. For soiled surfaces, clean the surface carefully before application 1. Follow agreed risk assessment policy guidelines regarding the use of PPE. 2. Choose the dispenser type and dispense the wipe. 3. Wipe the surface in an S Shape moving from clean to dirty. Use the wipe flat not scrunched. Do not go over the same area twice with the same wipe. 4. Use a fresh wipe if your wipe becomes soiled or dry. 5. Make sure to wet surfaces completely 6. Discard used wipes in the appropriate waste bin following local agreed guidelines. 7. Allow the surface to dry before use.

2.1.4.1.1.2 Use-specific risk mitigation measures

Wash hands and exposed skin before meals and after use. Avoid contact with eyes. When performing disinfection in areas where members of the public may be present, persons should be prevented from entering the room until the room has been well ventilated.

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

Eye contact: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention

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

Dispose of contents/container in accordance with local regulations. Do not flush wipes down the toilet. Do not macerate. Residual alcohol should be emptied prior to disposal of container.

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

Store in a cool, dry, well-ventilated place in original container. Keep container tightly closed. Shelf-life: 2 years

2.1.5 General directions for use

2.1.5.1 Instructions for use

See section 2.1.4.1.1.1

2.1.5.2 Risk mitigation measures

See section 2.1.4.1.1.2

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

See section 2.1.4.1.1.3

2.1.5.4 Instructions for safe disposal of the product and its packaging

See section 2.1.4.1.1.4

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

See section 2.1.4.1.1.5

2.1.6 Other information

Polypropylene or polyester wipes, 20-45 gsm, containing 1.7 – 7.5 ml product (0.93 – 4.12 g propan-2-ol) The product contains propan-2-ol (CAS No: 67-63-0), for which an European reference value of 52.6 ppm for the professional user was agreed and used for the risk assessment of this product.

2.1.7 Packaging of the biocidal product family

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user	Compatibility of the product with the proposed packaging materials
Impregated Wipes – 100% polypropylene					Acceptable. There were no adverse interactions between the liquid formulation alone and the HDPE packaging for 18 weeks at 30 °C. These data can be extrapolated to support the impregnated wipe products. The formulation can be considered similar to an aqueous based formulation due to the main component being an aliphatic alcohol; therefore extrapolation between packaging types is acceptable. In addition propan-2-ol is known to have good resistance to a range of plastics. Packaging suitability will also be assessed following long-term storage.
Canister	150 wipes, 0.5 L 200 wipes, 2 L 240 wipes, 2L	HDPE	Lid - PP	Professional	
Bucket	500, 1000 or 1500 wipes, 8 L	PP	Lid - PP	Professional	
Impregated Wipes – 100% polyester					
Flow wrap packet	25, 50 or 100 wipes	Laminate film flow	Closer - PET/PE	Professional	
Single sachets	1 wipe	Aluminium foil	Sealed sachet – Aluminium foil	Professional	

The specification of the wipes is as follows:

Polypropylene wipes

Product size manufactured	Mass of active substance in product manufactured (g)[1]	Additional information
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[1] *Density of propan-2-ol: 0.785 g/ml*

Polyester wipes

Product size manufactured	Mass of active substance in product manufactured (g)[1]	Additional information
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[1] *Density of propan-2-ol: 0.785 g/ml*

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance has been submitted as part of this product family application. Please see Annex 3.1 for the list of studies used to support the product family.

2.1.8.2 Access to documentation

The applicant, Pal International Limited, is the data owner of a number of the submitted studies listed in Annex 3.1, [redacted].

[redacted].

[redacted].

2.1.8.3 Similar conditions of use

The outcome of the Union Authorisation Pre-Submission Phase was communicated to the applicant, Pal International Limited, by ECHA in communication number D(2016)0697 dated 18th February 2016 and states the following:

The biocidal product family Pal IPA Product Family is deemed to be eligible for Union authorisation.

Reasons

Based on the information provided by the applicant, it appears that the application could meet the basic requirements of Article 42(1) of the Biocidal Products Regulation.

No objections were raised from either the Commission or the Member States Competent Authorities (MSCAs) as regards the eligibility of the prospective application for Union authorisation on the grounds that the biocidal product family Pal IPA Product Family falls outside of the scope of the Biocidal Products Regulation, or had been attributed the wrong product type, or that it would have non-similar conditions of use across the Union.

This document can be found in section 13 of the IUCLID dossier.

2.2 Assessment of the biocidal product family

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

Table 2. Intended use # 1 – General Disinfection of hard surfaces in industrial and institutional areas including food contact surfaces (Meta SPC 1)

Product Type(s)	PT2: Disinfectants and algaecides not intended for direct application to humans or animals PT4: Disinfectants for food and feed area
Where relevant, an exact description of the authorised use	General Disinfection of hard surfaces in industrial and institutional areas including food contact surfaces
Target organism (including development stage)	Bacteria, yeast, mycobacteria and viruses: TB, HIV, Hepatitis, SARS, MRSA, E. Coli, Pseudomonas, VRE, Candida
Field of use	Disinfectant of non invasive medical devices and equipment within healthcare environments; disinfectant of hard surfaces in professional environments; disinfectant for use in cleanrooms for biotechnology, pharmaceutical, manufacture of medical devices, healthcare industries and other critical life science applications; disinfectant of food contact surfaces.
Application method(s)	RTU wipe
Application rate(s) and frequency	Use one wipe to disinfect the surface. On heavily soiled surfaces, more than one wipe may be required.
Category(ies) of user(s)	Professional users
Pack sizes and packaging material	100% Polypropylene wipes: 150 wipes: 0.5 L HDPE canister, 130 × 180 mm, [redacted]. 200 wipes: 2 L HDPE canister, 200 × 200 mm, [redacted]. 150 wipes: 2 L HDPE canister, 300 × 200 mm, [redacted]. 240 wipes: 2 L HDPE canister, 195 x 155 mm, [redacted]. [redacted], 195 x 155 mm, [redacted]. 500 wipes: 8L PP Bucket, 200 × 240 mm, [redacted]. 1000 wipes: 8 L PP Bucket, 200 × 200 mm, [redacted]. 1500 wipes: 8 L PP Bucket, 200 × 200 mm, [redacted]. 100% Polyester wipes: 25 wipes: PET/PE laminate flow wrap, 200 × 200 mm, [redacted]. 50 wipes: PET/PE laminate flow wrap, 300 × 200 mm, [redacted]. 100 wipes: PET/PE laminate flow wrap, 200 x 200 mm, [redacted]

	[redacted]. 1 wipe: PET/Foil/PE single sachets, 180 × 180 mm, [redacted]. 25 wipes: PET/PE laminate flow wrap, 300 × 200 mm, [redacted].

2.2.2 Physical, chemical and technical properties

Pal IPA Product Family is a family of ready to use any other liquid products supplied to the user as impregnated wipes. Data have been provided on the 70 % v/v propan-2-ol solution alone in addition to the wipe product as it is supplied to the user. The liquid formulation alone is not an individual product within the Pal IPA Product Family; however the liquid formulation is identical to the solution impregnated on the wipe material of the products of meta SPC 1. Full details are provided in the Confidential Annex Section 3.6.1. The applicant has provided the following justification as to how the liquid formulation data is applicable to the product family:

The 70 % IPA liquid product has an identical composition to the liquid that is added to the wipes to form the wipe products. The wipe itself is an inert matrix that does not react in any way with the liquid. As such we consider the stability studies that are in progress on the 70 % liquid product to fully address the storage stability data requirement of the wipe products that are supported by this product family. The packaging of the wipe product is HDPE, PP and PET/PE which is considered to have the same chemical resistance or better compared with the packaging being assessed in the long term stability study on the liquid (HDPE) - all of these packaging materials are considered to have good chemical resistance to alcohols. It is therefore proposed that a read across approach from the liquid data to the wipes is acceptable.

Two accelerated storage stability studies for the wipe product have been submitted entitled 'Cosmetic Regulation Stability Test Report'. These reports lack the details required for biocidal product authorisation, nevertheless the data have been reported. No further data have been requested at this point as for the majority of properties it is possible to extrapolate data from the liquid product.

This was the representative formulation considered at active substance approval. However, as this was a 'model formulation' no physical, chemical or storage stability data were evaluated. The physical, chemical and storage stability data submitted to support this product family application are summarised in the following table.

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
Physical state at 20 °C and 101.3 kPa	Visual assessment	Propan-2-ol 70 % wipes	Alcohol solution on a solid support, white wipe.	[redacted]; 2016a and 2016b	Acceptable
Colour at 20 °C and 101.3 kPa					
Odour at 20 °C and 101.3 kPa	Assessment	Propan-2-ol 70 % wipes	Alcohol	[redacted]; 2016a and 2016b	Acceptable

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
Acidity / alkalinity	No specified method	Propan-2-ol 70 % wipes/liquid	pH = 5.8	[redacted]; 2016a	Acceptable. For the wipe product the experimental details (e.g. method and temperature) have not been provided. However as the liquid formulation of the impregnated wipes is identical to the liquid formulation alone, tested in Miller, R; 2016, it is possible to extrapolate the accelerated storage data from the liquid formulation to the impregnated wipes. Therefore further data has not been requested. As pH is within the range 4 – 10 acidity or alkalinity data are not required.
			pH = 5.7	[redacted]; 2016b	
	CIPAC MT 75.3		pH = 6.52 (at 20 °C, neat)	[redacted]; 2016	
Relative density	OECD 109	Propan-2-ol 70 % liquid	0.87334 g/mL at 20°C 0.85928 g/mL at 40°C	[redacted]; 2016	Acceptable, these data can be extrapolated to the impregnated wipes.
Storage stability test – **accelerated storage 12 weeks at 45°C**	No specified methods	Propan-2-ol 70 % wipes	Polyester wipe samples were stored in PP sealed packs (50 wipes) for 12 weeks at 45 °C <u>Appearance</u> Initial: White wipe with alcohol odour. After: No change. <u>pH</u> Initial: 5.8 After: 6.2 <u>Pack performance</u> Initial: Peel back After: Satisfactory, no change. <u>Pack weight change</u> -4.3 g (Weight of pack = 226g) = -1.9%	[redacted]; 2016a	Acceptable storage temperature and period, these conditions exceed those specified in the BPR guidance. The limited data provided show acceptable results, however active substance content has not been determined. As the liquid formulation of the impregnated wipes is identical to the liquid formulation alone, tested in Miller, R; 2016, it is possible to extrapolate the accelerated storage data from the liquid formulation to the impregnated wipes.
Storage stability test – **accelerated storage 12 weeks at 45°C**	No specified methods	Propan-2-ol 70 % wipes	Polypropylene wipe samples were stored in HDPE flip lid tubs (200 wipes) for 12 weeks at 45 °C <u>Appearance</u> Initial: White wipe with alcohol odour.	[redacted]; 2016b	Acceptable storage temperature and period, these conditions exceed those specified in the BPR guidance. The limited data provided show acceptable results, however active substance content

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
			After: No change. <u>pH</u> Initial: 5.7 After: 6.0 <u>Pack performance</u> Initial: Flip lid After: Satisfactory, no change. <u>Pack weight change</u> -14.6 g (Weight of pack = 811g) = -1.8%		has not been determined. As the liquid formulation of the impregnated wipes is identical to the liquid formulation alone, tested in Miller, R; 2016, it is possible to extrapolate the accelerated storage data from the liquid formulation to the impregnated wipes. In addition, the % weight change for the 50 wipe pack is -1.8%, the product is 62.9% active substance and therefore even if all the loss (2%) was the active substance this would still be less than allowed 10%. Therefore, the most pragmatic way forward, based on the data available on the liquid in the wipes, is to allow authorisation of the wipes (efficacy data indicate wipes are effective) and request ambient storage stability data on the wipes addressing active substance content, appearance and pH. The eCA considers this to be the best way forward, allowing authorisation of the wipes, with a safe guard of a data requirement.
Storage stability test – **accelerated storage 18 weeks at 30°C**	CIPAC MT 46.3	Propan-2-ol 70 % liquid	Liquid samples were stored in HDPE containers for 18 weeks at 30 °C.	[redacted]; 2016	Acceptable storage period and temperature.
	Visual assessment		<u>Appearance</u> Initial: A free flowing, uniform colourless liquid. After: No change.		Acceptable, no change in product appearance.
	Weighing method		<u>Weight change</u> -3.24 g		Acceptable.
	Validated GC-MSD method		<u>Active substance content</u> Initial: 69.67 % v/v After: 69.03 % v/v		Acceptable, a < 1 % decrease in active substance content was noted after storage.
	CIPAC MT 75.3		<u>pH (neat)</u> Initial: 6.52		Acceptable.

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
			After: 6.07 <u>pH (1 % dilution)</u> Initial: 6.86 After: 6.84		
	OECD 109		<u>Density (at 20°C)</u> Initial: 0.87334 g/mL After: 0.87244 g/mL		Acceptable.
Storage stability test – **long term storage at ambient temperature**	Active substance content: GC Analysis (FID) pH:CIPAC MT 75.3 Appearance: Visual Storage for 24 months at 25 ±2 °C in the dark.	Isopropanol Disinfectant Wipes (70 % v/v) Batch-no. 1385 Storage in three different container types: 1. HDPE Canister Container 2. Soft Flow wrap – PET/Foil/PE Container 3. Polypropylene Bucket Container	**Active substance content (% v/v)** <u>HDPE Canister Container:</u> t = 0: 71.02 t = 12 months: 67.21 (-5.4 %) t = 24 months: 70.77 (-0.4 %) <u>Soft Flow wrap – PET/Foil/PE Container:</u> t = 0: 71.76 t = 12 months: 73.51 (+2.4 %) t = 24 months: 78.68 (+9.6 %) <u>Polypropylene Bucket Container:</u> t = 0: 68.70 t = 12 months: 70.06 (+2.0 %) t = 24 months: 73.27 (+6.7 %) **Weight change (g)** <u>HDPE Canister Container:</u> t = 0: 695.92 t = 24 months: 642.62 (-7.7 %) <u>Soft Flow wrap – PET/Foil/PE Container:</u> t = 0: 623.69 t = 24 months: 571.82 (-8.3 %) <u>Polypropylene Bucket Container:</u>	[redacted], 2021 Study No.: BN36LV	**DE CA (August 2021):** Long term storage stability data was submitted as post-authorisation requirement. The data is acceptable.

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
			t = 0: 4561.3 t = 24 months: 4500.5 (-1.3 %) **pH (neat, T = 25 °C)** HDPE Canister Container: t = 0: 7.27 t = 12 months: 7.28 t = 24 months: 7.27 Soft Flow wrap – PET/Foil/PE Container: t = 0: 6.78 t = 12 months: 6.66 t = 24 months: 6.68 Polypropylene Bucket Container: t = 0: 7.37 t = 12 months: 7.33 t = 24 months: 7.49 No change in appearance of the product or the packaging observed during storage in any case.		
Storage stability test – **low temperature stability test for liquids**	No specified method	Propan-2-ol 70 % wipes/liquid	Limited freeze thaw data have been provided stating no change in product appearance after 12 weeks storage.	[redacted]; 2016a and 2016b	As these data do not state the exact test protocol they are not suitable to support low temperature stability. As the liquid formulation of the impregnated wipes is identical to the liquid formulation alone, tested in Miller, R; 2016, it is possible to extrapolate the low temperature storage data from the liquid formulation to the impregnated wipes.
	CIPAC MT 39.3		Post seven days storage at 0°C ±2.0°C and 3 hours at room temperature (and all interim time points) the product remained a clear colourless solution with no signs of separation into oil, cream, sediment	[redacted]; 2016	Acceptable.

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
			or crystallisation.		
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Propan-2-ol does not absorb ultraviolet radiation (No absorption > 290 nm). Consequently photolysis could not be a route of degradation of propan-2-ol, i.e. the stability of a propan-2-ol product will not be affected by luminous intensity.	Case	Acceptable.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	-	-	See section 'Storage stability test – accelerated storage'.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	Propan-2-ol 70 % wipes/liquid	There was no significant change in container appearance and container weight following storage at 30°C for 18 weeks for a liquid product and 12 weeks at 45°C for both wipe materials. This determination following ambient storage remains in progress.	[redacted]; 2016a and 2016b [redacted]; 2016	Acceptable based on the accelerated storage stability data. Further consideration to be made once the ambient temperature storage stability study is available.
Physical compatibility	-	-	Not applicable as the products are not designed to be used in combination with other products and no incompatibilities have been identified.	Case	Acceptable.
Chemical compatibility	-	-	Not applicable as the products are not designed to be used in combination with other products and no incompatibilities have been identified.	Case	Acceptable.
Surface tension	EC A.5	Propan-2-ol 70 % liquid	24.224 mN/m at 20°C 22.592 mN/m at 25°C	[redacted]; 2016	Acceptable.
Viscosity	OCED 114	Propan-2-ol 70 % liquid	<u>Dynamic viscosity at 20°C</u> 12.25-19.87 mPas (30-100 R.P.M.) Mean = 15.69 mPas	[redacted]; 2016	Acceptable.

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
			Kinematic viscosity at 20°C 0.1796 cm^2/s Dynamic viscosity at 40°C 10.11-14.14 mPas (50-100 R.P.M.) Mean = 11.80 mPas Kinematic viscosity at 40°C 0.1374 cm^2/s		

Conclusion on the physical, chemical and technical properties of the product family

The physical, chemical and technical properties for Pal IPA Product Family are acceptable for the liquid formulation supplied to the user as impregnated wipe products. For the majority of properties data on the liquid formulation alone can be extrapolated to the impregnated wipes as the liquid formulations are identical. Therefore the data provided are sufficient to support the product family.

Accelerated storage data for the liquid formulation alone were acceptable after 18 weeks at 30°C, therefore a shelf life of 2 years is supported for the product family. This was confirmed by long term storage stability data in 2021. The product labels state 'Store in a cool place.' therefore it is unlikely the products would be exposed to temperatures above 30°C. A low temperature storage stability study showed no significant change in the liquid product following storage at 0°C for seven days.

Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
Explosives	Expert statement	-	The major constituent of the product is propan-2-ol, which is the active ingredient and is not classified under CLP regulation (EC) No 1272/2008 for explosivity and oxidising. None of the components are explosive or oxidizing and it is therefore concluded that the solution is unlikely to undergo rapid decomposition with the evolution of gases or release of heat and, therefore does not present a risk of explosion. It is also important to note that the product as a whole would not be expected to behave differently with regards to explosivity compared with individual constituents when combined.	[redacted]; 2016	Acceptable. The product family is not classified as explosive.
Flammable liquids	EC A.9	Propan-2-ol 70 % liquid	The product had a flash point of 21.0°C and is classified as H225: Flammable liquid 2.	[redacted]; 2016	Acceptable, the product family is classified as a category 2 flammable liquid (H225).
Self-reactive substances and mixtures	Expert statement	-	None of the individual constituents of the solution are classified as explosive, oxidising, or are organic peroxides. The chemical structures of all of the constituents were examined for the presence of characteristic groups associated with self-reactivity, none were present and therefore the product would not be expected to be susceptible to rapid, exothermic chemical reaction. The major constituent of the solution is propan-2-ol, which is the active ingredient and is only classified under CLP regulation (EC) No 1272/2008 for the physical chemical property of flammability. The composition of the formulation is fully known (see confidential annex). When mixed, no self-reacting properties would be expected. The product as a whole would not be expected to behave differently with regards to this CLP	[redacted]; 2016	Acceptable, the product family is not classified as self-reactive.

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
			endpoint compared with the individual constituents. It is concluded that solution should not be considered for classification for self-reactivity.		
Self-heating substances and mixtures	Expert statement	-	Self-heating is generally a property of the substance when in bulk. As the preparation is a liquid, it should not be considered for the classification of self-heating as this property is generally only applicable to solids. The composition of the formulation is fully known (see confidential annex). Propan-2-ol is not classified for any physical hazard under CLP regulation (EC) No 1272/2008, apart from flammability. The product is a liquid at room temperature and the boiling point is between 80°C and 100°C. As the melting point is below 160°C, this product should not be considered under this endpoint according to BPR guidance. In the absence of test results from screening procedures, the self-heating property has been assessed theoretically based on the characteristics of the components. It is concluded that the formulation does not contain any substances that contribute to the properties of self-heating, and therefore it would not be considered for the classification of self-heating material.	[redacted]; 2016	Acceptable, the product family is not classified as self-heating.
Oxidising liquids	Expert statement	-	The major component of the solution is propan-2-ol, which is an alcohol and the active substance within the formulation. It is not classified under CLP regulation (EC) No 1272/2008 for oxidising properties and does not contain any oxidizing functional groups. It is classified for flammability under EU CLP but not for any other physical chemical CLP endpoint. It can be concluded that the preparation itself will not be oxidising and will therefore be incapable of reacting exothermically with combustible materials. Additionally, as all of the constituents only contain oxygen that is chemically bonded to carbon or hydrogen, and no halogens are present,	[redacted]; 2016	Acceptable, the product family is not classified as oxidising.

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
			according to BPR guidance the oxidising hazard class is not applicable to this formulation.		
Corrosive to metals	Expert statement	-	For a substance to be classified as Corrosive to Metals under CLP, it must corrode steel or aluminium at a rate of 6.5 mm per year or greater at 55°C. A material would have to be very corrosive to corrode metal at this rate, which would not be expected to apply to this product. Additionally the formulation would not be expected to have an extreme pH – the pH would be expected to be between 6.5 and 7.5, and the pKa of propan-2-ol in water is ≈ 17. The classification of the constituents indicates they do not possess general hazards related to the property of corrosivity. The major component of the solution is propan-2-ol, which functions as the active substance forming the bulk of the product. No functional groups present on any of the constituents of the solution would be considered strongly acidic or basic, and no halogens are present. The product as a whole would not be expected to behave differently with regards to this CLP endpoint compared with the combined individual constituents. It is therefore concluded that the formulation would not be considered for classification as a substance with "Corrosive to Metals" properties.	[redacted]; 2016	Acceptable, the product is not classified as being corrosive to metals.
	OPPTS 830.6320	Propan-2-ol 70 % liquid	The test material had no apparent changes take place in the corrosivity to metals test when in contact with aluminium and HDPE. The test material, when in contact with zinc produced a dull white coating on the surface which was easily removed with wet and dry sandpaper. There was an average weight loss of 2.9 mg and is not considered significant. The test material, when in contact with copper dulled the surface which was easily removed with wet and dry sandpaper. There were no signs of corrosion to the copper and there was no significant weight change. No significant changes were observed to occur during this	[redacted]; 2016	

Property	Guideline and Method	Purity of the test substance (% v/v)	Results	Reference	UK CA Comments
			corrosivity to metals test so the substance is not considered corrosive to metals.		
Auto-ignition temperatures of products (liquids and gases)	EC A.15	Propan-2-ol 70 % liquid	The product did not auto-ignite below 400°C and is therefore considered not highly auto-flammable.	[redacted]; 2016	Acceptable, the product is not classified as auto-flammable.

Conclusion on the physical hazards and respective characteristics of the product family
Based on expert consideration of the composition, Pal IPA Product Family is considered not to be explosive, oxidising, self-reactive, self-heating or corrosive to metals. The flash point was measured to be 21.0°C therefore the product family is classified as category 2 flammable liquid (H225). The auto-ignition temperature is > 400°C.

2.2.3 Methods for detection and identification

Analytical methods for the active and impurities in the technical material

The sources of the active substance are considered technically equivalent to that considered for active substance approval. Letters of access to the list of endpoints agreed at active substance approval and the alternative active substance dossier (Annex II) have been provided where methods of analysis for the active substance and impurities have already been considered. Therefore, no further consideration is required at product authorisation.

Analytical methods for the active substance in the biocidal product family

Propan-2-ol content in the product family was determined by GC-MS as follows:

In duplicate approximately 0.05 g of liquid formulation were accurately weighed and transferred to a 50 mL volumetric flask and made to partial volume with deionised water containing 40 g/L sodium chloride. Each sample was sonicated for 5 minutes before being made to volume with deionised water containing 40 g/L sodium chloride. The samples were diluted 1:10 by transferring 1.0 mL of sample into a 20 mL headspace vial and making to 10 mL volume with deionised water containing 40 g/L sodium chloride. The samples were subsequently analysed using GC-MSD with Headspace Sampler. This gives a sample concentration of 0.1 mg/mL (100 mg/L) and therefore a propan-2-ol concentration of 70 mg/L.

The following spectroscopic conditions were noted:

Instrument:	Shimadzu GC-MSD with HS-20 Headspace Sampler
Column:	Rtx-5MS, (30m x 0.32mm x 1.0µm)
Temperatures:	
Column:	30°C for 5 minutes, then 10°C/ minute to 200°C, held for 3 minutes
Detector:	Scan: 30 to 250 m/z
Carrier gas:	Helium
Data Collection:	GCMS Solutions
Retention Time:	Approximately 5.4-5.7 minutes

Headspace Conditions:
Cycle Time: 25 minutes
Shake Strength: 4/5

Oven Temperature: 70°C
Loop Temperature: 150°C
Transfer Line Temperature: 180°C

Analytical methods for the analysis of the product family as such including the active substance, impurities and residues								
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**LOQ**
					Range	**Mean**	**RSD**	
Propan-2-ol	GC-MS	70 mg/L (n=6)	5.0-200 mg/L (7-285 % of nominal content) R^2 = 0.9912	No interference	96.3 - 104.0	100.6	2.7	5.0 %v/v
		5 mg/mL (n=6)			98.36-102.9	100.4	1.499	

Precision: %RSD = 0.422 (at 69.45 % v/v, n=6)
Modified Horwitz = 1.41% - Method precision is less than the Horwitz value therefore the method is considered to be suitably precise.

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Methods of analysis for the determination of propan-2-ol residues in air have previously been evaluated at EU level. Methods for detection in body fluids and tissues methods are not required as the active substance is not considered toxic. Methods for detection in soil, water, food/feed of plant and animal origin are not available due to lack of exposure via the intended uses. Therefore, no further consideration is required at product authorisation.

While it is noted that the product family is intended for use as disinfectants for the treatment of food and feed area (PT4), residues of propan-2-ol are not expected within food or feed. The following case was made within the Assessment Report for propan-2-ol (PT4):

"Due to its high vapour pressure, the active substance evaporates completely within the time of application of the representative biocidal products, which are highly concentrated so that no transfer from treated hands or surfaces to food should occur. In the unlikely event that residue transfer does occur, the active substance will evaporate from the food before it is eaten."

Therefore, development of an analytical method for food or feedstuff is not necessary and scientifically not justified.

Conclusion on the methods for detection and identification of the product family
A GC-MS method has been developed and validated for the determination of the active substance in the biocidal product family. The method meets the EU criteria with respect to specificity, linearity, accuracy and precision as described in ECHA's 'Guidance on Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR), Version 1.0 July 2013'. A monitoring method for propan-2-ol residues in air has been evaluated and accepted at an EU level. For all other matrices monitoring methods are deemed scientifically unjustified due to a lack of exposure, this has been agreed at EU level.

2.2.4 Efficacy against target organisms

2.2.4.1 Function and field of use

Pal IPA Product Family is a family of PT 2 and 4 disinfectant products intended for professional indoor use. The product family includes one Meta SPC consisting of ready to use wipes.

The active substance is propan-2-ol at a concentration of 70% v/v. The products of the family are intended for use on hard surfaces in industrial and institutional areas including food contact surfaces, as well as non-invasive medical devices and equipment within healthcare environments.

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

The products of the family are intended to control bacteria (including mycobacteria), fungi, yeasts and viruses.

2.2.4.3 Effects on target organisms, including unacceptable suffering

The products of the family are sold as ready to use wipes (between 1.7 and 7.5 ml of liquid per wipe, equivalent to between 0.9 and 4.1 g propan-2-ol) to be applied as required. Typical use is one application every thirty minutes. On heavily soiled surfaces more than one wipe may be required. A fresh wipe should be used if the current wipe becomes soiled or dry.

The products work by denaturation, which leads to a loss of cellular activity, resulting in death of the cells.

No unacceptable suffering is foreseen as a result of the use of these products.

2.2.4.4 Mode of action, including time delay

The applicant has provided the following statement on the mode of action:

'Alcohols, such as propan-2-ol, exhibit an unspecific mode of action. 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. There is no time delay to the toxic effect.'

The UK CA accepts the applicant's statement on the mode of action.

2.2.4.5 Efficacy data

Tests with 1 minute contact time or shorter have been highlighted.

Studies discussed during WG-EFF VII which were considered not valid/unacceptable by member states are greyed out.

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and field of use envisaged	**Test substance**	**Test organism(s)**	**Test method/ Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Disinfectant for use on hard surfaces in industrial and institutional areas including food contact surfaces, as well as to non-invasive medical devices and equipment within healthcare environments.	Medipal Alcohol Wipes (liquid)	Bacteria: *Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	The EN 1276 standard protocol was followed. Phase 2, Step 1 test. Contact time: 1 minute. Test temperature: 20ºC. Interfering substance: 3.0 g/l Bovine Serum Albumin (BSA) to represent dirty conditions. Concentration: Ready to use (RTU).	For all of the test organisms, a reduction greater than 5 log reduction (the pass criterion for the standard) was observed.	[redacted]; 2014a
	Alcohol Spray (FH55)	Bacteria: *Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	The EN 1276 standard protocol was followed. Phase 2, Step 1 test. Contact time: 1 minute. Test temperature: 10ºC. Interfering substance: 0.3 % Bovine Serum Albumin (BSA) to represent dirty conditions and 0.03 % Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations: 10 %, 50 % and 80 %.	For all of the test organisms, a reduction greater than 5 log reduction (the pass criterion for the standard) was observed with the 80 % concentration.	[redacted]; 2017a
	70% IPA	Bacteria:	The EN 13697 standard protocol was followed.	For all of the test organisms, a	[redacted];

	Wipes Solution	*Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	Phase 2, Step 2 test. Interfering substance: 3.0g/l bovine albumin (dirty) Contact time: 30 s Temperature: 20°C	reduction greater than 4 log reduction (the pass criterion for the standard) was observed.	2013a
	FH55 70% v/v IPA clear liquid	Bacteria: *Pseudomonas aeruginosa* *Escherichia coli* *Staphylococcus aureus* *Enterococcus hirae*	The EN 13697 standard protocol was followed. Phase 2, Step 2 test. Interfering substance: 0.3% bovine albumin (dirty) Contact time: 1 minute. Temperature: 4°C	For all of the test organisms, a reduction greater than 4 log reduction (the pass criterion for the standard) was observed.	[redacted], P; 2016
	Contec ProSat Sterile Cell/Poly nonwoven 70/30 IPA PSC 2001	Bacteria: *Staphylococcus aureus*	The EN 16615 standard protocol was followed. Phase 2, Step 2 test. Concentrations tested: 100%, 0.1% Interfering substance: 0.3g/l bovine albumin (clean) Contact time: 1 minute Temperature: 20°C	For the test organism a reduction greater than 5 log reduction and less than 50 cfu on test fields 2 to 4 (the pass criterions for the standard) were observed.	[redacted]; 2016a
	Contec Meltblown Polypropylene 70/30 IPA PS-850	Bacteria: *Staphylococcus aureus*	The EN 16615 standard protocol was followed. Phase 2, Step 2 test. Concentrations tested: 100%, 0.1%. Interfering substance: 0.3 g/l bovine albumin	For the test organism a reduction greater than 5 log reduction and less than 50 cfu on test fields 2 to 4 (the pass criterions for the standard) were observed.	[redacted]; 2016b

			(clean) Contact time: 1 minute Temperature: 20°C		
	Medipal Alcohol Wipes (liquid)	Bacteria: *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	The EN 13727 standard protocol was followed. Phase 2, Step 2 test. Contact time: 1 minute Test temperature: 20ºC Interfering substance: 3.0 g/l Bovine Serum Albumin (BSA) and 3.0 ml/l sheep erythrocytes to represent dirty conditions. Concentration: Ready to use (RTU).	For all of the test organisms, a reduction greater than 5 log reduction (the pass criterion for the standard) was observed.	[redacted]; 2014b
	70% IPA Wipes Solution	Bacteria: *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	The EN 14561 standard protocol was followed. Phase 2, Step 2 test. Contact time: 30 s. Test temperature: 20ºC Interfering substance: 3.0 g/l Bovine Serum Albumin (BSA) and 3.0 ml/l sheep erythrocytes to represent dirty conditions. Concentration: Ready to use (RTU).	For all of the test organisms, a reduction greater than 5 log reduction (the pass criterion for the standard) was observed.	[redacted]; 2013b
	70% IPA Wipes Solution	Bacteria: *Staphylococcus aureus* (Methicillin-resistant) *Enterococcus faecium* (Vancomycin-resistant)	The EN 14561 standard protocol was followed. Phase 2, Step 2 test. Contact time: 30 s. Test temperature: 20ºC	For both of the test organisms, a reduction greater than 5 log reduction (the pass criterion for the standard) was observed.	[redacted]; 2013c

			Interfering substance: 3.0 g/l Bovine Serum Albumin (BSA) and 3.0 ml/l sheep erythrocytes to represent dirty conditions. Concentration: Ready to use (RTU).		
	Medipal Alcohol Wipes (liquid)	Mycobacteria: *Mycobacterium avium* *Mycobacterium terrae*	The EN 14348 standard protocol was followed. Phase 2, Step 1 test. Contact time: 1 minute Test temperature: 20ºC Interfering substance: 3.0 g/l Bovine Serum Albumin (BSA) and 3.0 ml/l sheep erythrocytes to represent dirty conditions. Concentration: Ready to use (RTU).	For both of the test organisms, a reduction greater than 4 log reduction (the pass criterion for the standard) was observed.	[redacted]; 2014
	70% IPA Wipes Solution	Mycobacteria: *Mycobacterium avium* *Mycobacterium terrae*	The EN 14563 standard protocol was followed. Phase 2, Step 2 test. Contact time: 1 minute Test temperature: 20ºC Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations: 0.1 %, 50 % and 100 %.	For both of the test organisms, a reduction greater than 4 log reduction (the pass criterion for the standard) was observed with both the 50 % and 100 % concentrations.	[redacted]; 2017
	Medipal Alcohol Wipes (liquid)	Fungi: *Aspergillus niger* Yeast: *Candida albicans*	The EN 1650 standard protocol was followed. Phase 2, Step 1 test. Contact time: 1 minute Test temperature: 20ºC	For *C. albicans* a reduction greater than 4 log reduction (the pass criterion for the standard) was observed. For *A. niger*, the reduction (lgR < 3.19) was less than 4 log	[redacted]; 2014c

			Interfering substance: 3.0 g/l Bovine Serum Albumin (BSA) to represent dirty conditions. Concentration: Ready to use (RTU).	reduction (the pass criterion for the standard). Therefore, it failed the test and did not possess sufficient fungicidal activity against this microorganism.	
	Alcohol Spray (FH55)	Yeast: *Candida albicans*	The EN 1650 standard protocol was followed. Phase 2, Step 1 test. Contact time: 15 minutes. Test temperature: 10ºC Interfering substance: 0.3 % Bovine Serum Albumin (BSA) to represent dirty conditions and 0.03 % Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations: 10 %, 50 % and 80 %.	For *C. albicans* a reduction greater than 4 log reduction (the pass criterion for the standard) was observed.	[redacted]; 2017c
	PAL Clinical Wipes Solution	Fungi: *Aspergillus niger* Yeast: *Candida albicans*	The EN 13624 (surface and instrument disinfection in the medical area) standard protocol was followed. Phase 2, Step 1 test. Contact time: 60 minutes Test temperature: 20ºC Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations: 25 %, 50 % and 80 % (v/v).	For *C. albicans* a reduction greater than 4 log reduction (the pass criterion for the standard) was observed with both the 50 % and 80 % concentrations. For *A. niger*, the reductions observed were less than 4 log reduction (the pass criterion for the standard) at all concentrations tested. The log reduction at 80 % was 3.95. Therefore, it failed the test and did not possess sufficient fungicidal activity against this microorganism.	[redacted]; 2006
	70 % IPA Wipe	Yeast: *Candida albicans*	The EN 13624 (surface and instrument disinfection in the medical area) standard	For *C. albicans* a reduction greater than 4 log reduction (the	[redacted]; 2016c

	Solutions		protocol was followed. Phase 2, Step 1 test. Contact time: 1 minute Test temperature: 20ºC Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations: 0.1 %, 50 % and 100 %.	pass criterion for the standard) was observed with both the 50 % and 100 % concentrations.	
	Sample A TX1130 wipes (IPA 70%)	Bacteria: *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* Yeast: *Candida albicans*	The EN 16615 standard protocol was followed. Phase 2, Step 2 test. Interfering substance: 0.3g/l bovine albumin (clean) Contact time: 5 minutes Temperature: 20°C	Against all bacteria species tested a ≥5.0 log reduction was observed together with ≤50 cfu in test fields 2 to 4, meeting the pass criterion of the standard. Against *C. albicans* a reduction of ≥4 was observed together with ≤50 cfu in test fields 2 to 4, meeting the pass criterion of the standard.	[redacted]; 2015a
	Sample C CTB 40 wipes (IPA 70%)	Bacteria: *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* Yeast: *Candida albicans*	The EN 16615 standard protocol was followed. Phase 2, Step 2 test. Interfering substance: 0.3g/l bovine albumin (clean) Contact time: 5 minutes Temperature: 20°C	Against all bacteria species tested a ≥5.0 log reduction was observed together with ≤50 cfu in test fields 2 to 4, meeting the pass criterion of the standard. Against *C. albicans* a reduction of ≥4 was observed together with ≤50 cfu in test fields 2 to 4, meeting the pass criterion of the standard.	[redacted]; 2015b
	Contec 70% IPA ProSat Sterile Polynit Heatseal IPA	Bacteria: *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae*	The EN 16615 standard protocol was followed. Phase 2, Step 2 test.	Against all bacteria species tested a ≥5.0 log reduction was observed together with ≤50 cfu in test fields 2 to 4, meeting the	[redacted]; 2016d

	70% PSWE0001	Yeast: *Candida albicans*	Interfering substance: 3.0g/l bovine albumin (dirty) Contact time: 1 minute (bacteria), 3 minutes (yeast) Temperature: 20°C	pass criterion of the standard. Against *C. albicans* a reduction of ≥4 was observed together with ≤50 cfu in test fields 2 to 4, meeting the pass criterion of the standard.	
	Contec Prosat Sterile Cell/Poly nonwoven 70/30 IPA PSC 2001	Bacteria: *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* Yeast: *Candida albicans*	The EN 16615 standard protocol was followed. Phase 2, Step 2 test. Concentrations tested: 100%, 0.1%. Interfering substance: 3.0g/l bovine albumin (dirty) Contact time: 1 minute (bacteria), 3 minutes (yeast) Temperature: 20°C	The log reduction was sufficient against *S. aureus* and *E. hirae*. However, the test failed against bacteria based on *S. aureus* result, where a less than 5 log reduction was observed. Against *C. albicans* a reduction of ≥4 was observed together with ≤50 cfu in test fields 2 to 4, meeting the pass criterion of the standard.	[redacted]; 2016e
	Contec Meltblown Polypropylene 70/30 IPA PS-850	Bacteria: *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* Yeast: *Candida albicans*	The EN 16615 standard protocol was followed. Phase 2, Step 2 test. Concentrations tested: 100%, 0.1%. Interfering substance: 3.0g/l bovine albumin (dirty) Contact time: 1 minute (bacteria), 3 minutes (yeast) Temperature: 20°C	The log reduction was sufficient against *S. aureus* and *E. hirae*. However, the test failed against bacteria based on *S. aureus* result, where a less than 5 log reduction was observed. Against *C. albicans* a reduction of ≥4 was observed together with ≤50 cfu in test fields 2 to 4, meeting the pass criterion of the standard.	[redacted]; 2016f
	70% IPA Wipes Solution	Yeast: *Candida albicans*	The EN 13967 standard protocol was followed. Phase 2, Step 2 test. Interfering substance: 0.3g/l bovine albumin	Against *C. albicans* a reduction of ≥3 was observed, meeting the pass criterion of the standard.	[redacted]; 2016g

			(clean) Contact time: 1 minute Temperature: 20°C		
	Alcohol Spray (FH55)	Yeast: *Candida albicans*	The EN 13967 standard protocol was followed. Phase 2, Step 2 test. Contact time: 15 minutes. Test temperature: 10ºC Interfering substance: 0.3 % Bovine Serum Albumin (BSA) to represent dirty conditions and 0.03 % Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations: 10 %, 50 % and 100 %.	Against *C. albicans* a reduction of ≥3 was observed both the 50 % and 100 % concentrations in dirty and clean conditions, meeting the pass criterion of the standard.	[redacted]; 2017b
	Contec Sterile 70% IPA	Bacteria: *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* Yeast: *Candida albicans* Fungi: *Aspergillus niger*	The EN 13967 standard protocol was followed. Phase 2, Step 2 test. Interfering substance: 0.3g/l bovine albumin (BSA) to represent clean conditions. Contact time: 1 and 5 minutes to for bacteria; 3 and 15 minutes for fungi and yeast. Temperature: 20ºC Concentration: Ready to use (RTU).	Against all bacteria species tested a >4 log reduction was observed after both 1 and 5 minutes, meeting the pass criterion of the standard. Against *C. albicans* and *A. niger* a reduction of >3 was observed after both 3 and 15 minutes, meeting the pass criterion of the standard.	[redacted]; 2014a
	Contec IPA (extract from wipe)	Bacteria: *Pseudomonas aeruginosa* *Staphylococcus aureus* *Enterococcus hirae* Yeast:	The EN 13967 standard protocol was followed. Phase 2, Step 2 test. Interfering substance: 0.3g/l bovine albumin (BSA) to represent clean conditions.	Against all bacteria species tested a >4 log reduction was observed after both 1 and 5 minutes, meeting the pass criterion of the standard.	[redacted]; 2014b

		Candida albicans Fungi: *Aspergillus niger*	Contact time: 1 and 5 minutes to for bacteria; 3 and 15 minutes for fungi and yeast. Temperature: 20ºC Concentration: Ready to use (RTU).	Against *C. albicans* and *A. niger* a reduction of >3 was observed after both 3 and 15 minutes, meeting the pass criterion of the standard.	
	70% IPA Wipe Solutions	Yeast: *Candida albicans*	The EN 14562 (instrument disinfection in the medical area) standard protocol was followed. Phase 2, Step 2 test. Contact time: 1 minute Test temperature: 20ºC Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations: 0.1 %, 50 % and 100 %.	For *C. albicans* a reduction greater than 4 log reduction (the pass criterion for the standard) was observed with both the 50 % and 100 % concentrations.	[redacted]; 2016h
	70% IPA Wipes	Viruses: *Adenovirus* 5 (ATCC VR-5/HeLa cells) *Murine norovirus* (s99/RAW 264.7 cells)	The EN 14476 (use in human medicine) standard protocol was followed. Phase 2, Step 1 test. Contact time: 1 minute Test temperature: 20ºC Interfering substance: 0.3 g/l Bovine Serum Albumin (BSA) to represent clean conditions. Concentrations: 5.0 %, 50 % and 80 %.	For *Murine norovirus*, the test product passed the test at 80 %, indicating that it possesses virucidal activity against this virus. For *Adenovirus*, the test product failed the test at 80 %, indicating that it does not possess sufficient virucidal activity against this virus.	[redacted]; 2016

After the efficacy working group additional studies were provided to address issues raised. These are summarised [redacted].

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and field of use envisaged	**Test substance**	**Test organism(s)**	**Test method/ Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Spray Product for use against bacteria and yeast.	Contec Sterile IPA. (Spray product)	*C. albicans*	Laboratory Surface test – EN13697 Temperature: 18 – 25 °C Interfering substances: 0.3 g/L BSA (Clean conditions) Concentration tested: Ready to use product. Contact times: 1, 3 and 5 mins	The pass criteria for the test against yeast is ≥ 3 log reduction. The product demonstrated the following log reductions. 1 min: >4.85 3 mins: >4.90 5 mins: >4.49 The results therefore meet the pass criteria and support contact times of 1, 3 and 5 minutes against yeast. The controls were sufficient to validate the test.	TRA-2018-326-02_1 (to replace [redacted], 2014b and [redacted] 2016g)
Wipe product for use against bacteria and yeast	Wipe solution on the standard wipe material (55% pulp, 45% PET Tork Premium Spezial Tucher)	*P. aeruginosa* *S. aureus* *E. hirae* *C. albicans*	Laboratory Surface test (with mechanical action) – EN16615. Temperature: 20 °C Interfering substances: 0.3 g/L BSA (Clean conditions) Contact times: 1 min and 3 mins (yeast only)	The pass criteria for the test is ≥ 5 log reduction against bacteria and ≥ 4 log reduction against yeast. The product demonstrated the following log reductions. 1 min: *P. aeruginosa* – 5 *S. aureus* – 5 *E. hirae* – >5 *C. albicans* – 4	J000973-1

				3 mins: *C. albicans* – 4 The results therefore meet the pass criteria and support contact times of 1 minute against bacteria yeast, as well as 3 minutes against yeast. The controls were sufficient to validate the test.	
	Prosat MBPP PS850 (100% polypropylene wipe)	*P. aeruginosa* *S. aureus* *E. hirae* *C. albicans*	Laboratory Surface test (with mechanical action) – EN16615. Temperature: 18-25 °C Interfering substances: 0.3 g/L BSA (Clean conditions) Contact times: 1 min for bacteria and 3 mins for yeast.	The pass criteria for the test is ≥ 5 log reduction against bacteria and ≥ 4 log reduction against yeast. The product demonstrated the following log reductions. 1 min: *P. aeruginosa* – 5.09 *S. aureus* – >5.32 *E. hirae* – >5.03 3 mins: *C. albicans* – >4.06 The results therefore meet the pass criteria and support contact times of 1 minute against bacteria yeast, as well as 3 minutes against yeast. The controls were sufficient to validate the test.	TRA-2018-332-01 (To replace [redacted] 2016d)

	Prosat Sigma PSC-20001 (55% cellulose/45% polyester wipe)	*P. aeruginosa* *S. aureus* *E. hirae* *C. albicans*	Laboratory Surface test (with mechanical action) – EN16615. Temperature: 18-25 °C Interfering substances: 0.3 g/L BSA (Clean conditions) Contact times: 1 min for bacteria and 3 mins for yeast.	The pass criteria for the test is ≥ 5 log reduction against bacteria and ≥ 4 log reduction against yeast. The product demonstrated the following log reductions. 1 min: *P. aeruginosa* – 5.09 *S. aureus* – >5.32 *E. hirae* – >5.03 3 mins: *C. albicans* – >4.06 The results therefore meet the pass criteria and support contact times of 1 minute against bacteria yeast, as well as 3 minutes against yeast. The controls were sufficient to validate the test.	TRA-2018-333-02 (to replace [redacted] 2016a and 2016)
	Prosat Polynit Heatseal PSWE0001 (100 % knitted polyester)	*P. aeruginosa* *S. aureus* *E. hirae* *C. albicans*	Laboratory Surface test (with mechanical action) – EN16615. Temperature: 18-25 °C Interfering substances: 0.3 g/L BSA (Clean conditions) Contact times: 1 min for bacteria and 3 mins for yeast.	The pass criteria for the test is ≥ 5 log reduction against bacteria and ≥ 4 log reduction against yeast. The product demonstrated the following log reductions. 1 min: *P. aeruginosa* – 5.09 *S. aureus* – >5.32 *E. hirae* – >5.03 3 mins:	TRA-2018-334-02 (to replace [redacted] 2016 b and f)

				C. albicans – >4.06 The results therefore meet the pass criteria and support contact times of 1 minute against bacteria yeast, as well as 3 minutes against yeast. The controls were sufficient to validate the test.	

Conclusion on the efficacy of the product

The Pal IPA Product Family claims the following:

- 'Medipal alcohol disinfectant wipes are proven to kill most microorganisms such as bacteria, fungi, yeasts and viruses.'
- Specifically claimed are:
  - TB, HIV, Hepatitis, SARS, MRSA, E. coli, Pseudomonas, VRE, Aspergillus and Candida.
  - EN 1276, EN 13697, EN 13727, EN 13624, EN 14476, EN 1650, EN 14561 and EN 14563.
- A 1 minute contact time is claimed for the following:

  Bactericidal (EN 1276, EN 13697, EN 13727, EN 14561, EN 16615)
- A 3 minute contact time is claimed for the following:

  yeasticidal (EN 1650, EN 13624 and EN 16615).
- 'For disinfecting hard surfaces of non-invasive medical devices and equipment within healthcare environments.'
- 'Intended to hygienically clean and disinfect hard surfaces in professional environments.'

The products of the family are proposed for use on hard surfaces in professional environments, including on non-invasive medical devices and equipment within healthcare environments. The products are formulated as ready to use wipes.

All of the products tested in the studies contain the same formulation and all of the products in the family contain the same formulation. Therefore, the products tested in the studies are acceptable in support of Pal IPA Product Family.

Efficacy against bacteria

For claims of bactericidal activity from disinfection in the food and feed area, it is a requirement to test the products in accordance with EN 1276 (phase 2, step 1) and EN 13697 (phase 2, step 2). For wipe products, testing with mechanical action according EN 16615 (phase 2, step 2), is typically required.

For bactericidal claims of instrument disinfection in the medical area, tests according to EN 13727 (phase 2, step 1) and EN 14561 (phase 2, step 2) are typically required. For bactericidal claims of surface disinfection in the medical area, tests following EN 13727 (phase 2, step 1) are required along with a test to EN 13697 (phase 2, step 2) for no mechanical action and a test to EN 16615 (phase 2, step 2) for mechanical action.

Against bacteria the product family has passed EN 1276 ([redacted]; 2014a) under dirty conditions at a one minute contact time against the standard test organisms for use as a general disinfectant. In this test the liquid extracted from a wipe product was used. The product family also passed EN 1276 ([redacted]; 2017a) when tested at a cold temperature (10°C) with a contact time of 1 minute in dirty conditions.

Efficacy has also been demonstrated in four separate tests following the EN 13697 standard. Two of these tests used dirty conditions and the standard test organisms; one of which used a 30 second contact time ([redacted]; 2013a) and the other 1 minute ([redacted]; 2016). The other two tests ([redacted]; 2014a & 2014b) used clean

conditions and a 1 minute contact time against the standard test organisms. One of these studies tested a cold temperature (4°C). The log reduction required to pass these tests was achieved in all cases.

The EN 1276 studies together with the EN 13697 studies sufficiently demonstrate that the product family is acceptable for use as a general surface disinfectant against bacteria in a general use area.

For use in the medical area studies according to EN 13727 and EN 14561 were submitted. Specifically for the wipe product numerous studies conducted to EN 16615 were submitted.

The study conducted to EN 13727 ([redacted]; 2014b) demonstrates that the product family is significantly efficacious against the standard test bacteria when applied for one minute in dirty conditions.

The two studies conducted to EN 14561 both used a 30 second contact time and dirty conditions; but they differ in the bacteria used. [redacted]; 2013b included the standard test organisms for surface disinfection claims in the medical area whereas [redacted]; 2013c tested against methicillin resistant *S. aureus* and vancomycin resistant *E. faecium*. Both tests conducted according to EN 14561 demonstrate acceptable efficacy against the respective test organisms included.

Two separate studies were conducted according to the EN 16615 standard and demonstrated acceptable efficacy of the wipe products against *S. aureus* (the only tested organism) using clean conditions and a 1 minute contact time ([redacted]; 2016a & 2016b). The five remaining EN 16615 studies all tested the efficacy of wipe products against *P. aeruginosa*, *S. aureus* and *E. hirae*. Of these five studies, two failed to demonstrate acceptable efficacy against *S. aureus* according to the standard under dirty conditions with a contact time of 1 minute ([redacted]; 2016e & 2016f). The other three studies all support the product family against bacteria according to EN 16615. Two of these studies used a 5 minute contact time and clean conditions ([redacted]; 2015a & 2015b) and 1 test ([redacted]; 2016d) passed the requirements of EN 16615 under dirty conditions with a 1 minute contact time.

When all 7 studies according to EN 16615 are considered as a complete package, two out of the three tests using dirty conditions fail to demonstrate acceptable efficacy. The UK CA therefore does not consider it appropriate to authorise the product family for use in areas of heavy soiling. Two of EN 16615 tests using clean conditions passed according to the standard; however both used a 5 minute contact time which is considered unrealistic for a wipe product. The test conducted according to EN 16615 using a one minute contact time and dirty conditions is considered as the main source of evidence that the wipe product is efficacious when used with mechanical action in the medical area.

Overall, for use with mechanical action according to EN 16615, efficacy against bacteria has been sufficiently demonstrated in clean conditions with a contact time of 1 minute. This use is considered to be supported in both general use areas and in medical areas, including instrument disinfection. The UK CA considers that in areas of heavy soiling, the surface should be cleaned (until it is visibly clean) prior to disinfection. This could be achieved for example by using 1 wipe to clean the surface/equipment and another to disinfect it.

Efficacy against mycobacteria

At present there are no standard tests to demonstrate mycobactericidal activity in the food and feed area specified in the guidance. However, given the similarity of the conditions, the UK CA considers that the tests specified for PT 2 can also be used for PT 4. For claims of mycobactericidal activity instrument disinfection in the medical area EN 14348 (phase 2, step 1) and EN 14563 (phase 2, step 2) are typically required. For surface disinfection with or without mechanical action, EN 14348 is typically required.

A test according to EN 14348 ([redacted]; 2014) which uses a 1 minute contact time under dirty conditions was submitted. Both *M. avium* and *M. terrae* show reductions that meet the test validation requirement.

A test according to EN 14563 ([redacted]; 2017) which uses a 1 minute contact time under clean conditions was submitted. Both *M. avium* and *M. terrae* show reductions that meet the test validation requirement.

Overall, the UK CA considers that efficacy (with and without mechanical action) against mycobacteria has been sufficiently demonstrated in clean conditions with a contact time of 1 minute. This use is considered to be supported in both general use areas and in medical areas, including instrument disinfection.

Efficacy against fungi/yeasts

For claims of fungicidal/yeasticidal activity for disinfectants in the food and feed area, it is typically a requirement to test the products in accordance with EN 1650 (phase 2, step 1) and EN 13697 (phase 2, step 2) when mechanical action is not required. To assess mechanical action, a test to EN 16615 (phase 2, step 2) should normally be conducted. However, as no mechanical action test is available for fungi, testing can be done with liquid extracted from the wipes in an EN 13697 test.

For claims of fungicidal/yeasticidal activity for an instrument disinfectant in the medical area, it is typically a requirement to test the products in accordance with EN 13624 (phase 2, step 1) and EN 14562 (phase 2, step 2) when mechanical action is not required.

For claims of fungicidal/yeasticidal activity for a surface disinfectant in the medical area, it is typically a requirement to test the products in accordance with EN 13624 (phase 2, step 1), along with the same phase 2, step 2 testing required for the food and feed area.

In the first EN 1650 study ([redacted]; 2014c), the product family demonstrated sufficient efficacy against *C. albicans* according to the pass criterion, with a contact time of 1 minute in dirty conditions. However, the product family did not demonstrate sufficient efficacy against *A. niger* to meet the pass criterion of the standard.

In the second EN 1650 test ([redacted]; 2017c) only *C. albicans* was tested. The product family demonstrated sufficient efficacy according to the pass criterion, with a contact time of 15 minutes in dirty conditions and at a cold temperature (10°C).

[redacted]; 2016c investigated the yeasticidal activity of the product family in the medical area, according to EN 13624. Clean conditions were tested. This test demonstrated the efficacy of the product family against *C. albicans* according to the pass

criterion for the relevant standard protocol. The contact time used in the tests was 1 minute.

[redacted]; 2006 investigated the yeasticidal and fungicidal activity of the product family in the medical area, according to EN 13624. Clean conditions were tested. The product familydemonstrated sufficient efficacy against *C. albicans* according to the pass criterion, with a contact time of 1 minute. However, the product family did not demonstrate sufficient efficacy against *A. niger* to meet the pass criterion of the standard.

In one EN 13697 study ([redacted]; 2016g), the product family demonstrated sufficient efficacy against *C. albicans* according to the pass criterion, with a contact time of 1 minute in clean conditions.

In a second EN 13697 study ([redacted]; 2017b), the product family demonstrated sufficient efficacy against *C. albicans* according to the pass criterion, with a contact time of 15 minutes in clean conditions and at a cold temperature (10°C).

In the two other EN 13697 studies ([redacted]; 2014a & 2014b), the product family demonstrated sufficient efficacy against both *C. albicans* and *A. niger* according to the pass criterion, with a contact time of 3 minutes in clean conditions.

[redacted]; 2016 investigated the yeasticidal activity of the product family in the medical area, according to EN 14562. Clean conditions were tested. This test demonstrated the efficacy of the product family against *C. albicans* according to the pass criterion for the relevant standard protocol. The contact time used in the tests was 1 minute.

The yeasticidal activity of the product damily was investigated in five studies conducted according to EN 16615 ([redacted]; 2015a, 2015b, 2016d, 2016e & 2016f). Dirty conditions were used in 2 of the tests and clean conditions were used in the other three tests. In all of the studies, the product family demonstrated sufficient efficacy against *C. albicans* according to the pass criterion, with a contact time of 3 to 5 minutes (3 minutes in dirty conditions was sufficient).

Overall, the UK CA considers that efficacy (with and without mechanical action) against yeast have been sufficiently demonstrated in clean conditions with contact time of 1 minute.

The use against yeast is supported in general use areas and in medical areas, including instrument disinfection. The use against fungi is supported in general use areas and on surfaces in the medical area; however, it is not supported for instrument disinfection, as efficacy against fungi has not been demonstrated in EN 13624 and EN 14562.

During the initial evaluation, the UK CA had concerns that a 3 minute contact time might not be appropriate for a wipe product.

The UK CA initiated an e-consultation with other MS on 4th January 2018 in order to discuss what contact times might be appropriate for wipe disinfectant products. Although there was no clear conclusion drawn in this e-consultation, it did appear that MS generally considered that contact times longer than 1 minute might be acceptable, provided a reasoned case is provided to justify why the times are appropriate for the formulation and use instructions.

The UK CA made the applicant aware that their claims against fungi are not considered to be supported and asked for them to provide a reasoned case to justify how a contact time of 3 minutes is appropriate for a wipe product. The applicant did not submit a reasoned case and chose to withdraw support for fungicidal claims. Therefore, the UK CA concludes that fungi claims are not currently supported.

If the applicant wishes to make fungicidal claims in the future, this may be possible if an acceptable reasoned case is provided to justify this use.

Efficacy against viruses

For claims of virucidal activity from a surface or instrument disinfectant in the medical area, it is typically a requirement to demonstrate ≥ 4.0 log reduction of *Poliovirus*, *Adenovirus* and *Murine norovirus* in accordance with EN 14476 (phase 2, step 1). Or for a claim of limited spectrum virucidal activity, only *Adenovirus* and *Murine norovirus* need to be tested.

In support of the efficacy against viruses one EN 14476 study ([redacted]; 2016) was submitted. The viruses tested in this study were *Adenovirus* and *Murine norovirus*. The contact time used in the test was 1 minute and clean conditions were tested. According to the results of this study, the 70 % v/v propan-2-ol wipes possessed sufficient virucidal activity against *Murine norovirus*. However, the product family did not possess sufficient virucidal activity against *Adenovirus* and failed the test for that virus.

Only efficacy against *Murine norovirus* has been demonstrated according to the pass criterion for the relevant standard protocol. Therefore, the UK considers that virucidal efficacy has not sufficiently been demonstrated in order to support a claim.

Decision

The UK CA concludes that the submitted data are sufficient to support all of the products in the Pal IPA Product Family.

All areas of use claimed for the product family are supported by the data provided with the exception of fungicidal activity with instrument disinfection.

Sufficient data were provided to demonstrate that the products are efficacious against bacteria and mycobacteria in clean conditions with a contact time of 1 minute and yeast in clean conditions with a contact time of 3 minutes, and fungi in clean conditions with a contact time of 3 minutes. However, no reasoned case was provided as to the appropriateness of a 3 minute contact time for wipe products, therefore use against fungi is not currently supported. Efficacy against viruses is not supported.

The UK CA considers that in accordance with the TNsG, specific organisms should not be claimed if they imply a false impression of superiority of the products. Therefore, the claims against MRSA, VRE, *E. coli*, *Pseudomonas*, *Aspergillus* and *Candida* are not acceptable. The claims against the viruses HIV, Hepatitis and SARS are also not supported. However, the UK CA considers that the claim against TB is supported as bactericidal and mycobactericidal efficacy has been sufficiently demonstrated in the recommended EN standards.

The UK CA considers that it is the applicant's responsibility to ensure any claims made do not fall within the remit of other legislation such as that relating to medicines or

medical devices. The applicant should, where necessary, clarify claims with the appropriate medical regulatory authorities, (in the UK, the Medicines and Healthcare products Regulatory Agency (MHRA)). If any medicinal claims are to be made, then the applicant must apply for and comply with any necessary authorisation under the relevant medical legislation. The applicant has stated to the UK CA that the claims related to this application do not fall within the remit of the medicines legislation.

Efficacy data was provided that show the product remained efficacious against bacteria at 10°C, 1 minute contact time in an EN 1276 test and at 4°C, 1 minute contact time in an EN 13697 test. This demonstrates efficacy at colder temperatures and we therefore consider use at 10°C to 20°C as acceptable against bacteria.

New data submitted after the efficacy working group

After the efficacy working group, additional studies were provided to address the issues raised. These are summarised in the table above and are discussed below.

According to the conclusions of the Efficacy Working Group, December 2018, the open points related to two key issues:

A. The efficacy of the spray product against yeast was proven only for the longer contact time of 15 minutes but not for the shorter contact times requested by the applicant of 1 – 3 minutes.

B. Due to issues with the old EN 16615 studies, the efficacy of the wipe products was not demonstrated against bacteria and yeast. The standard wipe (from EN16615) or the exact wipes used for the product should be tested.

Five new studies were provided to address these issues.

A. A new phase 2 step 2 study (TRA-2018-326-02_1) using the spray product against *C. albicans* was provided. This was conducted according to EN 13697. This new study demonstrates a sufficient reduction against yeast after contact times of 1, 3 and 5 minutes. The UK CA therefore considers that, alongside the existing acceptable 2,1 tests, sufficient evidence has now been provided to address this issue and the spray product can be authorised against yeast with a minimum contact time of 1 minute.

B. A new EN16615 study (J000973-1) has been provided using the standard wipe - 55% pulp, 45% PET Tork Premium Spezial Tucher. This study demonstrated sufficient log reductions against *P. aeruginosa, S. aureus* and *E. hirae* with a contact time of 1 minute and against *C. albicans* with a contact time of 3 minutes. These data, therefore, support the efficacy of the wipe products against bacteria and yeasts with contact times of 1 and 3 minutes respectively.

   Additionally, as this wipe is the standard wipe described in EN 16615 as the appropriate carrier to test where various different types of wipe may be used with the same product formulation, the UK CA considers that this study can also be used in support of the other wipe products as well. This seemed to be the view shared by the efficacy working group. We note that the applicant also provided a justification document to explain why they consider some types of wipe to be worst case. However, as the standard wipe has now been successfully tested, this justification may no longer be necessary.

In addition to this, the applicant has also provided new studies using other wipe materials to support the use of the product on other types of wipe. The studies TRA-2018-332-02, TRA-2018-333-02 and TRA-2018-334-02 tested 100% polypropylene wipes, 55% cellulose/45% polyester wipes, and 100 % knitted polyester respectively. In all of these studies the data demonstrate reductions sufficient to pass the test against bacteria with a 1 minute contact time and against yeast with a 3 minute contact time. Therefore, these data further support the efficacy of the wipe products against bacteria and yeasts with contact times of 1 and 3 minutes respectively.

Consequently, the UK CA considers that the new data provided addresses the concerns raised at the efficacy working group and supports the authorisation of all of the wipe products.

2.2.4.6 Occurrence of resistance and resistance management

The applicant has provided the following statement in relation to the occurrence of resistance and resistance management:

'The Active Substance Doc IIA indicates the following:
Due to the unspecific mode of action of alcohols, i.e., denaturation and coagulation of proteins, cell lysis and disruption of the cellular metabolism, resistance against alcohols is not expected. In none of the presented data resistance has been reported. Also, according to [redacted] *(2004) no acquired resistance to alcohols has been reported.* [redacted] *(1999) present an extensive overview over intrinsic and acquired resistance of antiseptics and disinfectants, but they did not find any evidence for acquired resistance of Propan-2-ol for bacteria, fungi or viruses.*

Management

According to the Assessment Report of the active substance, Propan-2-ol, no known resistance has been reported against the target species.'

[UK CA note: this refers to the Doc IIA submitted by ASD Consortium in support of the alternative source of propan-2-ol]

The UK CA accepts that there is no significant risk of the development of resistance for this active substance and products, however, if the applicant becomes aware of any reports of resistance to the active substance propan-2-ol and/or the product these should be reported to appropriate bodies (such as the efficacy working group and/or concerned member states) so that it can be determined if further action is required.

2.2.4.7 Known limitations

Surfaces or instruments should be visibly clean prior to using the products to disinfect them. For areas of heavy soiling, this could possibly be achieved by using one wipe to clean the surface prior to using another wipe to disinfect it.

2.2.4.8 Evaluation of the label claims

The UK CA considers that the following requested label claims are supported:

- 'Medipal alcohol disinfectant wipes are proven to kill microorganisms such as bacteria and yeasts.'
- 'EN 1276', 'EN 13697', 'EN 13727', 'EN 13624 (yeast only)', 'EN 14476', 'EN 1650 (yeast only)', 'EN 14561' and 'EN 14563'
- 'TB' *[bacteria]*
- A 1 minute contact time is supported for the following:
  Bactericidal (EN 1276, EN 13697, EN 13727, EN 14561, EN 16615)
- A 3 minute contact time is supported for the following:
  for yeasticidal (EN 1650, EN 13624 and EN 16615).
- 'For killing bacteria, mycobacteria and yeasts on hard surfaces of non-invasive medical devices and equipment within healthcare environments.'
- 'Intended to hygienically clean and disinfect hard surfaces in professional environments.'

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

The products of the family are not intended for use with other products.

2.2.5 Risk assessment for human health

2.2.5.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Pal IPA Product Family is not classified for skin corrosion or irritation.
Justification for the value/conclusion	None of the components of the product family are classified for skin corrosion or irritation according to Regulation (EC) No 1272/2008. The product family does not therefore meet the criteria for classification for skin corrosion or irritation according to Regulation (EC) No 1272/2008.
Classification of the product family according to CLP	Pal IPA Product Family is not classified for skin corrosion or irritation.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Pal IPA Product Family is classified for eye irritation cat. 2 (H319).
Justification for the value/conclusion	Propan-2-ol is classified as an eye irritant (Cat. 2) and is present at a maximum of 70 % v/v (equivalent to 62.9% w/w) in the product family. No other components in the product family are classified as eye irritants. According to Regulation (EC) No 1272/2008, a mixture which contains a total of 10 % or more of a substance or substances classified in Category 2 for eye irritation shall be classified in Category 2 for eye irritation. Therefore, the product family meets the criteria to be classified for eye irritation category 2 (H319).
Classification of the product family according to CLP	Pal IPA Product Family is classified for eye irritation cat. 2 - H319: Causes serious eye irritation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Pal IPA Product Family is not classified for respiratory tract irritation.
Justification for the conclusion	None of the components of the product family are classified for respiratory tract irritation according to Regulation (EC) No 1272/2008. The product family does not therefore meet the criteria for classification for respiratory tract irritation according to Regulation (EC) No 1272/2008.
Classification of the product family according to CLP	Pal IPA Product Family is not classified for respiratory tract irritation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Pal IPA Product Family is not classified for skin sensitisation.
Justification for the value/conclusion	None of the components of the product family are classified for skin sensitisation according to Regulation (EC) No 1272/2008. The product family does not therefore meet the criteria for classification for skin sensitisation according to Regulation (EC) No 1272/2008.
Classification of the product family according to CLP	Pal IPA Product Family is not classified for skin sensitisation.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Pal IPA Product Family is not classified for respiratory sensitisation.
Justification for the value/conclusion	None of the components of the product family are classified for respiratory sensitisation according to Regulation (EC) No 1272/2008. The product family does not therefore meet the criteria for classification for respiratory sensitisation according to Regulation (EC) No 1272/2008.
Classification of the product family according to CLP	Pal IPA Product Family is not classified for respiratory sensitisation.

Acute toxicity

Acute toxicity by oral route

Conclusion used in the Risk Assessment – Acute oral toxicity	
Value/conclusion	Pal IPA Product Family is not classified for acute oral toxicity.
Justification for the value/conclusion	None of the components of the product family are classified for acute oral toxicity according to Regulation (EC) No 1272/2008. The product family does not therefore meet the criteria for classification for acute oral toxicity according to Regulation (EC) No 1272/2008.
Classification of the product family according to CLP	Pal IPA Product Family is not classified for acute oral toxicity.

Acute toxicity by inhalation

Conclusion used in the Risk Assessment – Acute inhalation toxicity	
Value/conclusion	Pal IPA Product Family is not classified for acute inhalation toxicity.
Justification for the value/conclusion	None of the components of the product family are classified for acute inhalation toxicity according to Regulation (EC) No 1272/2008. The product family does not therefore meet the criteria for classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Classification of the product family according to CLP	Pal IPA Product Family is not classified for acute inhalation toxicity.

Acute toxicity by dermal route

Conclusion used in the Risk Assessment – Acute dermal toxicity	
Value/conclusion	Pal IPA Product Family is not classified for acute dermal toxicity.
Justification for the value/conclusion	None of the components of the product family are classified for acute dermal toxicity according to Regulation (EC) No 1272/2008. The product family does not therefore meet the criteria for classification for acute dermal toxicity according to Regulation (EC) No 1272/2008.
Classification of the product family according to CLP	Pal IPA Product Family is not classified for acute dermal toxicity.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Propan-2-ol at 70 % (v/v) or 62.9% (w/w)
Value(s)	0.85 mg/cm^2/h (transdermal flux rate)
Justification for the selected value(s)	Dermal absorption is read-across to the value presented in the agreed List of End Points (LoEP) for propan-2-ol which is based on *in vivo* data for male and female rats. The tested formulation was a dummy product, a model formulation consisting of the active substance and water; this is sufficiently similar to the product family to enable read-across of these data.

Assessment of endocrine disruption (ED) properties of active substances and co-formulants in biocidal products

According to the CAR for propan-2-ol, there is no indication for endocrine disrupting properties of the active substance. Additionally, there is no indication for endocrine disrupting properties of the the co-formulants of the biocidal product.
In summary, there is no indication for endocrine disrupting properties of the biocidal product.

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

Pal IPA Product Family does not contain any substances of concern.

Available toxicological data relating to a mixture

None of the co-formulants of Pal IPA Product Family are mixtures.

2.2.5.2 Exposure assessment

The products of the Pal IPA Product Family are ready-to-use (RTU) disinfectant products: impregnated wet wipes, containing 70% v/v (equivalent to 62.9% w/w) propan-2-ol as the active substance.

The products are for use by professionals for hard surface and equipment disinfection in industrial/manufacturing settings under two product types:

PT 2 – Hard surfaces in professional/industrial/manufacturing environments; hard surfaces in cleanrooms of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities and critical life science applications, non-invasive medical devices and equipment within healthcare environments (e.g. hospitals).

PT 4 - Food contact surfaces within industrial and professional environments (e.g. in food, beverage and dairy industries and, kitchens and canteens).

An overview of the products in the family is provided below.

Intended uses of the product family			
SPC	**Product category**	**Use**	**Application rate**
Meta SPC 1	Ready-to-use impregnated disinfectant wipe	**PT4:** Professional hard surface disinfectant for use in industrial food preparation settings (e.g. food and beverage industries) and in professional food preparation setting (e.g. kitchen and canteens)	2.3 – 5.7 ml/wipe depending on specific product
		PT2: Professional hard surface disinfectant for use in industrial/manufacturing settings (e.g. cleanrooms for biotechnology and medical devices) or in institutional settings (e.g. healthcare environments such as hospitals).	1.7 – 7.5 ml/wipe depending on specific product

The RTU disinfectant wipes are supplied in a packet with varying numbers of wipes per pouch depending on the specific product. The in-use product density of 0.785 g/ml has been used in the exposure calculations.

The amount of product in one wipe is 1.7 – 7.5 ml. The applicant informs that one wipe can treat a surface of 1 – 1.5 m^2 and has provided a written statement of confirmation

that this is sufficient to meet the contact time required by efficacy. Therefore the worst-case application rate is assumed to be 7.5 ml product/m^2.

It is assumed that ready-to-use impregnated wipes are intended for use to disinfection small surfaces.

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**	**General public use**	**Industrial use**	**Professional use**	**Bystanders**	**Via food**
Inhalation	N/A	Yes	N/A	N/A	Yes	Yes	N/A
Dermal*	N/A	Yes	N/A	N/A	No	No	N/A
Oral	N/A	No	N/A	N/A	No	No	N/A

*According to cleanroom standards and protocols[2], cleanroom clothing must be worn to eliminate dispersion of contamination from skin and non-cleanroom clothing e.g. coveralls, gloves and face masks. Whilst cleanroom clothing covers any exposed skin and is worn over normal clothing, these may not protect workers from chemicals. Level of dermal exposure has been predicted but is recognised that the critical route of exposure is via inhalation given the high volatility of propan-2-ol.

List of scenarios for PT2

Critically for this risk assessment, the amount of product and frequency of use at any one time or during the day is undefined. Use instructions include '*As required and according to use instructions'*, '*On heavily soiled surfaces, more than one wipe may be required'* and '*typical use frequency is one application every 30minutes'*. Although small area use/routine disinfection of 0.5 m^2 within laboratory environments is defined in the Assessment Report, there is no precedent for use within hospitals/care-homes and the associated secondary exposures within these situations. Furthermore there is no consideration of cleanroom environments or professional cleanroom users. As a result the UK CA has drawn values and approaches from various guidance (e.g. HEEG opinions, HEAdHoc recommendations, RIVM report 320104003/2006 Cleaning Products Fact Sheet) to construct a representative risk assessment.

[2] Cleanrooms and associated controlled environments —BS EN ISO 14644-5

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Routine disinfection of small surfaces in industrial/manufacturing settings e.g. cleanroom environments	Primary exposure: a technician performs routine disinfection of small surfaces e.g. equipment and work stations as part of their working procedures in industrial/manufacturing setting e.g. cleanroom	Professionals
2.	Disinfection of small surfaces in private and public health areas e.g. hospital	Primary exposure: healthcare professional in hospital disinfects small surfaces	Professionals
3.	Inhalation of volatilised residues in industrial/manufacturing settings e.g. cleanroom environments	Secondary exposure: bystander inhalation of volatilised residues during disinfection in industrial/manufacturing setting e.g. cleanroom	Professional bystanders
4.	Inhalation of volatilised residues in private and public healthcare areas e.g. hospital	Secondary exposure: bystander inhalation of volatised residues during disinfection in healthcare environments e.g. hospital	General public bystanders

Industrial exposure

Products of the Pal IPA Product Family are intended for use by professional users only.

Professional exposure

Scenario 1: Primary exposure: a technician performs routine disinfection of small surfaces e.g. equipment and work stations as part of their working procedures in industrial/manufacturing setting e.g. cleanroom

According to cleanroom protocols, professional workers working in cleanrooms are expected to disinfect personal work surfaces and equipment before and/or at the end of each work shift as good practice[2]. Since disinfecting these surfaces is performed as part of their work day which is in addition to the performing assigned tasks in the cleanroom, disinfection will take place on a routine basis. In considering this pattern of use, the UK CA considers the scenario presented in the PT 2 Assessment Report for small surface disinfection is representative for this scenario. However as the scenario in the Assessment Report is based on disinfecting 0.5 m^2 per event (45 mins) and the minimum application rate for this product family is 1 m^2 per wipe at a typical use frequency of every 30 minutes', the following modified parameters have been used:

Work rate = Area to be disinfected per event (1 m^2 using 1 wipe)
Exposure duration = 30 mins per event
Application duration = 2 min per event
Frequency = 5 events per day (5 m^2 using 5 wipes)

Ventilation in cleanrooms varies based on cleanroom standards where lower ventilation rates are observed in higher classed cleanrooms with higher levels of particulates. A tier 1 worst-case assumption for ventilation rate of 8/h in line with the ventilation rate for a laboratory in the propan-2-ol PT2 Assessment Report has been used. It should be recognised that a ventilation rate of 8/h is highly conservative for cleanrooms; according to the guidelines produced by the FDA[3], minimum air exchange rate for IOS 8 cleanrooms is 20 per hour. The applicant has proposed a representative room volume of 55 m^3 for a cleanroom from direct correspondence with NL CA.

Description of Scenario 1		
A professional user disinfects surfaces using impregnated ready-to-use wet wipes in private and public health environments e.g. cleanroom. Based on a similar use pattern as that in the propan-2-ol PT 2 Assessment Report for small surface disinfection and considering the application rate of this product family, a modified scenario based on a professional worker using 1 wipe to disinfect a work bench of 1 m^2 every 30 minutes is considered. Due to the high vapour pressure of propan-2-ol, the evaporation and airborne phase of the active from the surface is the critical route of exposure. In accordance with ConsExpo cleaning factsheet, inhalation exposure has been calculated using ConsExpo Web exposure to vapour: evaporation model (increasing area) for cleaning with wet tissue (surrogate for wet wipes).		
	Parameters	**Value**
Tier 1	Adult body weight	60 kg
	Concentration of active in impregnated wet wipe	62.9% w/w
	Density of product	0.785 g/ml (applicant information)
	Inhalation rate	1.25 m^3/hr
	Molecular weight	60 g/mol
	Vapour pressure (EU-agreed value (LoEP January 2015))	5780 Pa at 25°C
	Exposure duration	30 mins (applicant information for the frequency of use)
	Amount of product used to treat 1 m^2	5.89 g
	Room volume	55 m^3 (applicant information)
	Ventilation rate	8/hr
	Release area	1 m^2
	Application duration	2 min
	Mass transfer rate	Thibodeaux model
	Molecular weight matrix[1]	18 g/mol

[3] Guidance for Industry: Sterile drug products produced by aseptic processing – Current Good Manufacturing Practice, 2004

[1]The molecular weight of the matrix is based on the formulation. Please see the confidential Annex Section 3.6.1 for details of the full formulation.

Calculations for scenario 1

Dermal exposure

ConsExpo Cleaning Product Factsheet[4] (p.64) estimates that during wiping with wet tissues, 1.4% of the total liquid of the wet tissue remains on the surface of the inner hand. The amount of product available for dermal exposure when wiping using one wet wipe is 0.082 g product (7.5 ml/wipe x 0.785 g/ml x 1.4%) or 52.75 mg propan-2-ol. Following the assumption in the propan-2-ol Assessment Report, one palm of hand (205 cm^2) is exposed during wiping; the time of evaporation is calculated according to TGD on risk assessment, App. I, App. If;

$T = mRTK/M\beta pA$

t = time [s]
m = mass of propan-2-ol on surface [mg] (52.75 mg)
R = gas constant [J K-1 mol-1] (8.314 J K^{-1} mol^{-1})
T = skin/surface temperature [K] (303.15 K)
K = conversion factor (36000)
M = molar mass [g mol-1] (60.1 g mol^{-1})
β = mass transfer coefficient [m h-1], for calculation see TGD (8.7 m h-1)
p = vapour pressure of the pure substance [Pa] (7600 Pa (30°C))
A = surface area [cm^2] (205 cm^2)

According to this equation the evaporation time is 5.9 seconds. Therefore for a worst case scenario it is assumed that the total amount evaporates at once after this time interval. The absorption/dermal flux rate for propan-2-ol in a 70% w/w aqueous dilution is 0.85 mg/cm^2/h (EU-agreed value (LoEP January 2015)). During the time interval of 5.9 seconds on the skin surface of palm of one hand 205 cm^2, this result in a total amount absorbed is 0.28 mg.

Therefore the total amount absorbed from the use of 5 wipes (5 m^2) is 1.42 mg (0.024 mg/kg bw/d) without PPE or 0.142 mg (0.0024 mg/kg bw/d) with PPE gloves.

Inhalation exposure

The estimated mean event concentration is 16.6 mg/m^3 calculated from ConsExpo Web. After 30 mins (one event), the residual air concentration has declined to 1.5 mg/m^3. Therefore the systemic inhalation exposure during an 8-hour working day is calculated as follows:

Systemic inhalation uptake (mg/kg bw/d) = ((mean event concentration + residual air concentration) x inhalation rate x total exposure duration)/body weight

Where:
Total air concentration calculated from ConsExpo Web = 18.1 mg/m^3

4 RIVM report 320104003/2006 Cleaning Products Fact Sheet

Inhalation rate = 1.25 m^3/h
Total exposure duration = 8 h
Body weight = 60 kg

Summary table: estimated exposure from professional uses			
Tier/PPE	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
1 (no PPE)	3.02	0.024	3.04
Please see Annex 3.2.1 for detailed calculations			

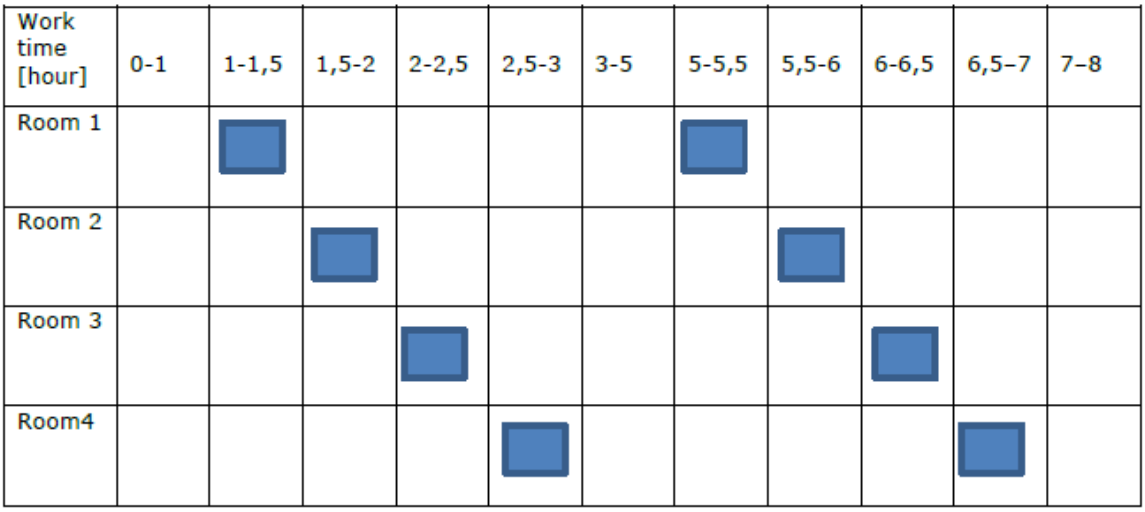
Scenario 2: Primary exposure: healthcare professional in hospital disinfects small surfaces

There is no guidance on how to assess primary exposure of professional users in institutional settings (e.g. healthcare environments such as hospitals and residential care homes) to volatile disinfectants. The work pattern of healthcare professionals i.e. nurses is described in HEADhoc Recommendation 9 (hand disinfection in hospitals) and is considered representative for this scenario.

Extract from HEADhoc Recommendation 9 – Hand disinfection in hospitals:

One nurse is responsible for 8 patients. This figure is in line with the research done for the HEAdhoc recommendation No. 1 among Europe. Two patients are in one patient room of 80 m3 size with a ventilation rate of 1.5 per hour. During her work in the patient room, 3 hand disinfections are performed. The nurse stays for 20 minutes in every room. After visiting of 4 patient rooms and 12 hand disinfections, she enters the first room again and performs again 3 hand disinfections in each room resulting in additional 12 hand rubs. One hand rub is performed e.g. at start of the shift in an 80 m^3 room and staying for 10 minutes. In summary, 25 applications per shift are performed.

Below is an illustration of the work pattern of a healthcare professional in a hospital:



Description of Scenario 2

In the absence of default/harmonised values for the surface area required for disinfection in healthcare environments, a first tier assessment assuming small surface disinfection i.e. 1m^2 is performed considering the work pattern of healthcare professionals described in HEADhoc Recommendation 9. Since there is no specific information regarding the scale of use for the product, an additional reverse reference scenario has been included to support the assumed small-scale use of impregnated wipes

A healthcare professional in a hospital disinfects surfaces in a patient room. During their working day (i.e. 8 hours), they stay for 20 minutes in every room to perform their work (e.g. disinfection of surfaces). After visiting 4 patient rooms, she enters the first room again, thus pays 2 visits per room in one working day.

Due to the high vapour pressure of propan-2-ol, the evaporation and airborne phase of the active from the surface is the critical route of exposure. In accordance with ConsExpo cleaning factsheet, inhalation exposure has been calculated using ConsExpo Web exposure to vapour: evaporation model (increasing area) for cleaning with wet tissue.

	Parameters	**Value**
Inhalation exposure	Adult body weight	60 kg
	Concentration of active in impregnated wet wipe	62.9% w/w
	Product density	0.785 g/ml (applicant information)
	Inhalation rate	1.25 m^3/hr
	Inhalation absorption	100%
	Molecular weight	60 g/mol
	Vapour pressure (EU-agreed value (LoEP January 2015))	5780 Pa at 25°C
	Exposure duration (HEAdhoc recommendation 9)	20 mins
	Room volume (HEAdhoc Recommendation 9)	80 m^3
	Ventilation rate (HEAdhoc Recommendation 9)	1.5/hr
	Molecular weight matrix[1]	18 g/mol
	Mass transfer rate	Thibodeaux method

[1]The molecular weight of the matrix is based on the formulation. Please see the confidential Annex Section 3.6.1 for details of the full formulation.

Inhalation exposure

Tier 1

As the product is a ready-to-use impregnated wipe, it is assumed that the intended use is for small surfaces i.e. 1 m^2 (dictated by the minimum application rate of the product). Considering the work pattern of healthcare professionals as described in HEADhoc Recommendation 9, the following parameters is used:

Area disinfected per room visit (1 wipe): 1 m^2 (8 m^2 per day = 8 wipes)

Amount of product used per room visit (1 wipe): 5.89 g (7.5 ml x 0.785 g/ml)
Application duration per room visit: 2 mins (extrapolation from the Assessment Report of 1 min per 0.5 m^2)

Mean event concentration (20 mins): 35 mg/m^3 calculated from ConsExpo Web.
Remaining air concentration after 240 mins: 0.12 mg/m^3 extrapolated from ConsExpo Web graph.

Systemic inhalation exposure = [(Mean event conc x 20 min x 4 rooms (1st visit) x 1.25 m^3/h) + ((mean event conc + remaining air conc) x 20 min x 4 rooms (2nd visit) x 1.25 m^3/h))]/60 kg

= 1.95 mg/kg bw/d

Reverse reference calculation

A reverse reference approach based on the above parameters has been used to estimate the amount of product used/area to be disinfected by a healthcare professional without exceeding the AEL (17.9 mg/kg bw/d).

The application duration has been estimated based on extrapolation from the Assessment Report of 1 min per 0.5 m^2.

Area disinfected per room visit (10 wipes): 10 m^2 (80 m^2 per day = 80 wipes/day)
Amount of product used per room visit (10 wipes): 58.9 g (7.5 ml x 10 wipes x 0.785 g/ml)
Application duration per room visit: 20 mins

Mean event concentration (20 mins): 200 mg/m^3 calculated from ConsExpo Web.
Remaining air concentration after 240 mins: 1.6 mg/m^3 extrapolated from ConsExpo Web graph.

Systemic inhalation exposure = [(Mean event conc x 20 min x 4 rooms (1st visit) x 1.25 m^3/h) + ((mean event conc + remaining air conc) x 20 min x 4 rooms (2nd visit) x 1.25 m^3/h))]/60 kg

= 11.16 mg/kg bw/d

Dermal exposure

ConsExpo Cleaning Product Factsheet[5] (p.64) estimated that during wiping with wet tissues, 1.4% of the total liquid of the wet tissue remains on the surface of the inner hand. The amount of product available for dermal exposure when wiping using one wet wipe is 0.082 g product (7.5 ml/wipe x 0.785 g/ml x 1.4%) or 52.75 mg propan-2-ol. Following the assumption in the propan-2-ol Assessment Report, one palm of hand (205 cm^2) is exposed during wiping; the time of evaporation is calculated according to TGD on risk assessment, App. I, App. If:

$T = mRTK/M\beta$pA

t = time [s]

[5] RIVM report 320104003/2006 Cleaning Products Fact Sheet

m = mass of propan-2-ol on surface [mg] (52.75 mg)
R = gas constant [J K-1 mol-1] (8.314 J K^{-1} mol^{-1})
T = skin/surface temperature [K] (303.15 K)
K = conversion factor (36000)
M = molar mass [g mol-1] (60.1 g mol^{-1})
β = mass transfer coefficient [m h-1], for calculation see TGD (8.7 m h-1)
p = vapour pressure of the pure substance [Pa] (7600 Pa (30°C))
A = surface area [cm^2] (205 cm^2)

According to this equation the evaporation time is 5.9 seconds. Therefore for a worst case scenario it is assumed that the total amount evaporates at once after this time interval. The absorption/dermal flux rate for propan-2-ol in a 70% w/w aqueous dilution is 0.85 mg/cm^2/h (EU-agreed value (LoEP January 2015)). During the time interval of 5.9 seconds on the skin surface of palm of one hand 205 cm^2, this result in a total amount absorbed is 0.28 mg.

Therefore the total amount absorbed from the use of 80 wipes/day (10 m^2) is 22.4 mg (0.37 mg/kg bw/d) without PPE.

Calculations for Scenario 2

Summary table: estimated exposure from professional uses			
Scenario/PPE	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Tier 1 (no PPE, area treated per day 8 m^2 i.e. 8 wipes per day)	1.95	0.00467	1.95
Reverse reference (no PPE, area treated per day 10 m^2 i.e. 80 wipes/day)	11.16	0.37	11.53
Please see Annex 3.2.1 for detailed calculations			

Further information and consideration on scenario 2

The reverse reference scenario performed illustrates that a healthcare professional using 10 wipes in one patient room every 4 hours during their working day (80 wipes/day) will be within acceptable limits. It should be noted that a healthcare professional is unlikely to disinfect >10 m^2 (application duration is 20 mins based on extrapolation from the Assessment Report of 1 min per 0.5 m^2) since the scenario assumes a healthcare professional stays for 20 mins per room visit. Healthcare professionals are likely to perform other tasks during their visit and therefore the above reverse scenario represents a worst-case.

Scenario 3: Secondary exposure: bystander inhalation of volatilised residues during disinfection in industrial/manufacturing setting e.g. cleanroom

Inhalation exposure may occur to re-entry by professional bystanders (e.g. cleanroom staff or manufacturing assistant) in manufacturing/industrial settings where surface disinfection is performed. The inhalation exposure will be in the same order of magnitude

as for the person who disinfected the surfaces. In a worst case scenario it is assumed that the bystander stays for 8 hours in the room where surface disinfection is performed. Therefore the level of inhalation exposure of a bystander is estimated to be equivalent or lower compared to the professional user applying/using the products.

Consequently the dermal exposure of bystanders follows the assumption that there is a very low probability for direct contact to freshly disinfected surfaces, and a very short duration of dermal exposure if casual contact happens. Furthermore due to the high vapour pressure of the active substance, dermal exposure by contact (hands) with treated surfaces is likely to be very low due to rapid evaporation. Therefore the dermal exposure is considered to be negligible.

Combined scenarios

No combined scenarios have been identified. It is not expected that a professional user would use the products in industrial/manufacturing setting (e.g. cleanroom) and institutional setting (e.g. hospital) in the same day.

General public user exposure

Products of the Pal IPA Product Family are intended for use by professional users only.

Exposure of bystanders

Scenario 4: Secondary exposure: bystander inhalation of volatised residues during disinfection in healthcare environments e.g. hospital

Although members of the public are excluded from controlled professional environments of manufacturing/industrial settings (e.g. cleanrooms), bystanders in healthcare environments (e.g. hospitals), where the products have been used to disinfect surfaces may be at risk of long-term exposure.

Based on the work pattern of healthcare professionals in hospitals (e.g. nurse) described in HEADhoc Recommendation 9 (hand disinfection in hospital), *two patients are in one patient room of 80 m^3 size with a ventilation rate of 1.5 per hour. During their work in the patient room (e.g. disinfection of surfaces) the nurse stays for 20 minutes in every room. After visiting of 4 patient rooms, she enters the first room again (after 240 mins).* As a worst-case it is assumed that the patient remains in the room for the whole duration of the day.

Work time [hour]	0-1	1-1,5	1,5-2	2-2,5	2,5-3	3-5	5-5,5	5,5-6	6-6,5	6,5–7	7–8
Room 1											
Room 2											
Room 3											
Room4											

In considering the working pattern of healthcare professionals, a secondary exposure scenario concerning a patient exposed to disinfectant products at 4 hours intervals over a 24-hour period (i.e. 6 disinfections per day per room) has been assessed. Inhalation exposure of volatilised residues has been predicted for bystanders staying in healthcare environments for ≤24 hours a day. Based on the ratio of inhalation rate and body weight, the worst-case bystander exposure group is represented by a toddler.

Description of Scenario 4		
A toddler exposure to volatilised residues of propan-2-ol in healthcare environment during and after disinfection. For the worst-case scenario, long-term exposure (≤24 hrs) has been calculated for a toddler (worst-case bystander). ConsExpo Web exposure to vapour: evaporation model has been used to predict inhalation exposure. In the absence of default/harmonised values for the surface area required for disinfection in healthcare environments, a reverse reference scenario has been conducted following the work pattern of healthcare professionals described in HEADhoc Recommendation 9. Due to the high vapour pressure of propan-2-ol, the evaporation and airborne phase of the active from the surface is the critical route of exposure. In accordance with ConsExpo cleaning factsheet, inhalation exposure has been calculated using ConsExpo Web exposure to vapour: evaporation model (increasing area) for cleaning with wet tissue.		
	Parameters	**Value**
Tier 1	Toddler body weight	10 kg
	Concentration of active in impregnated wet wipe	62.9% w/w
	Product density	0.785 g/ml (applicant information)
	Toddler inhalation rate[2]	8 m^3/day
	Inhalation absorption	100%
	Molecular weight	60 g/mol

	Vapour pressure (EU-agreed value (LoEP January 2015))	5780 Pa at 25°C
	Exposure duration (HEAdhoc Recommendation 9)	4 hours
	Room volume (HEAdhoc Recommendation 9)	80 m^3
	Ventilation rate (HEAdhoc Recommendation 9)	1.5/hr
	Molecular weight matrix[1]	18 g/mol
	Mass transfer rate	Thibodeaux method
[1]The molecular weight of the matrix is based on the formulation. Please see the confidential Annex Section 3.6.1 for details of the full formulation. [2] HEAdhoc Recommendation 14 – long-term exposure values for inhalation (toddler)		

Inhalation exposure

A tier 1 (toddler exposed during the disinfection of a small surface 1m^2)/reverse reference approach based on the above parameters has been used to estimate the amount of product/release area a toddler can be exposed to without exceeding the AEL (10.7 mg/kg bw/d).

The application duration has been estimated based on extrapolation from the Assessment Report of 1 min per 0.5 m^2.

- **Tier 1/Reverse reference calculation 1**

Area disinfected per room visit (1 wipe): 1 m^2 (6 m^2 per day)
Amount of product used per room visit (1 wipe): 5.89 g (7.5 ml)
Application duration per room visit: 2 mins

Mean event concentration (4 h): 7.7 mg/m^3 calculated from ConsExpo Web.
Remaining air concentration after 4 hours: 0.12 mg/m^3 extrapolated from ConsExpo Web graph.

Systemic inhalation exposure = [(Mean event concentration + remaining air concentration) x 8 m^3]/10 kg bw

= 6.3 mg/kg bw/d

- **Reverse reference calculation 2**

Area disinfected per room visit (2 wipes): 2 m^2 (12 m^2 per day)
Amount of product used per room visit (2 wipes): 11.78 g (15 ml)
Application duration per room visit: 4 mins

Mean event concentration (4 h): 15 mg/m^3 calculated from ConsExpo Web.
Remaining air concentration after 4 hours: 0.25 mg/m^3 extrapolated from ConsExpo Web graph.

Systemic inhalation exposure = [(Mean event concentration + remaining air concentration) x 8 m^3]/10 kg bw
= 12.2 mg/kg bw/d

Dermal exposure

Secondary dermal exposure to freshly treated surfaces is likely to be low due to the high vapour pressure of the active substance as a result of rapid evaporation and therefore can be considered negligible.

Calculations for Scenario 4

Summary table: systemic exposure from professional uses			
Exposure Scenario	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Reverse reference 1 (area treated 1 m^2 (1 wipe) at 4 hour intervals in a 24-hour period)	6.3	Negligible	6.3
Reverse reference 2 (area treated 2 m^2 (2 wipe) at 4 hour intervals in a 24-hour period)	12.2	Negligible	12.2
Please see Annex 3.2.1 for detailed calculations			

Further information and consideration for scenario 4

The tier 1 assessment and the reverse reference scenario performed above illustrates that a toddler (bystander) exposed to a disinfected area of 1 m^2 (1 wipe) at 4 hours intervals over a 24-hour period (i.e. a total treated area of 6 m^2 per day) is within acceptable levels of systemic exposure.

Disinfection wipes are intended for small scale/precision use for surfaces or equipment e.g. stethoscopes, scissors and drip stands[6,7,8,9] which requires routine disinfection at least once a day and after each use. It is therefore not envisaged that > 1m^2 would be disinfected. However where areas >1 m^2 is required for disinfection, and given the associated P-phrases triggered by the classification of the product family (P261 - Avoid breathing vapours and P271 - Use only outdoors or in a well ventilated area), users should consider appropriate risk mitigation measures for exposed bystanders; such as ensuring the room is well ventilated prior to entry.

List of scenarios for PT4

6 https://www.hse.ie/eng/about/who/healthwellbeing/infectcont/sth/gl/ipcc-guidelines-section-8.pdf

7http://www.westerntrust.hscni.net/pdf/Disinfection_and_Decontamination_Policy_(Patient_Care_Equipment)_(Dec15).pdf

8 http://www.newcastle-hospitals.org.uk/downloads/policies/Infection%20Control/CleaningDisinfectionProcedure201512.pdf

9 https://shsc.nhs.uk/wp-content/uploads/2014/05/DecontaminationAndDisinfectionPolicy.pdf

In the absence of specific guidance on surface disinfection in food preparation settings and product specific information regarding the scale of use/sizes of area being treated, the UK CA has followed the pattern of use outlined in the propan-2-ol PT 4 Assessment Report for surface disinfection in professional kitchen/canteen setting and in food processing setting.

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
5.	Disinfection of hard surfaces in professional food preparation settings e.g. canteen/kitchen	Primary exposure: professional user disinfecting surfaces in professional food preparation settings e.g. canteen/kitchen setting	Professionals
6.	Disinfection of hard surfaces in professional food preparation settings e.g. food processing setting	Primary exposure: professional user disinfecting surfaces in professional food preparation settings e.g. food processing setting	Professionals
7.	Inhalation of volatilised residues in industrial/manufacturing settings	Secondary exposure: professional bystander exposure to volatilised residues during disinfection in professional food preparation setting	Professional bystanders

Industrial exposure

Products of the Pal IPA Product Family are intended for use by professional users only.

Professional exposure

Scenario 5: Primary exposure: professional user disinfecting surfaces in professional food preparation settings e.g. canteen/kitchen setting

The scenario outlined in the PT 4 Assessment Report considers a professional user disinfecting surfaces in professional canteens or kitchens.

Work rate = Area to be disinfected per event (1 $m^{2)}$
Application duration = 2 mins per event
Exposure duration = 2 hours per event
Frequency = 4 events per day

Description of Scenario 5		
A professional user disinfects surfaces in professional food preparation setting e.g. canteens/kitchens. The disinfection scenario considered in the Assessment Report has been followed to estimate the exposure from the use of the product family. Due to the high vapour pressure of propan-2-ol, the evaporation and airborne phase of the active from the surface is the critical route of exposure. In accordance with ConsExpo cleaning factsheet, inhalation exposure has been calculated using ConsExpo Web exposure to vapour: evaporation model (increasing area) for cleaning with wet tissue.		
	Parameters	**Value**
Inhalation exposure	Adult body weight	60 kg
	Concentration of active in impregnated wet wipe	62.9% w/w
	Product density	0.785 g/ml (applicant information)
	Inhalation rate	1.25 m^3/hr
	Inhalation absorption	100%
	Molecular weight	60 g/mol
	Vapour pressure (EU-agreed value (LoEP January 2015))	5780 Pa at 25°C
	Mass transfer rate	Thibodeaux model
	Molecular weight matrix[1]	18 g/mol
	Exposure duration (AR)	2 hours
	Room volume (AR)	25 m^3
	Ventilation rate (AR)	15/hr
	Amount of product to treat 1 m^2 (1 wipe)	5.89 g (7.5 ml)
	Release area (AR)	1 m^2
	Application duration (AR)	2 min
[1]The molecular weight of the matrix is based on the formulation. Please see the confidential Annex Section 3.6.1 for details of the full formulation.		

Calculations for Scenario 5

Dermal exposure

ConsExpo Cleaning Product Factsheet[10] (p.64) estimated that during wiping with wet tissues, 1.4% of the total liquid of the wet tissue remains on the surface of the inner hand. The amount of product available for dermal exposure when wiping using one wet wipe is 0.082 g product (7.5 ml/wipe x 0.785 g/ml x 1.4%) or 52.75 mg propan-2-ol.

[10] RIVM report 320104003/2006 Cleaning Products Fact Sheet

Following the assumption in the propan-2-ol Assessment Report, one palm of hand (205 cm^2) is exposed during wiping; the time of evaporation is calculated according to TGD on risk assessment, App. I, App. If:

$T = mRTK/M\beta pA$

t = time [s]
m = mass of propan-2-ol on surface [mg] (52.75 mg)
R = gas constant [J K-1 mol-1] (8.314 J K^{-1} mol^{-1})
T = skin/surface temperature [K] (303.15 K)
K = conversion factor (36000)
M = molar mass [g mol-1] (60.1 g mol^{-1})
β = mass transfer coefficient [m h-1], for calculation see TGD (8.7 m h-1)
p = vapour pressure of the pure substance [Pa] (7600 Pa (30°C))
A = surface area [cm^2] (205 cm^2)

According to this equation the evaporation time is 5.9 seconds. Therefore for a worst case scenario it is assumed that the total amount evaporates at once after this time interval. The absorption/dermal flux rate for propan-2-ol in a 70% w/w aqueous dilution is 0.85 mg/cm^2/h (EU-agreed value (LoEP January 2015)). During the time interval of 5.9 seconds on the skin surface of palm of one hand 205 cm^2, this result in a total amount absorbed is 0.28 mg.

Therefore the total amount absorbed from the use of 4 wipes/day (1 m^2 x 4 events = 4 m^2) is 1.12 mg (0.0187 mg/kg bw/d) without PPE.

Inhalation exposure

The estimated mean event concentration is 5.0 mg/m^3 calculated from ConsExpo Web. After 2 hours, the residual air concentration is $1.2x10^{-5}$ mg/m^3. Therefore as the residual air concentration at the end of each event is essentially negligible (0.0002% of the mean air concentration), this has not been added to the mean event concentration to estimate worker inhalation exposure during a working day. Therefore the systemic inhalation exposure during an 8-hour working day is calculated as follows:

The systemic inhalation uptake (mg/kg bw/d) = (mean event concentration x inhalation rate x total exposure duration)/body weight

Where:
Event concentration calculated from ConsExpo Web = 5.0 mg/m^3
Inhalation rate = 1.25 m^3/h
Total exposure duration = 8 h
Body weight = 60 kg

Summary table: estimated exposure from professional uses			
Scenario/PPE	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
6 (no PPE)	0.83	0.0187	0.85
Please see Annex 3.2.1 for detailed calculations			

Scenario 6: Primary exposure: professional user disinfecting surfaces in professional food preparation settings e.g. food processing setting

The scenario outlined in the PT 4 Assessment Report considers a professional user disinfecting a cutting and packaging machine in a food processing setting.

Work rate = Area to be disinfected per event
(1 m^2 – cutting machine)
(3.6 m^2 – packaging machine)
Application Duration = 5 min per event
Exposure duration = 120 min per event
Frequency = 4 events per day

The UK CA notes that the Assessment Report mentions the temperature in the working hall [food processing setting] is regulated between 0–5°C and that the calculations were performed at 4°C. Given the high vapour pressure of propan-2-ol, volatility is likely to be significantly affected by the temperature. However it is unclear from the calculations whether they were performed at a lower temperature nor is the vapour pressure of propan-2-ol at this lower temperature stated. As such, the UK CA has performed calculations based on the vapour pressure of propan-2-ol of 5780 Pa at 25°C.

Description of Scenario 6		
A professional user disinfects surfaces in professional food preparation setting e.g. food processing settings. The disinfection scenario considered in the Assessment Report has been followed to estimate the exposure from the use of this product family. Due to the high vapour pressure of propan-2-ol, the evaporation and airborne phase of the active from the surface is the critical route of exposure. In accordance with ConsExpo cleaning factsheet, inhalation exposure has been calculated using ConsExpo Web exposure to vapour: evaporation model (increasing area) for cleaning with wet tissue.		
	Parameters	**Value**
Inhalation exposure	Adult body weight	60 kg
	Concentration of active in impregnated wet wipe	62.9% w/w
	Product density	0.785 g/ml (applicant information)
	Inhalation rate	1.25 m^3/hr
	Inhalation absorption	100%
	Molecular weight	60 g/mol
	Vapour pressure (EU-agreed value (LoEP January 2015))	5780 Pa at 25 °C
	Mass transfer rate	Thibodeaux model
	Molecular weight matrix[1]	18 g/mol
	Exposure duration (Assessment Report)	120 mins
	Room volume (Assessment Report)	300 m^3

	Ventilation (Assessment Report)	20/hr
	Amount of product to treat 4.6 m^2 (5 wipes)	29.4 g (37.5 ml)
	Release area (Assessment Report)	4.6 m^2
	Application duration (Assessment Report)	5 mins
[1]The molecular weight of the matrix is based on the formulation. Please see the confidential Annex Section 3.6.1 for details of the full formulation.		

Calculations for scenario 6

Dermal exposure

ConsExpo Cleaning Product Factsheet[11] (p.64) estimated that during wiping with wet tissues, 1.4% of the total liquid of the wet tissue remains on the surface of the inner hand. The amount of product available for dermal exposure when wiping using one wet wipe is 0.082 g product (7.5 ml/wipe x 0.785 g/ml x 1.4%) or 52.75 mg propan-2-ol. Following the assumption in the propan-2-ol Assessment Report, one palm of hand (205 cm^2) is exposed during wiping; the time of evaporation is calculated according to TGD on risk assessment, App. I, App. If:

$T = mRTK/M\beta pA$

t = time [s]
m = mass of propan-2-ol on surface [mg] (52.75 mg)
R = gas constant [J K-1 mol-1] (8.314 J K^{-1} mol^{-1})
T = skin/surface temperature [K] (303.15 K)
K = conversion factor (36000)
M = molar mass [g mol-1] (60.1 g mol^{-1})
β = mass transfer coefficient [m h-1], for calculation see TGD (8.7 m h-1)
p = vapour pressure of the pure substance [Pa] (7600 Pa (30°C))
A = surface area [cm^2] (205 cm^2)

According to this equation the evaporation time is 5.9 seconds. Therefore for a worst case scenario it is assumed that the total amount evaporates at once after this time interval. The absorption/dermal flux rate for propan-2-ol in a 70% w/w aqueous dilution is 0.85 mg/cm^2/h (EU-agreed value (LoEP January 2015)). During the time interval of 5.9 seconds on the skin surface of palm of one hand 205 cm^2, this result in a total amount absorbed is 0.28 mg.

Therefore the total amount absorbed from the use of 19 wipes/day (4.6 m^2 x 4 events = 18.4 m^2/day) is 5.32 mg (0.089 mg/kg bw/d) without PPE.

Inhalation exposure

The estimated mean event concentration is 1.5 mg/m^3 calculated from ConsExpo Web. After 2 hours, the air concentration is 8.0×10^{-7} mg/m^3. As the residual air concentration at the end of each event is essentially negligible (0.00005% of the mean air concentration), this has not been added to the mean event concentration to estimate

[11] RIVM report 320104003/2006 Cleaning Products Fact Sheet

worker inhalation exposure during a working day. Therefore the systemic inhalation exposure during an 8-hour working day is calculated as follows.

The systemic inhalation uptake (mg/kg bw/d) = (mean event concentration x inhalation rate x total exposure duration)/body weight

Where:
Event concentration calculated from ConsExpo Web = 1.5 mg/m^3
Inhalation rate = 1.25 m^3/h
Total exposure duration = 8 h
Body weight = 60 kg

Summary table: estimated exposure from professional uses			
Scenario/PPE	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
7 (no PPE)	0.25	0.089	0.34
Please see Annex 3.2.1 for detailed calculations			

Scenario 7: Secondary exposure: professional bystander exposure to volatilised residues during disinfection in professional food preparation setting

Inhalation exposure may occur to re-entry of professional bystanders (e.g. staff) in industrial and professional food preparation settings where surface disinfection is performed. The inhalation exposure will be in the same order of magnitude as for the person who disinfected the surfaces. In a worst case scenario it is assumed that the bystander stays for 8 hours in the room where surface disinfection is performed. Therefore the level of inhalation exposure of a bystander is estimated to be equivalent or lower compared to the professional user applying the products.

Consequently the dermal exposure of bystanders follows the assumption that there is a very low probability for direct contact to freshly disinfected surfaces, and a very short duration of dermal exposure if casual contact happens. Furthermore due to the high vapour pressure of the active substance, dermal exposure by contact (hands) with treated surfaces is likely to be very low due to rapid evaporation. Therefore the dermal exposure is considered to be negligible.

Combined scenarios

No combined scenarios have been identified. It is not expected that a professional user would be disinfecting surfaces in industrial/manufacturing setting e.g. food processing industry setting and in professional food preparation setting e.g. canteen/kitchen in the same day.

General public user exposure

Products of the Pal IPA Product Family are intended for use by professional users only.

Bystander exposure

Pal IPA Product Family is intended for use in professional food preparation setting (industrial/institutional) where members of the public e.g. toddler will be excluded. As such no general public bystander exposure scenarios are foreseen.

Dietary exposure

The formulation of the products of the family is similar to the representative formulation considered at active substance approval and therefore the same conclusion is applicable. No residues in food or feed are expected to arise from the use of the products of the family (PT 4) due to the high vapour pressure of the active substance (5780 Pa at 25°C).

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
Scenario 1: Primary exposure: a technician performs routine disinfection of small surfaces e.g. equipment and work stations as part of their working procedures in industrial/manufacturing setting e.g. cleanroom	Professionals	No PPE	3.04
Scenario 2: Primary exposure: healthcare professional in hospital disinfects surfaces	Professionals	Tier 1 (no PPE, area treated per day 8 m2 i.e. 8 wipes per day)	1.95
		Reverse reference (no PPE, area treated per day 10 m^2 i.e. 80 wipes/day)	11.53
Scenario 3: Secondary exposure: bystander inhalation of volatilised residues during disinfection in industrial/manufacturing setting e.g. cleanroom	Professional bystanders	N/A	<3.04
Scenario 4: Secondary exposure: bystander inhalation of volatised residues during disinfection in healthcare environments e.g. hospital	General public bystanders	Tier 1/Reverse reference 1 (area treated 1 m^2 (1 wipe) at 4 hour intervals in a 24-hour period i.e 6 m^2/day)	6.3

Scenario 5: Primary exposure: professional user disinfecting surfaces in professional food preparation settings e.g. canteen/kitchen setting	Professionals	No PPE	0.85
Scenario 6: Primary exposure: professional user disinfecting surfaces in professional food preparation settings e.g. food processing setting	Professionals	No PPE	0.34
Scenario 7: Secondary exposure: professional bystander exposure to volatilised residues during disinfection in professional food preparation setting	Professional bystanders	N/A	<0.85

2.2.5.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
Professional workers AELacute/ Medium-term/ long-term	EU-agreed value (LoEP January 2015)	NOAEC – 200 ppm LOAEL 400 ppm for acute systemic (neurological) effects (over 8 hours), based on the deterioration of postural balance	3.8	-	17.9 mg/kg bw/d (52.6 ppm for 8 hours/d)
Professional workers Reference value for inhalation (proposed OEL)	EU-agreed value (LoEP January 2015)	-	-	-	200 ppm
General population AEL acute/medium/ long-term	EU-agreed value (LoEP January 2015)	NOAEC – 200 ppm LOAEL 400 ppm	6.4	-	10.7 mg/kg bw/d (31.25 ppm for 8 hours/d)
ARfD	Not required; no residues in food expected				
ADI	Not required; no residues in food expected				

[1] Default assessment factors of 6.4 for the general population and 3.8 for professional users were applied to account for intraspecies variability.

Note on local effects: The $AEC_{acute/medium/long-term}$ is assumed to also sufficiently cover local irritant effects in the eyes/airways.

Risk for industrial users

Products of the Pal IPA Product Family are intended for use by professional users only.

Risk for professional users PT 2

Systemic effects

Task/ Scenario	**Tier**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Scenario 1: Primary exposure: a technician performs routine disinfection of small surfaces e.g. equipment and work stations as part of their working procedures in industrial/ manufacturing setting e.g. cleanroom	1 (no PPE)	17.9	3.04	17	Yes
Scenario 2: Primary exposure: healthcare professional in hospital disinfects surfaces	1 (no PPE, area treated per day 8 m^2 i.e. 8 wipes per day)	17.9	1.95	11	Yes
Scenario 3: Secondary exposure: bystander inhalation of volatilised residues during disinfection in industrial/ manufacturing setting e.g. cleanroom	-	-	<3.04	<17	Yes

Combined scenarios

No combined scenarios have been identified. It is not expected that a professional user would use the products in industrial/manufacturing setting (e.g. cleanroom) and institutional setting (e.g. hospital) in the same day.

Local effects

Pal IPA Product Family is classified for Eye Irritant 2 (H319: Causes serious eye irritation) and STOT SE 3 (H336: May cause drowsiness or dizziness). The propan-2-ol Assessment Report informs that the AEC for professional users of 52.6 ppm for 8 hours/day (converted to a systemic AEL of 17.9 mg/kg bw/d) also sufficiently covers

local irritant effects in the eyes/airways. As all professional exposure scenarios were below the AEL, no further consideration for local effects is necessary.

Conclusion

On the basis of the risk assessment, and considering local effects have been taken into account in the setting of the AEL, exposure is within acceptable limits for professional users without PPE.

Risk for bystanders PT 2

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 4: Secondary exposure: bystander inhalation of volatised residues during disinfection in healthcare environments e.g. hospital	Tier 1/Reverse reference 1 (area treated 1 m^2 (1 wipe) at 4 hour intervals in a 24-hour period i.e 6 m^2/day)	10.7	6.3	59	Yes

Conclusion

The reverse reference scenario performed illustrates that a toddler (bystander) exposure to a disinfected area of 1 m^2 (1 wipe) every 4 hours over 24-hour period (i.e. 6 m^2 per day) is within acceptable limits.

Disinfection wipes are intended for small scale use to disinfect small surfaces which have frequent contact e.g. door handles, visitor's chair and realistically patient's rooms are likely to be disinfected once a day or after patient discharge. However where areas >1 m^2 is required for disinfection, and given the associated P-phrases triggered by the classification of the product family (P261: Avoid breathing vapours, and P271: Use only outdoors or in a well ventilated area) users should consider appropriate risk mitigation measures for exposed bystanders; such as "When performing disinfection in areas where members of the public may be present, persons should be prevented from entering the room until the room has been well ventilated".

Risk for professional users PT 4

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 5: Primary exposure: professional user disinfecting	1 (no PPE)	17.9	0.85	5	Yes

surfaces in professional food preparation settings e.g. canteen/kitchen setting					
Scenario 6: Primary exposure: professional user disinfecting surfaces in professional food preparation settings e.g. food processing setting	1 (no PPE)	17.9	0.34	2	Yes
Scenario 7: Secondary exposure: professional bystander exposure to volatilised residues during disinfection in professional food preparation setting	N/A	17.9	<0.85	<5	Yes

Combined scenarios

No combined scenarios have been identified. It is not expected that a professional user would be disinfecting surfaces in industrial/manufacturing e.g. food processing industry setting and institutional setting e.g. canteen in the same day.

Local effects

Pal IPA Product Family is classified for Eye Irritant 2 (H319: Causes serious eye irritation) and STOT SE 3 (H336: May cause drowsiness or dizziness). The propan-2-ol Assessment Report informs that the AEC for professional users of 52.6 ppm for 8 hours/day (converted to a systemic AEL of 17.9 mg/kg bw/d) also sufficiently covers local irritant effects in the eyes/airways. As all professional exposure scenarios were below the AEL, no further consideration for local effects is necessary.

Conclusion

On the basis of the risk assessment and considering local effects have been taken into account in the setting of the AEL, exposure is within acceptable limits for professional users without PPE.

Risk for bystanders PT 4

Pal IPA Product Family is intended for use in controlled professional food preparation setting (industrial/institutional) where members of the public will be excluded. As such no general public exposure scenarios are foreseen.

Risk for consumers via residues in food

The formulation of the products of the family is similar to the representative formulation considered at active substance approval and therefore the same conclusion is applicable. No residues in food or feed are expected to arise from the use of the products of the family (PT 4) due to the high vapour pressure of the active substance (5780 Pa at 25°C). Furthermore, reference values for dietary intake (ADI or ARfD) have not been derived for propan-2-ol (2015 Assessment Report).

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

Pal IPA Product Family contains only one active substance and no substances of concern relevant for human health. Therefore the consideration of combined exposure is not required.

2.2.6 Risk assessment for animal health

Primary and secondary exposure of animals to the biocidal product family is not expected via the intended uses.

2.2.7 Risk assessment for the environment

The Pal IPA Product Family products are pre-saturated wipes. The products are available ready-to-use (RTU) and each contains 70% (v/v) propan-2-ol as the active substance. The products are used to disinfect non-invasive medical devices and equipment within healthcare environments; hard, non-porous surfaces in professional environments such as in cleanrooms for biotechnology, pharmaceutical, manufacture of medical devices, healthcare industries and other critical life science applications. The area treated per wipe is dependent on the size of the wipe (ranging from 1 to 1.5 m^2), however a treated area of 1 m^2 per wipe is used for risk assessment purposes in order to determine the worst case application rate of the different wipe products. The wipes contain a maximum of amount of 7.5 ml propan-2-ol per wipe, so 7.5 ml has been considered in the calculation of emissions. The use of wipes will vary, but the typical use frequency is one application every 30 minutes, and could be used for several hours per day. The products are formulated by mixing 700 ml of propan-2-ol (density 0.785 g/ml) with 300 ml of water, giving 0.5502 kg/l of active substance in the products.

The UK CA notes that 0.785 g/ml x 700 ml = 549.5 g - then correcting for the percentage technical material of 99 % w/w gives a value of (549.5 x 100/99) = 555 g/l (0.555 kg/l) which has been used in the risk assessment.

Environmental and ecotoxicological data specific to the Pal IPA Product Family are not available. Instead, information required for the environmental risk assessment is based on the active substance, propan-2-ol, which is available in the EU Assessment Report (January 2015). This approach is justified because the type of formulation and inert substances used in the products are not expected to affect the environmental properties or ecotoxicological profile of propan-2-ol. Data generated with unformulated propan-2-ol can be extrapolated to the formulated products and environmental properties of the products do not need to be specifically tested.

2.2.7.1 Effects assessment on the environment

The product family contains only one active substance and no substances of concern. Therefore all toxicity data can be obtained from the Assessment Report. The PNECs are summarised below:

Aquatic = 2.82 mg a.s./L
Sediment = 2.41 mg/kg ww sediment
Sewage = 10 mg/L
Soil = 0.496 mg/kg ww soil
Log Pow = 0.05 and no surface tension properties

Not B or T

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

No additional data submitted. The agreed LoEP for propan-2-ol has been used in the risk assessment.

Further Ecotoxicological studies

No additional data submitted. The agreed LoEP for propan-2-ol has been used in the risk assessment.

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

No additional data submitted. The agreed LoEP for propan-2-ol has been used in the risk assessment.

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

No additional data submitted. The agreed LoEP for propan-2-ol has been used in the risk assessment.

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

No additional data submitted. The agreed LoEP for propan-2-ol has been used in the risk assessment.

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

No additional data submitted. The agreed LoEP for propan-2-ol has been used in the risk assessment.

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

The products in the family are applied indoors to hard surfaces in industrial and institutional areas; no direct exposure of soil or surface waters is expected.

The emission pathways considered in the risk assessment include indirect emissions of the formulation to surface water (and sediment), the STP itself, groundwater and air. The main emission pathway during use will be to air since propan-2-ol is known to evaporate completely within a short time due to its relatively high vapour pressure.

The deposition of propan-2-ol to soil and subsequent movement to groundwater has also been considered.

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

The fate and behaviour of the active substance propan-2-ol is not expected to be altered by the co-formulants in the products. As such, the data submitted for the active substance is considered sufficient to cover all endpoints for environmental fate and behaviour. No further product specific studies are required.

Leaching behaviour (ADS)

The products of the family are formulated products and not treated articles. The products are not intended for addition to a matrix or impregnation into another material. As such, testing for leaching behaviour is neither relevant nor required according to the Guidance on the Biocidal Product Regulation, Volume IV, Part A.

Testing for distribution and dissipation in soil (ADS)

The fate and behaviour of the active substance propan-2-ol is not expected to be altered by the co-formulants in the products. As such, the data submitted for the active substance is considered sufficient to cover all endpoints for environmental fate and behaviour. No further product specific studies are required.

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

The fate and behaviour of the active substance propan-2-ol is not expected to be altered by the co-formulants in the products. As such, the data submitted for the active substance is considered sufficient to cover all endpoints for environmental fate and behaviour. No further product specific studies are required.

Testing for distribution and dissipation in air (ADS)

The fate and behaviour of the active substance propan-2-ol is not expected to be altered by the co-formulants in the products. As such, the data submitted for the active substance is considered sufficient to cover all endpoints for environmental fate and behaviour. No further product specific studies are required.

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)

No additional data submitted. The agreed LoEP for propan-2-ol has been used in the risk assessment.

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)

No additional data submitted. The agreed LoEP for propan-2-ol has been used in the risk assessment.

2.2.7.2 Exposure assessment

The Pal IPA Product Family biocidal products are used under PT 2 and PT 4.

Exposure assessments are conducted separately for each product type.

Product type 2
The product type is PT 2 (disinfectants not intended for direct application to humans or animals, mainly healthcare applications).

Products in the Pal IPA Product Family are ready-for-use, alcoholic disinfectant products which are intended to be used as private and public health area disinfectants. Their use is restricted to routine disinfection of hard surfaces in professional/industrial/ manufacturing environments; hard surfaces in cleanrooms and controlled areas of pharmaceutical, biopharmaceutical, medical device and diagnostic product manufacturing facilities and critical life science applications, non-invasive medical devices and equipment within healthcare environments (e.g. hospitals and residential care homes). The products in this family all contain the active substance: propan-2-ol (at a maximum concentration of 70 % v/v).

These products are applied to surfaces by professionals in controlled, occupational settings only and will be used according to different disinfection regimes.

There is no general public (consumer) use of these products.

Although a number of scenarios could be considered for a propan-2-ol product the UK CA proposes that only the following are relevant for a RTU wipe product which is left to evaporate and is not washed to a drain.

In the Propan-2-ol BPC opinion, it is stated that the distribution of releases between air and waste water at a ratio of 90 % and 10 % has to be re-evaluated at product authorisation stage. In In the absence of any further information and in view of the high similarity between this product and the representative product we assume that the 90 : 10 ratio is still appropriate for this propan-2-ol containing product

General information for PT 2

Assessed PT	PT 2
Assessed scenarios	Based on the environmental emission scenarios for Product Type 2: Private and public health area disinfectants and other biocidal products, the following scenarios were identified as relevant to generate local emission values (i.e. emission rate to wastewater (standard STP)). **Scenario 1** Disinfection of small surfaces for sanitary purposes in institutional areas – professional user **Scenario 2**: "PT 2-industrial areas" (emission scenario for calculating the releases of disinfectants used in industrial areas).

ESD(s) used	Environmental Emission Scenarios for Product Type 2: Private and public health area disinfectants and other biocidal products
Approach	Emission estimations were calculated for the four relevant scenarios identified listed above, using ECHA's environmental emission scenarios for PT 2 Excel spread sheet.
Distribution in the environment	Calculated based on the ECHA Guidance on Environmental Risk Assessment, Volume IV, Part B and the TAB.
Groundwater simulation	Tier 1 plus a reasoned argument
Confidential Annexes	No
Life cycle steps assessed	Industrial use
Remarks	Exposure based on worst case assumptions and relevant guidance documents. Consumption based modelling carried out (as found to be worst case in the propan-2-ol AR).

Emission estimation for PT 2

Scenario 1
Disinfection of small surfaces for sanitary purposes in institutional areas – professional user

The emission scenario for disinfectants used for sanitary purposes in institutional areas is described in Chapter 2.1 of the ESD for PT2 (JRC, 2011). The default consumption per capita for general purpose is 5 ml/ d. The resulting local emission of propan-2-ol to the waste water and air from the application of this product is calculated in the following Table.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Disinfection of small surfaces for sanitary purposes in institutional areas – professional user			
Number of inhabitants feeding one STP	10000	-	Default
Consumption per capita	0.005	l/d	Default
Concentration of active substance in the product	0.555	kg/l	Based 70 % v/v propan-2-ol
Fraction released to wastewater	0.1	-	AR
Fraction released to air	0.9	-	AR
Penetration factor	0.3	-	AR
Emission rate to water	0.833	kg/d	
Emission to air	7.49	kg/d	

Scenario 2: "PT 2-industrial areas" (emission scenario for calculating the releases of disinfectants used in industrial areas).

The local release to wastewater was calculated based on an assumed application rate of the biocidal products of 0.0075 l/m^2, a concentration of active substance in the products of 0.555 kg/l and "Small scale application (RTU)". The propan-2-ol AR states that the distribution of releases between air and wastewater occurs at a ratio of 90 % and 10 % respectively. The fraction released to wastewater was therefore set to 0.1 to derive the release to wastewater and the release to air calculated from this value (i.e. ($Elocal_{water}$ x 10) x 0.9).

It was agreed in the TAB version 1.3 for PT 2 that the treated area for a RTU product could be reduced to 25 m^2 (when product is applied by means of trigger spray or wipes), this has been used in the exposure calculation and can be assumed to be protective for a number of smaller repeat applications made to a localised area during the day.
All other parameters used were defaults (number of applications per day and fraction of substance disintegrated during or after application (before release to the sewage system)).

Input parameters for calculating the local emission - Small scale RTU			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: "PT 2-industrial areas" (emission scenario for calculating the releases of disinfectants used in industrial areas).			
Application rate of biocidal product	0.0075	l/m^2	Based on a worst case application rate of 7.5 ml per wipe per m^2
Concentration of active substance in the product	555	g/l	Based 70 % v/v propan-2-ol
Surface area to be disinfected	25	m^2	TAB 1.3 RTU small scale applications
Fraction released to wastewater	0.1	-	Assessment report 2015
Fraction released to air	0.9	-	Assessment report 2015
Local release to wastewater	1.04E-02	kg/d	Output
Local release to air	9.37E-02	kg/d	Output

Product type 4

The product type is PT 4 (disinfectants used in food and feed areas).

Products in the Pal IPA Product Family are also used to disinfect food contact surfaces within industrial and professional environments (e.g. in food, beverage and dairy industries and, kitchens and canteens). Products in the Pal IPA Product Family intended for food and feed area disinfection are all ready-for-use, alcoholic disinfectant wipes which are used indoors and are effective against bacteria and yeast. These products are used in controlled, occupational settings in areas where members of the public will be excluded. The products are applied to surfaces as such and no post-application rinsing of surfaces is required.

There is no general public (consumer) use of these products.

The products are formulated as ready-to-use wipes and are therefore applied by wiping. The products in this family are intended for professional use only and are provided ready-to-use. No mixing and loading is required.

General information for PT 4

Assessed PT	PT 4
Assessed scenarios	Based on ECHAs environmental emission scenarios for Product Type 4: Disinfectants used in food and feed areas, the following two scenarios were identified as relevant to generate local emission values (i.e. effluent concentration of active substance in the effluent of the on-site STP, influent concentration of active substance in the off-site STP and local emission to waste water). **Scenario 1**: "PT 4-FDM industries" (assessment of entire plants *e.g.* breweries, dairies, beverage processing plants). **Scenario 2**: "PT 4-large scale kitchens, etc" (emission scenario for calculating the release of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries).
ESD(s) used	Environmental Emission Scenarios for Product Type 4: Disinfectants used in food and feed areas
Approach	Emission estimations were calculated for the four relevant scenarios identifed listed above, using ECHA's environmental emission scenarios for PT 4 Excel spread sheet.
Distribution in the environment	Calculated based on the ECHA Guidance on Environmental Risk Assessment, Volume IV, Part B and the TAB.
Groundwater simulation	Tier 1 plus a reasoned argument
Confidential Annexes	No
Life cycle steps assessed	Industrial use
Remarks	Exposure based on worst case assumptions and relevant guidance documents

Emission estimation for PT 4

Scenario 1: "PT 4-FDM industries" (assessment of entire plants e.g. breweries, dairies, beverage processing plants).

An influent concentration of active substance to the off-site STP of 0.031 mg/l was calculated using the "PT 4-FDM industries" model (assessment of entire plants e.g. breweries, dairies, beverage processing plants) from ECHAs "Environmental Emission Scenarios for Product Type 4: Disinfectants used in food and feed areas". This scenario is based on a number of default parameters and the assumption that 143 kg/yr of propan-2-ol is used in a brewery (using the agreed ECHA excel sheet).

It is accepted that this scenario seems less relevant for a product applied as a RTU wipe, but it has been retained in this instance to take account of any liquid product applied within an industrial plant with emissions going to STP. The default value of 143 kg/yr must be considered to be an extreme worst case for the RTU wipe use.

All other parameters were default parameters (i.e. amount of biocidal active substance used per year in the local plant, number of emission days per year, fraction released to waste water, capacity of STP and dilution factor in surface water).

For the fraction released to waste water, the default value of 10 % loss was taken as assumed in the AR (relating to a surface treatment).

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: "PT 4-FDM industries" (assessment of entire plants e.g. breweries, dairies, beverage processing plants).			
Active ingredient applied in breweries	Propan-2-ol	N/A	Pick-list
Amount of active substance used per year in local plant (Qai)	143	kg/yr	Default from ESD table 6
Number of emission days per year (Temission)	231	d/yr	Default
Fraction released to wastewater (Fwater)	0.1	-	AR default
Effluent concentration from the on-site STP $C_{effluent}$ = Clocal $_{water}$	3.43E-03	mg/l	Output
Influent concentration of active substance in the off-site STP	3.10E-02	mg/l	Output
Emission to Air (Elocalair)	5.57E-01	kg/d	Output

Scenario 2: "PT 4-large scale kitchens, etc" (emission scenario for calculating the release of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries).

The local release to wastewater was calculated using the "PT 4-large scale kitchens, etc" model (emission scenario for calculating the release of disinfectants used in catering kitchens, canteens, slaughterhouses and butcheries) from the ESD "Environmental Emission Scenarios for Product Type 4: Disinfectants used in food and feed areas".

Following item 54 in the TAB version 1.3, a default surface area of 50 m^2 can be applied for a small scale RTU product such as a trigger spray or wipes. This value is also protective for the use in slaughterhouses where a default area of 10 m^2 is assumed (for small scale use).

The propan-2-ol AR states that the distribution of releases between air and waste water occurs at a ratio of 90 % and 10 % respectively. The fraction released to waste water was therefore set to 0.1 to derive the release to waste water and the release to air calculated from this value (i.e. ($Elocal_{water}$ x 10) x 0.9). All other parameters were default parameters (volume to be disinfected and number of applications per day).
The application rate was calculated based on 0.0075 l/ m^2 x 555 g/l = 4.16 g/m^2**.**

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: "PT 4- Emission scenario for calculating the release of disinfectants used in large scale catering kitchens, canteens, slaughterhouses and butcheries.			
Type of application	Spraying/ Wiping	-	Pick-list
Size of the area treated	50	m^2	TAB 1.3 RTU small scale applications
Fraction released to waste water (Fwater)	0.1	-	Assessment Report 2015
Fraction released to air (Fair)	0.9	-	Assessment Report 2015
Application rate of the active substance	4.16	g/m^2	Based on a worst case application rate of 7.5 ml per wipe per m^2
Local release to waste water	2.08E-02	kg/d	Output
Local release to air	0.187	kg/d	Output

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
PT 2									
Scenario 1	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No
Scenario 2	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No
PT 4									
Scenario 1	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No
Scenario 2	Yes	Yes	No	No	Yes	Yes	Yes	Yes	No

Input parameters (only set values) for calculating the fate and distribution in the environment (PT 2 & PT 4)			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	60.09	g/mol	EU-agreed value (LoEP January 2015)
Melting point	-89.5	°C	EU-agreed value (LoEP January 2015)
Boiling point	82.5	°C	EU-agreed value (LoEP January 2015)
Vapour pressure at 25°C (12 °C)	5780 (2302)	Pa	EU-agreed value (LoEP January 2015)

Water solubility at 25°C (12 °C)	1000000 (831846)	mg/l	EU-agreed value (LoEP January 2015)
Log Octanol/water partition coefficient	0.05	Log 10	EU-agreed value (LoEP January 2015)
Organic carbon/water partition coefficient (K_{OC})	3.3	l/kg	EU-agreed value (LoEP January 2015)
Henry's Law Constant (at 25°C) (12°C)	0.80 (0.383)	$Pa/m^3/mol$	EU-agreed value (LoEP January 2015)
DT_{50} for degradation in air	3.1	days	EU-agreed value (LoEP January 2015)
Biodegradability	Readily biodegradable	N/A	EU-agreed value (LoEP January 2015)

Fate and distribution in the STP PT 2 and PT 4		
Compartment	**Percentage [%]**	**Remarks**
	All scenarios	
Air	0.3	EU-agreed value (LoEP January 2015)
Water	12.5	EU-agreed value (LoEP January 2015)
Sludge	0	EU-agreed value (LoEP January 2015)
Degraded in STP	87.1	EU-agreed value (LoEP January 2015)

In exposure modelling it has been assumed that the amount of propan-2-ol binding to sludge can be considered to be negligible.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{water}$) [kg/d]**	**Local emission ($Elocal_{air}$) [kg/d]**
PT 2		
Scenario 1	0.833	7.49
Scenario 2	1.04E-02	0.094
PT 4		
Scenario 1	6.19E-02*	0.557
Scenario 2	0.021	0.187

*****Back calculated from C_{inf} value of 0.031 mg/ l

Calculated PEC values (PT 2 & PT 4)

Please refer to Annex 3.2.2 for the calculation of PECs following Volume IV Part B, guidance on environmental risk assessment.

Summary table on calculated PEC values						
	PEC_{STP} [mg/l]	**PEC_{water} [mg/l]**	**PEC_{sed}[a] [mg/kg_{wwt}]**	**PEC_{soil} [mg/kg]**	**PEC_{GW} [µg/l]**	**PEC_{air} [mg/m^3]**
PT 2						

Scenario 1	5.20E-02	5.20E-03	NC	2.05E-04	1.17	2.08E-03
Scenario 2	6.50E-04	6.50E-05	NC	2.56E-06	0.015	2.60E-05
PT 4						
Scenario 1	3.87E-03	3.43E-03* 3.87E-04#	NC	1.52E-05	0.087	1.55E-04
Scenario 2	1.30E-03	1.30E-04	NC	5.12E-06	0.029	5.20E-05

[a]$PEC_{sediment}$ values were not calculated as there are no sediment effects data available for propan-2-ol. It is assumed that the levels of risk to the sediment will be the same as the values calculated for surface water; *Value from on-site STP; #Value from off-site STP

Primary and secondary poisoning

Primary poisoning

The proposed uses of the products preclude any risk of primary poisoning.

Secondary poisoning

There is a low risk of secondary poisoning from the use of propan-2-ol products as the active substance has a very low potential for secondary poisoning. Propan-2-ol has a low log Kow of 0.05 and the calculated bioaccumulation factors (BCFs) for fish and earthworms are 0.22 and 0.85 l/kg respectively. Consequently, the approach taken in the Assessment Report was followed and no PNEC or PEC values have been calculated.

2.2.7.3 Risk characterisation

Atmosphere

Conclusion: As stated in the propan-2-ol AR there is a potential for long range environmental transport, however effects on stratospheric ozone and acidification are not expected as propan-2-ol does not contain halogens, nitrogen or sulphur and is not listed as an ozone depleting substance. Inhalation studies with mammals also indicate that adverse effects are not expected to occur to terrestrial mammals.

As there are no effects data available it was accepted in the AR that the risk to air can be considered to be acceptable.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
PT 2	
Scenario 1	< 0.001
Scenario 2	< 0.001

PT 4	
Scenario 1	0.001*
Scenario 2	0.001

*Value from on-site STP

Conclusion: As the PEC/PNEC ratios for the STP are below the value of 1 for all scenarios, an acceptable level of risk to the STP is indicated.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
PT 2		
Scenario 1	0.002	NC
Scenario 2	< 0.001	NC
PT 4		
Scenario 1	0.001* <0.001#	NC
Scenario 2	0.001	NC

*Value from on-site STP; #Value from off-site STP

Conclusion: As the PEC/PNEC ratios for the aquatic compartment are below the trigger value of 1 for all scenarios, acceptable risks to the aquatic compartment are indicated. As effects data have not been provided for the sediment compartment it is accepted that the level of risk to this compartment can be considered to be the same as that for the aquatic compartment.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
PT 2	
Scenario 1	< 0.001
Scenario 2	< 0.001
PT 4	
Scenario 1	< 0.001
Scenario 2	< 0.001

Conclusion: As the PEC/PNEC ratios for the terrestrial compartment are below the trigger value of 1 for all scenarios, acceptable risks to the terrestrial compartment are indicated.

Groundwater

When a tier 1 approach to the calculation of groundwater levels is applied following guidance in Vol IV Part B, acceptable levels are predicted for almost all scenarios. This porewater calculation is generally assumed to be a conservative approach as it does not take into account any lateral movement processes, degradation within the soil or removal by volatilisation from the soil.
An acceptable risk of propan-2-ol to groundwater is therefore expected.

Summary table on Tier 1 Porewater concentration	
	PEClocal$_{soil,\ porewater}$ [µg/l]
PT 2	
Scenario 1	1.17
Scenario 2	0.015
PT 4	
Scenario 1	0.087
Scenario 2	0.029

Following discussions at WG-VII-2018 it was agreed that the following argument forms an acceptable weight of evidence approach to support FOCUS PEARL not offering an appropriate tier 2 refinement for these proposed uses of propan-2-ol.

For the environmental risk assessment, dry and wet deposition, expressed as DEPTtotal$_{ann}$, is assumed to be the main emission pathway to the soil and subsequently to the groundwater compartment due to the high volatility of propan-2-ol. The DEPTtotal$_{ann}$ is calculated by use of the OPS model (as described in the Guidance on the BPR IV ENV B, 2015), which assumes that the major fraction (90%) of the applied propan-2-ol is released to the ambient air and subsequently deposited in close vicinity (within a radius of 1000 m) to the source of emission. In the case of propan-2-ol this assumption represents an unrealistic worst-case and it can be considered highly unlikely that the assumed magnitude of exposure truly occurs under relevant field conditions.

- The FOCUS PEARL model was developed for the determination of groundwater concentrations related to the application of plant protection products (PPP) on agricultural land. Accordingly, the model assumptions for the nine locations rely on e.g. soil properties that are representative for agriculturally used areas in Europe. The unlimited applicability of the model for the very diverse field of biocidal applications is thus questionable. For biocidal applications where the release of active substances to the environment is related to the application of sewage sludge or manure/slurry to agricultural land, the applicability of FOCUS PEARL might be given. In the present case, where the products of the BPF are used in urban areas where a direct exposure to the urban environment is assumed, the model assumptions of FOCUS PEARL may not be

accurate and the results of such a refinement should be evaluated with caution. The same applies, when FOCUS PEARL is used for the groundwater assessment of volatile compounds, for which the model is might not be suitable, since it might overestimate the leaching rate to the groundwater for such compounds. Consequently, the results of the refined groundwater assessment with FOCUS PEARL must also be considered as an unrealistic worst-case.

This discussion is supported by the conclusion at the 21st BPC meeting that if not all nine scenarios show a safe use and the applicability of the models for the substance evaluated can be questioned, a qualitative approach could be applied using expert judgement in a weight of evidence approach.

An acceptable risk of propan-2-ol to groundwater is therefore expected.

Primary and secondary poisoning

Primary poisoning

The proposed uses of the products preclude any risk of primary poisoning.

Secondary poisoning

There is an acceptable level of risk of secondary poisoning from the use of propan-2-ol products as the active substance has a very low potential for secondary poisoning. Propan-2-ol has a low log Kow of 0.05 and the calculated bioaccumulation factors (BCFs) for fish and earthworms are 0.22 and 0.85 l/kg respectively. Consequently, no risk of secondary poisoning is foreseen and no PNEC or PEC values have been calculated.

Mixture toxicity

As the biocidal products contain only one active substance, an assessment of mixture toxicity is not required.

Aggregated exposure (combined for relevant emmission sources)

Propan-2-ol is used in a number of biocidal PTs (1, 2 and 4) and has a number of other non-biocidal uses. An aggregated exposure assessment was performed in the propan-2-ol Assessment Report (2015) and is reproduced below.

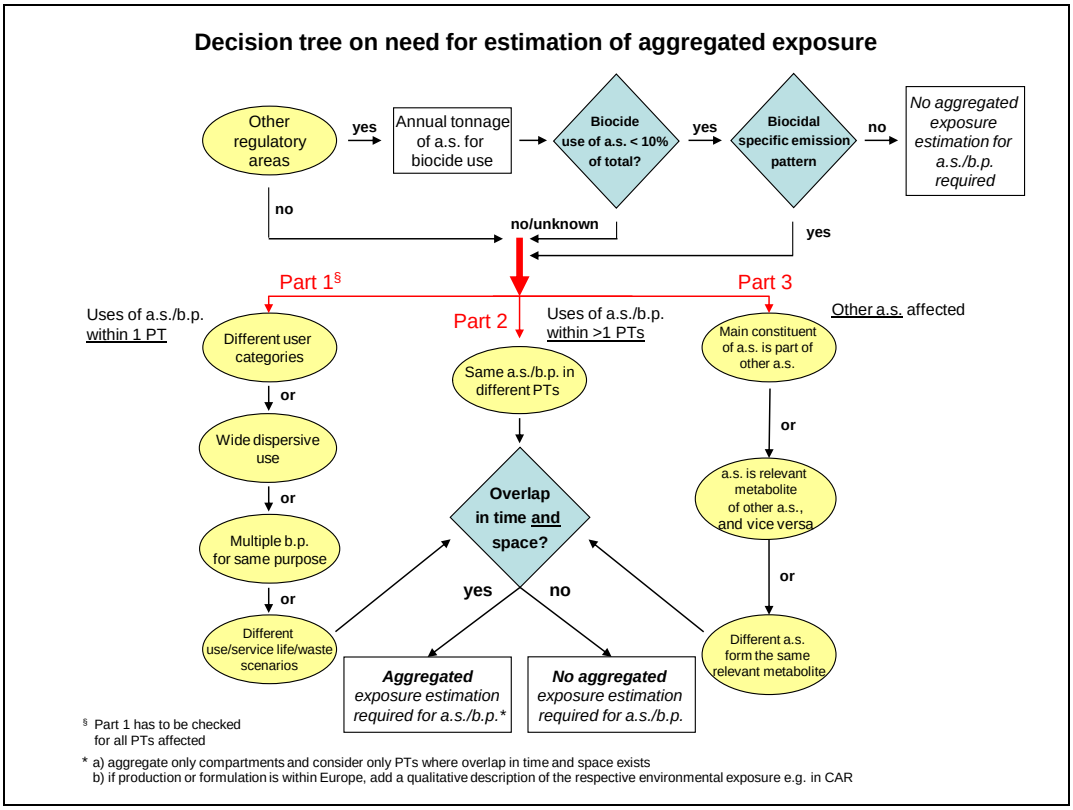


Figure 1: Decision tree on the need for estimation of aggregated exposure

"*Propan-2-ol is notified for Annex I inclusion in PT 1, 2, and 4. For all mentioned PTs, DE is RMS. The respective CA reports consider the following uses: PT 1 - skin and hand disinfectant in hospitals; PT 2 - disinfection of rooms, furniture and objects in the sanitary sector; PT 4 - assessment of small-scale applications (spraying of surfaces) / industrial kitchens / meat processing industry. As b.p. containing propan-2-ol are used in a wide dispersive way, an aggregated environmental exposure assessment may be reasonable. According to the "Decision tree on the need for estimation of aggregated exposure" (BIP6.7 Decision Tree Agg Expo), the requirement for aggregated exposure estimations was checked for propan-2-ol. In summary, it has been concluded that no aggregated exposure assessment for propan-2-ol has to be performed as the biocidal uses of propan-2-ol is less than 10 % of the total tonnage produced and no specific biocidal emission patterns are identified.*"

On this basis further consideration of aggregated exposure is not necessary.

Overall conclusion on the risk assessment for the environment of the product
The assessment for this family of RTU wipes has followed the agreements made within the propan-2-ol Assessment Report and assumed a 90 % loss to air and 10 % loss to drain following application for a number of scenarios. As a protective approach for the aquatic compartment, the scenario for the use of propan-2-ol in a brewery has also been considered although this is not one of the uses proposed by the applicant. This is an extreme worst case situation and acceptable risks to the environment were still predicted for this use. The highest proposed application rate of 7.5 ml/m^2 for a 70 % propan-2-ol product has been used in the risk assessment to cover the use of this product family. It is noted that

this is an extreme worst case as it has been assumed that all of the liquid is removed from the largest available wipe over a surface multiple times during the day.

In conclusion, even using a number of worst case assumptions, acceptable uses to the environment have been demonstrated for the Pal IPA Product Family for the proposed use as RTU wipes under PT 2 and PT 4.

2.2.8 Measures to protect man, animals and the environment

Please see section 2.1.4.

2.2.9 Assessment of a combination of biocidal products

The products of the Pal IPA Product Family are not intended to be used in combination with other biocidal products.

2.2.10 Comparative assessment

A comparative assessment is not required as the active substance is not a candidate for substitution.

3 ANNEXES

3.1 List of studies for the biocidal product family

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
[redacted]	2016	Determination of Storage Stability and Shelf Life Specification Data for a Formulation containing 70% Isopropanol stored at various temperatures for Two Years, in Compliance with Good Laboratory Practice.	David Norris Analytical Laboratories Ltd.	DNA3465	Yes	No	Yes	[redacted]	3.1-1
[redacted]	2016	Cosmetic Regulation Stability Test Report	Microbiological Solutions Limited	15/01551/2	No	No	Yes	Pal International Limited	3.1-2
[redacted]	2016	Cosmetic Regulation Stability Test Report	Microbiological Solutions Limited	15/01551/1	No	No	Yes	Pal International Limited	3.4.1.1-03
[redacted]	2016	Expert Statement on the EU CLP Charachteristics of a Propan-2-ol/water Solution (70:30): Explosivity, Oxidising Properties, Self-Reacting, Self-Heating and Corrosive to Metals	TSGE Consulting Limited	TSGE_16-070-01_IPA_CLP_2.0	No	No	Yes	Pal International Limited, Contec Cleanroom (UK) Limited, Selden Research	4.1

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
								Limited	
[redacted]	2016	Validation of the Methods of Determination of a Formulation containing Isopropanol, in Compliance with Good Laboratory Practice.	David Norris Analytical Laboratories Ltd.	DNA3466	Yes	No	Yes	[redacted]	5.1
[redacted]	2014	Microbiological Analysis Based on EN 1276 (2009) Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics (Phase 2 / Step 1)	MGS Laboratories Limited	TRA-2014-091-01	No	No	Yes	Pal International Limited	6.7-01
[redacted]	2014	Microbiological Analysis Based on EN 1650 (2008) + A1:2013 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and	MGS Laboratories Limited	TRA-2014-089-01	No	No	Yes	Pal International Limited	6.7-02

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		institutional areas – Test method and requirements (Phase 2, Step 1)							
[redacted]	2013	EN 13697, Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action (Phase 2, Step 2)	Abbott Analytical	13C.079SB.PAL	No	No	Yes	Pal International Limited	6.7-03
[redacted]	2014	Microbiological Analysis Based on EN 13727 (2012) Chemical Disinfectant and Antiseptics - Quantitative Suspension Test for the Evaluation of Bactericidal Activity in the Medical Area – Test Method and	MGS Laboratories Limited	TRA-2014-090-01	No	No	Yes	Pal International Limited	6.7-04

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		Requirements (phase 2 / step 1)							
[redacted]	2006	Test Report BS EN 13624:2003 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area – Test method and requirements (phase 2, step 1)	BluScientific Test Data	N/A	Yes	No	Yes	Pal International Limited	6.7-05
[redacted]	2015	Test for the evaluation of bactericidal activity on non-porous surfaces with mechanical action in the medical area BSEN 16615:2015	Microbiological Solutions Limited	15/04606-1	No	No	Yes	Pal International Limited	6.7-06
[redacted]	2015	Test for the evaluation of bactericidal activity on non-porous surfaces with mechanical action in the medical area BSEN 16615:2015	Microbiological Solutions Limited	15/04606-3	No	No	Yes	Pal International Limited	6.7-07
[redacted]	2014	EN 14348 (2005)	MGS	TRA-2014-	No	No	Yes	Pal	6.7-08

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		Quantitative suspension test for the evaluation of tuberculocidal activity of chemical disinfectants in the medical area including instrument disinfectants. (Phase 2 / Step 1)	Laboratories Limited	110-01				International Limited	
[redacted]	2013	EN 14561, Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity of chemical disinfectants used in the medical area – Test method and requirements (phase 2, step 2)	Abbott Analytical	13C.079CB.PAL	No	No	Yes	Pal International Limited	6.7-09
[redacted]	2013	EN 14561, Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area – Test method and	Abbott Analytical	13C.079CVrMr.PAL	No	No	Yes	Pal International Limited	6.7-10

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		requirements (phase 2, step 2)							
[redacted]	2016	Quantitative carrier test for evaluation of fungicidal or yeasticidal activity for instruments used in the medical area BSEN 14562:2006	Microbiological Solutions Limited	J000181	No	No	Yes	Pal International Limited	6.7-11
[redacted]	2017	Chemical disinfectants and antiseptics — Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area BS EN 14563:2008	Microbiological Solutions Limited	J000181	No	No	Yes	Pal International Limited	6.7-12
[redacted]	2016	BS EN 13624:2013 Quantitative suspension test for the evaluation of bactericidal / fungal activity in the medical area	Microbiological Solutions Limited	J000181	No	No	Yes	Pal International Limited	6.7-13
[redacted]	2016	Quantitative non-	Microbiological	J000188	No	No	Yes	Pal	6.7-14

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		pourous surface test for the evaluation of bactericidal / fungal activity of chemical disinfectants	Solutions Limited					International Limited	
[redacted]	2016	Test Report: EN 14476 2013 + A1 2015 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area- Test method and requirements (Phase 2/Step 1)	BluTest Laboratories Ltd	N/A	Yes	No	Yes	Pal International Limited	6.7-15
[redacted]	2016	Test for the evaluation of bactericidal activity on non-porous surfaces with mechanical action in the medical area BSEN 16615:2015	Microbiological Solutions Limited	16/00872-2	No	No	Yes	[redacted]	6.7-16
[redacted]	2016	Test for the evaluation of bactericidal activity on non-porous surfaces with mechanical action in the medical area BSEN 16615:2015	Microbiological Solutions Limited	16/00872-1	No	No	Yes	[redacted]	6.7-17

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
[redacted]	2016	Test for the evaluation of bactericidal activity on non-porous surfaces with mechanical action in the medical area BSEN 16615:2015	Microbiological Solutions Limited	16/00872-1 RETEST	No	No	Yes	[redacted]	6.7-18
[redacted]	2016	Test for the evaluation of bactericidal activity on non-porous surfaces with mechanical action in the medical area BSEN 16615:2015	Microbiological Solutions Limited	16/00872-3	No	No	Yes	[redacted]	6.7-19
[redacted]	2016	Test for the evaluation of bactericidal activity on non-porous surfaces with mechanical action in the medical area BSEN 16615:2015	Microbiological Solutions Limited	16/00872-3 RETEST	No	No	Yes	[redacted]	6.7-20
[redacted]	2017	Investigation into the Effectiveness of FH55 When Tested in Accordance With: UKAS Accredited Method for BS EN 1276:2009 Chemical disinfectants and antiseptics – Quantitative suspension	Microbiology Dept Selden Research Limited	43	No	No	Yes	[redacted]	6.7-21

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas							
[redacted]	2016	Investigation into the Effectiveness of FH55 When Tested in Accordance With: Method for BS EN 13697:2015 Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas – Test method and requirements without mechanical action	Microbiology Dept Selden Research Limited	3	No	No	Yes	[redacted]	6.7-22
[redacted]	2017	Investigation into the Effectiveness of FH55 When Tested in Accordance With:	Microbiology Dept Selden Research Limited	4	No	No	Yes	[redacted]	6.7-23

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		Non-UKAS Accredited Method for BS EN 1650:2008 + A1:2013 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas							
[redacted]	2017	Investigation into the Effectiveness of FH55 When Tested in Accordance With: Non-UKAS Accredited Method for BS EN 13697:2015 Chemical disinfectants and antiseptics – Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and	Microbiology Dept Selden Research Limited	4	No	No	Yes	[redacted]	6.7-24

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/ No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	IUCLID Section No.
		institutional areas – Test method and requirements without mechanical action							
[redacted]	2014	Certificate of Analysis	Food & Drug Analytical Services Limited	8992	No	No	Yes	[redacted]	6.7-25
[redacted]	2014	Certificate of Analysis	Food & Drug Analytical Services Limited	8992 SBT170IW	No	No	Yes	[redacted]	6.7-26
[redacted]	2021	Isopropanol Disinfectant Wipes: Determination of Long-Term Storage Stability	Labcorp Early Development Laboratories Ltd.	BN36LV	Yes			PAL International Ltd.	

3.2 Output tables from exposure assessment tools

3.2.1 Human Health Exposure Output Tables

Scenario 1: Primary exposure: a technician performs routine disinfection of small surfaces e.g. equipment and work stations as part of their working procedures in industrial/manufacturing setting e.g. cleanroom

ConsExpo Web -	
Substance	
Name	propan-2-ol
Molecular weight	60 g/mol
K_{OW}	–
Product	
Name	
Weight fraction substance	62.9 %
Population	
Name	
Body weight	60 kg

Scenario Technician in cleanroom

Frequency	1 per day
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	30 minute
Product amount	5.89 g
Weight fraction substance	62.9 %
Room volume	55 m³
Ventilation rate	8 per hour
Inhalation rate	1.25 m³/hr
Application temperature	25 °C
Vapour pressure	5.78E+03 Pa
Molecular weight	60 g/mol
Mass transfer coefficient	20.1 m/hr
Release area mode	Increasing
Release area	1 m²
Application duration	2 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	Fixed fraction

Absorption fraction 100 %

Dermal

Exposure model n.a.
Absorption model n.a.

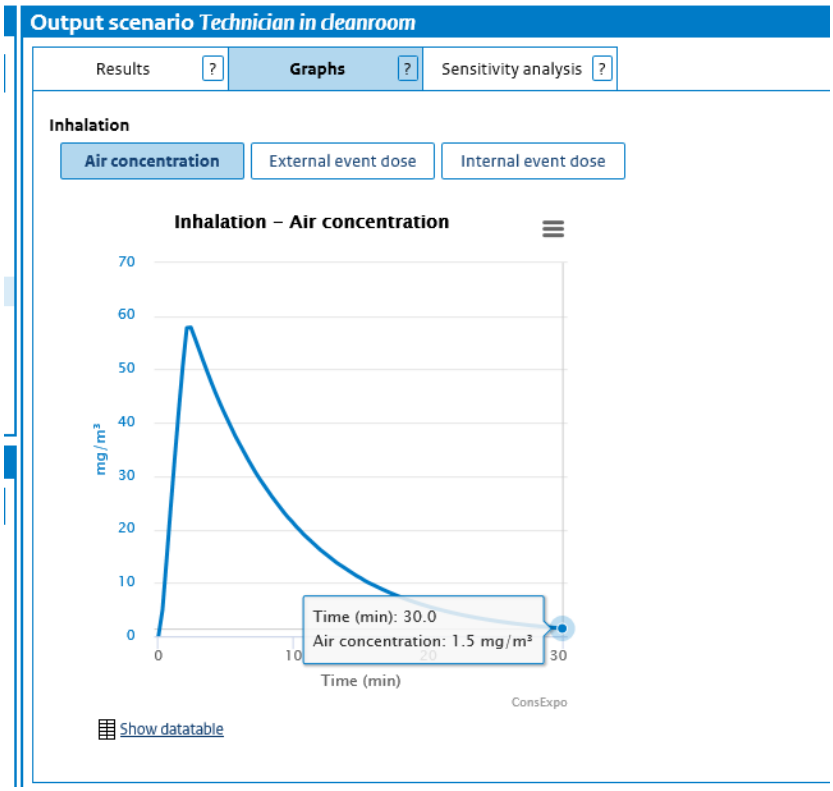
Oral

Exposure model n.a.
Absorption model n.a.

Results for scenario Technician in cleanroom

Inhalation

Mean event concentration 16.6 mg/m³


Output scenario Technician in cleanroom
Results
Graphs
Sensitivity analysis
Inhalation
Air concentration
External event dose
Internal event dose
Inhalation – Air concentration
70
60
50
40
30
20
10
0
mg/m³
0
10
30
Time (min)
Time (min): 30.0
Air concentration: 1.5 mg/m³
ConsExpo
Show datatable

Scenario 2 (tier 1): Primary exposure: healthcare professional in hospital disinfects small surfaces

ConsExpo Web	
Substance	
Name	propan-2-ol
Molecular weight	60 g/mol
K_{OW}	–
Product	
Name	
Weight fraction substance	62.9 %
Population	
Name	
Body weight	60 kg

Scenario Primary exposure in hospital

Frequency	1 per day
Description	Healthcare professional in a hospital

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	20 minute
Product amount	5.89 g
Weight fraction substance	62.9 %
Room volume	80 m³
Ventilation rate	1.5 per hour
Inhalation rate	1.25 m³/hr
Application temperature	25 °C
Vapour pressure	5.78E+03 Pa
Molecular weight	60 g/mol
Mass transfer coefficient	20.1 m/hr
Release area mode	Increasing
Release area	1 m²
Application duration	2 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	n.a.
Absorption model	n.a.

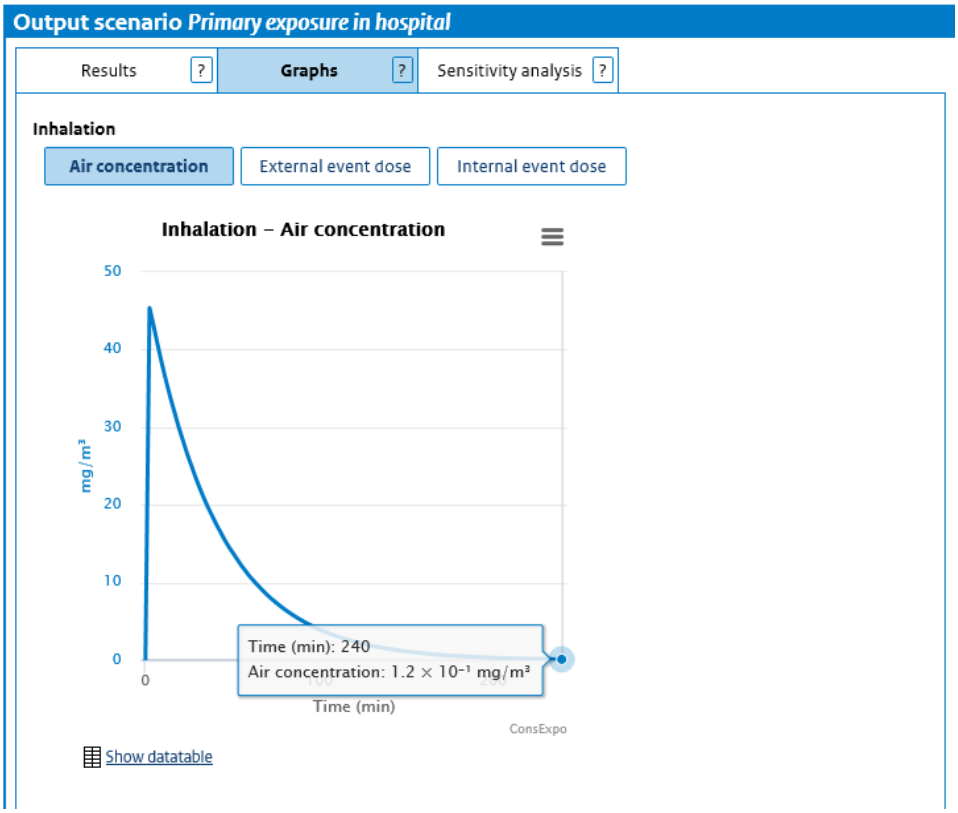
Oral

Exposure model n.a.
Absorption model n.a.

Results for scenario Primary exposure in hospital

Inhalation

Mean event concentration 3.5×10^{1} mg/m³



Scenario 2 (reverse reference calculation): Primary exposure: healthcare professional in hospital disinfects surfaces

ConsExpo Web	
Substance	
Name	propan-2-ol
Molecular weight	60 g/mol
K_{OW}	–
Product	
Name	
Weight fraction substance	62.9 %
Population	
Name	
Body weight	60 kg

Scenario Primary exposure in hospital

Frequency	1 per day
Description	Healthcare professional in a hospital

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	20 minute
Product amount	58.9 g
Weight fraction substance	62.9 %
Room volume	80 m³
Ventilation rate	1.5 per hour
Inhalation rate	1.25 m³/hr
Application temperature	25 °C
Vapour pressure	5.78E+03 Pa
Molecular weight	60 g/mol
Mass transfer coefficient	20.1 m/hr
Release area mode	Increasing
Release area	10 m²
Application duration	20 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	n.a.
Absorption model	n.a.

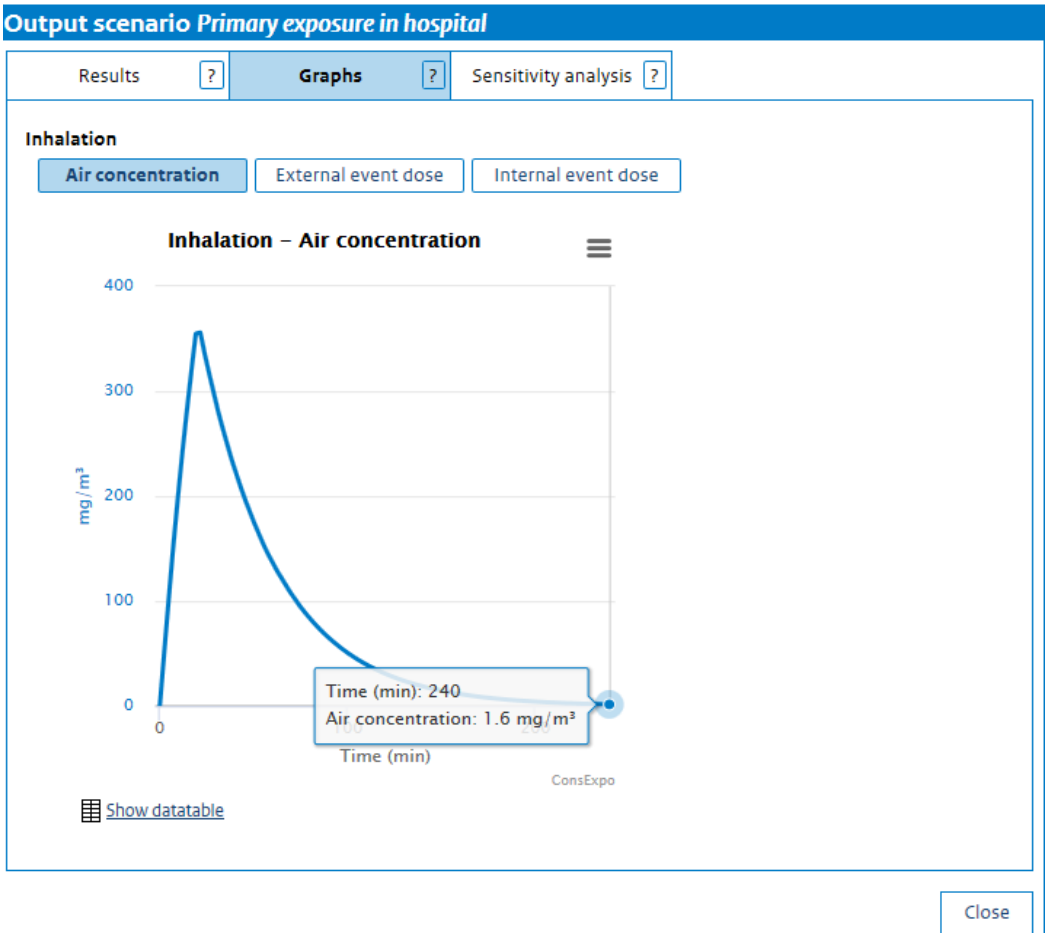
Results for scenario Primary exposure in hospital

Inhalation

Mean event concentration	2.0 × 10² mg/m³
Mean concentration on day of exposure	2.7 mg/m³
Year average concentration	2.7 mg/m³
External event dose	1.4 mg/kg bw
External dose on day of exposure	1.4 mg/kg bw
Internal event dose	1.4 mg/kg bw
Internal dose on day of exposure	1.4 mg/kg bw/day
Internal year average dose	1.4 mg/kg bw/day

Integrated

Internal event dose	1.4 mg/kg bw
Internal dose on day of exposure	1.4 mg/kg bw/day
Internal year average dose	1.4 mg/kg bw/day


Output scenario Primary exposure in hospital
Results
Graphs
Sensitivity analysis
Inhalation
Air concentration
External event dose
Internal event dose
Inhalation – Air concentration
400
300
200
100
0
mg/m³
0
Time (min)
Time (min): 240
Air concentration: 1.6 mg/m³
ConsExpo
Show datatable
Close

Scenario 4 (tier 1/reverse reference calculation 1): Secondary exposure: bystander inhalation of volatised residues during disinfection in healthcare environments e.g. hospital

ConsExpo Web	
Substance	
Name	propan-2-ol
Molecular weight	60 g/mol
K_{OW}	–
Product	
Name	
Weight fraction substance	62.9 %
Population	
Name	
Body weight	

Scenario Secondary exposure in hospital

Frequency 1 per day
Description toddler

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	4 hour
Product amount	5.89 g
Weight fraction substance	62.9 %
Room volume	80 m^3
Ventilation rate	1.5 per hour
Inhalation rate	8 m^3/day
Application temperature	25 °C
Vapour pressure	5.78E+03 Pa
Molecular weight	60 g/mol
Mass transfer coefficient	20.1 m/hr
Release area mode	Increasing
Release area	1 m^2
Application duration	2 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model n.a.
Absorption model n.a.

Oral

Exposure model n.a.
Absorption model n.a.

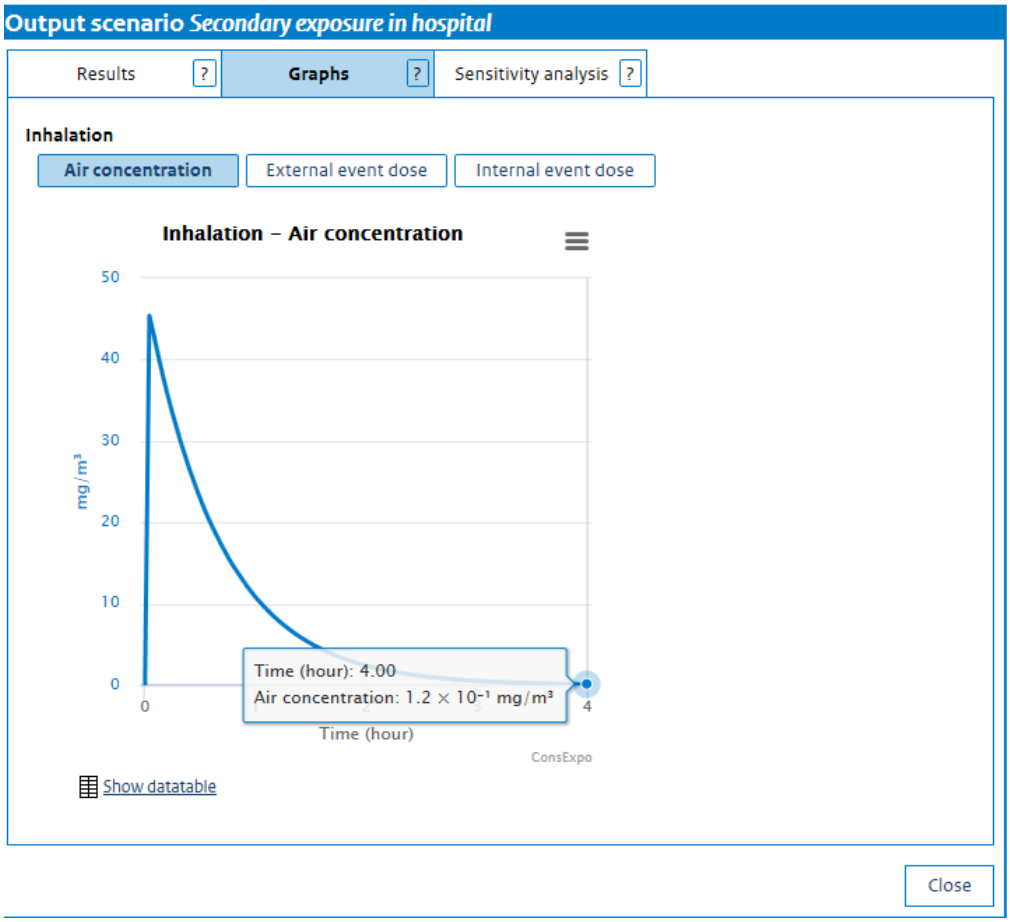
Results for scenario Secondary exposure in hospital

Inhalation

Mean event concentration	7.7 mg/m³
Mean concentration on day of exposure	1.3 mg/m³
Year average concentration	1.3 mg/m³
External event dose	1.7×10^{-1} mg/kg bw
External dose on day of exposure	1.7×10^{-1} mg/kg bw
Internal event dose	1.7×10^{-1} mg/kg bw
Internal dose on day of exposure	1.7×10^{-1} mg/kg bw/day
Internal year average dose	1.7×10^{-1} mg/kg bw/day

Integrated

Internal event dose	1.7×10^{-1} mg/kg bw
Internal dose on day of exposure	1.7×10^{-1} mg/kg bw/day
Internal year average dose	1.7×10^{-1} mg/kg bw/day


Output scenario Secondary exposure in hospital
Results
Graphs
Sensitivity analysis
Inhalation
Air concentration
External event dose
Internal event dose
Inhalation – Air concentration
50
40
30
20
10
0
mg/m³
0
4
Time (hour)
Time (hour): 4.00
Air concentration: 1.2 × 10⁻¹ mg/m³
ConsExpo
Show datatable
Close

Scenario 4 (reverse reference calculation 2): Secondary exposure: bystander inhalation of volatised residues during disinfection in healthcare environments e.g. hospital

ConsExpo Web	
Substance	
Name	propan-2-ol
Molecular weight	60 g/mol
K_{OW}	–
Product	
Name	
Weight fraction substance	62.9 %
Population	
Name	
Body weight	60 kg

Scenario Secondary exposure in hospital

Frequency	1 per day
Description	toddler

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	4 hour
Product amount	11.78 g
Weight fraction substance	62.9 %
Room volume	80 m³
Ventilation rate	1.5 per hour
Inhalation rate	8 m³/day
Application temperature	25 °C
Vapour pressure	5.78E+03 Pa
Molecular weight	60 g/mol
Mass transfer coefficient	20.1 m/hr
Release area mode	Increasing
Release area	2 m²
Application duration	4 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model n.a.
Absorption model n.a.

Oral

Exposure model n.a.
Absorption model n.a.

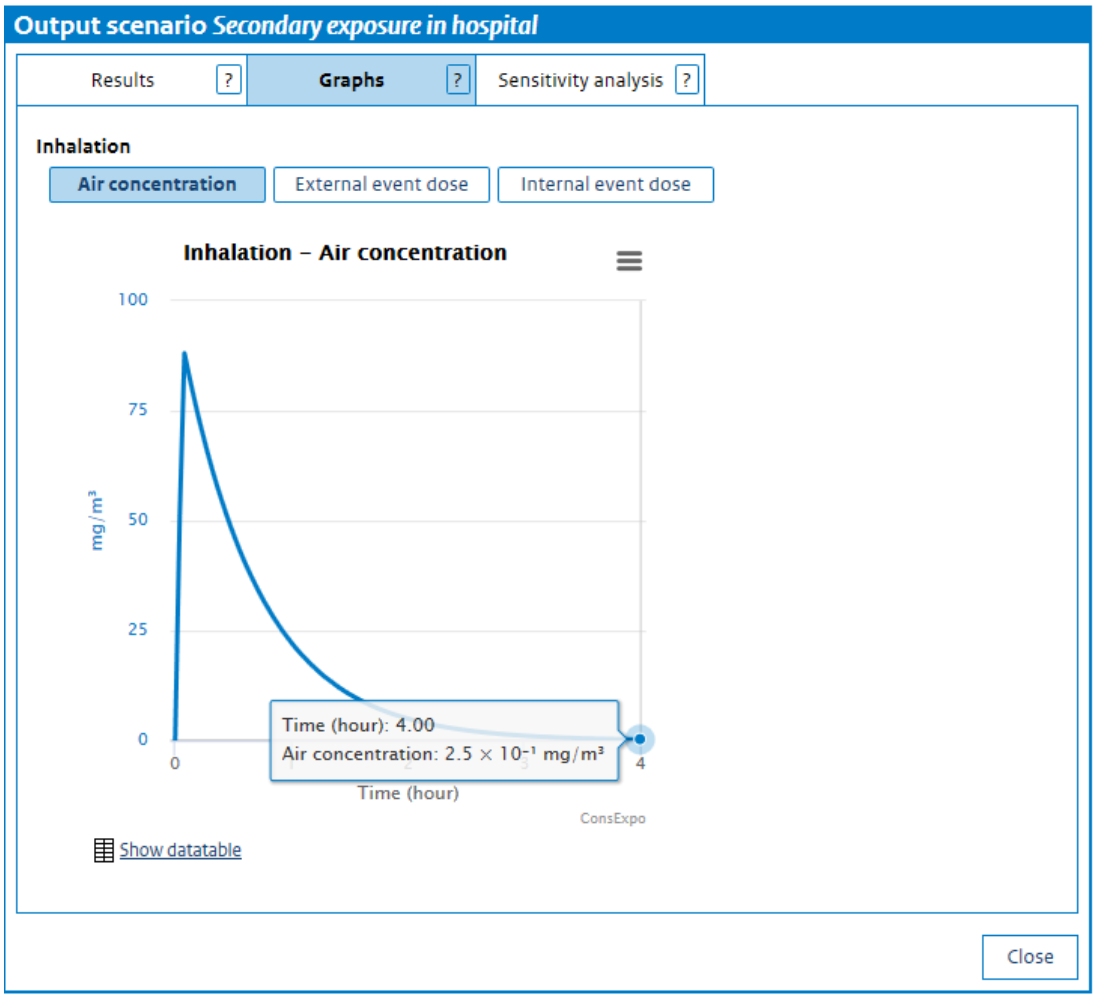
Results for scenario Secondary exposure in hospital

Inhalation

Mean event concentration	1.5×10^{1} mg/m³
Mean concentration on day of exposure	2.6 mg/m³
Year average concentration	2.6 mg/m³
External event dose	3.4×10^{-1} mg/kg bw
External dose on day of exposure	3.4×10^{-1} mg/kg bw
Internal event dose	3.4×10^{-1} mg/kg bw
Internal dose on day of exposure	3.4×10^{-1} mg/kg bw/day
Internal year average dose	3.4×10^{-1} mg/kg bw/day

Integrated

Internal event dose	3.4×10^{-1} mg/kg bw
Internal dose on day of exposure	3.4×10^{-1} mg/kg bw/day
Internal year average dose	3.4×10^{-1} mg/kg bw/day


Output scenario Secondary exposure in hospital
Results
Graphs
Sensitivity analysis
Inhalation
Air concentration
External event dose
Internal event dose
Inhalation – Air concentration
100
75
50
25
0
mg/m³
0
4
Time (hour)
Time (hour): 4.00
Air concentration: 2.5 × 10⁻¹ mg/m³
ConsExpo
Show datatable
Close

Scenario 5: Primary exposure: professional user disinfecting surfaces in professional food preparation settings e.g. canteen/kitchen setting

ConsExpo Web -	
Substance	
Name	propan-2-ol
Molecular weight	60 g/mol
K_{OW}	–
Product	
Name	
Weight fraction substance	62.9 %
Population	
Name	
Body weight	60 kg

Scenario Primary exposure in kitchen

Frequency	1 per day
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	2 hour
Product amount	5.89 g
Weight fraction substance	62.9 %
Room volume	25 m³
Ventilation rate	15 per hour
Inhalation rate	1.25 m³/hr
Application temperature	25 °C
Vapour pressure	5.78E+03 Pa
Molecular weight	60 g/mol
Mass transfer coefficient	20.1 m/hr
Release area mode	Increasing
Release area	1 m²
Application duration	2 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	n.a.
Absorption model	n.a.

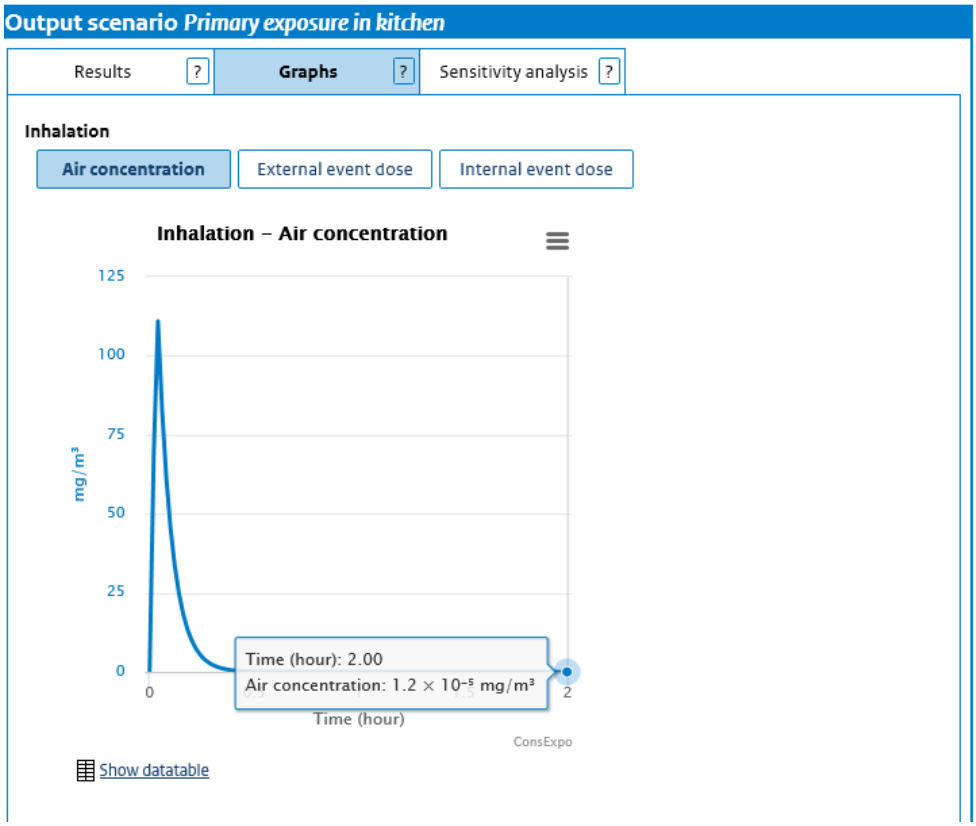
Oral

Exposure model n.a.
Absorption model n.a.

Results for scenario Primary exposure in kitchen

Inhalation

Mean event concentration 5.0 mg/m³



Scenario 6: Primary exposure: professional user disinfecting surfaces in professional food preparation settings e.g. food processing setting

ConsExpo Web -	
Substance	
Name	propan-2-ol
Molecular weight	60 g/mol
K_{OW}	–
Product	
Name	
Weight fraction substance	62.9 %
Population	
Name	
Body weight	60 kg

Scenario Food processing setting

Frequency	1 per day
Description	

Inhalation

Exposure model	Exposure to vapour - Evaporation
Exposure duration	120 minute
Product amount	29.4 g
Weight fraction substance	62.9 %
Room volume	300 m³
Ventilation rate	20 per hour
Inhalation rate	1.25 m³/hr
Application temperature	25 °C
Vapour pressure	5.78E+03 Pa
Molecular weight	60 g/mol
Mass transfer coefficient	20.1 m/hr
Release area mode	Increasing
Release area	4.6 m²
Application duration	5 minute
Product in pure form	No
Molecular weight matrix	18 g/mol
Absorption model	Fixed fraction
Absorption fraction	100 %

Dermal

Exposure model	n.a.
Absorption model	n.a.

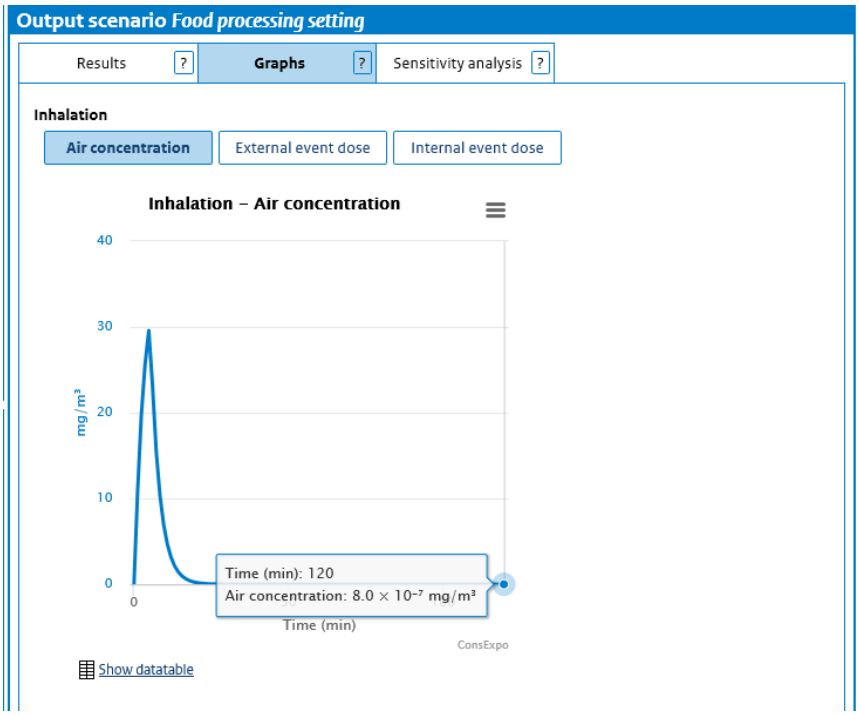
Oral

Exposure model n.a.
Absorption model n.a.

Results for scenario Food processing setting

Inhalation

Mean event concentration 1.5 mg/m³



3.2.2 Environmental Exposure Output Tables

PEC$_{air}$

Calculation of the emission to air has been made following the calculations laid out in the ECHA Guidance on ERA as follows.

$$Estp_{air} = Fstp_{air} \cdot Elocal_{water} \quad (35)$$

$$Clocal_{air} = \max\left(Elocal_{air}, Estp_{air} \right) \cdot Cstd_{air} \quad (42)$$

Where:
Fstp$_{air}$ = 0.003
Cstd$_{air}$ = 2.78E-04 mg/m^3 (default value)

Following the ECHA guidance on ERA the local concentration in the air has been calculated based on the maximum value of Estp$_{air}$ or Elocal$_{air}$.

The fraction of active associated with aerosol particles (Fass$_{aer}$) was then calculated following the equations in the ECHA guidance on ERA.

Using as a default CON$_{junge}$ x SURF$_{aer}$ = 10^{-4} Pa and a vapour pressure for propan-2-ol of 2302 Pa (corrected to 12°C).

$$Fass_{aer} = \frac{CONjunge \cdot SURF_{aer}}{VP + CONjunge \cdot SURF_{aer}} \quad (19)$$

Hence Fass$_{aer}$ = 1.73E-08

The deposition flux can then be calculated summing the emission to air from the STP and direct emission from the indoor application using equations 43 and 44.

$$DEPtotal = \left(Elocal_{air} + Estp_{air} \right) \cdot \left(Fass_{aer} \cdot DEPstd_{aer} + (1 - Fass_{aer}) \cdot DEPstd_{gas} \right) \quad (43)$$

$$DEPtotal_{ann} = DEPtotal \cdot \frac{Temission}{365} \quad (44)$$

If it is assumed that emissions take place throughout the year then T$_{emission}$ is 365 and the annual average total deposition flux is the same as the total deposition per emission episode.

Where:
DEPstd $_{air}$ = 1.00E-002
DEPstd $_{gas}$ = 4.00E-04

Scenario	Local emission rate to water [Elocal$_{water}$ kg/d]	Local indirect emission to air from STP [ESTP$_{air}$ kg/d]	Local emission to air [Elocal$_{air}$ kg/d]	Local concentration in air during emission episode [Clocal$_{air}$ kg/d]	DEPtotal (DEPtotal$_{ann}$)
PT 2					
Scenario 1	0.833	2.50E-03	7.49	2.08E-03	3.00E-03
Scenario 2	1.04E-02	3.12E-05	0.094	2.60E-05	3.75E-05
PT 4					
Scenario 1	6.19E-02*	1.55E-04	0.557	1.55E-04	2.23E-04
Scenario 2	2.08E-02	5.20E-05	0.187	5.20E-05	7.49E-05

*From back calculation from Clocal$_{inf}$ of 0.031 mg/ l

The aerial deposition flux per kg of soil, D$_{air}$ is then derived from the total deposition flux (DEPtotal$_{ann}$) and is used in the calculation of PEC$_{soil}$.

$$D_{air} = \frac{DEPtotal_{ann}}{DEPTH_{soil} \cdot RHO_{soil}} \quad (52)$$

Scenario	Ecosystem and arable crops Aerial deposition flux D$_{air}$	Grassland Aerial deposition flux D$_{air}$
PT 2		
Scenario 1	8.82E-06	1.76E-05
Scenario 2	1.10E-07	2.20E-07
PT 4		
Scenario 1	6.56E-07	1.31E-06
Scenario 2	2.20E-07	4.41E-07

Calculation of PEC$_{STP}$ and PEC$_{surface_water}$ (and PEC$_{sediment}$)

Indoor scenarios

Taking the $Elocal_{water}$ values previously calculated, the aquatic PEC values can be calculated using the following equations and default values taken from the ECHA guidance on ERA.

$$Clocal_{\inf} = \frac{Elocal_{water} * 10^{6}}{EFFLUENT_{stp}} \quad (32)$$

$$Clocal_{eff} = Clocal_{inf} \cdot Fstp_{water} \quad (33)$$

$$Clocal_{water} = \frac{Clocal_{eff}}{(1 + Kp_{susp} * SUSP_{water} * 10^{-6}) * DILUTION} \quad (45)$$

As this product is intended for daily use, the $Clocal_{eff}$ will be used to assess the risk to microorganisms at STP.

Calculation of PEC_{stp} for Indoor application

Parameters	**Nomenclature**	**Value**	**Unit**	**Origin**
Effluent discharge rate of STP	$EFFLUENT_{stp}$	2000000	l	Default
Conc in untreated wastewater PEC_{STP}	**$Clocal_{eff}$**		**mg/l**	**Output**
PT 2				
Scenario 1		5.20E-02	mg/l	Output
Scenario 2		6.50E-04	mg/l	Output
PT 4				
Scenario 1		3.87E-03	mg/l	Output
Scenario 2		1.30E-03	mg/l	Output

Calculation of $PEC_{surface\ water}$ for Indoor application

Parameters	Nomenclature	Value	Unit	Origin
Fraction directed to water by STP (Simpletreat)	$Fstp_{water}$	0.125	[-]	Input
Weight fraction organic carbon in suspended solids	Foc_{susp}	0.1		Default
Partition coefficient organic carbon - water	Koc	3.30	l/kg	Input
Partition coefficient solid – water in suspended matter	Kp_{susp}	0.330		Default
Concentration of suspended matter	$SUSP_{water}$	15	mg/l	Default
	DILUTION	10		Default
$PEC_{surface\ water}$	**$Clocal_{water}$**		**mg/l**	**Output**
PT 2				
Scenario 1		5.20E-03	mg/l	Output
Scenario 2		6.50E-05	mg/l	Output
PT 4				
Scenario 1		3.87E-04	mg/l	Output
Scenario 1 (on site STP to water)		3.43E-03	mg/l	Output
Scenario 2		1.30E-04	mg/l	Output

Calculation of PEC_{soil} and $PEC_{groundwater}$

Calculation of Soil removal rate constants

Given that propan-2-ol is a volatile substance, volatilisation as an additional route of removal from soil was considered appropriate when calculating the PEC_{soil}. Following the ECHA guidance on risk assessment, Volume IV Part B- the total rate constant for removal is made up of several parts:

- Biodegradation rate constant (30 days based on propan-2-ol ready biodegradability) $kbio_{soil}$
- Volatilisation of substance from soil k_{volat}
- Leaching to deeper soil layer k_{leach}

As the soil concentration will be used to calculate pore water concentrations the third of the above rate constants (leaching) will not be considered in the following calculations. The overall rate constant is given by

$$k = k_{volat} + k_{leach} + kbio_{soil} \quad (56)$$

The diffusive transfer from soil to air is estimated using the classical two film resistance model.

$$\frac{1}{K_{volat\ i}} = \left(\frac{1}{Kasl_{air} * K_{air-water}/K_{soil-water}} + \frac{1}{Kasl_{soilair}}\right)$$

Where:

$Kasl_{air}$ = partial mass transfer coeff. at air-side of the air soil-interface [m/d^{-1}] [m/d^{-1}] (**90.72** based on 1.05E-03 m s^{-1} x 60 x 60 x 24 a correction of Vol IV Part B+C of 2017 from the TGD of 2003)

$Kasl_{soilair}$ = partial mass transfer coeff. at soilair-side of the air soil-interface [m/d^{-1}] (calculated value see footnote at end of emissions)

$K_{air-water}$ = air-water partitioning coefficient [m^3/m^{-3}] (1.62E-04) (see calculation below)

$K_{soil-water}$ = soil-water partitioning coefficient [m^3/m^{-3}] (0.299) (see calculation below)

$Depth_i$ = mixing depth of soil [m] (0.1 (grassland); 0.2 (agricultural soil))

$K_{volat\ i}$ = rate constant for volatilisation from soil I [d^{-1}]

$$K_{air-water} = \frac{HENRY}{R * TEMP}$$

Where:

HENRY = Henry's law constant [Pa/m^3/mol^{-1}] (0.8 at 25°C corrected to 0.3 83 at 12°C using equation 25 Volume IV Parts B + C 2017 as HENRY was derived experimentally)

R = Gas constant [Pa/m^3/mol^{-1}k^{-1}] (8.314)

TEMP = temperature at the air-water interface [k] (285)

$K_{air-water}$ = air-water partitioning coefficient [m^3/m^{-3}] (7.02E-05)

$$K_{soil-water} = Fair_{comp} * K_{air-water} + Fwater_{comp} + Fsolid_{comp} * \frac{Kp_{comp}}{1000} * RHOsolid$$

Where:

$Fair_{comp}$ = fraction air in soil compartment [m^3/m^{-3}] (0.2)

$Fwater_{comp}$ = fraction water in soil compartment [m^3/m^{-3}] (0.2)

$Fsolid_{comp}$ = fraction solids in soil compartment [m^3/m^{-3}] (0.6)

Kp_{comp} = solids-water part. coeff. in soil compartment [l/kg] (0.066) (Koc x Foc_{soil}; 3.3 x 0.02)

RHOsolid = density of the solid phase [kg/m^{-3}] (2500)

$K_{soil-water}$ = soil-water partitioning coefficient [m^3/m^{-3}] (0.29903)

As the mixing depth for soil varies between the different soil types, two values for k_{volat} can be calculated.

Ecosystem and arable soil k_{volat} = 1.19E-02 d^{-1}
Grassland k_{volat} = 2.38E-02 d^{-1}

When combined with the soil rate constant derived from the default value of 30 days the following values for k are given.

Ecosystem and arable soil k = 4.30E-02 d^{-1}
Grassland k = 6.29E-02 d^{-1}

These values are then used in equation 59 to calculate the deposition to soil following 10 years of use.

$$Cdep_{soil\,10}(0) = \frac{D_{air}}{k} - \frac{D_{air}}{k} \cdot e^{-365 \cdot 10 \cdot k} \quad (59)$$

Parameters	Ecosystem and arable crop $Cdep_{soil10}$ (0)	Grassland $Cdep_{soil10}$ (0)	Unit	Origin
PT 2				
Scenario 1	2.05E-04	2.80E-04	mg/kg	Output
Scenario 2	2.56E-06	3.50E-03	mg/kg	Output
PT 4				
Scenario 1	1.52E-05	2.08E-05	mg/kg	Output
Scenario 2	5.12E-06	7.00E-06	mg/kg	Output

As only a negligible amount of a.s. reaches the sludge via STP the contribution from $Csludge_{soil\ 10}$ (0) can be ignored and the concentration of propan-2-ol in soil can be assumed to come only via deposition.

$$C_{soil\,10}(0) = Cdep_{soil\,10}(0) + Csludge_{soil\,10}(0) \quad (63)$$

This initial soil concentration can then be used in equation 54 and 55 to calculate the average concentration in soil over 180 or 30 days.

$$Clocal_{soil} = \frac{D_{air}}{k} + \frac{1}{kT}\left[C_{soil}(0) - \frac{D_{air}}{k} \right] \cdot \left[1 - e^{-kT}\right] \quad (55)$$

Parameters	Ecosystem (30 days)- PEC_{soil}	Arable (180 days)	Grassland (180 days)	Unit	Origin
PT 2					
Scenario 1	2.05E-04	2.05E-04	2.80E-04	mg/kg	Output
Scenario 2	2.56E-06	2.56E-06	3.50E-03	mg/kg	Output
PT 4					
Scenario 1	1.52E-05	1.52E-05	2.08E-05	mg/kg	Output
Scenario 2	5.12E-06	5.12E-06	7.00E-06	mg/kg	Output

The PEC_{soil} value taken from the arable PEC after 180 days has then been used to calculate the porewater concentration using the following equations from the ECHA guidance on ERA.

Where:

$$K_{soil\text{-}water} = Fair_{soil} \times K_{air\text{-}water} + Fwater_{soil} + Fsolid_{soil} \times (Kp_{soil}/1000) \times RHO_{solid} \quad (24)$$

and

$$PEClocal_{soil,porewater} = (PEClocal_{soil} \times RHO_{soil}) / (K_{soil\text{-}water} \times 1000) \quad (67)$$

Tier 1 Calculation of concentration in Porewater

Parameters	Nomenclature	Value	Unit	Origin
Fraction of air in soil	$Fair_{soil}$	0.2	m_{air}^3/m_{soil}^3	Default
Fraction of water in soil	$Fwater_{soil}$	0.2	m_{water}^3/m_{soil}^3	Default
Fraction of solids in soil	$Fsolid_{soil}$	0.6	m_{solid}^3/m_{soil}^3	Default
Solids - water partitioning coefficient in soil	Kp_{soil}	0.066	l/kg	Calculated Foc_{soil} x Koc
Density of the solid phase	RHO_{solid}	2500	kg_{solid}/m_{solid}^3	Default
	Foc_{soil}	0.02	kg_{oc}/kg_{solid}	Default
Soil- water partitioning coefficient	$K_{soil\text{-}water}$	0.3		Output
PT 2				
Scenario 1	$PEClocal_{soil,\ porewater}$	1.17E-03	mg/l	Output
Scenario 2	$PEClocal_{soil,\ porewater}$	1.46E-05	mg/l	Output
PT 4				
Scenario 1	$PEClocal_{soil,\ porewater}$	8.66E-05	mg/l	Output
Scenario 2	$PEClocal_{soil,\ porewater}$	2.91E-05	mg/l	Output

Calculation of $kasl_{soil}$

Calculation of $kasl_{soil}$

Parameter		Symbol	Unit	Value	Comment	Equation
Molecular weight		M	$kg_c\ mol^{-1}$	6.01E-02	Input value	
Molecular diffusivity of the substance in the gas phase		DIFFgas	$m^2\ d^{-1}$	1.22E+00	OUTPUT	equation 79
Molecular diffusivity of the substance in the water phase		DIFFwater	$m^2\ d^{-1}$	1.26E-04	OUTPUT	equation 80
Volume fraction of water in the soil compartment		$Fwater_{soil}$	$m_{water}^3.m_{soil}^{-3}$	0.20	Table 3	
Volume fraction of air in the soil compartment		$Fair_{soil}$	$m_{air}^3.m_{soil}^{-3}$	0.20	Table 3	
Air-water partitioning coefficient		$K_{air\text{-}water}$	(-)	1.62E-04	OUTPUT	Equation 24
Volume fraction of solids in the soil compartment		$Fsolid_{soil}$	$m_{solid}^2.m_{soil}^{-3}$	0.60	Table 3	
Partition coefficient solid-water in soil		$K\rho_{soil}$	$L\ kg^{-1}$	6.60E-02	OUTPUT	Equation 26
Density of the solid phase		RHOsolid	$kg\ m^{-3}$	2500	Table 3	
Mass fraction of the substance in the water phase of the soil		FRw.soil	(-)	0.669	OUTPUT	Equation 76
Mass fraction of the substance in the solid phase of the soil		FRs.soil	(-)	0.331	OUTPUT	Equation 77
Mass fraction of the substance in the air phase of soil		FRa.soil	(-)	1.08E-04	OUTPUT	Equation 78
Average daily rate of wet precipitation		RAINRATE	$m\ d^{-1}$	1.92E-03	BPR guidance value	
Fraction of precipitationthat penetrates into the soil		$Finf_{soil}$	(-)	2.50E-01	BPR guidance value	
Rate of advective downward transport of soil particles		SOLIDadv.soil	$m\ d^{-1}$	5.48E-07	BPR guidance value	
Solid phase diffusion coefficient in the soil compartment		SOLIDdiff.soil	$m^2\ d^{-1}$	5.50E-07	BPR guidance value	
Effective advection (with penetrating porewater)		$Veff_{soil}$	$m\ d^{-1}$	1.61E-03	OUTPUT	Equation 74
Effective diffusion coefficient		$Deff_{soil}$	$m^2 d^{-1}$	9.68E-05	OUTPUT	Equation 75
Rate constant for degradation in bulk soil		$kdeg_{soil}$	d^{-1}	0.0231	INPUT	
Substance-dependent penetration depth		dp	m	1.08E-01	OUTPUT	Equation 73
Partial mass-transfer coefficient at soil side at the air-soil interface		$kasl_{soil}$	$m\ d^{-1}$	2.50E-03	OUTPUT	Equation 72
Partial mass transfer coefficient at air side of the air-soil interface		$kasl_{air}$	$m\ s^{-1}$	1.05E-03	BPR guidance value	
Partial mass transfer coefficient at air side of the air-soil interface		$kasl_{air}$	$m\ d^{-1}$	90.72	BPR guidance value	
Mixing depth of soil *i*	soil	$DEPTH_{soil}$	m	0.20	Table 9	
	agric. soil	$DEPTH_{soil}$	m	0.20	Table 9	
	grassland	$DEPTH_{soil}$	m	0.10	Table 9	

3.3 New information on the active substance

No new information on the active substance has been provided in support of this biocidal product family.

3.4 Residue behaviour

No residues in food or feed are expected to arise from the use of the products of the family (PT 4) due to the high vapour pressure of the active substance (5780 Pa at 25°C).

3.5 Summaries of the efficacy studies

Please see section 3.1 above and the efficacy section 2.2.5 of this PAR which summarises these data.

3.6 Confidential annex

Please refer to separate document

3.7 Other