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

Evaluation of active substances

Assessment Report

Propan-1-ol

Product-types 1, 2, 4

- Hyman hygiene biocidal products
- Disinfectants and algaecides not intended for direct application to humans or animals
- Food and feed area disinfectants

June 2017

RMS: DE

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance propan-1-ol as product-type 1 (human hygiene biocidal products), product-type 2 (disinfectants and algaecides not intended for direct application to humans or animals) and product-type 4 (food and feed area disinfectants) carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Propan-1-ol (CAS no. 71-23-8) was notified as an existing active substance, by “Task Force 1-Propanol”, hereafter referred to as the applicant, in product-types 1, 2 and 4.

The Task Force “1-Propanol” consists of:
BODE Chemie GmbH
B. Braun Melsungen AG
Ecolab Deutschland GmbH
Lysoform Dr. Hans Rosemann GmbH
Schuelke & Mayr GmbH
Diversey Europe Operations BV, part of SealedAir

Commission Regulation (EC) No 1062/2014 of 4 August 2014[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

On 31 July 2007, the German Competent Authority received a dossier from Task Force 1-Propanol. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 29 January 2008.

On 18 July 2016, the evaluating Competent Authority submitted to the Agency (ECHA) and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the the "Agency” (ECHA). Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings and the competent authority report was amended accordingly.

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of propan-1-ol for product-types 1, 2 and 4, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency website shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

[1] COMMISSION DELEGATED REGULATION (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council. OJ L 294, 10.10.2014, p. 1

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

CAS-No.	71-23-8
EINECS-No.	200-746-9 (EINECS)
Other No. (CIPAC, ELINCS)	Index No: 603-003-00-0
IUPAC Name	Propan-1-ol
CAS Name	1-Propanol
Common name, synonyma	1-Hydroxypropane 1-propanol n-propanol n-propyl alcohol ethyl carbinol
Molecular formula	C_3H_8O
Structural formula	CH_3-CH_2-CH_2-OH
Molecular weight (g/mol)	60.09 g/mol
Typical concentration or concentration range (% w/w)	Min. 99.5 Max. 100

Propan-1-ol is a colourless liquid and has a mild alcohol like odour. It is indefinitely miscible with water (1000 g/L at 25 °C) and miscible with many organic liquids. Propan-1-ol has a relatively high vapour pressure of 27.26 hPa at 25 °C. With its low measured Henry's law constant of 0.76 Pa • m^3/mol at 25 °C, the substance volatilizes only slowly from aqueous solutions under environmental conditions according the scheme of Thomas (1990). Furthermore, propan-1-ol has a low log P_{OW} from 0.25 and no surface tension properties. The surface tension is 67.1 mN/m for a concentration of 1 g/L at 25 °C. The flash-point is 23.5 °C for propan-1-ol (99.9 %.) and the autoignition temperature is 385 °C. Due to structural reasons explosive and oxidising properties can be excluded for propan-1-ol. Based on experience in production and handling it can be concluded that propan-1-ol is not pyrophoric and does not evolve any flammable gases in contact with water or humid air.

Suitable analytical methods for propan-1-ol are available. These methods showed sufficient specificity, accuracy and sensitivity.
An acceptable GC method according Pharmacopoea Europaea (Ph. Eur. Monograph 1/2005: 2036) is available for the determination of the purity of propan-1-ol.

2.1.2. Intended Uses and Efficacy

Propan-1-ol is employed as a broad-spectrum microbicide for the disinfection of skin (PT 1, professional and non-professional use), disinfection of surfaces, inanimate objects and material and equipment in private, public health and industrial areas (PT 2) and disinfection of surfaces in canteens or kitchens (professional and non-professional use) and industrial food processing areas (professional use).

The intended use concentration as described by the applicant is given as 70 % propan-1-ol for all PTs. However, in case of PT 1 a concern was determined regarding exposure of professionals for 70 % propan-1-ol. Consequently, basic efficacy had to be shown for 60 % propan-1-ol for this use.

The quantitative suspension tests supporting the efficacy of the accompanying product demonstrate that propan-1-ol has a sufficient level of efficacy against the target organism(s) bacteria (including *Mycobacterium terrae* but excluding bacterial spores), yeast and some non-enveloped viruses (feline calicivirus, bovine rota virus) at a concentration of or below 60 %. Sufficient efficacy against moulds was shown at a concentration of 80 % propan-1-ol. Basis

efficacy as a hand disinfectant was shown for 60 % (against microbial floar on hands) and 70 % (against feline calicivirus) propan-1-ol.

The following studies were performed:

- Effectiveness of 30 % propan-1-ol against three gram-positive bacterial species including a mycobacterium (Staphylococcus aureus, Enterococcus faecium, Mycobacterium terrae), two gram-negative bacterial species (Pseudomonas aeruginosa, Proteus mirabilis) and one yeast (Candida albicans) was demonstrated (viability reduction ≥ 10^5). Against Aspergillus niger conidia, propan-1-ol was only effective at a concentration of 80 % and an exposure time of 5 min thereby achieving almost a log 5 reduction (method: European Suspension Test, Test methods for the antimicrobial activity of disinfectants in food hygiene).
- At a concentration of 60 %, propan-1-ol was sufficiently effective (RF ≥ 5) against Methicillin-resistent and –sensitive strains of Staphylococcus aureus at ≥ 30 s exposure time (method: DGHM guideline test procedure).
- At a concentration of 50 and 70 % propan-1-ol was effective against feline calicivirus at ≥ 0.5 min exposure time (method: Guidelines of the German Federal Health Office and the German Association for the Control of Virus Diseases for testing the effectiveness of chemical disinfectants against viruses).
- At a concentration of 40 % propan-1-ol was effective against bovine rota virus at an exposure time of 1 min (RF ≥ 4) (method: no Guideline, laboratory method).
- Propan-1-ol was effectively removing the resident microbial flora present on the finger tips at the concentration of 60 % and at an exposure time of 3 min proving basic effectiveness as a hand disinfectant (method: prEN 12791).
- Furthermore, in an in vivo experiment, a log10 reduction of 3.58 of feline calicivirus was observed for 70 % propan-1-ol after an exposure time of 30 s on fingertips (method: ASTM E-1838-96).

The studies performed are regarded as sufficient at the approval stage, even though the studies performed are not suitable to demonstrate the complete label claim bactericidal, fungicidal and virucidal. Efficacy shall be reviewed in accordance with the relevant guidance documents in the framework of active substance renewal and relevant data shall be provided in the scope of product authorisation.

Mode of action

Propan-1-ol exhibits an unspecific mechanism of effect. It affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm's proteins. It similarly interacts with corresponding viral structures. This process (referred to as denaturation) and the enzymes' coagulation leads to a loss of cellular activity resulting in the cell's death.

Occurrence of resistance

Due to the unspecific mode of action of 1-propanol, the development of resistance is not expected and not reported. A natural resistance against sporulated bacteria is known where 1-propanol in ineffective at any concentration. Likewise, 1-propanol is more effective against enveloped viruses compared to non-enveloped viruses. This is mainly due to the second layer of the enveloped viruses, which can be easily destroyed by alcoholic solutions leading to inactivation of the virus. The non-enveloped viruses have one protein-layer (capsid), which shows a pronounced natural resistance against chemical and physical disinfection methods.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Propan-1-ol (CAS-No. 71-23-8) is in Annex VI of Regulation (EC) No 1272/2008 and its classification and labelling is as follows:

Table 2-1 Current classification of propan-1-ol based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Flam. Liq. 2 Eye Dam. 1 STOT SE 3	
Hazard statements	H225 H318 H336	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness.

Remark:
The content of this table is based on table 3.2 of Annex VI of Regulation (EC) No 1272/2008. The flash-point of 23.5 °C was corrected for commercial propan-1-ol to 22 °C because of iso-propanol which is usually present as an impurity. Therfore, current classification is Flam. Liq. 2.

Table 2-2 Current labelling of propan-1-ol based on Regulation (EC) No 1272/2008

	Classification	Wording
Pictograms	GHS02 GHS05 GHS07	
Signal Word	Danger	
Hazard statements	H225 H318 H336	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness.
Suppl. Hazard statements	-	-
Precautionary statements	-	-

Remark:
The content of this table is based on table 3.1 of Annex VI of Regulation (EC) No 1272/2008. In accordance with the entry there Precautionary statements are not listed here either.

Table 2-3 Proposed classification of propan-1-ol based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Flam. Liq. 2 Eye Dam. 1 STOT SE 3	
Hazard statements	H225 H318 H336 EUH066	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.

Remark:
In addition to current classification/labelling, EUH066 is proposed, based on local skin effects and reactions that have been described for human individuals exposed to formulations

containing propan-1-ol or to propan-1-ol dilutions.

Table 2-4 Proposed labelling of propan-1-ol based on Regulation (EC) No 1272/2008

	Classification	Wording
Pictograms	GHS02 GHS05 GHS07	
Signal Word	Danger	
Hazard statements	H225 H318 H336 EUH066	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Suppl. Hazard statements	-	-
Precautionary statements	-	-

Remark:
Current labelling is based on table 3.1 of Annex VI of Regulation (EC) No 1272/2008. In accordance with the entry there Precautionary statements are not listed here either. In addition to current labelling according to table 3.1 of Annex VI of Regulation (EC) No 1272/2008, EUH066 (Repeated exposure may cause skin dryness or cracking) is proposed by the eCA, based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-1-ol or to propan-1-ol dilutions.

Classification and Labelling of model formulation

As the biocidal product contains 70 % propan-1-ol, it is suggested to classify and label it in almost the same way as the active substance.

Table 2-5 Proposed classification of model formulation based on Regulation (EC) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	Flam. Liq. 3 Eye Dam. 1 STOT SE 3	
Hazard statements	H226 H318 H336 EUH066	Flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.

Remark:
No environmental classification of the model formulation is required.

Table 2-6 Proposed labelling of model formulation based on Regulation (EC) No 1272/2008

	Classification	Wording
Pictograms	GHS02 GHS05 GHS07	
Signal Word	Danger	

Hazard statements	H226 H318 H336 EUH066	Flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.
Suppl. Hazard statements	-	-
Precautionary statements	(P102) P210 P233 P261 P271 P280 P304 + P340 P305 + P351 + P338 P312 P403 + P233 P501	(Keep out of reach of children.) Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Avoid breathing vapours/spray. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor / physician if you feel unwell. Store in a well-ventilated place. Keep container tightly closed. Dispose of contents/container to …

Remark:
No labelling according to environmental classification of the model formulation is required. Based on the given hazard statements the number of the precautionary statements recommended in Annex VI of the Regulation (EC) No 1272/2008 is quite big and could only partly be reduced , so to lose no essential information.
Labelling of the biocidal product includes P280 (Wear eye protection/face protection.).

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification and effects assessment

Valid toxicological data are missing for propan-1-ol concerning several endpoints of toxicity, e.g. for carcinogenicity or chronic toxicity. Therefore, a concept of bridging between propan-1-ol- and propan-2-ol-derived data has been proposed by the applicant. Theoretically, effects presumably emanating from parent compounds might be compared on the basis of similarities in physicochemical properties. However, the rate of metabolism and the spectrum of metabolites differ between propan-1-ol and propan-2-ol. From the presently available information, it is not clear to which extent the parental alcohols or their metabolites may contribute to toxicity, particularly regarding medium-term or long-term effects. It is therefore concluded that the bridging concept is not accepted as long as the relevant metabolites responsible for the characteristic pattern of toxicity have not been defined. NOAELs/NOAECS from toxicity studies with propan-2-ol are not taken into account in derivation of reference values for propan-1-ol or in considering AFs to compensate for database quality. Anyhow, information gained from propan-2-ol is not disregarded and will be used for certain endpoints during the human health risk assessment of propan-1-ol.

Absorption, Distribution, Excretion, and Metabolism

Oral absorption

Propan-1-ol was rapidly absorbed following oral administration to different mammalian species. Peak blood levels were observed after oral gavage within 1-2 h in rat studies [redacted] and within 10 min in a mouse study [redacted]. In human volunteers who were exposed to propan-1-ol via a beverage also containing ethanol, peak blood levels were attained within 15 min after the end of the drinking period [redacted].

Regarding quantitation of gastrointestinal absorption, calculations based only on the course of propan-1-ol blood levels are expected to lead to an underestimation of actual total uptake, as propan-1-ol is rapidly metabolised. More detailed information on the extent of absorption was obtained in a study in which rats were dosed with [14C]-labelled propan-1-ol via oral gavage [redacted]. About 77 % of the radioactivity were excreted within 72 h, the major portion being eliminated already within the first 24 h after propan-1-ol administration. Exhalation represented the major route of 14C excretion (about 72 % in 72 h), while less than 5 % and less than 1 % were eliminated via urine and faeces, respectively. The low portion recovered with the faeces (1 %) supported the conclusion that propan-1-ol is readily absorbed to a high extent after oral administration, and that up to 100 % uptake can be assumed.

Inhalation absorption

A study employing isolated rabbit tracheae indicated considerable retention of propan-1-ol during flow of vapour though the trachea, but also recovery of the retained portion by flushing with clean air [redacted]. These results suggest that propan-1-ol is readily solubilised/desorbed within/from the mucosal layer of the upper airways.

Propan-1-ol blood levels were determined in female rats exposed to propan-1-ol vapours for 7 h [redacted]. Following single exposure to 10000 ppm, blood levels were about 25-fold higher in young animals weighing 110-120 g than in adult animals (200-300 g). Higher blood levels in young rats were reflected by the severity of effects: While narcosis and death were observed for the young rats, no noticeable signs of neurotoxicity were reported for the adult animals. Although factors responsible for the higher blood levels and thus susceptibility of immature animals were not defined in the study, it may tentatively be assumed that a higher inhaled dose in relation to body weight in immature animals may be crucial. Whether or not propan-1-ol elimination is less efficient in younger rats than in adult animals is unknown.

In summary, the presented data demonstrate that propan-1-ol is absorbed during inhalation exposure. An exact calculation of the extent of inhalation uptake is not possible, as no studies involving radiolabelled propan-1-ol vapours are available, and determination of unlabelled propan-1-ol blood levels alone does not account for the metabolised portion. Nevertheless, key parameters consistently indicate that propan-1-ol has a high potential to be completely absorbed: Propan-1-ol is miscible with water (>10 g/L) and for gases and vapours that readily dissolve into blood, a large proportion of what is inhaled per breath will be absorbed. Propan-1-ol has a log Kow of 0.25. Such a moderate value is in favor of absorption across the epithelium of the respiratory tract by passive diffusion. Water solubility and the blood: air partition coefficients, the parameters that contribute most of all to the passage of inhaled volatile compounds into blood, are also the most indicative parameters for an absorption.In conclusion and considering the extensive inhalation absorption of other short-chain alcohols, e. g. propan-2-ol (up to 100 %, based on animal data, e. g. Slauter et al. 1994), inhalation absorption of propan-1-ol is assumed to amount to up to 100 %.

Percutaneous absorption

No in vitro studies or animal in vivo tests on dermal absorption of propan-1-ol were available.

Propan-1-ol blood levels were investigated in human volunteers subjected to different

procedures of disinfection of hands (Bieber 2006, hygienic disinfection) or hands and forearms (Peschel 1992; Bieber 2006, surgical disinfection), using commercial hand rub formulations containing propan-1-ol along with one or more other alcohol(s). In the study by Peschel 1992, higher propan-1-ol levels were observed in blood drawn from a site near the area of application (cubital vein) as compared to blood drawn from the back of a foot, suggesting that systemic distribution and liver passage may lead to lower levels in blood drawn from a distal site. In the study conducted by Bieber 2006, peak propan-1-ol blood levels were obtained within 20-30 min. Maximum propionaldehyde blood levels were higher than background levels for the handrub containing 30 % (w/w) propan-1-ol, although they remained considerably lower than maximum blood levels of parental propan-1-ol (about 100-fold lower in mg/L). Average propan-1-ol absorption, based only on propan-1-ol blood levels, was estimated to amount to less than 3 % of the applied dose. However, interindividual differences in the establishment of propan-1-ol blood levels appear to exist.

In summary, the available data support the conclusion that propan-1-ol, applied as a component of disinfectant formulations, is absorbed through human skin to some extent. Under non-occlusive conditions with considerable evaporation, dermal absorption of propan-1-ol for humans appears to be low. In the presented studies following the course of propan-1-ol blood levels in human volunteers, several confounding factors limit a reliable estimation of the extent of dermal absorption. The extent of systemic distribution at the time of early sampling (from the cubital vein or elbow flexure) was unclear. Since metabolites were not taken into account, the calculated values based on propan-1-ol blood levels are regarded as reflecting the bioavailable portion of unchanged parental compound, but to underestimate the totally absorbed amount of applied substance. Finally, it is difficult to discern to which extent vapour inhalation may have contributed to overall substance absorption, as the studies with volunteers were conducted under non-occlusive conditions under which evaporation was to be expected.

In a well-documented study by [redacted], in vivo dermal absorption rates for male and female rats were investigated under occlusive conditions, using 70 % (w/w) of the isomer propan-2-ol in aqueous solution, with 2-14C-propan-2-ol as a tracer. Notably, deviations from OECD guideline conditions included shorter exposure duration (4 vs. at least 6 h) and a smaller area of application (4.3 vs. the recommended 10 cm^2). Propan-2-ol levels in blood were shown to increase linearly within the 4 hours of dermal exposure without reaching a plateau. Total recovery of radioactivity within 48 h amounted to about 92 % of the applied dose. Based on recovered absorbed 14C in relation to total recovery, the percutaneously absorbed portion of applied dose was calculated as amounting to about 7 % in 4 h for an application area of 4.3 cm^2. Assuming a linear relationship of absorption with the area of application and the duration of exposure, this corresponds to an absorption rate of about 0.85 $mg/cm^2/h$ or ca. 0.4 $\%/cm^2/h$.

In comparison to assessment of the isomer propan-1-ol, similar uncertainties associated with the human dermal absorption studies were also encountered in the assessment of the isomer propan-2-ol in the context of CAR preparation for propan-2-ol.

Consequently, the eCA proposed to employ the transdermal flux derived from the well-documented rat study performed with propan-2-ol [redacted] for further calculation of systemic exposure via the dermal route. Even so, the rat dermal flux rate is assumed to provide a conservative assumption for the following reasons: Use of the results obtained in the rat study are probably more likely to overestimate dermal absorption of propan-2-ol for humans, since occlusive exposure conditions were used in the animal study, while in human exposure situations a significant degree of volatilisation can be expected, reducing the amount of substance available for absorption already during the period of exposure. Calculation of absorption for very short exposure durations (for less than time required for establishment of a steady-state in the flux rate) would be expected to result in an overestimation of the actually absorbed proportion. Finally, it is known that for many chemicals, rats show a higher dermal absorption rate in vivo as compared to humans.

In careful consideration of the available information, particularly given the uncertainties within the available human studies and the absence of animal data regarding dermal absorption of propan-1-ol, the eCA is of the opinion that the transdermal flux rate of 0.85 mg/cm2/h, which represents the absorption value implemented by the eCA in the propan-2-ol CARs, would constitute a prudent assumption to be used in further risk characterisation also for the isomer propan-1-ol.

Distribution, metabolism and excretion

In a study in which rats had been dosed with [14C]-labelled propan-1-ol via oral gavage [redacted], differential distribution among tissues was detected already 2 h after administration, with amounts in liver and kidney (related to g tissue) exceeding levels in blood. A marked decline in tissue levels was observed after 6 h in comparison to the 2 h levels, indicating that prolonged retention (bioaccumulation) of propan-1-ol or of metabolites did not occur.

A scheme of propan-1-ol metabolism in mammals, as proposed in the Environmental Health Criteria EHC 102 (WHO 1990), is shown in Figure 2-1. Oxidation via the cytosolic alcohol dehydrogenase system (ADH; EC 1.1.1.1, several isoforms) constitutes a rate-limiting step in the elimination of aliphatic alcohols. Propan-1-ol appears to be a better substrate for ADH than ethanol or propan-2-ol (Dalziel & Dickinson 1966). This might explain the lower blood levels and absence of narcotic effects for propan-1-ol as compared to propan-2-ol in adult female rats exposed to the respective alcohol vapours [redacted]. Evidence exists that to some extent, a microsomal ethanol oxidising system (MEOS, cytochrome P-450 isoforms) contributes to propan-1-ol oxidation. The product of oxidation, propionaldehyde, is further oxidised to propionic acid via aldehyde dehydrogenase. Propionic acid may further be conjugated to coenzyme A, yielding propionyl-CoA, which may enter different metabolic pathways, e. g. those leading to the tricarboxylic acid cycle with ultimate oxidation to CO2 and H2O, or to lactate formation (WHO 1990). In accordance with propionic and lactic acid production, propan-1-ol poisoning in humans presents a. o. with metabolic acidosis (Vujasinović et al. 2007).

Radiocarbon of [14C]-propan-1-ol administered to rats via oral gavage was mainly eliminated in the form of volatile compounds by exhalation (72 % of applied dose within 72 h), although the identity of exhaled compounds was not specified. Urinary and faecal excretion of 14C equivalents was low, amounting to < 5 % and < 1 %, respectively, of the applied dose within 72 h [redacted]. Urinary excretion was confirmed as a minor pathway of propan-1-ol elimination also for human volunteers that had consumed propan-1-ol as a component of an alcoholic beverage: urinary recovery amounted to ≤ 2.1 % of the ingested dose, consisting of the parental compound propan-1-ol and propan-1-ol glucuronide at approximately equal portions (Bonte et al. 1981b).

In general, propan-1-ol is rapidly eliminated. It displayed a half-life in blood of 1-2 h after oral administration of a single high dose of 3000-4000 mg/kg bw in rat and mouse studies. Data from the literature indicate that elimination is saturated above a single oral dose of 1000-1200 mg/kg bw in rats [redacted]. Half-lives are expected to be lower for doses within the range of first order elimination kinetics. Accordingly, i. p. administration of 1000 mg/kg bw to rats resulted in a half-life in blood of 45 min [redacted]. By contrast, in human volunteers that had consumed low doses of propan-1-ol (3.75/5 mg/kg bw) as a component of an alcoholic beverage, the half-life in blood was estimated as being about 1-2 h [redacted] or approximately 70 min [redacted]. Evidence was provided that the kinetic parameters were influenced by the presence of ethanol (and/or the presence of other alcohols) in the human volunteer studies: Propan-1-ol elimination appeared to be more rapid, with lower peak blood levels and a lower propan-1-ol half-life (ca. 1 vs. 2 h), after co-administration of 15 % as compared to 40 % ethanol within the beverage, and propan-1-ol blood levels were below the limit of detection after administration of a mixture containing only 5 % ethanol (Bonte et al. 1981). Furthermore, in the dermal exposure study by Peschel et al. 1992, the concomitant oral consumption of ethanol led to higher peak propan-1-ol blood levels in volunteers. Thus, the presence of ethanol appears to delay propan-1-ol elimination.

Concentration-dependent competition of propan-1-ol with other alcohols and vice versa for the key step of ADH-dependent oxidation yields a plausible explanation for toxicokinetic interactions.

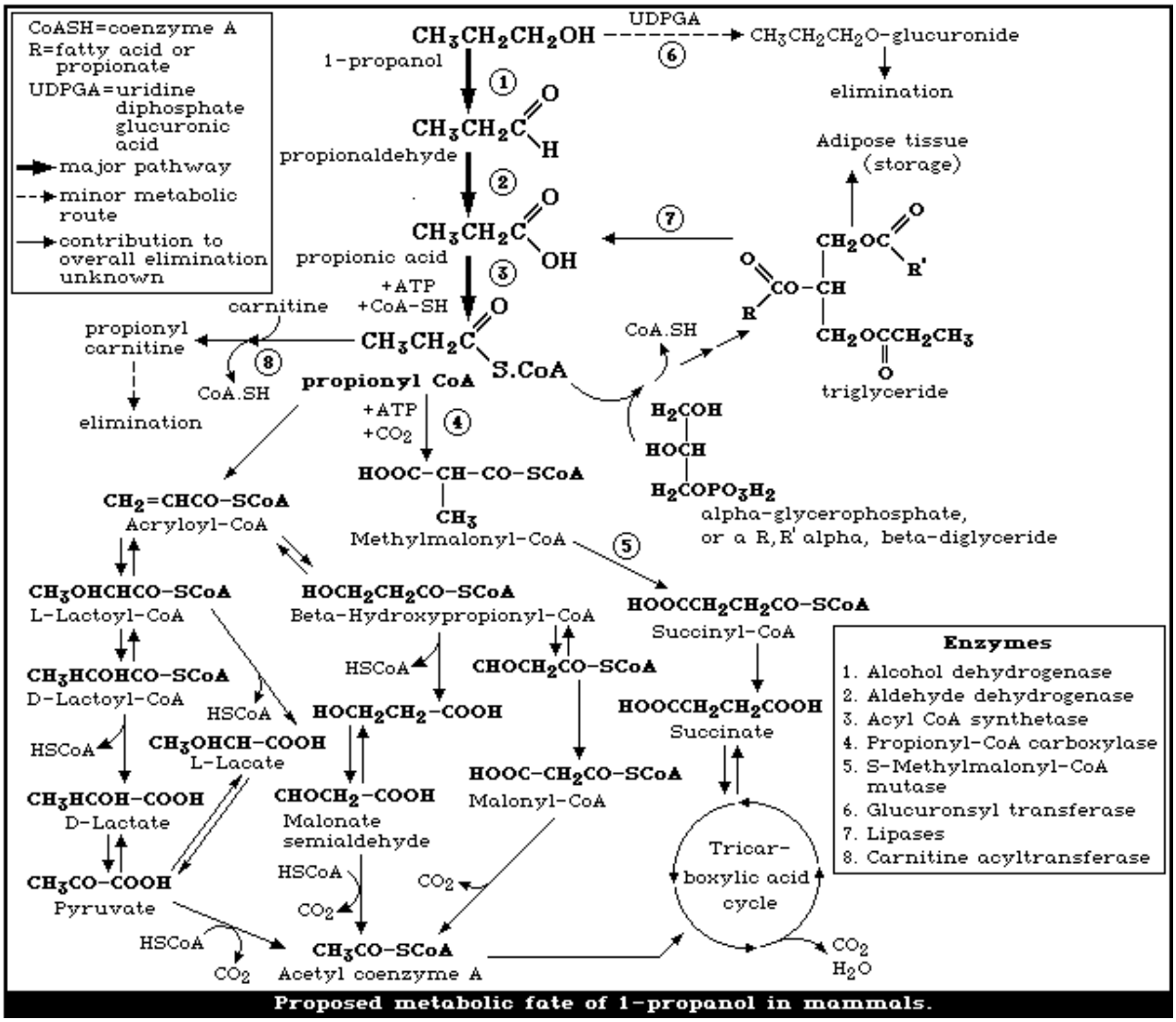

Figure 2-1 Proposed pathways of propan-1-ol metabolism in mammals. From: WHO 1990: 1-propanol. Environmental health criteria – EHC 102.

Acute Toxicity

Propan-1-ol displayed low acute toxicity in experimental animals. Major effects resulting from acute oral exposure comprised neurological symptoms, e. g. stupor, loss of voluntary movements, nystagmus, loss of corneal reflexes in rabbits, or coma in rats. Oral LD_{50} values reported for three different species dosed by the oral route ranged between 1870-8038 mg/kg bw (rat), 2825 mg/kg bw (rabbit) and 6790 mg/kg bw (mouse). A rat oral LD_{50} value of 1870 mg/kg bw was obtained in a study with young animals (weighing 90-120 g; [redacted]), while higher oral LD_{50} values of 6500 or 8038 mg/kg bw were reported in studies involving adult animals (180-350 g; [redacted]) or animals of unspecified age [redacted], respectively. The reasons for the discrepancy in the rat studies are unknown, but might be linked to differences in strains, in post-exposure observation periods, or in animal age. Noteworthy, in juvenile female rats exposed to propan-1-ol via the inhalation route, higher blood levels were obtained than in adult females. In addition, (fatal) neurotoxicity was only observed in the young animals [redacted]. These results suggest that the lower oral LD_{50} value in young rats might be explained by a generally higher susceptibility in juvenile animals, although this issue has not been resolved for the oral route of exposure. Assuming a closer proximity to guideline conditions (e. g. with respect to the use of adult animals), the

study by [redacted] is regarded as yielding the relevant LD_{50} (6500 mg/kg bw) for rats. As this value exceeds the limit dose of 2000 mg/kg bw, no classification as harmful according to Regulation (EC) No 1272/2008 is warranted.

In a pre-guideline study involving acute dermal exposure under occlusive conditions for 24 h, the LD_{50} of rabbits was given as 4032 mg/kg bw [redacted].
Inhalation exposure of rats to propan-1-ol vapours led to local effects that were interpreted as eye irritation (periocular and perinasal wetness, lacrimation, blepharospasm), as well as to depression of the central nervous system. These effects were observed during or shortly after exposure, but were reversible, as they did not persist beyond the day of exposure [redacted]. The hypoactivity observed at and above the lowest concentration of 5185 ppm (12.9 mg/L) may be regarded as a narcotic effect, but may also be considered to be related to eye or mucosal irritation. Nevertheless, severe signs of CNS depression were reported at the next concentration level of 9741 ppm (24.3 mg/L) during exposure (narcosis and /or prostration, loss of startle reflex) or on the same day following exposure (decrease in reflexes).
In an earlier inhalation study [redacted], mortalities (2/6) resulted already from a 4 h exposure to a nominal concentration of 4000 ppm, indicating that the LC_{50} value was above, but in the vicinity of 4000 ppm (10 mg/L air x 4 h). However, concentrations appear to not have been confirmed by analytical methods. In the more recent acute inhalation study [redacted], no deaths occurred up to and at the highest concentration tested (dynamic exposure to 13548 ppm, equivalent to about 33.9 mg/L for 4 h, corresponding to a calculated inhaled internal dose of ca. 5700 mg/kg bw).
No noticeable signs of narcosis or mortalities were reported by [redacted] for adult female rats (200-300 g) exposed to up to 10000 ppm for 7 h, equivalent to about 25 mg/L x 7 h. By contrast, exposure to 10000 ppm led to severe narcosis and death in young female rats (110-120 g). Accordingly, blood levels of young rats were found to be considerably higher than in adult animals, explaining their enhanced susceptibility to neurotoxic effects [redacted]. Thus, differences between the two rat acute inhalation toxicity studies [redacted] may be related to the age of the animals employed. Although age was not clearly documented in the study by [redacted], it appears that the weight of animals used in the later study is in line with the age of test animals recommended in the standard guideline procedure [redacted]. Under guideline conditions, the LC_{50} value (equiv. to 33.9 mg/L) for a 4 h exposure period exceeds 20 mg/L air. Thus, no classification as harmful by inhalation according to Regulation (EC) No 1272/2008 is proposed, although evidence exists that susceptibility to propan-1-ol vapours may be higher in immature individuals.
Propan-1-ol is currently classified according to Regulation (EC) No 1272/2008 as **H336 (*may cause drowsiness or dizziness*)**.
According to CLP guidance (June 2015), there are no guidance values for Category 3. Therefore, if the study shows clear evidence for narcotic effects or respiratory tract irritation at any dose level then this could support classification with Category 3.
T The effect concentration of 12.9 mg/L for hypoactivity from the rat acute inhalation study [redacted] could be interpreted as a sign of neurotoxicity and is not regarded as a consequence of mucosal/eye irritation. However, narcotic effects were not reported in several repeated dose inhalation studies for adult rats at higher concentrations, e. g. at 18 mg/L air over 6 h/d [redacted] cf. 3.5) or at 17.5 mg/L over 7 h/d [redacted] cf. 3.1 and 3.8), challenging the interpretation of neurotoxicity at 12.9 mg/L. Nevertheless, unambiguous neurotoxicity was observed at the next highest concentration (24.3 mg/L x 4 h) in the acute inhalation study, and exposure of young rats to 25 mg/L x 7 h in the study by [redacted], led to complete narcosis and death within 24 h. Under careful consideration of both the severity of narcosis and CNS depression resulting from vapour concentrations and the equivocality of interpretation of the effect of hypoactivity, it is <u>not</u> proposed to change the current classification of propan-1-ol as STOT SE 3; H336, *may cause drowsiness or dizziness*). Narcotic effects from human use are only reported in very rare cases upon oral abuse.

Classification and labelling for acute toxicity according to Regulation (EC) No 1272/2008:
STOT SE 3; H336 (Specific target organ toxicity - Single exposure, hazard category 3, narcosis; H336, *may cause drowsiness or dizziness*)

Irritation and corrosivity

Conflicting reports exist concerning the skin-irritating potential of propan-1-ol. Following application of 0.01 mL propan-1-ol to rabbit skin, only very slight skin reactions ('least visible capillary injection from undiluted chemical') were recorded [redacted]. However, it is doubted that reliable conclusions can be drawn from this study, as rapid evaporation of test substance is expected to occur after application of the small volume (0.01 mL, as opposed to 0.5 mL recommended in OECD guideline 404). In human individuals, the effect of propan-1-ol was tested on hydrated vs. dry skin. An acute skin reaction was observed for hydrated, but not for dry skin, 10 min after application in the majority of test subjects. The reaction was reported as slight to severe erythema, and was ascribed to enhanced penetration of hydrated skin by propan-1-ol, leading to local vasodilation (Haddock & Wilkin 1982). Cutaneous erythema after topical propan-1-ol application to humans was shown to be blocked by pre-treatment with 4-methylpyrazole, an inhibitor of alcohol dehydrogenase, indicating that a propan-1-ol metabolite, possibly propionaldehyde, was responsible for the skin reaction (Wilkin & Fortner 1985). Concerning the use of human data for classification of skin irritation no clear guidance is provided in Regulation (EC) No 1272/2008 and corresponding guidance. The described reactions (erythema due to acute vasodilation) in the study on human individuals (Haddock & Wilkin 1982) is considered not sufficient for classification as Skin irrit. 2, H315.
However, evidence exists that repeated exposure to undiluted propan-1-ol may cause skin dryness, flaking or cracking. In a study by Lübbe et al. 2001 (cf. Medical data, 3.10), repeated dermal application of undiluted propan-1-ol was associated with enhanced transepithelial water loss (TEWL), which is indicative of skin desiccation: Human volunteers were repeatedly exposed to undiluted propan-1-ol, 60 % propan-1-ol or water under unoccluded conditions (3 times for 5 minutes) following pre-treatment with water. Undiluted propan-1-ol led to higher transepithelial water loss as compared to the water control, while the TEWL for 60 % propan-1-ol was comparable to that of the water control. In a more recent study with human volunteers (Clemmensen et al. 2008, cf. the Medical data section, 3.10), daily skin exposure to 0.8 mL undiluted propan-1-ol for 11 days produced a time-dependent response similar to that of a sodium dodecyl sulfate solution (1 %), as determined by enhanced transepithelial water loss, a decreased conductance and visual scoring according to the European Society of Contact Dermatitis (ESCD) guideline on cumulative/subacute SLS irritation (Tupker et al. 1997). A decline in visual scores at a follow-up six days after the last exposure indicated healing/reversibility of skin effects (Clemmensen et al. 2008).
In conclusion, information on skin irritating potential of propan-1-ol is not regarded as sufficient for classification as **H315**. However, classification in accordance with Regulation (EC) No 1272/2008 as **EUH066** is proposed, based on additional studies with human volunteers (not submitted by the applicant).

In the only available animal eye irritation study, instillation of 0.005 mL undiluted propan-1-ol into the rabbit eye led to corneal damage within 24 h, described as 'severe burns' [redacted]. The damage was graded according to a non-guideline system proposed by [redacted]. As details on eye injury and further information, e. g. concerning reversibility of effects, were not provided, the criteria outlined in Regulation (EC) No 1272/2008 cannot be matched for classification. However, since the eyes were exposed to a considerably lower volume of test substance than recommended in the standard OECD protocol for this endpoint (0.005 vs. 0.1 mL), it can be assumed that under standard conditions, eye damage would be highly severe. Regarding human data, exposure of workers to propan-1-ol is one of several substances which might be associated with the appearance of 'vacuole-like alterations in the corneal epithelium' that healed, however, 'without residual scars', although nothing was reported on possible co-exposure to other irritating substances [redacted]. Eye irritation, especially corneal and conjunctiva irritation and ocular hyperaemia, were described in case reports following human occupational exposure, although cases are considered very

rare in relation to frequency of exposure (cf. Medical data, 3.10). In conclusion, based on animal data and on experience relating to human occupational exposure, classification of propan-1-ol as **Eye Dam. 1; H318**, *causes serious eye damage*) is regarded as appropriate, which is in line with the current classification listed in Annex VI of Regulation (EC) No 1272/2008.

Classification and labelling for irritation/corrosivity according to Regulation (EC) No 1272/2008:
Eye Dam. 1; H318 (Severe eye damage - hazard category 1; H318, *causes serious eye damage*),
EUH066 (Repeated exposure may cause skin dryness or cracking)

Sensitisation

In both an adjuvant-based mouse ear swelling test (MEST) and a guinea pig maximisation test (GPMT), in which appropriate positive controls have been considered [redacted], propan-1-ol displayed no potential for sensitisation.

Classification and labelling for sensitisation according to Regulation (EC) No 1272/2008:
Not required

Short-term Toxicity

Rats were exposed to propan-1-ol via drinking water (1 M concentration) for 4 months in a study focussing on potential hepatic and gastrointestinal toxicity [redacted]. No adverse effects were reported, neither for macroscopic examinations of the liver and digestive tract, nor for liver histopathology. Nevertheless, derivation of a NOAEL is not feasible, since relevant toxicological parameters, e. g. exact uptake of propan-1-ol, were not specified.
Reports on three repeated-dose rat inhalation toxicity studies were submitted by the applicant. In a two-week study [redacted], propan-1-ol vapours were tested up to a nominal concentration of 1000 ppm (ca. 2.5 mg/L air). No signs of systemic toxicity (no neurotoxic effects) were reported up to and at this highest concentration. Local effects apparently became evident at 1000 ppm as swelling of periocular tissue and periocular/perinasal encrustations. However, the study results were only made available in the form of a IUCLID summary file and therefore neither the severity of these effects nor the reliability of the study as a whole could be assessed by the eCA.
Overall, classification as '*irritating to respiratory system*' (**H335**) does not appear to be appropriate, since the more recently performed inhalation toxicity studies (referred to below) revealed no histological abnormalities in the respiratory tract, including the nasal cavities [redacted] and, in fact, did not report any irritation of the respiratory system at all.
In a further 2-week inhalation toxicity study that was intended as a range-finding pre-study for a subchronic 13-week study, rats were exposed to up to 18 mg/L air for 6 h/d via the nasal region only. No adverse effects were reported for the respiratory pathway. A decrease in food consumption and in body weight gain was observed in all male dose groups, although the mean body weight after two weeks was not more than 8 % below the weight of controls, and this finding was therefore not regarded as adverse. Interestingly, clinical (e. g. neurotoxic) symptoms were not reported in daily observations for any dose group. In males of the high dose (18 mg/L air) group, a slight to moderate diffusely distributed degeneration (atrophy) of the testicular germinal epithelium and a tendency towards lower testis weight were observed. These findings provided the basis for establishment of the LOAEC for this study as 18 mg/L air over 6 h/d, yielding a NOAEC of 6 mg/L air over 6 h/d, which was estimated to correspond to an inhaled internal dose of about 1620 mg/kg bw/d. The effects in testes pathology are assumed to be related to an impairment of male fertility that was demonstrated in earlier rat inhalation studies after 6 weeks of exposure to propan-1-ol vapours (17.5 mg/L for 7 h/d; [redacted] cf. Reproductive toxicology section). Based on the information obtained from the range-finding 2-week inhalation study [redacted] and using comparable technical equipment, a further subchronic (13 weeks) rat study was

performed [redacted]. Standard examinations included investigation of clinical signs, body weight development, food/water consumption, haematology, clinical chemistry, organ weight, as well as gross and histopathology. In addition, functional neurological tests were performed during the last week of the study, and, as testes were considered a major target for propan-1-ol-dependent organ toxicity, detailed analyses were conducted on testis and sperm parameters. A reduction in epididymides weight (by less than 10 %) was significant in medium and high-dose groups, but was not dose-dependent. A decrease in testes weight and examples of very slight to moderate degeneration of the germinal epithelium were observed in all treated groups, but were not statistically significant as compared to controls, dose-dependent, or associated with functional disturbances with respect to sperm parameters. Hence, no abnormalities that were clearly significant and dose-dependent were observed up to the highest concentration of 8 mg/L air x 6 h/d. Therefore, 8 mg/L air x 6 h/d were established as the NOAEC for subchronic systemic toxicity in rats, corresponding to an inhaled internal dose of about 1830 mg/kg bw/d. Concerning testes effects, this NOAEC is in accordance with data obtained from two rat fertility studies [redacted], in which the ability to produce pregnancies in mated females was impaired for males exposed to propan-1-ol vapours for 6 weeks prior to mating at 17.5 mg/L air, but not at 8.75 mg/L air for 7 h/d (cf. 3.8.2).
Studies on repeated-dose dermal toxicity or on repeated-dose toxicity for a second species have not been submitted.

Classification and labelling for repeated dose toxicity according to Regulation (EC) No 1272/2008:
Further classification is not required.

Genotoxicity

In vitro tests:

No evidence for a genotoxic potential of propan-1-ol was provided in three bacterial tests (2 Ames mutagenicity assays and one SOS-DNA damage study), neither with nor without metabolic activation. Reliability of the bacterial Ames tests is restricted, due to limited reporting and non-adherence to guideline conditions. Since only results are available for 2 strains (of the 5 bacterial test strains recommended in OECD 471 that probe for different types of DNA alterations), the potential of propan-1-ol to cause mutations in the bacterial system cannot be fully excluded.
Propan-1-ol was tested as negative in mammalian *in vitro* systems involving Chinese hamster lung fibroblasts (V79 cells) with and without metabolic activation (HGPRT cell gene mutation assay, mammalian sister chromatid exchange test and chromosome aberration test). A further *in vitro* micronucleus test, although performed only in the absence of S9 mix, also yielded no evidence for cytogenetic damage [redacted]. A yeast assay focusing on aneuploidy frequency in *Aspergillus nidulans* rendered only inconclusive results [redacted].
Propan-1-ol metabolism involves oxidation to propionaldehyde primarily by the alcohol dehydrogenase system, followed by further oxidation to propionic acid by aldehyde dehydrogenase isoforms (cf. toxicokinetics section). Although propan-1-ol tested negative for genotoxicity in bacterial and mammalian *in vitro* systems, it is not known whether propan-1-ol metabolism is adequately represented in these tests. For example, *in vitro* tests conducted with S9-mix are generally optimised for activity of microsomal cytochrome P-450 enzymes, e. g. by ensuring high levels of the P-450 co-factor $NADPH+H^+$, while NAD^+ is required for alcohol dehydrogenase activity.
The primary metabolite of propan-1-ol, propionaldehyde, is regarded as a metabolite of concern, with indications of a genotoxic potential *in vitro*. Although it was found not to be genotoxic in *Salmonella* strains up to 10 mg/plate, with and without metabolic activation [redacted], positive results for propionaldehyde were obtained in several mammalian cytogenetic toxicity assays: Chromosomal aberrations were increased in Chinese hamster ovary cells [redacted]. Induction of aneuploidy and chromosomal aberrations were reported at concentrations of 8-16 µg/ml for Chinese hamster embryonic diploid cells [redacted]. An induction of unscheduled DNA synthesis was found for rat, but not human hepatocytes at 1.7 mg/mL (30 mM), which was below the concentration causing cytotoxicity [redacted]. Finally, an increase in DNA-protein cross-links was reported

for cultured human lymphoma cells at 75 mM (4.4 mg/mL; [redacted]).

In vivo tests:

Several *in vitro* tests with the primary metabolite propionaldehyde suggested a genotoxic potential for propionaldehyde. Concerning *in vivo* testing of propionaldehyde, the outcome of a mouse *in vivo* micronucleus test involving oral gavage of propionaldehyde dissolved in olive oil was reported as being negative ([redacted] cf. Table 3-8). On the other hand, a mouse *in vivo* micronucleus test performed with propionaldehyde, dissolved in water and administered via the i. p. route, indicated a slight but significant increase in micronucleated cells in male animals of the highest dose group, (corresponding to 80 % of the LD_{50}) for sampling times of 24 and 48 hours [redacted] cf. Table 3-8). Based on the *in vitro* data and the ambiguous data from the *in vivo* micronucleus tests, propionaldehyde was considered by the eCA to be a metabolite of concern. In view of the uncertainty whether *in vitro* genotoxicity tests performed with propan-1-ol adequately represent the *in vivo* toxicokinetics of propan-1-ol, further information on the outcome of *in vivo* genotoxicity testing for 1-propanol was deemed to be necessary to resolve whether a relevant genotoxic potential *in vivo* may emanate from propan-1-ol or a product of its metabolism. Accordingly, performance of an *in vivo* comet assay was arranged [redacted] The assay involved administration of propan-1-ol to rats via oral gavage, with the highest dose of 2000 mg/kg bw complying to the maximum recommended dose for acute genotoxicity tests. Animals were sacrificed 3 or 24 hours following administration, to detect both early and delayed changes in DNA integrity. Subsequently, analyses of cell suspensions of the stomach (as the site of first contact), the liver (as the major organ of metabolism of propan-1-ol to propionaldehyde) and blood were performed. More precisely, single cell suspensions were transferred to slides, lysed, subjected to electrophoresis under alkaline conditions, and the comet mean tail intensities evaluated. Principally, the assay was designed to detect possible DNA single and double strand breaks as well as alkaline labile sites representing primary DNA damage, which may result in mutations or may be repaired. Furthermore, as the *in vitro* study with propionaldehyde [redacted] had indicated that DNA-protein cross-links might represent a primary lesion, conditions of electrophoresis were adjusted to more sensitively detect possible DNA-DNA or DNA-protein cross-links, which would be expected to become evident as a reduction in DNA migration under extended electrophoresis. According to the study report, no statistically significant change in tail intensity in liver, stomach or blood cells was observed, irrespective of sacrifice or electrophoresis time. In conclusion, propan-1-ol displayed no relevant genotoxic potential in the *in vivo* comet assay in rats.

Classification and labelling for genotoxicity according to Regulation (EC) No 1272/2008:

The presently available *in vitro* and *in vivo* data for propan-1-ol do not warrant classification and labelling for genotoxicity.

Chronic Toxicity / Carcinogenicity

A single carcinogenicity study was submitted, in which rats were subjected to intermittent, but life- time exposure to propan-1-ol via the oral or subcutaneous route [redacted]. The study does not conform to standard protocol (intermittent dosing twice per week, testing of only one dose that caused severe organ toxicity, limited reporting of toxicological parameters, e. g. concerning exact histological specifications or assignment of effects to individual animals). For treated groups, an incidence of malignancies was reported as 5 tumours/18 animals (oral administration) and 15 tumours/31 animals (subcutaneous administration). By contrast, no malignancies were observed in the control groups (25 animals per route of administration). In addition, the number of benign tumours was increased in treated groups, with 10 tumours/18 animals vs. 3/25 (controls) for oral, and 7 tumours/31 animals vs. 2/25 (controls) for s. c. administration. The absence of spontaneous malignancies in controls is remarkable in comparison to control Wistar rat data that have been summarised in a meta-analysis by [redacted]: In groups of untreated Wistar rats examined after two

years of life, 27/30 % of male/female animals displayed malignancies. In relation to all tumours (malignant + benign), 20/18 % were malignant [redacted]. The malignant tumour numbers as given by [redacted] appear to refer to the total number of malignancies. Since it is not clear from this information how many treated animals were affected by one or more tumour(s), it is difficult to relate the data of this study to the historical spontaneous tumour incidences in Wistar rats. It is regarded as a subject of concern that some of the malignancies that were described as being treatment-related by [redacted] (bladder carcinoma, liver sarcomas) appear to otherwise occur rarely in the rat [redacted]. However, the severe organ toxicity that was observed in the treated animals may have promoted tumour formation. In conclusion, the issue of a possible carcinogenic potential of propan-1-ol is not resolved by the study by [redacted]. No further chronic toxicity or carcinogenicity studies have been submitted. However, 1-propanol did not display mutagenic properties in several in vitro studies, and was tested negative for genotoxic properties in vivo in an in vivo comet assay. These data indicate that propan-1-ol does not exhibit relevant genotoxic or initiating carcinogenic potential.

In addition, in repeated-dose studies (subacute and subchronic inhalation; Doc III A6.3.3/02 and Doc III A6.4.3/01), propan-1-ol was tested up to relatively high concentrations. In the subacute (2-week) study, animals were exposed to up to 18 mg/L air for 6 h/day. This concentration is in the vicinity of the limit concentration of 20 mg/L for vapours, which has been referred to in the current OECD TG 412 (subacute inhalation toxicity: 28 day study) in the case of absence of data-based concentration limits for testing. For the subacute study, 18 mg/L x 6h/d were calculated to correspond to a systemic dose of ca. 4860 mg/kg bw/d. In the subchronic study, animals were exposed to up to 8 mg/L air for 6h/d, which was calculated to correspond to a systemic dose of ca. 1830 mg/kg bw/d.
Even at these high concentrations/doses, no signs of effects which might be indicative for tumour promoting properties, e. g. organ or tissue hyperplasia, were reported. Thus it appears unlikely that propan-1-ol would exhibit tumour promoting effects under chronic exposure conditions.
In conclusion, these lines of evidence do not indicate a relevant carcinogenic potential for propan-1-ol. Further carcinogenicity testing or carcinogenicity data on propan-1-ol have therefore not been required.

However, a data gap concerning chronic toxicity still remains in absence of a valid chronic toxicity study. Consequently, the eCA suggests to apply an additional safety factor of 2 for derivation of the $AEL_{long\text{-}term}$, in extrapolation from medium-term to long-term systemic toxicity (cf. 3.12, overall summary).

Classification and labelling for carcinogenicity according to Regulation (EC) No 1272/2008:
Not required

Reproduction Toxicity

Developmental Toxicity

In the study by [redacted], pregnant rats were exposed to 3500, 7000, or 10000 ppm propan-1-ol via inhalation during days 1-19 of pregnancy, and thus for a period including preimplantation and organogenesis. No noticeable narcotic effects were reported for maternal animals at any tested propan-1-ol concentration, in contrast to animals exposed to isopropanol (propan-2-ol) concentrations of 7000 or 10000 ppm. This may be explained by a more rapid oxidation of propan-1-ol in comparison to propan-2-ol. (It should be borne in mind, however, that exposure of immature females led to severe toxicity (narcosis and death), suggesting either an increased inhaled internal dose and/or a lower rate of metabolism in young animals, cf. 3.1). Substance-related toxicity in adult maternal animals comprised decreased food consumption at the medium and high propan-1-ol concentrations, and was accompanied by a significant reduction in body weight gain at the end of gestation for the high concentration group. Developmental toxicity was observed at propan-1-ol concentrations ≥ 7000 ppm, with growth retardation (decreased body weight) and an increased incidence of skeletal

malformations. An additional increase in external and visceral malformations as well as litter resorptions were indicative of severe developmental toxicity at 10000 ppm. Thus, the LOAECs for both maternal and developmental toxicity were set at 7000 ppm, resulting in a NOAEC of 3500 ppm. Considering the high rate of oral absorption of propan-1-ol, it is assumed that propan-1-ol easily distributes through the placenta. Hence, an independent and specific nature of developmental effects (independent of maternal toxicity at the same exposure level) cannot be ruled out. However, the NOAEC for developmental effects (3500 ppm or 8.75 mg/L over 7 h/d) corresponded to an estimated maternal internal dose of roughly 2760 mg/kg bw/d, and thus exceeded the limit dose level of 1000 mg/kg bw/d for developmental toxicity testing (OECD 414) by far. In conclusion, based on information obtained from the rat studies, no classification/labelling of propan-1-ol for developmental toxicity is proposed. No developmental toxicity studies involving a second species have been submitted.

Reproduction Toxicity

Two studies were performed to investigate the effect of whole body propan-1-ol vapour exposure on neurological developmental parameters and male fertility [redacted]. Male rats were exposed for six weeks prior to mating, while sperm-positive females mated to unexposed males were exposed for days 1-20 [redacted] or days 1-19 [redacted] of gestation. Both reproduction toxicity studies yielded a NOAEC for maternal and developmental toxicity of 3500 ppm that was based on decreased food consumption/decreased bw gain (maternal animals) and on reduced body weight gain and malformations (crooked tails) in offspring at 7000 ppm. This is in accordance with the developmental toxicity study involving inhalation exposure [redacted]. No adverse behavioural effects (regarding neuromuscular, exploratory or circadian activity, aversive learning, appetitive learning) or alterations in neurochemistry were observed in offspring of propan-1-ol-exposed maternal animals [redacted].
Fertility of males of the parental generation treated for 6 weeks prior to mating, however, was impaired at 7000 ppm: Only 2 of 18 males [redacted] or 2/16 males [redacted] produced litters in sperm-positive females. Uterus dissection of respective females confirmed that the absence of litters was not due to resorptions, but to the inability to cause pregnancies. Repeated mating of affected males demonstrated, however, that the impairment of male fertility was completely reversible by 13 weeks following exposure [redacted]. In conclusion, a reproductive NOAEC of 3500 ppm at 7 h/d is established, corresponding to 8.75 mg/L air at 7h/d or to an internal dose of ca. 2321 mg/kg bw/d for male rats (assuming a body weight of 475 g and an inhalation volume of 300 mL/min), and is based on reversible impairment of male fertility at 7000 ppm (ca. 4642 mg/kg bw/d). Since the internal NOAEL exceeds the limit dose for one-generation reproduction toxicity testing (OECD 415) of 1000 mg/kg bw/d by far, no further classification regarding reproduction toxicity is proposed. The fertility studies by [redacted] do not conform to guideline in that the treatment of males was performed for less than the recommended duration of a spermatogenic cycle (70 days). Nevertheless, the NOAEC values deduced from testes effects were similar in more recent inhalation repeated-dose (2-week and 13-week, 6 h inhalation/d) studies [redacted], the latter of which included detailed analyses of testis and sperm parameters (cf. section 3.5).

Classification and labelling for reproduction toxicity according to Regulation (EC) No 1272/2008:
Not required as developmental toxicity occurred at very high doses (≥ 5500 mg/kg bw/d).

Neurotoxicity

No further neurotoxicity studies have been submitted for the active substance by the applicant. However, neurotoxic effects were described or investigated in other studies:

Acute toxicity studies

Acute neurotoxic effects (narcosis or depression of the central nervous system) were observed in several acute toxicity studies involving oral or inhalation routes of administration. Oral

gavage of 1442 mg/kg bw to rabbits resulted in 'stupor and loss of voluntary movements in 50 % of dosed animals' [redacted]. In a rat inhalation study, neurological effects after single exposure to 10000 ppm (25 mg/L) for 7 h were only reported for immature females (narcosis/death), but not for adult female rats [redacted]. By contrast, propan-1-ol vapour at 5185 ppm (12.9 mg/L air, corresponding to an internal dose of about 2200 mg/kg bw after 4 hours of exposure) led to hypoactivity in rats already during the exposure period. Higher concentrations (≥ ca. 9700 ppm) resulted in narcosis and/or prostration during exposure and reduction in reflexes on the same day of exposure ([redacted] cf. section 3.2). Propan-1-ol is currently classified as **H336 (*may cause drowsiness or dizziness*)** according to Regulation (EC) No 1272/2008. To meet the criteria for classification as H336, CNS depression should be observed at vapour concentrations/exposure times not exceeding 20 mg/L x 4 h. Although it is unclear whether the effect observed under the classification threshold in the acute rat inhalation study (hypoactivity at 12.9 mg/L x 4 h) was attributable to CNS depression (cf. 3.5), unambiguous signs of neurotoxicity were observed at the next highest exposure concentration (24.3 mg/L x 4 h). In addition, severe (fatal) neurotoxicity occurred at 25 mg/L x 7 h in immature animals in the study by [redacted]. It is therefore proposed not to change the current classification of propan-1-ol as STOT SE 3; H336, *may cause drowsiness or dizziness*).

Repeated-dose studies

In a non-guideline study, male mice were dosed by oral gavage with 1000, 2000, or 4000 mg/kg bw/d on five consecutive days. Dose-dependent (substance-related) transient acute effects were observed shortly after administration on each day of exposure: Hypothermia, which may be caused by both vasodilation and alteration of central thermoregulation, occurred at all doses (≥ 1000 mg/kg bw/d), and was maximally developed during the first time points of analyses (10-20 min). A transient impairment in rotarod performance was significant for the 2000 mg/kg bw/d group at 10 min and for animals receiving 4000 mg/kg bw/d at 10-40 min after administration [redacted].
No neurotoxic effects were observed in a two-week rat inhalation study up to 18 mg/L (7200 ppm) x 6 h/d [redacted]. In a 13-week subchronic rat inhalation study involving exposure via the nose region for 6 h/d, no signs of neurotoxicity were reported up to 8 mg/L air (equivalent to an internal dose of 1830 mg/kg bw/d). In addition, functional tests performed during the last week of the 13-week study (functional observational battery and locomotor activity tests over 90 minutes) revealed no abnormalities [redacted].

Developmental neurotoxicity

No adverse effects were observed on behavioural measures (neuromuscular, exploratory or circadian activity, aversive learning, appetitive learning) or on brain neurochemistry in offspring of maternal animals exposed to up to 17.5 mg/L (7000 ppm) propan-1-ol vapours for 7 h/d during days 1-20 or 1-19 of gestation [redacted], equivalent to a maternal dose of ca. 5512 mg/kg bw/d (cf. 3.8.2).

Classification and labelling for neurotoxicity according to Regulation (EC) No 1272/2008:
STOT SE 3; H336
(Specific target organ toxicity - Single exposure, hazard category 3, narcosis; H336, *may cause drowsiness or dizziness*)

Further Studies
No further mechanistic or other studies have been submitted by the applicant for the active substance.

Medical Data

Epidemiological studies
Epidemiological studies to assess long-term effects of propan-1-ol in humans are not available.

Case reports, studies with human volunteers

Ingestion
Intoxications of humans have been reported after oral ingestion of propan-1-ol. The most likely acute effects of systemic intoxication in humans are narcosis and central nervous depression, resembling symptoms of acute ethanol intoxication. Symptoms may include headache, nausea, dizziness, vomiting, and incoordination. High exposures may result in unconsciousness, respiratory depression, and death. Animal studies indicate that the narcotic potential for propan-1-ol is stronger than for ethanol, the ED_{50} of propan-1-ol for narcosis in rabbits being about four times lower than that for ethanol [redacted].
A further symptom of systemic propan-1-ol intoxication is metabolic acidosis, which results from production of propionic and lactic acid (cf. propan-1-ol metabolism). Although narcosis is typical of both propan-1-ol and propan-2-ol poisonings, metabolic acidosis is a criterion by which to differentiate between the two intoxications, since propan-2-ol may lead to ketosis and ketonuria, but not typically to acidosis (Vujasinović et al. 2007). A case of mixed ingestion of propan-1-ol and propan-2-ol presented in the first 12 hours with acidosis, while ketonuria became evident only at a later stage (Vujasinović et al. 2007, Table 3-13). These observations indicate that in the early phase of mixed intoxication, competition occurs between propan-1-ol and propan-2-ol for alcohol dehydrogenase-dependent metabolism. Since propan-1-ol is preferentially oxidised, transformation of propan-2-ol to acetone is delayed.
The lethal dose of propan-1-ol in humans is unknown. However, an estimated amount of about 500 mL oral propan-1-ol was suspected to have caused death of a 46-year old woman 4-5 hours after ingestion. Autopsy in this case revealed accompanying symptoms of ‘swollen brain’ and lung oedema (Dürwald & Degen 1956, cited in WHO 1990).

Inhalation
No case reports or further human volunteer studies, apart from an absorption study (Peschel et al. 1992, cf. Toxicokinetics section), are available on effects of inhalation exposure for humans.

Dermal exposure
Reactions resulting from repeated exposure to a hand disinfectant formulation containing ethanol (52.4 % w/w) and propan-1-ol (21 % w/w) as active ingredients have recurrently been reported [redacted]. Both reddening of skin and desiccation may be effects caused by the alcohols. Appearance of skin erythema within 10 min of application to hydrated skin of human volunteers was reported by Haddock and Wilkin 1982 (cf. 3.3), and was explained by local vasodilation. Transepithelial water loss (TEWL) was demonstrated for human volunteers dermally exposed to undiluted propan-1-ol (Lübbe et al. 2001; Clemmensen et al. 2008, Table 3-13). Concerning the severe hypersensitivity reaction involving circulatory disturbance, skin reddening and severe tongue oedema after exposure to a preparation containing ethanol and propan-1-ol [redacted], it is not possible to discern which constituent(s) of the hand rub was/were responsible for this reaction, since the disinfectant also contains additional compounds, e. g. ‘skin care agents’ and fragrances (diisopropyl adipate, PEG-6 caprylic/capric glycerides, dexpanthenol, bisabolol, allantoin, limonene, linalool), that may have contributed to the reaction. In conclusion, human (or animal) data do not provide sufficient evidence for classification of propan-1-ol as a skin irritant or as a sensitising substance. However, classification/labelling according to Regulation (EC) No 1272/2008 as EUH066 is proposed (cf. 3.3).

Eye contact
Exposure of workers to propan-1-ol (presumably to vapours, though not reported clearly) has been associated with the appearance of ‘vacuole-like alterations in the corneal epithelium’ that healed, however, ‘without residual scars’ (Heydenreich 1966). In addition, propan-1-ol was found to cause severe corneal burns in a rabbit study [redacted]. Thus, based on both human and animal data (cf. 3.3), classification of propan-1-ol as Eye Dam. 1; H318, *causes serious eye damage*) is regarded as appropriate.

Specific treatment in case of an accident or poisoning
Treatment includes prevention of further absorption (to be performed within minutes of oral ingestion) and symptom-oriented measures of life support (prevention of hypothermia, correction of fluid and electrolyte imbalances, correction of acidosis, respiratory support/mechanical ventilation). In severe cases, haemodialysis may be applied as a measure of detoxification. In case of eye contact with propan-1-ol or a solution containing propan-1-ol, rinsing with water for several minutes is advised [redacted].
Information reported in the course of pharmacovigilance of propan-1-ol containing antiseptics showed only rare cases of adverse drug reactions, concerning predominantely the skin and to a lower extent the eyes. It is concluded that sufficient long-term experience exists with propan-1-ol- (and ethanol-) containing antiseptics (as medicinal product) including use during pregnancy and lactation. Adverse effects on reproduction were not reported and were not retrieved from the literature in the course of pharmacovigilance between 1993 and 2016. Cases reports regarding effects on reproduction following propanol-containing disinfections were not retrieved from the data bases and from literature search.

Classification and labelling according to Regulation (EC) No 1272/2008, supported by human data:
Eye Dam. 1; H318
(Severe eye damage - hazard category 1; H318, *causes serious eye damage*)
EUH066 (R*epeated exposure may cause skin dryness or cracking*)

Summary & Conclusion
In summary, the following Acceptable Exposure Levels were derived from the toxicological data evaluated:

- A systemic/internal reference dose **AEL_{acute} of 27.6 mg/kg bw**, based on the rat inhalation developmental toxicity study (foetal skeletal malformations; [redacted]), supported by rat behavioural developmental toxicity studies [redacted], applying an AF of 100.

- A systemic/internal reference dose **$AEL_{medium-term}$ of 18.3 mg/kg bw/d,** based on impairment of male fertility parameters and abnormalities in testis histopathology in repeated-dose rat inhalation studies [redacted], derived from the overall NOAEL of 1830 mg/kg bw/d from the 13-week rat inhalation study, applying an AF of 100.

- A systemic/internal reference dose **$AEL_{long-term}$ of 9.2 mg/kg bw/d**, based on impairment of male fertility parameters and abnormalities in testis histopathology in repeated-dose rat inhalation studies (derived from an overall NOAEL of 1830 mg/kg bw/d from the 13-week rat inhalation study). In addition to the default AF of 100, an extra AF of 2 was applied for extrapolation from medium-term to long-term systemic toxicity, since no studies suitable for the assessment of the risk of long-term exposure to propan-1-ol have been submitted.

- For a potential dietary risk assessment at product authorisation level, ADI and ARfD were derived. Generally, NOAELs from oral toxicity studies are considered most suitable for deriving ADI and ARfD. However, the only available oral repeat dose study, a 4-month non-guideline drinking water study in Wistar rats [redacted], was evaluated as not reliable. Consequently, ADI and ARfD were derived from other studies:

    - The **ADI** of **9.2 mg/kg bw/d** was derived from the overall NOAEL from rat 13-week inhalation studies (fertility and subchronic) with an AF of 200.

    - The **ARfD of 27.6 mg/kg bw** was derived from the rat developmental toxicity study with a default AF of 100.

The exposure of humans is expected to occur primarily via inhalation of vapours or by contact with skin. Data derived from oral (bolus) application have been considered as less relevant for

human risk assessment than those from inhalation studies.

Summarising the study results and all considerations above, the following classification and labelling according to Regulation (EC) No 1272/2008 is proposed for the active substance propan-1-ol:

- Eye Dam. 1; H318 (Serious eye damage, hazard category 1; *causes serious eye damage*)
- EUH066 (Repeated exposure may cause skin dryness or cracking)
- STOT SE 3; H336 (*Specific target organ toxicity – single exposure, hazard category 3, narcosis; may cause drowsiness or dizziness).*

2.2.1.2. Exposure assessment

Exposure of Professionals

The active substance propan-1-ol and the biocidal products are produced within the EU.

Product-type 1

The following scenarios are covered by the exposure assessment in this report:
- Hand disinfection in hospitals (scenario 1)
- Secondary exposure to propan-1-ol (scenario 2)

For hand disinfection in hospitals a ready-to-use solution with 70 % propan-1-ol is used (scenario 1). The disinfectant is poured into the palms of one hand out of an automatic dispenser and the complete surface of both hands is moistened with ready-to-use solution and let to dry. A total amount of 3 ml biocidal product for one hand disinfection task stays on both hands.
Due to its physico-chemical properties, propan-1-ol evaporates during the application as hand disinfectant. The propan-1-ol concentration in air depends mainly on the applied dose, the room volume, the temperature (influence on vapour pressure), and the air exchange rate. Air exchange rates in hospitals depend on the use of the room (e.g. patient room 1.5/h).

The propan-1-ol concentrations of air are calculated with ConsExpo 4.1 (Recommendation no. 9 of the BPC Adhoc Working Group of Human Exposure). For reasonable worst case it is assumed that a nurse performs 25 hand disinfections per shift (Recommendation no. 1 of the BPC Adhoc Working Group of Human Exposure). Due to the evaporation of propan-1-ol the assessment of external dermal exposure is difficult to perform. The potential dermal exposure is limited to the time that propan-1-ol remains on hands. This time is calculated according to the formula presented in the TGD (EC 2003). According to these calculations the evaporation of 3 ml of 70 % propan-1-ol takes approx. 106 seconds. The exposed skin area is 820 cm^2 (palm and back of both hands). It is assumed that propan-1-ol with an area dose of 2.2 mg a.s./cm^2 is available for dermal absorption for this period of time, respectively, for one hand disinfection.

The risk characterisation for the professional hand disinfection with 70 % propan-1-ol expressed a concern (see below). Since it is not applicable to use gloves during hand disinfection or respiratory equipment it is decided to assess a lower concentration of active substance in the product. According to the efficacy evaluation, products with 60 % of active substance are still effective.
For hand disinfection with 60 % propan-1-ol the evaporation time is lower and is determined to be 93 sec. It is assumed that propan-1-ol with an area dose of 1.93 mg a.s./cm^2 is available for dermal absorption for this period of time, respectively, for one hand disinfection.

For the application of the b.p. no contact to the eyes is expected since only small amounts of product are used in a controlled way. Moreover the liquid evaporates rapidly and no residues on the skin are available for a possible hand to eye exposure. Due to local effects the use of eye protection would be necessary. Since no contact of liquid propan-1-ol to the eyes is

expected the use of eye protection for hand disinfection in hospitals is not announced.

A secondary exposure to propan-1-ol using hand disinfectants cannot be excluded.

Inhalation exposure may occur to professional bystanders (e.g. nurse or cleaning staff) in patients' rooms where hand disinfection is performed. In a reasonable worst case it is assumed that the bystander stays in the room where 3 hand disinfections for one time per shift are performed. Dermal exposure is not expected since propan-1-ol evaporates within a short time during hand disinfection and a direct contact to the hand disinfection solution is not conceivable. Since there is no risk for the bystander due to the use of products with 70 % active substance this assessment is not refined with 60 % active substance.

Product-type 2

The following scenarios are covered by this exposure assessment:
- Disinfection of small surfaces (scenario 1)
- Secondary exposure to propan-1-ol (scenario 2)

Disinfection of small surfaces in laboratories is considered. For surface disinfection in areas where hygiene is important, a ready-for-use solution with 70 % propan-1-ol is used (scenario 1). For small-scale disinfection of surfaces (0.5 m^2) the disinfectant is usually poured or sprayed onto the working bench and wiped over the surface with paper tissues. The propan-1-ol concentrations in air are calculated with ConsExpo 4.1 under the assumption that the ventilation rate is 8/h, that the surfaces are disinfected every 45 minutes during 8 hours, and that the person does not leave the room. The concentration in air quickly reaches a maximum concentration and then declines due to the air exchange in the room.
To assess the dermal exposure of small scale wiping, the worked example for PT02 („small scale wiping") implemented in the "BEAT" database is adopted. This model is based on Hughson et al. (2004) "Determination of dermal exposures during mixing, spraying and wiping activities". This model is sufficiently conservative to assess the exposure in the present case as well. The palm of one hand (205 cm^2) is exposed to the disinfectant and 10 events per day with duration of 1 minute per event are performed. The resulting level of potential dermal exposure is 0.63 mg/cm^2 for one disinfection. It should be taken into account that this result is probably an overestimation if the evaporation of propan-1-ol is considered.

For the application of the b.p. no contact to the eyes is expected since only small amounts of product are used in a controlled way. Moreover the liquid evaporates rapidly and no residues on the skin are available for a possible hand to eye exposure. Due to local effects the use of eye protection would be necessary. Since no contact of liquid propan-1-ol to the eyes is expected the use of eye protection for disinfection of small surfaces is not announced.

Inhalation exposure may also occur to professional bystanders (e.g. nurse, laboratory assistant or cleaning staff) in laboratories where surface disinfection is performed (scenario 2). The inhalation exposure will be in the same order of magnitude as for the person who disinfects the surfaces. In a worst case scenario it is assumed that the bystander stays 8 hours in the room where surface disinfection is performed. To assess the dermal exposure of bystanders the rapporteur follows the assumption of the participant that there is a very low probability for direct contact to freshly disinfected surfaces. Therefore the dermal exposure is not expected.

Product-type 4

The following scenarios are covered by this exposure assessment:
- Surface disinfection in canteens or kitchens (scenario 1)
- Surface disinfection in the food processing industry (scenario 2)
- Secondary exposure to propan-1-ol (scenario 3)

For surface disinfection in canteens or kitchens a ready-for-use solution with 70 % propan-1-ol is used (scenario 1). For disinfection of small surfaces (1 m^2) the disinfectant is directly poured or sprayed onto the surface and then wiped over with disposable tissues which are disposed of

into the wastepaper basket, afterwards. The b.p. itself is used up during the application process. Therefore, no exposure has to be considered during the mixing and post-application phase.

For the application phase the propan-1-ol concentrations in air are calculated with ConsExpo 4.1 after every disinfection phase under the assumption that the ventilation rate is 15/h, that the surfaces are disinfected every 2 hours during 8 hrs, and that the person does not leave the room. It seems to be obvious that this reflects an addition of worst case assumptions.

To assess the dermal exposure of small scale wiping the worked example for PT 2 („small scale wiping") implemented in the "BEAT" database is adopted. This model is based on Hughson et al. (2004) "Determination of dermal exposures during mixing, spraying and wiping activities". This model is sufficiently conservative to assess the exposure in the present case as well. The palm of one hand (205 cm^2) is exposed to the disinfectant and 4 events per day with duration of 2 minute per event are performed. The resulting level of potential dermal exposure is 1.26 mg/cm^2 for one disinfection. It should be taken into account that this result is probably an overestimation considering the evaporation of propan-1-ol.

For surface disinfection in food processing industry, a ready-to-use solution with 70 % propan-1-ol is used (scenario 2). The following data are obtained from a visit to a sausage processing factory by the participant. The working hall visited consists of three working lines. Each one contains a cutting machine and packaging machinery. It is assumed that one person performs an intermediate disinfection every 2 hours (in total 4 events per day) followed by a 10 min break (the machines must be dry for correct processing). During this time a break for all employees is foreseen and the workers leave the hall. One packaging machine and 8 band-conveyors are disinfected with alcohol-based disinfectant. The propan-1-ol concentration in air is calculated with ConsExpo 4.1 for +15°C. The concentration quickly reaches a maximum and then declines due to the air exchange rate in the room. After disinfection and the following 10 min break propan-1-ol does not remain in air due to the high air exchange rate of 20/h.

During the disinfection an intensive dermal contact with the soaked endless wipes is assumed. To assess dermal exposure of small scale wiping, the worked example for PT 2 („small scale wiping") implemented in the "BEAT" database is adopted. This model is based on Hughson et al. (2004) "Determination of dermal exposures during mixing, spraying and wiping activities". This model is sufficiently conservative to assess the exposure in the present case as well. The palm of both hands (410 cm^2) is exposed to the disinfectant and 4 events per day with duration of 5 minute per event are performed. The resulting level of potential dermal exposure is 1.57 mg/cm^2 for one disinfection. It should be taken into account that this result is probably an overestimation considering the evaporation of propan-1-ol.

For the application of the b.p. no contact to the eyes is expected. In the above described cases the use of treated wipes will avoid further spillage. However in case of food industry over 1 L disinfectant is used for several times therefore the use of eye protection is recommended due to local effects of the b.p..

Secondary exposure to propan-1-ol using surface disinfectants cannot be excluded (scenario 3).

The inhalation exposure may occur to professional bystanders in areas where surface disinfection is performed. The inhalation exposure will be in the same order of magnitude as for the person who disinfects the surfaces. Therefore, the level of inhalation exposure of a bystander is estimated to be equivalent or lower compared to the operator. There is a very low probability for direct contact to freshly disinfected surfaces. Therefore, dermal exposure is considered to be negligible for bystanders.

Exposure of Non-Professionals

Product-type 1

Primary exposure
Intensive health care patient's visitors

Visitors of patients in intensive health care units have to disinfect their hands before entry. As proposed by the applicant it is assumed that up to 3 applications are performed per day. It was expected that the minimum room size for patients is about 25 m^3. This would be equivalent to an area of 10 m^2 and a height of 2.5 m, which is expected to be a minimum for patient rooms in hospitals. The air changing rate in normal intensive care units is about 3 h^{-1} according to German DIN 1946-4. It is assumed that application is a serial event performed every 2.5. h. After 2.5 h level of propan-1-ol is almost zero with the air change rates chosen above. It is assumed that exposure according to this scenario takes place on at most 30 subsequent days per year corresponding to medium-term exposure or to acute exposure if limited to one day. Additional uses of the same biocidal product by other persons are not considered.

Acute exposure
Inhalation exposure: 0.5 mg/kg bw
Dermal exposure: 0.5 mg/kg bw
Total exposure: 1.0 mg/kg bw

Medium-term exposure
Inhalation exposure: 1.5 mg/kg bw/d
Dermal exposure: 1.4 mg/kg bw/d
Total exposure: 2.9 mg/kg bw/d

Home dialysis
Patients performing home dialysis have to disinfect their hands before the operation. According to the applicant such a dialysis is performed in maximum once each day. Thus, patients are daily and therefore chronically exposed to the biocidal product and the active substance. The room volume is assumed as 25 m^3. This would be equivalent to a (small) room with an area of 10m^2 and 2.5 m height. The air exchange rate in private houses and the exposure duration are assumed to be 0.6 h^{-1} and 10 h, respectively. It is expected that persons performing home dialysis are of low activity and exercise level. Thus, for respiration rate the activity level "resting" is assumed.

Chronic exposure
Inhalation exposure: 1.3 mg/kg bw/d
Dermal exposure: 0.5 mg/kg bw/d
Total exposure: 1.8 mg/kg bw/d

Secondary exposure
Visitors of home dialysis patients after primary exposure
Secondary non-professional exposure may occur if persons enter rooms after use of the biocidal product, for instance after home dialysis has been performed. Inhalation exposure may occur, whereas dermal exposure by contact to treated surfaces (hands) is considered negligible due to rapid evaporation. Secondary exposure estimates by inhalation should be in the same range as for primary exposure since uptake bases primarily on the vapour pressure of the active substance and secondarily exposed persons stay in the same room as the person that applies the biocidal product. Exposure might be acute or chronic depending on the frequency a person stays in rooms after use of the biocidal product. It is expected that persons performing home dialysis or which stay in such rooms are of low activity and exercise level.

Acute or chronic exposure
Adults
Inhalation exposure: 1.3 mg/kg bw(/d)

Total exposure: 1.3 mg/kg bw(/d)

Children
Inhalation exposure: 2.5 mg/kg bw(/d)
Total exposure: 2.5 mg/kg bw(/d)

Residues in food or feed from the intended use of propan-1-ol in PT 1 biocidal products are not expected, as no direct or indirect contact with food or feed is intended. Even so, use as a non-professional hand disinfectant could potentially lead to residues in food. However, due to its high vapour pressure, the active substance evaporates completely within the time of application of the biocidal product, so that no transfer from hands 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, dietary exposure to humans from the use of propan-1-ol as a biocide of PT 1 can be excluded.

Product-type 2

Primary exposure
Surface disinfection in bathrooms

Disinfection products with a composition comparable to the biocidal model formulation might be used by non-professionals to disinfect surfaces in bathrooms or toilets. Usually this may occur once per week. However, in specific cases (e.g. infectious disease of a household member) it is expected that they are applied more frequently. A number of five applications per day is assumed to be representative for such cases. Both cases are considered as acute exposure.

It is expected that the biocidal product is used as a pump spray or wipes. Exposure by wiping is considered to be lower or in maximum in the same range as exposure by spraying and has therefore not been assessed separately. Since these sprays usually only develop aerosol particle of large diameter, the application time is short and the application is directed away from the operator to a surface, exposure by direct inhalation is expected negligible. However, due to the high vapour pressure of the active substance inhalation exposure may occur if the person stays in the room during and after application. It is assumed that the person does not stay in the (bath)room after use of the biocidal product and leaves the room after application. For special cases, if the biocidal product is applied more frequently, exposure of 5 times 5 min is assumed (e.g. in case of an acute infectious disease in a household). Dermal exposure is expected when the operator uses the spray. It is assumed as a worst case scenario that the total surface of the hands will be covered with the biocidal product for a short time interval until the active substance is evaporated. Dermal exposure due to contact to treated surfaces is considered negligible due to rapid evaporation.

In the strict sense, primary inhalation exposure as presented in the following section is restricted to the time of use (here the time, in which a person is disinfecting a room). The time afterwards in this sense - when the subject stays in the room - would be secondary exposure. However, since both kinds of exposure are integrated in one scenario, both are directly linked to each other and separation is neither reasonable nor easy to perform, the whole time interval of exposure was assessed as primary exposure.

Household use, one application (acute exposure)
Inhalation exposure: 1.74 mg/kg bw
Dermal exposure: 1.2 mg/kg bw
Total exposure: 2.94 mg/kg bw

Household use, five applications on one day (acute exposure)
Inhalation exposure: 8.7 mg/kg bw
Dermal exposure: 6.1 mg/kg bw
Total exposure: 14.8 mg/kg bw

Secondary exposure
Re-entry after primary exposure (acute exposure)

Secondary acute (daily) non-professional exposure may occur if persons (adults or children) enter rooms after use of the biocidal product. Inhalation exposure as presented for primary exposure assessment is expected, whereas dermal exposure as assessed for primary exposure is not relevant for secondary exposure since it is directly related to the use of the biocidal product. Exposure by contact to treated surfaces (hands) is considered negligible due to rapid evaporation. Secondary exposure estimates by inhalation should be in the same range as for primary exposure since uptake is based primarily on the vapour pressure of the active substance and secondarily exposed persons may stay in the same room as the person applying the biocidal product. As for primary exposure these persons will be exposed acutely.

It is also expected that this estimate covers secondary exposure of non-professionals after professional use of a biocidal product (e.g. exposure in medical care facilities). For exposure of children a body weight of 23.9 kg has been selected. According to Consexpo the respiration rate for a 23.9-kg-child (light exercise) is 1.32 m^3/h.

Adults
Inhalation exposure: 1.74 mg/kg bw
Total exposure: 1.74 mg/kg bw

Children
Inhalation exposure: 4.6 mg/kg bw
Total exposure: 4.6 mg/kg bw

Product-type 4

Primary Exposure

Disinfection products with a composition comparable to the biocidal model formulation might be used by non-professionals to disinfect surfaces in kitchens. Usually this may occur once per week.

It is expected that the biocidal product is used as a pump spray or wipes. Exposure by wiping is considered to be lower or in maximum in the same range than exposure by spraying and has therefore not been assessed separately. Since these sprays usually only develop aerosol particle of large diameter, the application time is short and the application is directed away from the operator to a surface, exposure by direct inhalation is expected negligible. However, due to the high vapour pressure of the active substance inhalation exposure may occur if the person keeps in the room after application. Disinfection is usually performed after conventional cleaning of the kitchen. Thus, it is assumed that persons will leave the kitchen briefly after use within 15 min. Dermal exposure is expected in the moment when the operator applies the spray. It is assumed that the total surface of the hands will be covered with the biocidal product for a short time interval until the active substance is evaporated. Dermal exposure because of contact to treated surfaces is considered negligible due to rapid evaporation.

In the strict sense, primary inhalation exposure as presented in the following section is restricted to the time of use (here the time, in which a person is disinfecting a room). The time afterwards in this sense - when the subject keeps staying in the room - would be secondary exposure. However, since both kinds of exposure are integrated in one scenario, both are directly linked to each other and separation is neither reasonable nor easily to perform, the whole time interval of exposure was assessed as primary exposure. Secondary exposure of non-professionals not using the biocidal product is assessed in 8.2.4.2 in a similar manner.

Household use, one application (acute exposure)
Inhalation exposure: 3.51 mg/kg bw
Dermal exposure: 1.2 mg/kg bw
Total exposure: 4.71 mg/kg bw

Secondary Exposure

Secondary acute (daily) non-professional exposure may occur if persons (adults or children) enter rooms after use of the biocidal product. Inhalation exposure is expected, whereas dermal exposure as assessed for primary exposure is not relevant for secondary exposure since it is directly related to the use of the biocidal product. Exposure by contact to treated surfaces (hands) is considered negligible due to rapid evaporation. Secondary exposure estimates by inhalation are in the same range as for primary exposure since uptake bases primarily on the vapour pressure of the active substance and secondarily exposed persons stay in the same room as the person that has applied the biocidal product. As for primary exposure these persons will be exposed acutely. According to Consexpo 4.1 for children a body weight of 23.9 kg and an inhalation rate (light exercise) of 1.32 m^3/h are assumed.

It is also expected that this estimate covers secondary exposure of non-professionals after professional use of a biocidal product (e.g. in medical facilities).

Adults
Inhalation exposure: 3.51 mg/kg bw
Total exposure: 3.51 mg/kg bw

Children
Inhalation exposure: 9.31 mg/kg bw
Total exposure: 9.31 mg/kg bw

Residues in food or feed from the intended use of propan-1-ol in PT 4 biocidal products are not expected. Due to its high vapour pressure, the active substance evaporates completely within the time of application of the biocidal product, so that no transfer from treated 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, dietary exposure to humans from the use of propan-1-ol as a biocide of PT 4 can be excluded.

Cumulative / Combined exposure

Propan-1-ol is assessed to decide on inclusion in the Union list of approved active substances for PT 1, 2, and 4. The CA-reports consider primary exposure of professionals and non-professionals and secondary exposure of the general public and professionals. For professional users it can be assumed that cumulative exposure to propan-1-ol from biocidal products of different product types is unlikely. Some product types are limited to specific professions. Thus, professional exposure to skin and hand disinfectants in PT 1 is restricted to health care professions whereas professionals in the food area are only exposed to propan-1-ol from PT 4. Thus, a person working in a restaurant or other similar institutions will not be exposed by disinfectants used by hospital staff for hand disinfection etc. and vice versa.

<u>Accumulation of primary professional exposure</u>

An accumulation of professional exposure to non-professional and secondary exposure is not considered reasonable. Professional exposure is a very regular frequent event compared to non-professional exposure. Thus, the fraction of non-professional exposure to total exposure is small, particularly if also the frequency of exposure is taken into account. For professional exposure assessment daily exposure is assumed, whereas non-professional and secondary exposure is relatively rare.

<u>Accumulation of primary non-professional exposure</u>

Non-professional exposure to PT 1 is restricted to visitors of hospital intensive health care units and to dialysis patients. Both exposure scenarios are relatively rare events. For the first scenario it is assumed that this is a medium-term scenario assuming that relatives visit hospital patients each day over a period of 30 days. However, if cumulative exposure is assessed this exposure scenario should be considered as acute scenario since it is unlikely that

persons are exposed to all or even a few scenarios over a longer time period. The scenario for dialysis patients is not included into the acute exposure assessment because it is limited to a very small and specific group. For PT 2 and 4 only acute exposure scenarios have been identified as relevant for non-professional uses. For PT 2 only the single application has been considered since multiple exposure is a very rare event. Other scenarios are unlikely if this scenario gets real. Thus, as a worst case the following is assumed for non-professional exposure assessment:

1. All relevant exposure scenarios happen on the same day. Since this is a rare event it is considered as an acute cumulative scenario. Thus, estimates of all acute (medium-term) exposure scenarios are added and subsequent compared to the AEL_{acute} in section 2.1.1.3.

2. The exposure scenarios happen one after the other on subsequent days. This exposure is compared to the $AEL_{medium\text{-}term}$ or $AEL_{long\text{-}term}$ in section 2.1.1.3. For exposure assessment the average is calculated from all acute and medium-/long-term exposure estimates.

Accumulation of secondary exposure

Secondary exposure of adults does not need to be added to the non-professional primary exposure estimates since it is already integrated in the primary exposure assessment as discussed above. Thus, cumulative secondary exposure has to be considered only for children, who are unaccounted for primary exposure. Calculations are identical to adult exposure assessment. Professional secondary exposure is also covered by the primary professional exposure.

On the basis of the considerations above the following cumulative exposure estimates have been identified.

Exposure of professionals

A cumulative exposure of professionals using different products for PT 1, 2 and 4 is not expected and therefore not assessed. The risk assessment of primary and secondary exposure for PT 1, 2 and 4 is described in chapter 12.2.1.1 of this CAR.

Primary and secondary exposure of the general public

Table 2-7 Cumulative acute exposure assessment for the general public

Exposure scenario	Exposure (mg/kg bw/[d])
Acute exposure - internal dose	
Adults	
Intensive care unit visitors (PT 1)	2.9
Household use (PT 2)	2.94
Household use (PT 4)	4.7
Total	10.5
Children	
Household use, secondary exposure (PT 2)	4.6
Household use, secondary exposure (PT 4)	9.3
Total	13.9

Table 2-8 Cumulative medium-/long-term exposure assessment for the general public

Exposure scenario	Exposure (mg/kg bw/[d])
Medium-term (long-term) exposure - internal dose	
Adults	
Average (PT 1 intensive care unit visitors, PT1 Home dialysis, PT 2, PT 4)	8.1

Exposure scenario	Exposure (mg/kg bw/[d])
Children	
Average (PT 1, PT 2, PT 4)	5.5

2.2.1.3. Risk characterisation

Risk Assessment for Professionals

The occupational risk assessment of propan-1-ol in PT 1, 2 and 4 takes into account systemic effects as well as local effects (damage of the eye, classification with H318) of the active substance.

Product-type 1

The risk characterisation for systemic effects of propan-1-ol is performed with the AEL approach. In this approach total internal body burden is compared to the $AEL_{long\text{-}term}$ of 9.2 mg/kg bw/d. The long-term AEL is taken because repeated exposure at the workplace cannot be excluded for the use of propan-1-ol.
The AEL (an internal reference value) is based upon the oral NOAEL of 1830 mg/kg bw/day for impairment of male fertility parameters and abnormalities in testis from a 13-week rat study, and the knowledge of 100 % oral absorption rate. In addition to the default assessment factor (AF) of 100, an extra AF of 2 was applied for extrapolation from medium-term to long-term systemic toxicity. Thus, an $AEL_{long\text{-}term}$ of 9.2 mg/kg bw/day is derived for long term exposure towards propan-1-ol.
If the total internal body burden is lower than the reference dose, health risks leading to concern are not anticipated.

For scenario 1a (hand disinfection in hospitals - 70 % a.s.) total potential exposure exceed the long-term AEL by a factor of 1.1. It cannot be excluded that the high exposure levels of propan-1-ol from this exposure scenario will result in toxic effects in workers.

However, in this case a more detailed analysis for propan-1-ol is necessary. Since it is not applicable to use gloves during hand disinfection or respiratory equipment, the eCA decided to assess a lower concentration of active substance in the product. According to efficacy evaluation, products with 60 % of active substance are still effective. Therefore refinement of the risk assessment (scenario 1b) takes into account the concentration of 60 % active substance.

Taking into account the above mentioned refinement, for the professional exposure scenario 1b (hand disinfection in hospitals – 60 % a.s.) as well as for secondary exposure the estimated uptake / reference value is below 100 % and thus a safe use is identified.

Due to its intrinsic propertiers, damage of the eye can arise from exposure to propan-1-ol. Therefore a qualitative risk assessment for local effects is carried out. Considering all scenarios assessed the exclusion of eye contact minimizes the anticipated health risks to an acceptable level for professional user.

It is essential to indicate that the conclusion only applies to the active substance in the biocidal product (and not to other ingredients).

Product-type 2

The risk characterisation for systemic effects of propan-1-ol is performed with the AEL approach. In this approach total internal body burden is compared to the $AEL_{long\text{-}term}$ of 9.2 mg/kg bw/d. The long-term AEL is taken because repeated exposure at the workplace cannot be excluded for the use of propan-1-ol.

The AEL (an internal reference value) is based upon the oral NOAEL of 1830 mg/kg bw/day for impairment of male fertility parameters and abnormalities in testis from a 13-week rat study, and the knowledge of 100 % oral absorption rate. In addition to the default assessment factor (AF) of 100, an extra AF of 2 was applied for extrapolation from medium-term to long-term systemic toxicity. Thus, an $AEL_{long\text{-}term}$ of 9.2 mg/kg bw/day is derived for long term exposure towards propan-1-ol.

If the total internal body burden is lower than the reference dose, health risks leading to concern are not anticipated.

For both professional exposure scenarios disinfection of small surfaces (0.5 m^2) and secondary exposure the estimated uptakes / reference values are below 100 % and thus safe uses are identified.

Based on these results and conclusions on systemic health risks in tier 1, a further refinement of the risk characterisation is considered not necessary.

Due to its intrinsic properties, damage of the eye can arise from exposure to propan-1-ol. Therefore a qualitative risk assessment for local effects is carried out. Considering the assessed scenario the exclusion of eye contact minimizes the anticipated health risks to an acceptable level for professional user.

It is essential to indicate that the conclusion only applies to the active substance in the biocidal product (and not to other ingredients).

Product-type 4

The risk characterisation for systemic effects of propan-1-ol is performed with the AEL approach. In this approach total internal body burden is compared to the $AEL_{long\text{-}term}$ of 9.2 mg/kg bw/d. The long-term AEL is taken because repeated exposure at the workplace cannot be excluded for the use of propan-1-ol.

The AEL (an internal reference value) is based upon the oral NOAEL of 1830 mg/kg bw/day for impairment of male fertility parameters and abnormalities in testis from a 13-week rat study, and the knowledge of 100 % oral absorption rate. In addition to the default assessment factor (AF) of 100, an extra AF of 2 was applied for extrapolation from medium-term to long-term systemic toxicity. Thus, an $AEL_{long\text{-}term}$ of 9.2 mg/kg bw/day is derived for long term exposure towards propan-1-ol.

If the total internal body burden is lower than the reference dose, health risks leading to concern are not anticipated.

For all professional exposure scenarios surface disinfection in canteens or kitchens, surface disinfection in food processing industry and secondary exposure in canteens as well as secondary exposure in food processing industry the estimated uptakes / reference value are below 100 % and thus safe uses are identified.

Based on these results and conclusions on systemic health risks in tier 1, a further refinement of the risk characterisation is considered not necessary.

Due to its intrinsic properties, damage of the eye can arise from exposure to propan-1-ol. Therefore a qualitative risk assessment for local effects is carried out. In case of food industry over 1 L disinfectant is used for several times therefore the use of eye protection is recommended. The use of eye protection minimizes the anticipated health risks to an acceptable level for professional user.

It is essential to indicate, that the conclusion only applies to the active substance in the biocidal product (and not to other ingredients).

Safety Measures for Professionals

Product-type 1

As the total internal exposure exceeds the AEL if product containing 70 % propan-1-ol is used, risk reduction measures (RMM) would be necessary. But, for hand disinfection liquids used in a clinical context, personal protection equipment (chemical protective gloves, respiratory equipment) is not applicable.

As no engineering and/or technical measures were recommended by the participant (e.g. small exhausting systems beneath the dispensers), and the air exchange rate cannot be prescribed for hospitals but has to comply with other factors (e.g. hygienic reasons, sensation of patients), the eCA decided to assess a lower concentration of active substance in a refined risk assessment. According to the efficacy evaluation, products with 60 % of active substance are still effective. A safe use is identified for a product with concentrations of ≤60 % propan-1-ol. Due to local effects the use of eye protection would be necessary. Since no contact of liquid propan-1-ol to the eyes is expected the use of eye protection is not announced.

Product-type 2

As 'no concern' is assumed for the use of propan-1-ol for disinfection of small surfaces (0.5 m^2), further risk reduction measures are not necessary. Nevertheless, it should be kept in mind that in Tier 1- exposure calculation carried out here presumes a ventilation rate of 8 air changes per hour. Due to local effects the use of eye protection would be necessary. Since no contact of liquid propan-1-ol to the eyes is expected the use of eye protection is not announced.

Product-type 4

As 'no concern' is assumed for the use of propan-1-ol for disinfection of small surfaces (1 m^2 in kitchens / canteens resp. 4.6 m^2 of packaging machines in the food processing industry), further risk reduction measures are not necessary. Nevertheless, it should be kept in mind that the Tier 1- exposure calculation carried out here presumes a ventilation rate of 15 resp. 20 air changes per hour. Due to local effects the use of eye protection would be necessary. In case of food industry over 1 L disinfectant is used for several times therefore the use of eye protection is recommended.

Risk Assessment for Non-Professionals

Product-type 1

Table 2-9 Summary risk assessment for primary exposure to propan-1-ol

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure - internal dose Intensive care unit visitors	Covered by medium-term exposure		
Medium-term exposure - internal dose Intensive care units visitors			
Inhalation	1.5	18.3	8
Dermal	1.35	18.3	7
Total	2.9	18.3	16

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Long-term (chronic) exposure - internal dose Home dialysis			
Inhalation	1.33	9.2	15
Dermal	0.449	9.2	5
Total	1.78	9.2	19

Table 2-10 Summary risk assessment for secondary exposure to propan-1-ol

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure – internal dose Intensive care units visitors	Covered by long-term exposure		
Medium-term exposure – internal dose Intensive care units visitors	Covered by long-term exposure		
Long-term (chronic) exposure - internal dose Home dialysis - Adults			
Inhalation	1.33	9.2	15
Total	1.33	9.2	15
Long-term (chronic) exposure - internal dose Home dialysis - Children			
Inhalation	2.51	9.2	27
Total	2.51	9.2	27

Primary and secondary exposure of non-professionals and the general public is considered acceptable.

Local risk assessment

Labelling of the biocidal product includes P280 (Wear eye protection/face protection.). Eye contact is considered unlikely due to the following reasons:

Ready-to-use hand disinfection products are alcoholic solutions that are rubbed into the hands until the product is evaporated. The haptic properties of liquid alcoholic products (smooth feeling, characteristic alcoholic odour, different wetting and missing foaming properties) clearly differ from soaps or hygienic hand wash products. Even if alcoholic hand disinfection products are available in bathrooms confusion with cleaning products such as soaps is therefore very unlikely.

Ready-to-use alcoholic hand disinfection products are used in a different contexts than soap (hand wash). In hospitals, hand disinfection opportunities are often provided at doors (site of entry of a room) or at the site of patient contact (bed side). In this context confusion with hand or face cleaning soap is not a reasonable consideration.

Visitors of medical facilities and institutional areas such as old people's homes should be aware of a setting that is different from the private environment. Therefore, the assumption that the product will lead to eye contact is unlikely if appropriate labelling is provided.

Additionally, due to the liquid character of usual alcoholic ready-to-use hand disinfection formulations it is expected that the hand disinfection product is almost completely rinsed off with the first water touching the hand if confusion with hand/face cleaning products occurs.

Overall, labelling of the product with P280 (Wear eye protection/face protection.) is considered

not necessary, but a likelihood of eye exposure resulting from the use by the consumer in the private area has to be minimized by additional labelling with "Avoid contact with eyes".In addition, national authorisation should address the risk of eye damage, e.g. by taking into account product-integrated risk mitigation measures.

Product-type 2

Table 2-11 Summary risk assessment for primary exposure to propan-1-ol

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure - internal dose Household use (1 application)			
Inhalation	1.74	27.6	6.3
Dermal	1.2	27.6	4.3
Total	2.94	27.6	11
Acute exposure - internal dose Household use (5 applications)			
Inhalation	8.7	27.6	32
Dermal	6.1	27.6	22
Total	14.8	27.6	54

Table 2-12 Summary risk assessment for secondary exposure to propan-1-ol

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure – internal dose Household use (1 application), adults			
Inhalation	1.74	27.6	6.3
Total	1.74	27.6	6.3
Acute exposure – internal dose Household use (1 application), children			
Inhalation	4.6	27.6	16.7
Total	4.6	27.6	16.7

Primary and secondary exposure to non-professionals and the general public is considered acceptable.

Local risk assessment

For the application of the biocidal product by non-professional users no contact with the eyes is expected. The application is directed away from the operator to a surface. This is reasonable since only small amounts of product are used in a controlled way. Moreover, the liquid evaporates rapidly and no relevant amount of residues on the skin is available for a possible hand to eye exposure. However, labelling with "Avoid contact with eyes." is considered necessary. In addition, product authorisation should address the risk of eye damage, e.g. by taking into account product-integrated risk mitigation measures.

Product-type 4

Table 2-13 Summary risk assessment for primary exposure to propan-1-ol

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure - internal dose Household use			
Inhalation	3.51	27.6	13
Dermal	1.2	27.6	4.3
Total	4.71	27.6	17

Table 2-14 Summary risk assessment for secondary exposure to propan-1-ol

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure – internal dose Household use, adults			
Inhalation	3.51	27.6	13
Total	3.51	27.6	13
Acute exposure – internal dose Household use, children			
Inhalation	9.31	27.6	34
Total	9.31	27.6	34

Primary and secondary exposure to non-professionals and the general public is considered acceptable.

Local risk assessment

For the application of the biocidal product by non-professional users no contact with the eyes is expected. The application is directed away from the operator to a surface. This is reasonable since only small amounts of product are used in a controlled way. Moreover, the liquid evaporates rapidly and no relevant amount of residues on the skin is available for a possible hand to eye exposure. However, labelling with "Avoid contact with eyes." is considered necessary. In addition, product authorisation should address the risk of eye damage, e.g. by taking into account product-integrated risk mitigation measures.

Safety Measures for Non-Professionals

Product-type 1

As a result of the classification the instruction of use has to contain the following additional information:
Windows have to be opened or ventilation has to be switched on if used in bathrooms, toilets and other small rooms.

Product-type 2

Specific safety measurements for non-professionals and the general public with respect to human health exposure assessment and risk characterisation are not required.

Product-type 4

Specific safety measurements for non-professionals and the general public with respect to human health exposure assessment and risk characterisation are not required.

Cumulative / Combined Risk Assessment

On the basis of the considerations in 8.2.5 the following cumulative exposure estimates have been identified and compared to the relevant AEL.
Professionals A cumulative exposure of professionals using different products for PT 1, 2 and 4 is not expected and therefore not assessed.
Primary non-professional and secondary exposure

Table 2-15 Summary cumulative acute risk assessment for the general public

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Acute exposure - internal dose			
Adults			
Total (PT 1: Intensive care unit visitors PT 2, PT 4: Household use)	10.5	27.6	38
Children			
Total (PT 2, PT 4: Household use)	13.9	27.6	50

Table 2-16 Summary Cumulative medium-/long-term risk assessment for the general public

Exposure scenario	Exposure (mg/kg bw/[d])	AEL (mg/kg bw/[d])	Exposure (% of AEL)
Medium-term (long-term) exposure - internal dose			
Adults			
Average (PT 1 intensive care unit visitors, PT 1 Home dialysis, PT 2, PT 4)	8.1	**9.2**	88
Children			
Average (PT 1, PT 2, PT 4)	5.5	**9.2**	60

The exposure estimates are up to 88 % of the systemic AEL. Thus, it is concluded that cumulative non-professional exposure to propan-1-ol by application in PT 1, 2 and 4 is acceptable for human health.

Aggregate exposure

Propan-1-ol may also occur in other biocidal product types as non-active substance. It is also used by consumers and workers in other fields that are not covered by biocide regulation (e.g. solvent in household cleaners or coatings).

Currently a combined/aggregate exposure assessment for all sources of exposure is not possible. It can practically not be elucidated in detail at the moment, which kinds of products will be authorised in all different areas of application and which influence may arise from exposure due to use in non-biocidal products. This lack of knowledge cannot be filled before the finalisation of approval procedure and the REACH registration procedure. Propan-1-ol has been used for many years in various applications and grave non-accidental intoxications in this

context have not been reported to our knowledge.
Therefore, the approval of propan-1-ol (PT 1, 2 and 4) is proposed.
Nevertheless, for product authorisation it is essential to consider whether exposure from all other sources than the foreseen biocidal use have a significant influence on risk assessment.

Overall conclusion

Acceptable exposure levels for acute, medium- and long-term exposure could be derived for propan-1-ol. Therefore, no risk to human health could be anticipated for the active substance. All studies required by Directive 98/8/EC are available or statements for non-submission have been accepted. Different exposure scenarios or parameters might be relevant during product authorisation, therefore applicability of scenarios described in the report has to be evaluated and exposure should be re-assessed on a case-by-case basis.

2.2.2. Environmental Risk Assessment

The environmental risk characterisation is based on the concept of releases of the active substance to the environment taking into account all relevant life cycle stages. The estimation of predicted environmental concentration (PEC) for the “dummy product” as well as the derivation of predicted no effect concentrations (PNECs) for different environmental compartments was performed according to the Guidance on the Biocidal Product Regulation Vol. IV Environment – Part B Risk Assessment (active substance) (April 2015, Version 1.0), hereinafter referred to as Guidance BPR IV ENV B (2015) and to the Environmental Emission Scenarios for PT 1 (Royal Haskoning, 2004), PT 2(van der Poel, Matrch 2001, RIVM report 601450 008) and PT 4 ´Disinfectants used for food and feed area`(JRC, 2011).

2.2.2.1. Fate and distribution in the environment

Biodegradation

According to ready biodegradability tests and a weight of evidence approach, propan-1-ol is classified as “readily biodegradable, but failing the 10-d window”.
Further studies on biodegradability in soil, water/sediment or sewage treatment plant were not deemed to be necessary.

Abiotic Degradation

Experimentally derived data on hydrolysis in water are not available. Propan-1-ol, as an alcohol, possesses no hydrolysable functional groups and therefore, is resistant to hydrolysis. For this reason, hydrolysis under environmental conditions is not expected.
Experimentally derived data on photolysis in water are not available. The molecular structure of propan-1-ol has no chromophore. In addition, for propan-1-ol a cut-off point of 210 nm is given in UV/VIS spectrophotometry. Therefore, no absorption between 290 nm and 750 nm takes place. Chemicals with UV/absorption maximum of < 290 cannot undergo direct photolysis in sunlight. Therefore, the substance is unaccessible for direct photodegradation in sunlight.
The vapour pressure of propan-1-ol at 25°C is 27.6 hPa and direct evaporation is expected, consequently. The Henry’s law constant (0.76 $Pa \times m^3/mol$ at 25°C) indicates moderate volatility from water. Propan-1-ol present in the atmosphere will react with photo-chemically produced OH and NO_3 radicals. The half-life of propan-1-ol in the troposphere was estimated to be 2.8 days considering a global 24-hours mean OH-radical concentration of 5×10^5 OH radicals/cm.

Distribution and Mobility

Experimentally derived soil sorption coefficients are not available. A K_{OC} of 1.3 L/kg can be estimated based on the model PCKOCWIN v1.66. In addition, the K_{OC} was estimated according to a QSAR model described in Guidance BPR IV ENV B (2015). Based on a log K_{OW} of 0.25 and the QSAR for alcohols, the K_{OC} was calculated to 3.96 L/kg. This K_{OC} is used for the

environmental exposure assessment. Therefore, propan-1-ol is expected to exhibit only a weak adsorption in soils and sediments indicating a very high mobility of propan-1-ol in soil and a very low geoaccumulation potential. Adsorption of relevant amounts of propan-1-ol on soils and sediments is not expected.
The distribution in the sewage treatment plant calculated by eCA using the SimpleTreat 3.0-model (a rate constant of 1 h^{-1} for STP was concluded since propan-1-ol is ready biodegradable, fulfilling the 10-day window criterion) results in: release fractions to air 0.3 %, water 12.6 %, sludge 0 % and degraded fraction 87.1 %.

Bioaccumulation and Secondary Poisoning

Based on the physicochemical properties of the propan-1-ol an approximate estimation of bioconcentration factors for the aquatic (BCF_{Fish}), as wells as for the terrestrial compartment ($BCFE_{arthworm}$) was performed according to Guidance BPR IV ENV B (2015). Applying the experimentally derived $logK_{OW}$ of 0.25 results in a BCF_{Fish} of 0.33 $L/kg_{wet\ fish}$ and a $BCF_{Earthworm}$ of 0.86 $L/kg_{wet\ earthworm}$. Consequently, the aquatic and terrestrial bioaccumulation potential of propan-1-ol can be assumed as low. In consequence of the $logK_{OW}$ < 3, the low estimated BCF values and the fact that no other indicators point to an intrinsic potential for bioconcentration (e.g. surface tension > 50 mN/m) no experimental studies on bioaccumulation are required.

With regard to the low estimated BCF values in aquatic and terrestrial indicator species, propan-1-ol is not expected to accumulate in the environment. The risk of secondary poisoning is therefore assumed to be negligible via ingestion of contaminated food by birds or mammals.

2.2.2.2. Hazard identification and effects assessment

Aquatic Compartment including sediment

The active substance propan-1-ol shows a very low toxicity towards aquatic organisms. The lowest acute effect concentration was derived from a study with *Nitocra spinipes* resulting in an EC_{50} of 2,300 mg/L after 48 hours. Studies investigating the acute toxicity of propan-1-ol on fish and algae are also available. In a study with P*imephales promelas, a* 96 h LC_{50} of 4,554 mg a.s./L for fish was determined. An E_rC_{50} of 9,170 mg/L for *Pseudokirchneriella subspicata* was assessed in a study on the toxicity of propan-1-ol on algae. Since there are no valid long term studies with propan-1-ol available, an assessment factor of 1,000 was applied to the lowest acute effect value (EC_{50} = 2,300 mg/L, 96 h) obtained for *Nitocra spinipes* resulting in a $PNEC_{water}$ of 2.3 mg/L.
Studies on sediment dwelling organisms were not provided by the applicant and are not required for the intended use. By using the equilibrium partioning method (EPM) a $PNEC_{sediment}$ of 1.998 mg/kg ww was estimated according the Guidance BPR IV ENV B (2015, Chapter 3.5.3), based on the $PNEC_{water}$.

Inhibition of microbial activity (STP)

In a test on the respiration inhibition of activated sludge conducted according to OECD Guideline 209, the EC_{50} was calculated to be >1000 mg a.s./L (nominal, graphical analysis). For the risk assessment an EC_{50} value of 1000 mg/L will be used as a worst case.
Since chemicals may cause adverse effects on microbial activity in STPs it is necessary to derive a $PNEC_{microorganisms,\ STP}$. The $PNEC_{microorganisms,\ STP}$ is used for the calculation of the PEC/PNEC ratio concerning microbial activity in STPs. Considering an assessment factor of 100 to the EC_{50} of the respiration inhibition test a $PNEC_{m\ croorganisms,\ STP}$ of 10 mg/L was derived.

Terrestrial Compartment

Direct exposure of the active substance to the soil compartment relating to the intended use does not occur and adsorption to soil is not expected. Therefore, tests on terrestrial organisms (inclusive inhibition to microbial activity) with propan-1-ol are scientifically not justified.
Based on $PNEC_{water}$ and according to the Guidance BPR IV ENV B (2015, Chapter 3.6.2.1) a $PNEC_{soil}$ of 0.432 mg/kg ww was derived by using equilibrium partioning method (EPM).

Atmosphere

A $PNEC_{air}$ cannot be derived, but acute and subchronic inhalation studies with rats can be used as indication of adverse effects of chemicals on species arising from atmospheric contamination. Available results of these studies reveal that effect values are clearly above the environmental concentration in air. Therefore, no adverse effects on terrestrial organisms (mammals) are expected. A similar conclusion can be drawn for honeybees or terrestrial plants, for which negative effects as a result of the intended uses of the active substance are also not to be expected.

2.2.2.3. Exposure assessment

The biocidal product, containing 70 % of propan-1-ol is used

- in PT 1 as a ready-to-use solution for hand and skin disinfection in health care areas and other areas. It can be described as “leave-on” product.
- In PT 2 as a ready-to-use solution for disinfection of small surfaces in the sanitary sector
- In PT 4 for disinfection of small surfaces in food industry (e.g. slaughterhouses)

For the environmental exposure assessment of the biocidal product (b.p.) the following life cycle stages are selected as relevant:

- production of a.s.
- formulation of b.p.
- life cycle considering several intended uses as described above

The environmental release estimation for the life cycle stages “production” and “formulation” can be found in the confidential annex to Doc II-8.3, but is at the moment not further considered for risk assessment.

For the use phase in PT 1 and PT 2 two approaches are calculated: (1) based on annual tonnage applied and (2) based on average consumption. According to the EU-Report on the Workshop for PT 1-6 (2008) both approaches shall be presented by the eCA in the CA report. For the environmental risk assessment, the worst-case estimations are chosen to be relevant, respectively. The calculation of the tonnage approach is reported in the Confidential Annex to Doc II-8.3, chapter 8.3.3 because of data protection claims made by the applicant.
For the use phase in PT 4 only the consumption based approach is considered since there is no tonnage based approach presented in the ESD PT 4 (JRC, 2011).
In general, regional and continental concentrations should be considered if the total tonnage of a.s. brought on the market exceeds 10 t per year (refer to former EU TGD on Risk Assessment, Part II, Chapter 2.1.2, 2003). However, as no comprehensive information on all intended uses of propan-1-ol is available the estimation of $PEC_{regional}$ and $PEC_{continental}$ could not be performed. But eCA used the $PEC_{regional}$ values from the EU Risk Assessment Report (RAR) for propan-1-ol (EC 2007) for both approaches. As discussed at the EU PT 1-6 Environmental Workshop (March 2008), PEC_{local} with inclusion of $PEC_{regional}$ shall be given in the CA Report for information purposes (see Doc II-8.3 and Confidential Annex to Doc II-8.3), but for the final environmental risk assessment the PEC_{local} values without $PEC_{regional}$ shall be taken.

Aggregated Exposure Assessment
Article 19(2) of the new BPR (EU, 2012) states that “the evaluation […] shall take into account the following factors: […] (d) cumulative effects, (e) synergistic effects.” This is further elaborated in Annex VI (common principles for the evaluation of biocidal products) where it is stated that the risks associated with the relevant individual components of the b.p. shall be assessed, taking into account any cumulative and synergistic effects. This refers to the environmental risk assessment of an a.s. which is contained in different products of the same Product Type (PT) or of different PTs.

Propan-1-ol is notified for inclusion in the Union list of active substances approved for use in biocidal products in PT 1, 2, and 4. For all mentioned PTs, DE is eCA. The respective CA reports consider the following uses: PT 1 - skin and hand disinfectant in hospitals; PT 2 - disinfection of small surfaces in the sanitary sector; PT 4 - assessment of small surfaces in the food industry (e.g. slaughterhouses).
In eCA's opinion each of the above mentioned intended uses can lead to an overlap in time and space in different environmental compartments. The main entry pathways into the environment are equal for all applications mentioned above (via STP and via air). A combination of exposures to propan-1-ol for all environmental compartments affected is possible and realistic regarding a complete environmental risk characterisation according to BPR as well as feasible in technical terms.

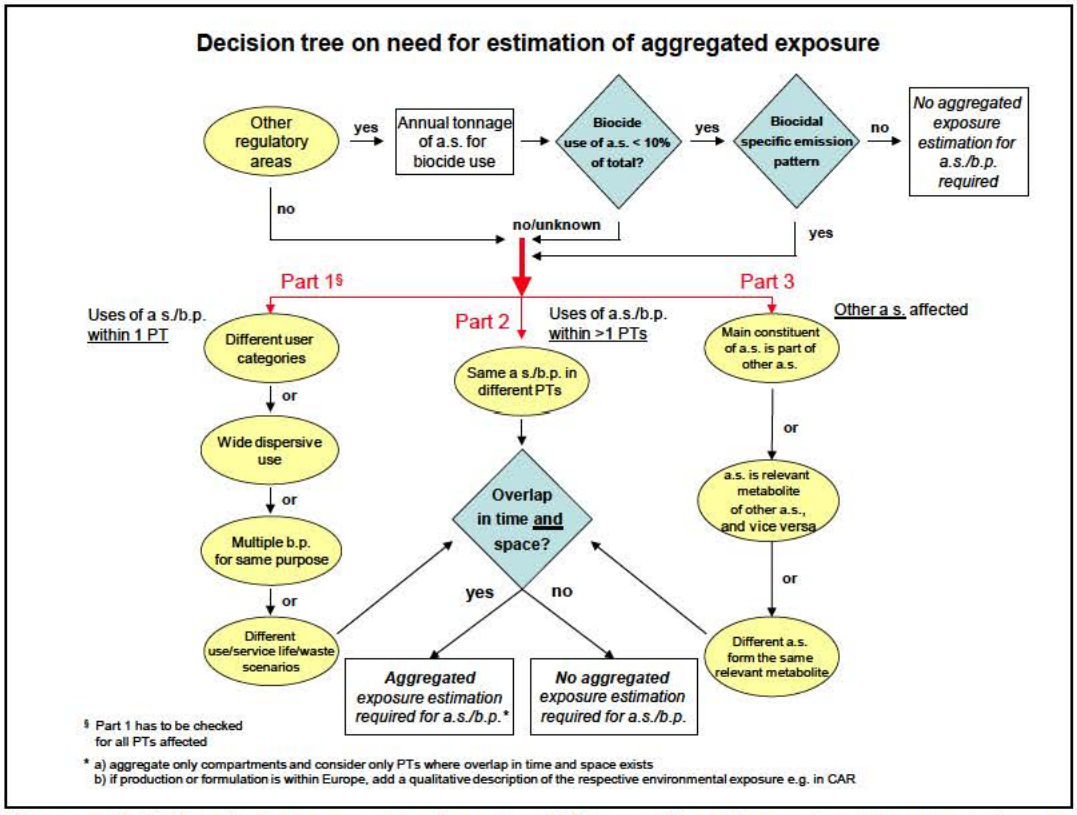

Figure 2-2: Decision tree on the need for estimation of aggregated exposure

The decision tree (Figure 2-2) was discussed and revised at the TM I 12 and will be used to discuss the need for the estimation of aggregated exposure. Propan-1-ol is also regulated in other regulatory areas (e.g. REACH). Consequently, the annual EU tonnage of an a.s for biocidal use should be compared with the total annual tonnage that is produced or imported for all applications in the EU. The amount of propan-1-ol that is used annually for biocidal purposes accounts for less than 5 % of the total production and import volume in the EU in 2007 (trigger value is below 10 % of the total production and import volume in the EU). The intended uses (hand and skin disinfection (leave-on-product), disinfection of small surfaces in the sanitary sector and small surfaces in food industry (e.g. slaughterhouses) are widely dispersive and do not represent a specific emission pattern. Hence, according to the decision tree it has been concluded that no aggregated exposure assessment for a.s. propan-1-ol has to be performed.

2.2.2.4. Risk characterisation

Aquatic Compartment including Sediment

A $PNEC_{water}$ for the active substance propan-1-ol of 2.3 mg/L was derived from the lowest acute effect value obtained with *Nitocra spinipes*. Further, a $PNEC_{sediment}$ of 1.998 mg/kg ww was determined by using equilibrium partioning method based on the $PNEC_{water}$. For the effect

assessment of the sewage treatment plant a $PNEC_{microorganisms, STP}$ of 10 mg/L was derived. During life cycle stage use a partial release of the b.p. via waste water – due to leakage or rinse-off and via cleaning of treated areas - to STP and subsequent to surface water and sediment can not be excluded. The PEC values were calculated on the basis of the uses in the differet product types:

- PT 1 - ready-to-use solution for hand and skin disinfection in health care areas and other areas.
- PT 2 - ready-to-use solution for disinfection of small surfaces in the sanitary sector
- PT 4 - for disinfection of small surfaces in food industry (e.g. slaughterhouses)

In PT 1 and PT 2 the estimated release fractions into waste water and air are higher in case of using the consumption based approach. In the PT 4 the consumption based approach is applied anyway. Thus, the environmental exposure and risk assessment are based for all PTs on the consumption based approach.

Table 2-17 PEC/PNEC ratios for the use of the b.p. in PT 1 as hand and skin disinfectant

Compartment	PEC [µg/L]	PNEC [µg/L]	PEC / PNEC
STP	37.8	10,000	3.78×10^{-3}
Surface water	3.78	2,300	1.64×10^{-3}
Compartment	**PEC [µg/kg]**	**PNEC [µg/kg ww]**	**PEC / PNEC**
Sediment	3.28	1,998	1.64×10^{-3}

Table 2-18 PEC/PNEC ratios for the use of the b.p. in PT 2 as disinfectant for small surfaces in the sanitary sector

Compartment	PEC [µg/L]	PNEC [µg/L]	PEC / PNEC
STP	87.88	10,000	8.79×10^{-3}
Surface water	8.79	2,300	3.82×10^{-3}
Compartment	**PEC [µg/kg]**	**PNEC [µg/kg ww]**	**PEC / PNEC**
Sediment	7.64	1,998	3.82×10^{-3}

Table 2-19 PEC/PNEC ratios for the use of the b.p. in PT 4 as disinfectant for small surfaces in food industry (e.g. slaughterhouses)

Compartment	PEC [µg/L]	PNEC [µg/L]	PEC / PNEC
STP	0.75	10,000	7.5×10^{-5}
Surface water	0.075	2,300	3.26×10^{-5}
Compartment	**PEC [µg/kg]**	**PNEC [µg/kg ww]**	**PEC / PNEC**
Sediment	0.065	1,998	3.25×10^{-5}

The estimated PEC/PNEC values for the sewage treatment plant, surface water as well as for sediment are below the trigger value of 1 in all of the considered PTs. Thus, the use of the dummy product containing propan-1-ol for all intended uses indicates no unacceptable risk for the aquatic compartment.

Terrestrial Compartment including Groundwater

According to the intended uses of the active substance, direct exposure to the soil compartment does not occur. Indirect release into the terrestrial compartment as a result of deposition from the atmosphere is possible. The active substance is highly volatile and adsorption to soil is not expected. However, a risk characterisatio was conducted for the soil and the groundwater compartment, respectively.
The estimated PEC/PNEC-ratios for the soil compartment are below the trigger value of 1 for all intended uses. Thus, the use of the dummy product containing propan-1-ol indicates no unacceptable risk for the soil compartment.

Table 2-20 PEC/PNEC ratios for the use of the b.p. in PT 1 as hand and skin disinfectant

Compartment	PEC [µg/kg]	PNEC [µg/kg ww]	PEC / PNEC
Soil	0.19	432	4.4×10^{-4}
Compartment	**PEC [µg/L]**	**Trigger value [µg/L]***	**Risk Quotient**
Groundwater	1.01	0.1	10.1

*Quality standard for pesticides and biocidal products according to Directive 2006/118/EG (Annex I)

Table 2-21 PEC/PNEC ratios for the use of the b.p. in PT 2 as disinfectant for small surfaces in the sanitary sector

Compartment	PEC [µg/kg]	PNEC [µg/kg ww]	PEC / PNEC
Soil	0.44	432	1.02×10^{-3}
Compartment	**PEC [µg/L]**	**Trigger value [µg/L]***	**Risk Quotient**
Groundwater	2.36	0.1	23.6

*Quality standard for pesticides and biocidal products according to Directive 2006/118/EG (Annex I)

Table 2-22 PEC/PNEC ratios for the use of the b.p. in PT 4 as disinfectant for small surfaces in food industry (e.g. slaughterhouses)

Compartment	PEC [µg/kg]	PNEC [µg/kg ww]	PEC / PNEC
Soil	0.0037	432	8.57×10^{-6}
Compartment	**PEC [µg/L]**	**Trigger value [µg/L]***	**Risk Quotient**
Groundwater	0.02	0.1	0.2

*Quality standard for pesticides and biocidal products according to Directive 2006/118/EG (Annex I)

Since the legally admissible threshold for biocides in groundwater (according to the Drinking Water Directive as well as to the Groundwater Directive) is exceeded in tier 1 for the intended uses in PT 1 and PT 2, a refinement of the groundwater assessment has been carried out using FOCUS PEARL 4.4.4. The refined estimations with FOCUS PEARL revealed that the average concentration of propan-1-ol in groundwater (closest to the 80th percentile) remains below the threshold criterion of 0.1 µg/L in 1 or more than 1 EU scenario for both grassland and arable land situation (refer to the non-confidential annex to DocII-8.3 for refinement estimation). According to the minutes of the 47th CA-Meeting (document: "CAJuly12- Doc.6.1.b – Number

of EU standard FOCUS-Scenarios which should demonstrate no risk for Annex I inclusion") it was agreed that FOCUS groundwater model PEARL should be used and that for active substance approval one safe use is sufficient. Thus, the use of the b.p. containing propan-1-ol indicates no unacceptable risk for the groundwater compartment.

Atmosphere

The main emission pathway during application step of the b.p. will be via air, because the substance evaporates completely within a short time due to the relatively high vapour pressure. Therefore, nearly the whole amount of substance applied is released to indoor air. For PEC estimation we assumed that this air is emitted to the local outside air without deposition indoors. The exact distribution between air and waste water is not known, but as a reasonable worst-case it is assumed that 90 % of a.s. is emitted to air and 10 % to waste water.
The half-life of propan-1-ol in the troposphere was estimated to be 2.8 days. Therefore, the active substance propan-1-ol has a potential for long-range environmental transport referring to the Annex D of the Stockholm Convention on Persistent Organic Pollutants (17th May 2004): "… a chemical that migrates significantly through the air, its half-life in air should be greater than two days …". On the other hand, according to the Guidance BPR IV ENV B (2015) effects on stratospheric ozone and acidification are not expected because propan-1-ol does not contain halogens, nitrogen or sulphur substituent. The potential for global warming can not be characterised because there is no information available in the absorption spectrum in the range from 800 to 1200 nm.
As there are no ecotoxicological data on animal species for the air compartment available, no quantitative characterisation of risk by comparison of the PEC_{air} to $PNEC_{air}$ is possible. According to Guidance BPR IV ENV B (2015, chapter 3.7) a chemical may be dangerous for the atmospheric environment at a low concentration, if it is classified as R 48 ("Danger of serious damage to health by prolonged exposure"). This classification does not apply to propan-1-ol. Furthermore, inhalation studies with mammals can be used as indicators of adverse effects of volatile compounds on animals. The comparison of effect values obtained from inhalation studies with mammals (acute and subchronic studies with rats) with predicted environmental concentration for air indicate that there is no adverse effect of the volatile compound on terrestrial animals. Due to the intended use of the b.p. for product type 1 which is limited to indoor application and on basis of the available substance information the environmental risk of propan-1-ol for the atmosphere can be assumed as low.

Aggregated Risk Assessment

Since the amount of propan-1-ol that is used annually in biocidal products accounts for less than 10 % compared to the annual production and import volume of propan-1-ol in the EU, no aggregated risk assessment was performed.

Overall Conclusion to the Environment

On basis of the risk assessment done for the different environmental compartments, it is concluded that the model formulation ("dummy product") containing the active substance propan-1-ol at a concentration of 70 % does not pose an unacceptable risk to the environment if used for

- ready-to-use solution for hand and skin disinfection in health care areas and other areas (**product type 1**, 'Human hygiene').
- ready-to-use solution for disinfection of small surfaces in the sanitary sector (**product type 2**, 'Disinfectants and algaecides not intended for direct application to humans or animals')
- PT 4 - for disinfection of small surfaces in food industry (e.g. slaughterhouses; **product type 4**, 'Food and feed area').

2.2.2.5. PBT and POP assessment

The PBT assessment for propan-1-ol was performed according to the Guidance BPR IV ENV B (2015, chapter 3.11, pp. 171) as well as to Annex XIII of the REACH regulation.

P criterion:	Half life > 40 d in freshwater or > 120 d in freshwater sediment or > 120 d in soil (according to the REACH legislation)
vP criterion:	Half life > 60 d in freshwater or > 180 d in freshwater sediment or > 180 d in soil (according to the REACH legislation)

According to ready biodegradability tests and a weight of evidence approach, propan-1-ol is considered to be readily biodegradable. Generally, it is assumed that a chemical giving a positive result in a test of this type will rapidly biodegrade in the environment. On the basis of this assumption, the P criterion as well as the vP criterion is not fulfilled.

B criterion:	BCF > 2000 L/kg
vB criterion:	BCF > 5000 L/kg

For propan-1-ol with a log K_{ow} < 3, the calculated bioconcentration factor for fish is 0.33 $L/kg_{wet\ fish}$ and for earthworm 0.86 $L/kg_{wet\ earthworm}$. Therefore, the B criterion as well as the vB criterion is not fulfilled.

T criterion:	Long-term NOEC for freshwater organism < 0.01 mg/L or CMR or endocrine disrupting effects

The available long-term NOECs are clearly above the trigger value. There is no hint for CMR or endocrine disrupting effects. Therefore, the T criterion is not fulfilled.

Conclusion: The active substance **propan-1-ol is neither PBT - nor vP/vB** – candidate.

2.2.3. Assessment of endocrine disruptor properties

Referring to environmental and human health effect data there is no indication of endocrine disrupting properties of the active substance.

2.3. Overall conclusions

The outcome of the assessment for propan-1-ol in product-types 1, 2 and 4 is specified in the BPC opinions following discussions at the 20th meeting of the Biocidal Products Committee (BPC). The BPC opinions are available from the ECHA website.

2.4. List of endpoints

The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Name)	Propan-1-ol
Product-type	Bactericide, fungicide and virucide

Identity

Chemical name (IUPAC)	Propan-1-ol
Chemical name (CA)	1-Propanol
CAS No	71-23-8
EC No	200-746-9
Other substance No.	Index No: 603-003-00-0 RTECS No: UH8225000
Minimum purity of the active substance as manufactured (g/kg or g/l)	995 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	none
Molecular formula	C_3H_8O
Molecular mass	60.09 g/mol
Structural formula	CH3-CH2-CH2-OH

Physical and chemical properties

Melting point (state purity)	-127 °C
Boiling point (state purity)	97.2°C; 1013 hPa
Thermal stability / Temperature of decomposition	-
Appearance (state purity)	Clear colourless liquid, with a mild alcohol like odour
Relative density (state purity)	0.8053 (d20/4)
Surface tension (state temperature and concentration of the test solution)	67.1 mN/m (T= 25°C; c= 1 g/L)
Vapour pressure (in Pa, state temperature)	2760 Pa, 25°C
Henry's law constant (Pa m^3 mol^{-1})	0.76 Pa • m³/mol (bond method) 0.70 Pa • m³/mol (group method) at 25 °C each
Solubility in water (g/l or mg/l, state temperature)	dissolves indefinitely in water
Solubility in organic solvents (in g/l or mg/l, state temperature)	miscible with acetone, alcohol and ether

Stability in organic solvents used in biocidal products including relevant breakdown products	Not applicable
Partition coefficient (log P_{OW}) (state temperature)	log Pow = 0.25
Dissociation constant	The substance does not have acid or alkaline properties.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	No absorption maximum >210 nm
Flammability or flash point	Flash point: 23.5 °C (99.9 %) DIN 51755, ISO 3679 From the structural formula and composition of the substance it can be concluded that the substance does not evolve any flammable gases in contact with water or humid air and that it is stable at room temperature and is not pyrophoric.
Explosive properties	No explosive properties due to structural reasons.
Oxidising properties	No oxidising properties due to structural reasons
Auto-ignition temperature (liquids and gases)	385 °C, DIN 51794

Classification and proposed labelling

with regard to physical hazards	Flam. Liq. 2; H225 / GHS02; Danger
with regard to human health hazards	Eye Dam. 1; H318 / GHS05 STOT SE3; H336, / GHS07; Danger EUH066
with regard to environmental hazards	-

Chapter 2:Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	GC method according to Pharmacopoea Europaea (Ph. Eur. Monograph 1/2005: 2036) is suitable for the determination of the purity of propan-1-ol
Impurities in technical active substance (principle of method)	GC method according to Pharmacopoea Europaea (Ph. Eur. Monograph 1/2005: 2036) is suitable for the determination of the purity of propan-1-ol

Analytical methods for residues

Soil (principle of method and LOQ)	Not required, no residues expected

Air (principle of method and LOQ)	propan-1-ol (active substance) GC-FID, LOQ: 0.5 µg/m³ (EN ISO 16017-1:2000 method) GC-MS, LOQ: 1 µg/m³ (ISO 16000-6:2004 method, for confirmation)
Water (principle of method and LOQ)	Not required, no residues expected
Body fluids and tissues (principle of method and LOQ)	Not required, not classified as toxic or very toxic (T/T^+)
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required, no residues expected
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not required, no residues expected

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Rapid uptake, with peak blood levels within 10-15 min (mouse, human studies) to 1-2 h (rat study); Extent of absorption: Nearly 100 % (based on *in vivo* rat study)
Rate and extent of dermal absorption*:	No animal absorption studies are available. Human volunteer studies do not yield sufficient information for calculation of absorption (estimation as < 3 %). Absorption rate: 0.85 mg/cm²/h, based on *in vivo* rat study [redacted] for propan-2-ol; proposal of eCA to apply this rate also to the isomer propan-1-ol
Rate and extent of inhalation absorption	100 % default value. No absorption studies available. Physical chemical parameters and blood:air partition coefficients are indicative for a complete absorption comparable to propan-2-ol.
Distribution:	Widely distributed within 2 h, highest levels in liver, kidney (based on oral administration to rats)
Potential for accumulation:	No evidence for accumulation
Rate and extent of excretion:	77 % of ^{14}C in 72 h: predominantly via exhalation (72 %, volatile compounds not specified), < 5 % in urine, < 1 % in faeces (based on oral administration to rats)
Toxicologically significant metabolite(s)	Propionaldehyde, propionic acid, lactic acid

* the dermal absorption value is applicable for the active substance and might not be usable in product authorization

Acute toxicity	
Rat LD_{50} oral	6500 mg/kg bw
Rat LD_{50} dermal	No data
Rat LC_{50} inhalation	> 33.9 mg/L air x 4 h (whole body, vapour) (equiv. to > 5700 mg/kg bw)
Skin corrosion / irritation	Not irritant; Dryness of skin after repeated exposure (human data) **EUH066**
Eye irritation	Risk of serious eye damage (based on rabbit study and experience from human occupational exposure) **Eye dam. 1; H318**
Respiratory tract irritation	No histological abnormalities and no irritation observed in the respiratory tract in rats
Skin sensitisation (test method used and result)	Non-sensitising (GPMT, mouse ear-swelling test)
Respiratory sensitisation (test method used and result)	Not expected to be sensitising to the respiratory tract (no data available)
Repeated dose toxicity	
Short term	
Species / target / critical effect	Rat: Atrophy of testis germinal epithelium; impairment of fertility
Relevant oral NOAEL / LOAEL	No suitable data
Relevant dermal NOAEL / LOAEL	No data
Relevant inhalation NOAEL / LOAEL	Rat: 8 mg/L at 6 h/d, 5 d/wk (ca. 1830 mg/kg bw/d, 13-wks rat, supported by 2-wks study and 2 male reproduction toxicity studies)
Subchronic	
Species/ target / critical effect	Refer to short-term entries (short-term and subchronic studies were evaluated together).
Relevant oral NOAEL / LOAEL	
Relevant dermal NOAEL / LOAEL	
Relevant inhalation NOAEL / LOAEL	

Long term

Species/ target / critical effect	No suitable data
Relevant oral NOAEL / LOAEL	
Relevant dermal NOAEL / LOAEL	
Relevant inhalation NOAEL / LOAEL	

Genotoxicity	Negative in bacterial and mammalian *in vitro* tests; Negative in rat *in vivo* comet assay; metabolite propionaldehyde tested positive in mammalian *in vitro* tests

Carcinogenicity

Species/type of tumour	No suitable data
Relevant NOAEL/LOAEL	No suitable data

Reproductive toxicity

Developmental toxicity

Species/ Developmental target / critical effect	Rat, inhalation: *Maternal:* Food intake ↓ *Developmental:* Foetal body weights ↓, Skeletal malformations ↑
Relevant maternal NOAEL	8.75 mg/L air at 7 h/d (2756 mg/kg bw/d), for days 1-19 of gestation
Relevant developmental NOAEL	8.75 mg/L air at 7 h/d (2756 mg/kg bw/d), for days 1-19 of gestation

Fertility

Species/critical effect	Rat, inhalation: *Parental:* Food intake/body weight gain ↓ (maternal females) *Reproduction:* Impairment of male fertility *Offspring:* Body weight gain ↓ (females), malformations (crooked tails)
Relevant parental NOAEL	8.75 mg/L air at 7 h/d (2756 mg/kg bw/d; females), for days 1-19 or 1-20 of gestation
Relevant offspring NOAEL	8.75 mg/L air at 7 h/d (2756 mg/kg bw/d), for days 1-19 or 1-20 of gestation
Relevant fertility NOAEL	8.75 mg/L air at 7 h/d (2321 mg/kg bw/d; males), for 6 wks prior to mating

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Acute neurotoxicity *Mouse, oral gavage:* Impairment of rotarod performance *Rat, inhalation:* (Hypoactivity), narcosis, prostration, decrease in reflexes
Relevant neurotoxicity NOAEL(s)	NOAEL: 1000 mg/kg bw/d (impairment of rotarod performance; mouse, 5 d, oral gavage) NOAEC: 12.9 mg/L air for 4 h (ca. 2200 mg/kg bw/d; rat acute inhalation) **STOT SE 3; H336**

Immunotoxicity

Species/ target/critical effect	No data

Developmental Immunotoxicity

Species/ target/critical effect	No data

Other toxicological studies

No data, not required

Medical data

Case reports	<u>Ingestion:</u> 500 ml (estimated amount): unconsciousness, death (female, suicide, ingestion of cosmetic product) Intoxication by abuse of disinfectant formulation containing both propan-1-ol and propan-2-ol: Narcosis and metabolic acidosis (metabolic acidosis explained by metabolism of propan-1-ol to propionic acid and lactic acid)
Studies with human volunteers, case reports	<u>Dermal exposure:</u> Skin erythema; Desiccation of skin **EUH066**
Occupational exposure	<u>Eye contact:</u> Vacuole-like alterations in corneal epithelium that healed without residual scars were reported upon worker co-exposure with other substances. Data on propan-1-ol –containing antiseptics revealed occurrence of reversible eye irritation in very rare cases in relation to frequency of exposure. **Eye dam. 1; H318**

Summary

	Value	Study	Safety factor
$AEL_{long-term}$	**9.2 mg/kg bw/d**	Overall NOAEL from rat 13-week rat inhalation study (impairment in male fertility parameters)	200 (In addition to default AF of 100, application of separate AF of 2 for extrapolation from medium-term to long-term systemic toxicity)
$AEL_{medium-term}$	**18.3 mg/kg bw/d**	Overall NOAEL from rat 13-week inhalation study (impairment of male fertility parameters)	100
AEL_{acute}	**27.6 mg/kg bw/d**	Rat inhalation developmental toxicity studies (foetal skeletal malformations)	100
ADI[2]	9.2 mg/kg bw/d		
ARfD[8]	27.6 mg/kg bw		

MRLs

Relevant commodities	-

Reference value for groundwater

According to BPR Annex VI, point 68	-

Dermal absorption

Study (*in vitro/vivo*), species tested Formulation (formulation type and including concentration(s) tested, vehicle)	No animal absorption studies are available. Human volunteer studies do not yield sufficient information for calculation of absorption (estimation as < 3 %). Absorption rate: 0.85 mg/cm²/h, based on *in vivo* rat study [redacted] for propan-2-ol; proposal of the eCA to apply this rate also to the isomer propan-1-ol
Dermal absorption values used in risk assessment	0.85 mg/cm²/h

[2] If residues in food or feed.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	no hydrolysis
pH 5	-
pH 9	-
Other pH: *[indicate the value]*	-
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	not applicable, no absorption maximum >290 nm
Readily biodegradable (yes/no)	yes
Inherent biodegradable (yes/no)	-
Biodegradation in freshwater	-
Biodegradation in seawater	No data
Non-extractable residues	No data
Distribution in water / sediment systems (active substance)	No data
Distribution in water / sediment systems (metabolites)	No data

Route and rate of degradation in soil

Mineralization (aerobic)	No data
Laboratory studies (range or median, with number of measurements, with regression coefficient)	
DT_{50lab} (20°C, aerobic):	No data
DT_{90lab} (20°C, aerobic):	No data
DT_{50lab} (10°C, aerobic):	No data
DT_{50lab} (20°C, anaerobic):	No data
degradation in the saturated zone:	No data
Field studies (state location, range or median with number of measurements)	
DT_{50f}:	No data
DT_{90f}:	No data
Anaerobic degradation	No data
Soil photolysis	No data
Non-extractable residues	No data
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	No data

Soil accumulation and plateau concentration	No data

Adsorption / desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	K_{OC} was estimated by QSAR-model for alcohols described in Guidance BPR IV ENV B (2015): K_{OC} = 3.96 L/kg no

Fate and behaviour in air

Direct photolysis in air	No data
Quantum yield of direct photolysis	No data
Photo-oxidative degradation in air	tropospherical half-life of propan-1-ol: 2.8 d (according to Atkinson et al. (2006), reaction with OH radicals (global 24-hours-mean), concentration: 5 x 10^5 OH/cm^3)
Volatilization	Henry's law constant indicates moderate volatility

Reference value for groundwater

According to BPR Annex VI, point 68	-

Monitoring data, if available

Soil (indicate location and type of study)	-
Surface water (indicate location and type of study)	-
Ground water (indicate location and type of study)	-
Air (indicate location and type of study)	-

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Pimephales promelas	96 h	Mortality	LC_{50} = 4554 mg/L (m) (calculated as geometric mean)
Invertebrates			
Nitocra spinipes	96 h	Mortality	EC_{50} = 2300 mg/L

Algae			
Pseudokirchneriella subspicata	48 h	Growth rate	E_rC_{50} = 9170 mg/L
Microorganisms			
Activated sludge (municipal sewage treatment plant)	3 h (static)	respiration inhibition	EC_{50} > 1000 mg a.s./L (nominal)

Effects on earthworms or other soil non-target organisms

Acute toxicity to ……..…	No data
Reproductive toxicity to …….	No data

Effects on soil micro-organisms

Nitrogen mineralization	No data
Carbon mineralization	No data

Effects on terrestrial vertebrates

Acute toxicity to mammals	No data
Acute toxicity to birds	No data
Dietary toxicity to birds	No data
Reproductive toxicity to birds	No data

Effects on honeybees

Acute oral toxicity	No data
Acute contact toxicity	No data

Effects on other beneficial arthropods

Acute oral toxicity	No data
Acute contact toxicity	No data
Acute toxicity to ……..	No data

Bioconcentration

Bioconcentration factor (BCF)	Calculated BCFfish = 0.33 L/kgwet fish Calculated BCFearthworm = 0.86 L/kgwet earthworm
Depration time (DT_{50})	No data
Depration time (DT_{90})	No data
Level of metabolites (%) in organisms accounting for > 10 % of residues	No data

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Propan-1-ol is employed as a broad-spectrum microbiocide for the disinfection of skin, surfaces, inanimate objects and materials and equipment in private, public health and industrial areas.

Object and/or situation (a)	Product name	Organisms controlled (c)	Formulation		Application			Applied amount per treatment			Remarks:
			Type (b,d-f)	Conc. of a.s. (i)	method kind (f-h)	number min max	interval between applications (min)	g a.s./mL min max	mL/m^2 min max	g a.s./m^2 min max	
PT 1 (e.g. disinfection on skin)	Propan-1-ol based disin-fectant	Obligate or facultative pathogenic bacteria (including mycobacteria, but excluding bacterial spores), fungi and viruses	Ready-To-use-solution	70 %*	Hands rubbing	12 36**	10	0.6	3 /event	1.8 /event	
PT 2 (surface disinfection)	Propan-1-ol based disin-fectant	Obligate or facultative pathogenic bacteria (including mycobacteria, but excluding bacterial spores), fungi and viruses	Ready-To-use-solution	70 %	Spraying and Wiping	1 16**	30	0.6	$50/m^2$ (max)	$30/m^2$ (max)	

Object and/or situation (a)	Product name	Organisms controlled (c)	Formulation		Application			Applied amount per treatment			Remarks:
			Type (b,d-f)	Conc. of a.s. (i)	method kind (f-h)	number min max	interval between applications (min)	g a.s./mL min max	mL/m^2 min max	g a.s./m^2 min max	
PT 4 (surface disinfection)	Propan-1-ol based disin-fectant	Obligate or facultative pathogenic bacteria (including mycobacteria, but excluding bacterial spores), fungi and viruses	Ready-To-use-solution	70 %	Wiping	1 4	120	0.6	$50/m^2$ (max)	$30/m^2$ (max)	

* The intended use concentration as described by the applicant is given as 70 % propan-1-ol for PT 1. However, in case of PT 1 a concern was determined regarding exposure of professionals for 70 % propan-1-ol. Consequently, basic efficacy had to be shown for 60 % propan-1-ol for PT 1.

** For the exposure assessment the agreed default values from models were used: 25 applications per shift for hand disinfection (PT 1) and 10 applications for small surface disinfection (PT 2)

Appendix III: Human health tables for risk characterisation

Product Type 1:

Table 1: Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL & Reference Value $AEL_{long\text{-}term}$ [mg/kg bw/day][3]	AF MOE_{ref}	MOE[4]	Exposure /AEL
		oral uptake [mg/kg bw/day]	inhalation uptake [mg/kg bw/day][1]	dermal uptake [mg/kg bw/day][2]	total uptake [mg/kg bw/day]				
Tier 1 (no PPE)	hand disinfection in hospitals – 70 % a.s. (scenario 1a)	-	1.64	8.56	10.20	NOAEL = 1830 $AEL_{long\text{-}term}$ = 9.2 mg/kg/d	200	179	1.11
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	hand disinfection in hospitals – 60 % a.s. (scenario 1b) (scenario 1b)	-	1.45	7.51	8.96	NOAEL = 1830 $AEL_{long\text{-}term}$ = 9.2 mg/kg/d	200	204	0.97

1. Based on the assumption of 100 % absorption by inhalation, body weight 60 kg and breathing volume of 10 m^3
2. Based on dermal flux rate of 0.85 mg/cm^2/h, an exposed skin area of 820 cm^2 and an exposure time of 44,2 min (70 % a.s.; 25*106 sec.) resp. 38,8 min. (60 % a.s.; 25*93 sec.) body weight 60 kg
3. Based on impairment of male fertility parameters and abnormalities in testis histopathology in repeated-dose rat inhalation studies (derived from an overall NOAEL of 1830 mg/kg bw/d from the 13-week rat inhalation study). In addition to the default AF of 100, an extra AF of 2 was applied for extrapolation from medium-term to long-term systemic toxicity
4. Calculation MOE: NOAEL/estimated total uptake, concern MOE ≤ 200

Table 2: Non Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		oral uptake [mg/kg bw/day]	inhalation uptake [mg/kg bw/day]	dermal uptake [mg/kg bw/day]	total uptake [mg/kg bw/day]				
Tier 1 (no PPE)	Use by visitors of intensive health care patients: Acute	-	-	-	-	-			
		-	1.5	1.35	2.9	18.3 ($AEL_{medium-term}$)	100	610	0.16
	Medium-term	-	1.33	0.449	1.78	9.2 ($AEL_{long-term}$)	200	1227	0.19
	Home-dialysis: Chronic								
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	Not required								

Table 3: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)	Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
	oral uptake [mg/kg bw/day]	inhalation uptake [mg/kg bw/day]	dermal uptake [mg/kg bw/day]	total uptake [mg/kg bw/day]				
Tier 1 (Worst Case) Short term Scenario	Not expected or covered by Long-term scenario							
Tier 2 (Refinement) Short term Scenario	Not required							

Table 4: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL & Reference Value $AEL_{long-term}$ [mg/kg bw/day][3]	AF MOE_{ref}	MOE[3]	Exposure /AEL
		inhalation uptake [mg/kg bw/day][1]	dermal uptake [mg/kg bw/day]	oral uptake [mg/kg bw/day]	total uptake [mg/kg bw/day]				
Tier 1 (Worst Case) Chronic Scenario	Secondary exposure 70 % a.s. (scenario 2)	0.29	-	-	0.29	NOAEL= 1830 mg/kg/d $AEL_{long-term}$ = 9.2 mg/kg/d (2)	200	6310	0.03
	Exposure after use, home dia-lysis, adults	1.33	-	-	1.33	9.2 ($AEL_{long-term}$)	200	1840	0.15
	Exposure after use, home dia-lysis, children	1.8	-	-	1.8	9.2 ($AEL_{long-term}$)	200	1022	0.20
Tier 2 (Refinement) Chronic Scenario	Not required								

1. Based on the assumption of 100 % absorption by inhalation, body weight 60 kg and breathing volume of 10 m^3
2. Based on impairment of male fertility parameters and abnormalities in testis histopathology in repeated-dose rat inhalation studies (derived from an overall NOAEL of 1830 mg/kg bw/d from the 13-week rat inhalation study). In addition to the default AF of 100, an extra AF of 2 was applied for extrapolation from medium-term to long-term systemic toxicity
3. Calculation MOE: NOAEL/estimated total uptake, concern MOE ≤ 200

Product Type 2:

Table 1: Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL & Reference Value $AEL_{long\text{-}term}$ [mg/kg bw/day][3]	AF MOE_{ref}	MOE[4]	Exposure /AEL
		oral uptake [mg/kg bw/day]	inhalation uptake [mg/kg bw/day][1]	dermal uptake [mg/kg bw/day][2]	total uptake [mg/kg bw/day]				
Tier 1 (no PPE)	disinfection of small surfaces (0.5 m^2) (scenario 1)	-	5.25	0.48	5.73	NOAEL= 1830 mg/kg/d $AEL_{long\ term}$ = 9.2 mg/kg/d	200	319	0.62
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	Not required								

1. Based on 100 % absorption by inhalation, body weight 60 kg and breathing volume of 10 m^3
2. Based on the assumption of 0.85 mg/cm^2/h dermal flux, exposed skin of 205 cm^2 and an exposure time of 10 minutes
3. based on impairment of male fertility parameters and abnormalities in testes histopathology in repeated-dose rat inhalation studies (derived from an overall NOAEL of 1830 mg/kg bw/d from the 13-week rat inhalation study). In addition to the default AF of 100, an extra AF of 2 was applied for extrapolation from medium-term to long-term systemic toxicity
4. calculation MOE: NOAEL/estimated total uptake, concern MOE ≤ 200

Table 2: Non Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		oral uptake [mg/kg bw/day]	inhalation uptake [mg/kg bw/day]	dermal uptake [mg/kg bw/day]	total uptake [mg/kg bw/day]				
Tier 1 (no PPE)	Acute exposure Household use 1 application	-	1.74	1.2	2.94	27.6 (AEL_{acute})	100	863	0.11
	5 applications	-	8.7	6.1	14.8	27.6 (AEL_{acute})	100	175	0.54
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	Not required								

Table 3: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		oral uptake [mg/kg bw/day]	inhalation uptake [mg/kg bw/day]	dermal uptake [mg/kg bw/day]	total uptake [mg/kg bw/day]				
Tier 1 (Worst Case) Short term Scenario	After household use (1 application), adults	-	1.74	-	1.74	27.6 (AEL_{acute})	100	1453	0.06
	After household use (1 application), children	-	3.1	-	3.1	27.6 (AEL_{acute})	100	890	0.11
Tier 2 (Refinement) Short term Scenario	Not required								

Table 4: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL & Reference Value $AEL_{long\text{-}term}$ [mg/kg bw/day][3]	AF MOE_{ref}	MOE[3]	Exposure /AEL
		inhalation uptake [mg/kg bw/day][1]	dermal uptake [mg/kg bw/day]	oral uptake [mg/kg bw/day]	total uptake [mg/kg bw/day]				
Tier 1 (Worst Case) Chronic Scenario	Secondary exposure (scenario 2)	< 5.25	-	-	< 5.25	NOAEL = 1830 $AEL_{long\ term}$ = 9.2	200	>349	< 0.57
Tier 2 (Refinement) Chronic Scenario	Not required								

1. Based on the assumption of 100 % absorption by inhalation, body weight 60 kg and breathing volume of 10 m^3

2. Based on impairment of male fertility parameters and abnormalities in testis histopathology in repeated-dose rat inhalation studies (derived from an overall NOAEL of 1830 mg/kg bw/d from the 13-week rat inhalation study). In addition to the default AF of 100, an extra AF of 2 was applied for extrapolation from medium-term to long-term systemic toxicity

3. Calculation MOE: NOAEL/estimated total uptake, concern MOE ≤ 200

Product Type 4:

Table 1: Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL & Reference Value $AEL_{long\text{-}term}$ [mg/kg bw/day][3]	AF MOE_{ref}	MOE[4]	Exposure /AEL
		oral uptake [mg/kg bw/day]	inhalation uptake [mg/kg bw/day][1]	dermal uptake [mg/kg bw/day][2]	total uptake [mg/kg bw/day]				
Tier 1 (no PPE)	Surfaces disinfection in canteens or kitchens (scenario 1)	-	3.35	0.39	3.74	NOAEL = 1830 $AEL_{long\ term}$ = 9.2	200	490	0.41
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	Surfaces disinfection in food processing industry (scenario 2)	-	1.85	1.94	3.79		200	483	0.41
	Not required								

1. Based on 100 % absorption by inhalation, body weight 60 kg and breathing volume of 10 m^3
2. based on a dermal flux rate of 0.85 mg/cm^2/h, an exposed skin area of 205 cm^2 and an exposure time of 8 min (scenario 1) or rather an exposed skin area of 410 cm^2 and an exposure time of 20 min (scenario 2), body weight 60 kg
3. based on impairment of male fertility parameters and abnormalities in testes histopathology in repeated-dose rat inhalation studies (derived from an overall NOAEL of 1830 mg/kg bw/d from the 13-week rat inhalation study). In addition to the default AF of 100, an extra AF of 2 was applied for extrapolation from medium-term to long-term systemic toxicity
4. calculation MOE: NOAEL/estimated total uptake, concern MOE ≤ 200

Table 2: Non Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		oral uptake [mg/kg bw/day]	inhalation uptake [mg/kg bw/day]	dermal uptake [mg/kg bw/day]	total uptake [mg/kg bw/day]				
Tier 1 (no PPE)	Household use		3.51	1.2	4.71	27.6 (AEL_{acute})	100	540	0.17
Tier 2 (Refinement, PPE or other risk mitigation measures – Specify)	Not required								

Table 3: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL/ LOAEL [mg/kg b.w./day] & Reference Value e.g.: AEL (acute or medium or chronic)	AF MOE_{ref}	MOE	Exposure /AEL
		oral uptake [mg/kg bw/day]	inhalation uptake [mg/kg bw/day]	dermal uptake [mg/kg bw/day]	total uptake [mg/kg bw/day]				
Tier 1 (Worst Case) Short term Scenario	After household use, adults	-	3.51	-	3.51	27.6 (AEL_{acute})	100	726	0.13
	After household use, children	-	6.3	-	6.3	27.6 (AEL_{acute})	100	438	0.23
Tier 2 (Refinement) Short term Scenario	Not required								

Table 4: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure				Relevant NOAEL & Reference Value $AEL_{long\text{-}term}$ [mg/kg b.w/day][2]	AF MOE_{ref}	MOE[3]	Exposure /AEL
		inhalation uptake [mg/kg bw/day][1]	dermal uptake [mg/kg bw/day]	oral uptake [mg/kg bw/day]	total uptake [mg/kg bw/day]				
Tier 1 (Worst Case) Chronic Scenario	Bystander Disinfection of small surfaces in kitchens and canteens	< 3.35	-	-	< 3.35	NOAEL= 1830 mg/kg/d $AEL_{long\ term}$ = 9.2 mg/kg/d (2)	200	> 546	≤0.36
	BystanderDisinfection of small surfaces in food processing industry	< 1.85	-	-	< 1.85		200	> 987	≤0.20
Tier 2 (Refinement) Chronic Scenario	Not required								

1. Based on the assumption of 100 % absorption by inhalation, body weight 60 kg and breathing volume of 10 m^3
2. Based on impairment of male fertility parameters and abnormalities in testis histopathology in repeated-dose rat inhalation studies (derived from an overall NOAEL of 1830 mg/kg bw/d from the 13-week rat inhalation study). In addition to the default AF of 100, an extra AF of 2 was applied for extrapolation from medium-term to long-term systemic toxicity
3. Calculation MOE: NOAEL/estimated total uptake, concern MOE ≤ 200

Appendix IV: List of terms and abbreviations

Stand. term / Abbreviation	**Explanation**
A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AEL	Systemic (= Internal) Acceptable Exposure Level
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50 %
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor

Stand. term / Abbreviation	**Explanation**
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	*Bacillus thuringiensis*
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits

Stand. term / Abbreviation	**Explanation**
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRP	detailed review paper *(OECD)*
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose

Stand. term / Abbreviation	**Explanation**
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances
F	field
F_0	parental generation
F_1	filial generation, first
F_2	filial generation, second
FBS	full base set
FELS	fish early-life stage
FIA	fluorescence immuno-assay
FID	flame ionisation detector
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography

Stand. term / Abbreviation	**Explanation**
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPS	global positioning system
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)
ha	hectare(s)
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a

Stand. term / Abbreviation	**Explanation**
	given level of confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I_{50}	inhibitory dose, 50 %
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator

Stand. term / Abbreviation	**Explanation**
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
kg	kilogram
K_H	Henry´s Law constant (in atmosphere per cubic metre per mole)
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient

Stand. term / Abbreviation	**Explanation**
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation

Stand. term / Abbreviation	**Explanation**
	spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometre (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected

Stand. term / Abbreviation	**Explanation**
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a.	not applicable
n-	normal (defining isomeric configuration)
n	number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase

Stand. term / Abbreviation	**Explanation**
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid

Stand. term / Abbreviation	**Explanation**
	dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose

Stand. term / Abbreviation	**Explanation**
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
S	solubility
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating

Stand. term / Abbreviation	**Explanation**
	procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TDR	time domain reflectrometry
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio

Stand. term / Abbreviation	**Explanation**
	following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
TIm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex

Stand. term / Abbreviation	**Explanation**
	reaction products in biological material
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Appendix V: List of studies

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

Doc II (PT 1):

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.3	World Health Organisation (WHO)	1990	International Programme on Chemical Safety. Environmental Health Criteria 102: 1-Propanol. WorldHealth Organisation 1990. (http://www.inchem.org/documents/ehc/ehc/ehc102.htm)	No	-
Chap.3	Kampf G & Kramer A	2004	Epidemiologic background of hand hygiene and evaluation of the most important agents for scrubs and rubs. Clin. Microbiol. Reviews 17 (2004): 863-893	No	-
Chap.3	Moorer WR	2003	Antiviral activity of alcohol for surface disinfection. Int. J. Dent. Hygiene 1 (2003): 138-142	No	-
Chap.4	ECB	2000	Technical Guidance Document in support of the Directive 98/8/EC concerning the placing of biocidal products on the market, Guidance on data requirements for active substances and biocidal products (TNsG) , October 2000	No	Publi-cation
Chap.4	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publi-cation
Chap.4	EC	1967	Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances	No	Publi-cation
Chap.4	ECHA	2015	Guidance on the Biocidal Product Regulation-Volume IV Environment – Part B Risk Assessment (active substances) Version 1.0	No	Publi-cation
Chap.4	UNEP	2004	Stockholm Convention on Persistent Organic Pollutants (POP), entered into force 17 May 2004	No	Publi-cation
Chap.4	LYMAN et al.	1982	Handbook of chemical property estimation methods, McGraw-Hill Inc.; New York	No	Publi-cation
Chap.4	BUSTARD et al.	2000	Biodegradation of propanol and isopropanol by a mixed microbial consortium. Applied microbiology and biotechnology 54, 424-431	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.4	VAN DEN WIJNGAARD et al.	1992	Degradation of 1, 2-dichloroethane by Ancylobacter aquaticus and other facultative methylotrophs, Applied and environmental microbiology 58, 976-983	No	Publi-cation
Chap.4	POELARENDS et al.	1998	Degradation of 1, 3-dichloropropene by Pseudomonas cichorii 170. Applied and environmental microbiology 64, 2931-2936	No	Publi-cation
Chap.4	JANSSEN et al.	1987	Degradation of n-haloalkanes and alpha, omega-dihaloalkanes by wild-type and mutants of Acinetobacter sp. Strain GJ70. Applied and environmental microbiology 53, 561-566	No	Publi-cation
Chap.4	HARTMANS & DE BONT	1992	Aerobic vinyl chloride metabolism in Mycobacterium aurum L1. Applied and Environmental Microbiology 58, 1220-1226	No	Publi-cation
Chap.4	POELARENDS et al.	1999	Degradation of 1, 2-Dibromoethane byMycobacterium sp. Strain GP1. Journal of bacteriology 181, 2050-2058	No	Publi-cation
Chap.4	RABUS et al.	1993	Complete oxidation of toluene under strictly anoxic conditions by a new 81ulphate-reducing bacterium. Applied and Environmental Microbiology 59, 1444-1451	No	Publi-cation
Chap.4	DWORKIN et al.	2006	The Prokaryotes: Vol. 3: Archaea. Bacteria: Firmicutes, Actinomycetes. (Springer Science & Business Media, 2006)	No	Publi-cation
Chap.4	WIDDEL	1986	Growth of methanogenic bacteria in pure culture with 2-propanol and other alcohols as hydrogen donors. Applied and Environmental Microbiology 51, 1056-1062	No	Publi-cation
Chap.4	DEMIRER & SPEECE	1998	Anaerobic biotransformation of four 3-carbon compounds (acrolein, acrylic acid, allyl alcohol and n-propanol) in UASB reactors. Water research 32, 747-759	No	Publi-cation
Chap.4	SCHINK	1985	Mechanisms and kinetics of succinate and propionate degradation in anoxic freshwater sediments and sewage sludge. Microbiology 131, 643-650	No	Publi-cation
Chap.4	WIEGANT et al.	1986	Separation of the propionate degradation to improve the efficiency of thermophilic anaerobic treatment of acidified wastewaters. Water Research 20, 517-524	No	Publi-cation
Chap.4	MAWSON et al.	1991	Degradation of acetic and propionic acids in the methane fermentation. Water Research 25, 1549-1554	No	Publi-cation
Chap.4	KROONEMAN et al.	2002	Lactobacillus diolivorans sp. Nov., a 1, 2-propanediol-degrading bacterium isolated from aerobically stable maize silage. International journal of systematic and evolutionary microbiology 52, 639-646	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.4	SINHA et al.	2012	The PduM protein is a structural component of the microcompartments involved in coenzyme B12-dependent 1, 2-propanediol degradation by Salmonella enterica. Journal of bacteriology 194, 1912-1918	No	Publi-cation
Chap.4	GOBETTI et al.	1995	Volatile compound and organic acid productions by mixed wheat sour dough starters: influence of fermentation parameters and dynamics during baking. Food Microbiology 12, 497-507	No	Publi-cation
Chap.6	Boatman RJ, Perry LG, Fiorica LA, English JC, Kapp Jr RW, Bevan C, Tyler TR, Banton MI & Wright GA	1998	Dermal absorption and pharmacokinetics of isopropanol in the male and female F-344 rat. Drug Metab Dispos 26, 197 – 202	No	Publi-cation
Chap.8	Bieber, N.	2006	Absorption of alcohol from hand disinfection (Alkoholresorption nach Händedesinfektion) Dissertation Ernst-Moritz-Arndt-Universität Greifswald, Germany	No	Publi-cation
Chap.8	Brunner, A	2004	Neue Krankenhausrichtlinie in der Schweiz und in Deutschland: SWKI-Richtlinie 99-3 und VDI 2167, Blatt 1	No	Publi-cation
Chap.8	DGKH	2002	Deutsche Gesellschaft für Krankenhaushygiene. Leitlinienentwurf: Ausführung und Betrieb von raumlufttechnischen Anlagen (RLT-Anlagen) in Krankenhäusern Hyg. + Med. 27(3) 106-113	No	Publi-cation
Chap.8	DIN 1946-4	2007	Raumlufttechnik – Teil 4: Raumlufttechnische Anlagen in Krankenhäusern. Deutsches Institut für Normung e.V. Berlin	No	Publi-cation
Chap.8	EC	2003	Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulations No. 1488/94 on risk assessment for existing substances (Part I, II, III, IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocide products on the market. European Commission 2003 (TGD, App. I, App. IF, Evaporation rate, page 216)	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.8	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publi-cation
Chap.8	ECHA	2015	Guidance on the Biocidal Product Regulation-Volume IV Environment – Part B Risk Assessment (active substances) Version 1.0	No	Publi-cation
Chap.8	Royal Haskoning	2004	Supplement to the methodology for risk evaluation of biocides. Environmental Emission Scenarios for biocides used as human hygiene biocidal products (product type 1)	No	Publi-cation
Chap.8	[redacted]	[redacted]	Estimation of the Environmental Concentrations and the Preliminary Environmental Risk Assessment of 2-Propanol applied biocidal products (PT 1, 2 and 4). [redacted]	Yes	[redacted]
Chap.8	EC	2007	European Union Risk Assessment Report: PROPAN-1-OL, Part I – Environment, CAS No.: 71-23-8, EINECS No.: 200-746-9. SUMMARY RISK ASSESSMENT REPORT, Final report, 2007 [redacted], published	No	Publi-cation
Chap.8	CA Meeting	2008	EU Workshop PT 1-6 Report, document: "CA-Nov08-Doc[1].6.3 - Workshop Report PT1-6 CA 31 final track changes"	No	No owner
Chap.8	LYMAN et al.	1982	Handbook of chemical property estimation methods, McGraw-Hill Inc.; New York	No	Publi-cation
Chap.8	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Publi-cation
Chap.8	EC	1998	Biocidal Product Directive (BPD), Directive 98/8/EC concerning the placing of biocidal products on the market	No	Publi-cation
Chap.8	ECB	2002	TNsG on Annex I inclusion. Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB, April 2002	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.8	ECHA	2016	Technical Agreements for Biocides (TAB)	No	Publi-cation
Chap.13	ECHA	2015	Guidance on the Biocidal Product Regulation-Volume IV Environment – Part B Risk Assessment (active substances) Version 1.0	No	Publi-cation
Chap.13	EC	1998	Drinking Water Directive (DWD), Council Directive 98/83/EC on the quality of water intended for human consumption	No	Publi-cation
Chap.13	EC	2006	Groundwater Directive (GWD), Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration	No	Publi-cation
Chap.13	EC	2006	REACH-VO Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, authorisation and restriction of chemicals (REACH) establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC, Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC	No	Publi-cation
Chap.13	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publi-cation
Chap.13	UNEP	2004	Stockholm Convention on Persistent Organic Pollutants (POP), entered into force 17 May 2004	No	Publi-cation
Chap.13	EC	1998	Biocidal Product Directive (BPD), Directive 98/8/EC concerning the placing of biocidal products on the market	No	Publi-cation
Chap.13	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Publi-cation
Chap.13	EC	2007	European Commission, Risk Assessment Report on Propan-1-ol in the frame of the Existing Substance Regulation (Council Regulation 793/93/EEC of 23 March 1993 on the evaluation and control of existing substances)	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.13	EC	2008	European Commission, Workshop on environmental risk assessment for Product types 1 to 6, Arona, Italy, 11 March 2008	No	Publi-cation
Chap.13	ECHA	2016	Technical Agreements for Biocides (TAB)	No	Publi-cation
Chap.15	EC	1967	Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances	No	Publi-cation
Chap.15	German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety	1999	Administrative Regulation on the Classification of Substances Hazardous to Waters (VwVwS)	No	Publi-cation
Chap.15	EC	2001	European Waste List, Commission Decision of 16 January 2001 amending Decision 2000/532/EC as regards the list of wastes, OJ L 47, 16 February 2001	No	Publi-cation
Chap.15	EC	2006	Directive 2006/8/EEC amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations	No	Publi-cation

Doc II (PT 2):

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.3	World Health Organisation (WHO)	1990	International Programme on Chemical Safety. Environmental Health Criteria 102: 1-Propanol. WorldHealth Organisation 1990. (http://www.inchem.org/documents/ehc/ehc/ehc102.htm)	No	-

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.3	Kampf G & Kramer A	2004	Epidemiologic background of hand hygiene and evaluation of the most important agents for scrubs and rubs. Clin. Microbiol. Reviews 17 (2004): 863-893	No	-
Chap. 3	Moorer WR	2003	Antiviral activity of alcohol for surface disinfection. Int. J. Dent. Hygiene 1 (2003): 138-142	No	-
Chap.4	ECB	2000	Technical Guidance Document in support of the Directive 98/8/EC concerning the placing of biocidal products on the market, Guidance on data requirements for active substances and biocidal products (TNsG) , October 2000	No	Publi-cation
Chap.4	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publi-cation
Chap.4	EC	1967	Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances	No	Publi-cation
Chap.4	ECHA	2015	Guidance on the Biocidal Product Regulation-Volume IV Environment – Part B Risk Assessment (active substances) Version 1.0	No	Publi-cation
Chap.4	UNEP	2004	Stockholm Convention on Persistent Organic Pollutants (POP), entered into force 17 May 2004	No	Publi-cation
Chap.4	LYMAN et al.	1982	Handbook of chemical property estimation methods, McGraw-Hill Inc.; New York	No	Publi-cation
Chap.4	BUSTARD et al.	2000	Biodegradation of propanol and isopropanol by a mixed microbial consortium. Applied microbiology and biotechnology 54, 424-431	No	Publi-cation
Chap.4	VAN DEN WIJNGAARD et al.	1992	Degradation of 1, 2-dichloroethane by Ancylobacter aquaticus and other facultative methylotrophs, Applied and environmental microbiology 58, 976-983	No	Publi-cation
Chap.4	POELAREN DS et al.	1998	Degradation of 1, 3-dichloropropene by Pseudomonas cichorii 170. Applied and environmental microbiology 64, 2931-2936	No	Publi-cation
Chap.4	JANSSEN et al.	1987	Degradation of n-haloalkanes and alpha, omega-dihaloalkanes by wild-type and mutants of Acinetobacter sp. strain GJ70. Applied and environmental microbiology 53, 561-566	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.4	HARTMANS & DE BONT	1992	Aerobic vinyl chloride metabolism in Mycobacterium aurum L1. Applied and Environmental Microbiology 58, 1220-1226	No	Publi-cation
Chap.4	POELAREN DS et al.	1999	Degradation of 1, 2-Dibromoethane byMycobacterium sp. Strain GP1. Journal of bacteriology 181, 2050-2058	No	Publi-cation
Chap.4	RABUS et al.	1993	Complete oxidation of toluene under strictly anoxic conditions by a new sulfate-reducing bacterium. Applied and Environmental Microbiology 59, 1444-1451	No	Publi-cation
Chap.4	DWORKIN et al.	2006	The Prokaryotes: Vol. 3: Archaea. Bacteria: Firmicutes, Actinomycetes. (Springer Science & Business Media, 2006)	No	Publi-cation
Chap.4	WIDDEL	1986	Growth of methanogenic bacteria in pure culture with 2-propanol and other alcohols as hydrogen donors. Applied and Environmental Microbiology 51, 1056-1062	No	Publi-cation
Chap.4	DEMIRER & SPEECE	1998	Anaerobic biotransformation of four 3-carbon compounds (acrolein, acrylic acid, allyl alcohol and n-propanol) in UASB reactors. Water research 32, 747-759	No	Publi-cation
Chap.4	SCHINK	1985	Mechanisms and kinetics of succinate and propionate degradation in anoxic freshwater sediments and sewage sludge. Microbiology 131, 643-650	No	Publi-cation
Chap.4	WIEGANT et al.	1986	Separation of the propionate degradation to improve the efficiency of thermophilic anaerobic treatment of acidified wastewaters. Water Research 20, 517-524	No	Publi-cation
Chap.4	MAWSON et al.	1991	Degradation of acetic and propionic acids in the methane fermentation. Water Research 25, 1549-1554	No	Publi-cation
Chap.4	KROONEMAN et al.	2002	Lactobacillus diolivorans sp. nov., a 1, 2-propanediol-degrading bacterium isolated from aerobically stable maize silage. International journal of systematic and evolutionary microbiology 52, 639-646	No	Publi-cation
Chap.4	SINHA et al.	2012	The PduM protein is a structural component of the microcompartments involved in coenzyme B12-dependent 1, 2-propanediol degradation by Salmonella enterica. Journal of bacteriology 194, 1912-1918	No	Publi-cation
Chap.4	GOBETTI et al.	1995	Volatile compound and organic acid productions by mixed wheat sour dough starters: influence of fermentation parameters and dynamics during baking. Food Microbiology 12, 497-507	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.6	Boatman RJ, Perry LG, Fiorica LA, English JC, Kapp Jr RW, Bevan C, Tyler TR, Banton MI & Wright GA	1998	Dermal absorption and pharmacokinetics of isopropanol in the male and female F-344 rat. Drug Metab Dispos 26, 197 – 202	No	Publi-cation
Chap.8	EC	2003	Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulations No. 1488/94 on risk assessment for existing substances (Part I, II, III, IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocide products on the market. European Commission 2003 (TGD, App. I, App. IF, Evaporation rate, page 216)	No	Publi-cation
Chap.8	ECHA	2015	Guidance on the Biocidal Product Regulation-Volume IV Environment – Part B Risk Assessment (active substances) Version 1.0	No	Publi-cation
Chap.8	ECHA	2016	Technical Agreements for Biocides (TAB)	No	Publi-cation
Chap.8	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publi-cation
Chap.8	Royal Haskoning	2004	Supplement to the methodology for risk evaluation of biocides. Environmental Emission Scenarios for biocides used as human hygiene biocidal products (product type 1)	No	Publi-cation
Chap.8	[redacted]	[redacted]	Estimation of the Environmental Concentrations and the Preliminary Environmental Risk Assessment of 2-Propanol applied biocidal products (PT 1, 2 and 4). [redacted]	Yes	[redacted]

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.8	EC	2007	European Union Risk Assessment Report: PROPAN-1-OL, Part I – Environment, CAS No.: 71-23-8, EINECS No.: 200-746-9. SUMMARY RISK ASSESSMENT REPORT, Final report, 2007 [redacted], published	No	Publi-cation
Chap.8	CA Meeting	2008	EU Workshop PT 1-6 Report, document: "CA-Nov08-Doc[1].6.3 - Workshop Report PT1-6_CA_31_final_track_ changes"	No	No owner
Chap.8	LYMAN et al.	1982	Handbook of chemical property estimation methods, McGraw-Hill Inc.; New York	No	Publi-cation
Chap.8	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Publi-cation
Chap.8	EC	1998	Biocidal Product Directive (BPD), Directive 98/8/EC concerning the placing of biocidal products on the market	No	Publi-cation
Chap.8	ECB	2002	TNsG on Annex I inclusion. Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB, April 2002	No	Publi-cation
Chap.8	KlimaPartner	2007	Technisches Handbuch für Luft- und klimatechnik	No	Publi-cation
Chap.8	The Engineering Tool Box	2005	Air change rates in some typical rooms and buildings	No	Publi-cation
Chap.8	Hughson, G.W. and Aitken, R.J.	2004	Determination of dermal exposures during mixing, spraying and wiping activities, Ann. Occup. Hyg., Vol. 48, No.3, pp. 245-255	No	Publi-cation
Chap.8	RIVM	2001	Supplemment to the methology for risk evaluation of biocides. Emission Scenarios Document for Product Type 2: Private and public health area disinfectants and other biocidal products (sanitary and medical sector)	No	Publi-cation
Chap.13	ECHA	2015	Guidance on the Biocidal Product Regulation-Volume IV Environment – Part B Risk Assessment (active substances) Version 1.0	No	Publi-cation
Chap.13	EC	1998	Drinking Water Directive (DWD), Council Directive 98/83/EC on the quality of water intended for human consumption	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.13	EC	2006	Groundwater Directive (GWD), Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration	No	Publi-cation
Chap.13	EC	2006	REACH-VO Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, authorisation and restriction of chemicals (REACH) establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC, Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC	No	Publi-cation
Chap.13	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publi-cation
Chap.13	UNEP	2004	Stockholm Convention on Persistent Organic Pollutants (POP), entered into force 17 May 2004	No	Publi-cation
Chap.13	EC	1998	Biocidal Product Directive (BPD), Directive 98/8/EC concerning the placing of biocidal products on the market	No	Publi-cation
Chap.13	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Publi-cation
Chap.13	EC	2007	European Commission, Risk Assessment Report on Propan-1-ol in the frame of the Existing Substance Regulation (Council Regulation 793/93/EEC of 23 March 1993 on the evaluation and control of existing substances)	No	Publi-cation
Chap.13	EC	2008	European Commission, Workshop on environmental risk assessment for Product types 1 to 6, Arona, Italy, 11 March 2008	No	Publi-cation
Chap.15	EC	1967	Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.15	German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety	1999	Administrative Regulation on the Classification of Substances Hazardous to Waters (VwVwS)	No	Publi-cation
Chap.15	EC	2001	European Waste List, Commission Decision of 16 January 2001 amending Decision 2000/532/EC as regards the list of wastes, OJ L 47, 16 February 2001	No	Publi-cation
Chap.15	EC	2006	Directive 2006/8/EEC amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations	No	Publi-cation

Doc II (PT 4):

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.3	World Health Organisation (WHO)	1990	International Programme on Chemical Safety. Environmental Health Criteria 102: 1-Propanol. WorldHealth Organisation 1990. (http://www.inchem.org/documents/ehc/ehc/ehc102.htm)	No	Publi-cation
Chap.3	Kampf G & Kramer A	2004	Epidemiologic background of hand hygiene and evaluation of the most important agents for scrubs and rubs. Clin. Microbiol. Reviews 17 (2004): 863-893	No	Publi-cation
Chap. 3	Moorer WR	2003	Antiviral activity of alcohol for surface disinfection. Int. J. Dent. Hygiene 1 (2003): 138-142	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.4	ECB	2000	Technical Guidance Document in support of the Directive 98/8/EC concerning the placing of biocidal products on the market, Guidance on data requirements for active substances and biocidal products (TNsG) , October 2000	No	Publi-cation
Chap.4	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publi-cation
Chap.4	EC	1967	Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances	No	Publi-cation
Chap.4	ECHA	2015	Guidance on the Biocidal Product Regulation-Volume IV Environment – Part B Risk Assessment (active substances) Version 1.0	No	Publi-cation
Chap.4	UNEP	2004	Stockholm Convention on Persistent Organic Pollutants (POP), entered into force 17 May 2004	No	Publi-cation
Chap.4	LYMAN et al.	1982	Handbook of chemical property estimation methods, McGraw-Hill Inc.; New York	No	Publi-cation
Chap.4	BUSTARD et al.	2000	Biodegradation of propanol and isopropanol by a mixed microbial consortium. Applied microbiology and biotechnology 54, 424-431	No	Publi-cation
Chap.4	VAN DEN WIJNGAARD et al.	1992	Degradation of 1, 2-dichloroethane by Ancylobacter aquaticus and other facultative methylotrophs, Applied and environmental microbiology 58, 976-983	No	Publi-cation
Chap.4	POELARENDS et al.	1998	Degradation of 1, 3-dichloropropene by Pseudomonas cichorii 170. Applied and environmental microbiology 64, 2931-2936	No	Publi-cation
Chap.4	JANSSEN et al.	1987	Degradation of n-haloalkanes and alpha, omega-dihaloalkanes by wild-type and mutants of Acinetobacter sp. strain GJ70. Applied and environmental microbiology 53, 561-566	No	Publi-cation
Chap.4	HARTMANS & DE BONT	1992	Aerobic vinyl chloride metabolism in Mycobacterium aurum L1. Applied and Environmental Microbiology 58, 1220-1226	No	Publi-cation
Chap.4	POELARENDS et al.	1999	Degradation of 1, 2-Dibromoethane byMycobacterium sp. Strain GP1. Journal of bacteriology 181, 2050-2058	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.4	RABUS et al.	1993	Complete oxidation of toluene under strictly anoxic conditions by a new sulfate-reducing bacterium. Applied and Environmental Microbiology 59, 1444-1451	No	Publi-cation
Chap.4	DWORKIN et al.	2006	The Prokaryotes: Vol. 3: Archaea. Bacteria: Firmicutes, Actinomycetes. (Springer Science & Business Media, 2006)	No	Publi-cation
Chap.4	WIDDEL	1986	Growth of methanogenic bacteria in pure culture with 2-propanol and other alcohols as hydrogen donors. Applied and Environmental Microbiology 51, 1056-1062	No	Publi-cation
Chap.4	DEMIRER & SPEECE	1998	Anaerobic biotransformation of four 3-carbon compounds (acrolein, acrylic acid, allyl alcohol and n-propanol) in UASB reactors. Water research 32, 747-759	No	Publi-cation
Chap.4	SCHINK	1985	Mechanisms and kinetics of succinate and propionate degradation in anoxic freshwater sediments and sewage sludge. Microbiology 131, 643-650	No	Publi-cation
Chap.4	WIEGANT et al.	1986	Separation of the propionate degradation to improve the efficiency of thermophilic anaerobic treatment of acidified wastewaters. Water Research 20, 517-524	No	Publi-cation
Chap.4	MAWSON et al.	1991	Degradation of acetic and propionic acids in the methane fermentation. Water Research 25, 1549-1554	No	Publi-cation
Chap.4	KROONEMAN et al.	2002	Lactobacillus diolivorans sp. nov., a 1, 2-propanediol-degrading bacterium isolated from aerobically stable maize silage. International journal of systematic and evolutionary microbiology 52, 639-646	No	Publi-cation
Chap.4	SINHA et al.	2012	The PduM protein is a structural component of the microcompartments involved in coenzyme B12-dependent 1, 2-propanediol degradation by Salmonella enterica. Journal of bacteriology 194, 1912-1918	No	Publi-cation
Chap.4	GOBETTI et al.	1995	Volatile compound and organic acid productions by mixed wheat sour dough starters: influence of fermentation parameters and dynamics during baking. Food Microbiology 12, 497-507	No	Publi-cation
Chap.6	Boatman RJ, Perry LG, Fiorica LA, English JC, Kapp Jr RW, Bevan C, Tyler TR, Banton MI & Wright GA	1998	Dermal absorption and pharmacokinetics of isopropanol in the male and female F-344 rat. Drug Metab Dispos 26, 197 – 202	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.8	Bieber, N.	2006	Absorption of alcohol from hand disinfection (Alkoholresorption nach Händedesinfektion) Dissertation Ernst-Moritz-Arndt-Universität Greifswald, Germany	No	Publi-cation
Chap.8	DIN 33403-5	1997	Klima am Arbeitsplatz und in der Arbeitsumgebung - Teil 5: Ergonomische Gestaltung von Kältearbeitsplätzen	No	Publi-cation
Chap.8	EC	2003	Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulations No. 1488/94 on risk assessment for existing substances (Part I, II, III, IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocide products on the market. European Commission 2003 (TGD, App. I, App. IF, Evaporation rate, page 216)	No	Publi-cation
Chap.8	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publi-cation
Chap.8	ECHA	2015	Guidance on the Biocidal Product Regulation-Volume IV Environment – Part B Risk Assessment (active substances) Version 1.0	No	Publi-cation
Chap.8	AEAT	2007	Draft: Service contract for the development of environmental emission scenarios for active substances used in certain products; AEAT/ED/48587/R1	No	Publi-cation
Chap.8	[redacted]	[redacted]	Estimation of the Environmental Concentrations and the Preliminary Environmental Risk Assessment of 2-Propanol applied biocidal products (PT 1, 2 and 4). [redacted]	Yes	[redacted]
Chap.8	JRC	2011	Emission Scenario Document for Product Type 4, Disinfectants used in food and feed areas	No	Publi-cation
Chap.8	EC	2007	European Union Risk Assessment Report: PROPAN-1-OL, Part I – Environment, CAS No.: 71-23-8, EINECS No.: 200-746-9. SUMMARY RISK ASSESSMENT REPORT, Final report, 2007 [redacted], published	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.8	CA Meeting	2008	EU Workshop PT 1-6 Report, document: "CA-Nov08-Doc[1].6.3 - Workshop Report PT1-6 CA 31 final track changes"	No	No owner
Chap.8	LYMAN et al.	1982	Handbook of chemical property estimation methods, McGraw-Hill Inc.; New York	No	Publi-cation
Chap.8	ECHA	2016	Technical Agreements for Biocides (TAB)	No	Publi-cation
Chap.8	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Publi-cation
Chap.8	EC	1998	Biocidal Product Directive (BPD), Directive 98/8/EC concerning the placing of biocidal products on the market	No	Publi-cation
Chap.8	ECB	2002	TNsG on Annex I inclusion. Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Principles and Practical Procedures for the inclusion of active substances in Annexes I, IA and IB, April 2002	No	Publi-cation
Chap.8	KlimaPartner	2007	Technisches Handbuch für Luft- und klimatechnik	No	Publi-cation
Chap.8	The Engineering Tool Box	2005	Air change rates in some typical rooms and buildings	No	Publi-cation
Chap.8	Hughson, G.W. and Aitken, R.J.	2004	Determination of dermal exposures during mixing, spraying and wiping activities, Ann. Occup. Hyg., Vol. 48, No.3, pp. 245-255	No	Publi-cation
Chap.13	Royal Haskoning	2004	Supplement to the methodology for risk evaluation of biocides. Environmental Emission Scenarios for biocides used as human hygiene biocidal products (product type 1)	No	Publi-cation
Chap.13	EC	1998	Drinking Water Directive (DWD), Council Directive 98/83/EC on the quality of water intended for human consumption	No	Publi-cation
Chap.13	EC	2006	Groundwater Directive (GWD), Council Directive 2006/118/EG on the protection of groundwater against pollution and deterioration	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.13	EC	2006	REACH-VO Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, authorisation and restriction of chemicals (REACH) establishing a European Chemicals Agency amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC, Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC	No	Publi-cation
Chap.13	ECB	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Part II; Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2	No	Publi-cation
Chap.13	UNEP	2004	Stockholm Convention on Persistent Organic Pollutants (POP), entered into force 17 May 2004	No	Publi-cation
Chap.13	EC	1998	Biocidal Product Directive (BPD), Directive 98/8/EC concerning the placing of biocidal products on the market	No	Publi-cation
Chap.13	EC	2000	FOCUS groundwater scenarios in the EU review of active substances ". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000 Rev.2	No	Publi-cation
Chap.13	EC	2007	European Commission, Risk Assessment Report on Propan-1-ol in the frame of the Existing Substance Regulation (Council Regulation 793/93/EEC of 23 March 1993 on the evaluation and control of existing substances)	No	Publi-cation
Chap.13	EC	2008	European Commission, Workshop on environmental risk assessment for Product types 1 to 6, Arona, Italy, 11 March 2008	No	Publi-cation
Chap.13	ECHA	2015	Guidance on the Biocidal Product Regulation-Volume IV Environment – Part B Risk Assessment (active substances) Version 1.0	No	Publi-cation
Chap.13	ECHA	2016	Technical Agreements for Biocides (TAB)	No	Publi-cation
Chap.15	EC	1967	Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances	No	Publi-cation

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
Chap.15	German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety	1999	Administrative Regulation on the Classification of Substances Hazardous to Waters (VwVwS)	No	Publi-cation
Chap.15	EC	2001	European Waste List, Commission Decision of 16 January 2001 amending Decision 2000/532/EC as regards the list of wastes, OJ L 47, 16 February 2001	No	Publi-cation
Chap.15	EC	2006	Directive 2006/8/EEC amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations	No	Publi-cation

Additional references to propan-1-ol included into Doc II level, for which no Doc III is considered necessary

A6.1.4	[redacted]	1946	Chemical burns of the rabbit cornea. Am. J. Ophthalmol. 29 (1946) 1363-1372	No	-
A6.1.4	Tubker RA, Willis C, Berardesca E, Lee CH, Fartasch M, Agner T & Serup J	1997	Guidelines on sodium lauryl sulfate (SLS) exposure tests. A report from the Standardization Group of the European society of Contact Dermatitis. Contact Dermatitis 37 (1997): 53-69	No	-
A6.1.4	Wilkin JK & Fortner G	1985	Cutaneous vascular sensitivity to lower aliphatic alcohols and aldehydes in orientals. Alcohol. Clin. Exp. Res. 9 (1985): 522-525	No	-
A6.1.4, A6.12	Clemmensen A, Andersen F, Petersen TK, Kalden H, Melgaard A & Andersen KE	2008	The irritant potential of n-propanol (nonanoic acid vehicle) in cumulative skin irritation: a validation study of two different human *in vivo* test models. Skin research and technology (2008): Online early article, DOI 10.1111/j.1600-0846.2008.00291.x http://www.blackwell-synergy.com/doi/abs/10.1111/j.1600-0846.2008.00291.x	No	-
A6.1.4, A6.12	Heydenreich A	1966	Chemisch-toxische Schäden der Augen (Vergiftungen, Berufskrankheiten). Monatsblätter für Augenheilkunde 149 (1966) 145-165	No	-
A6.1.4, A6.12	Lübbe J, Ruffieux C, van Melle G & Perrenoud D	2001	Irritancy of the skin disinfectant n-propanol. Contact Dermatitis 45 (2001) 226-231	No	-
A6.12	Dürwald W & Degen W	1956	Eine tödliche Vergiftung mit n-Propylalkohol. Archiv für Toxikologie 16 (1956) 84-88	No	-
A6.2	Dalziel K & Dickinson FM	1966	The kinetics and mechanism of liver alcohol dehydrogenase with primary and secondary alcohols as substrates. Biochem. J. 100 (1966) 31-46	No	-
A6.2	Rietbrock N & Abshagen U	1971	Pharmacokinetics and metabolism of aliphatic alcohols. Arzneimittelforschung 21 (1971): 1309-1319	No	-

A6.2	[redacted]	1994	Disposition and pharmacokinetics of isopropanol in F-344 rats and B6C3F1 mice. Fundamentl.Appl. Toxicol. 23 (1994): 407-420	No	-
A6.2	World Health Organisation (WHO)	1990	International Programme on Chemical Safety. Environmental Health Criteria 102: 1-Propanol. WorldHealth Organisation 1990. (http://www.inchem.org/documents/ehc/ehc/ehc102.htm)	No	-
A6.2, A6.12	Vujasinović M, Kočar M, Bunc M & Brvar M	2007	Poisoning with 1-propanol and 2-propanol. Human Experimentl. Toxicol. 26 (2007): 975-978	No	-
A6.6.1	Dillon D, Combes R & Zeiger E	1998	The effectiveness of *Salmonella* strains TA100, TA102 and TA104 for detecting mutagenicity of some aldehydes and peroxides. Mutagenesis 13 (1998): 19-26	No	-
A6.6.2	Costa M, Zhitkovich A, Harris M, Paustenbach D &, Garqas M	1997	DNA-protein cross-links produced by various chemicals in cultured human lymphoma cells. J. Toxicol. Environ. Health 50 (1997): 433-449	No	-
A6.6.2	[redacted]	1994	Cytotoxic and genotoxic effects of five n-alkanals in primary cultures of rat and human hepatocytes. Mutat. Res. 323 (1994): 121-123	No	-
A6.6.2	Seoane AI & Dulout FN	1994	Use of the anaphase-telophase test to detect aneugenic compounds: Effects of propionaldehyde and cadmium chloride. Bull. Environ. Contam. Toxicol. 53 (1994): 924-929	No	-
A6.6.3	Lasne C, Gu ZW, Venegas W, Chourouli nkov I	1984	The in vitro micronucles assay for detection of cytogenetic effects induced by mutagen-carcinogens: Comparison with the in vitro sister-chromatid exchange assay. Mutat. Res. 130 (1984): 273-282	No	-

A6.7	[redacted]	1998	Spontaneous neoplasms in control Wistar rats: a comparison of reviews. Toxicol. Sciences 45 (1998): 1-8	No	-

Doc IIIA

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A2.10	[redacted]	[redacted]	Ermittlung und Beurteilung von ausgewählten Aldehyden und Lösemitteln in der Luft am Arbeitsplatz im Arbeitsbereich, [redacted]	Y	[redacted]
A2.10	ECB	2000	Occupational exposure limits from: 1-Propanol IUCLID-Dataset, 6 p. [redacted], published	N	-
A2.10	[redacted]	[redacted]	Estimation of the Environmental Concentrations and the Preliminary Environmental Risk Assessment of 1-propanol in biocidal products (Product types 1, 2 and 4). [redacted]	Y	[redacted]
A3.1.1/01	The Merck Index	1996	An encyclopedia of chemicals, drugs, and biologicals. Budavari S, Neil MJO, Smith A, Heckelman PE, and Kinneary JF (ed.), 12th ed.. Merck & Co., Whitehouse Station, USA, 1348 [redacted], published	N	-
A3.1.1/02	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A3.1.1/03	Riddick JA, Bunger WB & Sakano TK	1986	Organic solvents – physical properties and methods of purification. Volume II, 4th Ed., John Wiley & Sons, New York, 194-195 [redacted], published	N	-

A3.1.1/04	Sax NI	1984	Dangerous properties of industrial material. 6th Ed. Van Nostrand Reinhold Company, New York 2304 [redacted], published	N	-
A3.1.2/01	Ambrose D & Sprake CHS	1970	Thermodynamic properties of organic oxygen compounds XXV. Vapor pressures and normal boiling temperatures of aliphatic alcohols. J Chem Thermodynamics 2, 631-645 [redacted], published	N	-
A3.1.2/02	Hiaki T, Takahasi K, Tsuji T, Hongo M & Kojima K	1994	Vapor-liquid equilibria of 1-propanol or 2-propanol with 2,2,4-trimethylpentane at 101.3 kPa. J Chem Eng Data 39, 602-604 [redacted], published	N	-
A3.1.2/03	The Merck Index	1996	An encyclopedia of chemicals, drugs, and biologicals. Budavari S, Neil MJO, Smith A, Heckelman PE, and Kinneary JF (ed.), 12th ed.. Merck & Co., Whitehouse Station, USA, 1348 [redacted] published	N	-
A3.1.2/04	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A3.1.3/01	The Merck Index	1996	An encyclopedia of chemicals, drugs, and biologicals. Budavari S, Neil MJO, Smith A, Heckelman PE, and Kinneary JF (ed.), 12th ed.. Merck & Co., Whitehouse Station, USA, 1348 [redacted], published	N	-
A3.1.3/02	Riddick JA, Bunger WB & Sakano TK	1986	Organic solvents – physical properties and methods of purification. Volume II, 4th Ed., John Wiley & Sons, New York, 194-195 [redacted], published	N	-
A3.1.3/03	Sax NI	1984	Dangerous properties of industrial material. 6th Ed. Van Nostrand Reinhold Company, New York 2304 [redacted], published	N	-
A3.1.3/04	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-

A3.1.3/05	Sakurai M & Nakagawa T	1984	Densities of dilute solutions of water in n-alkanols at 278.15, 288.15, 298.15, 308.15, and 318.15 K. Partial molar volumes of water in n-alkanols. J Chem Thermodynamics 16, 171-174 [redacted], published	N	-
A3.1.3/06	Hiaki T, Takahasi K, Tsuji T, Hongo M & Kojima K	1994	Vapor-liquid equilibria of 1-propanol or 2-propanol with 2,2,4-trimethylpentane at 101.3 kPa. J Chem Eng Data 39, 602-604 [redacted], published	N	-
A3.2/01	Riddick JA, Bunger WB & Sakano TK	1986	Organic solvents – physical properties and methods of purification. Volume II, 4th Ed., John Wiley & Sons, New York, 194-195 [redacted], published	N	-
A3.2/02	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A3.2/03	Hiaki T, Takahasi K, Tsuji T, Hongo M & Kojima K	1994	Vapor-liquid equilibria of 1-propanol or 2-propanol with 2,2,4-trimethylpentane at 101.3 kPa. J Chem Eng Data 39, 602-604 [redacted], published	N	-
A3.2/04	Boublik T, Fried V & and Hala E	1984	The vapor pressures of pure substances – selected values of the temperature dependence of the vapor pressures of some pure substances in the normal and low pressure region. Elsevier 2nd Ed., Amsterdam, pp 1-6, 196-197 [redacted], published	N	-
A3.2.1/01	Snider JR & Dawson GA	1985	Tropospheric light alcohols, carbonyls, and acetonitrile concentrations in the southwestern United States and Henry's Law Data. J Geophys Res 90, 3797-3805 [redacted], published	N	-
A3.2.1/02	Altschuh J, Brüggeman n R, Santl H, Eichinger G & Piringer OG	1999	Henry's law constants for a diverse set of organic chemicals: experimental determination and comparison of estimation methods. Chemosphere 39, 1871-1887 [redacted] published	N	-
A3.2.1/03	EPI-Suite	2005	EPIWIN 3.12 estimations for 1-Propanol [redacted], unpublished	N	-

A3.2.1/04	[redacted]	[redacted]	Conversion of Henry's law constants for 1-propanol. [redacted]	Y	[redacted]
A3.3/01	The Merck Index	1996	An encyclopedia of chemicals, drugs, and biologicals. Budavari S, Neil MJO, Smith A, Heckelman PE, and Kinneary JF (ed.), 12th ed.. Merck & Co., Whitehouse Station, USA, 1348 [redacted], published	N	-
A3.3/02	Sax NI	1984	Dangerous properties of industrial material. 6th Ed. Van Nostrand Reinhold Company, New York 2304 [redacted], published	N	-
A3.4/01	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A3.4/02	SDBS	2007	SDBS No. 1212 (IR, NMR) SDBS Web : http://www.aist.go.jp/RIODB/SDBS/ (National Institute of Advanced Industrial Science and Technology) [redacted], published	N	-
A3.4/03	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A3.4/04	[redacted]	[redacted]	UV/VIS Scan of n-propanol. [redacted]	N	-
A3.4/05	[redacted]	[redacted]	IR spectrum of n-propanol and reference spectrum. [redacted]	N	-
A3.4/06	[redacted]	[redacted]	Mass spectrum of 1-Propanol from two suppliers [redacted]	N	-

A3.4/07	[redacted]	[redacted]	IR, MS and NMR spectrum of n-propanol. [redacted]	N	-
A3.4/08	[redacted]	[redacted]	UV/VIS Scan and NMR spectrum of 2-propanol. [redacted]	N	-
A3.5/01	The Merck Index	1996	An encyclopedia of chemicals, drugs, and biologicals. Budavari S, Neil MJO, Smith A, Heckelman PE, and Kinneary JF (ed.), 12th ed.. Merck & Co., Whitehouse Station, USA, 1348 [redacted], published	N	-
A3.7/01	The Merck Index	1996	An encyclopedia of chemicals, drugs, and biologicals. Budavari S, Neil MJO, Smith A, Heckelman PE, and Kinneary JF (ed.), 12th ed.. Merck & Co., Whitehouse Station, USA, 1348 [redacted], published	N	-
A3.7/02	Sax NI	1984	Dangerous properties of industrial material. 6th Ed. Van Nostrand Reinhold Company, New York 2304 [redacted], published	N	-
A3.7/03	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A3.9/01	Dillingham EO, Mast RW, Bass GE & Autian J	1973	Toxicity of methyl- and halogen-substituted alcohols in tissue culture relative to structure-activity models and acute toxicity in mice. J Pharm Sci 62, 22 [redacted], published	N	-
A3.9/02	Hansch C, Leo A & Hoekman D	1995	Exploring QSAR. Hydrophobic, electronic, and steric constants. ACS Prof Ref Book. Heller SR, consult. ed., Washington, DC, Amer Chem Soc [redacted], published	N	-
A3.9/03	Hansch C & Anderson SM	1967	The effect of intramolecular hydrophobic bonding on partition coefficients. J Org Chem 32, 2583-2586 [redacted], published	N	-

A3.9/04	EPI-Suite	2005	EPIWIN 3.12 estimations for 1-Propanol [redacted], unpublished	N	-
A3.11/01	Sax NI	1984	Dangerous properties of industrial material. 6th Ed. Van Nostrand Reinhold Company, New York 2304 [redacted], published	N	-
A3.11/02	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A3.12/01	The Merck Index	1996	An encyclopedia of chemicals, drugs, and biologicals. Budavari S, Neil MJO, Smith A, Heckelman PE, and Kinneary JF (ed.), 12th ed.. Merck & Co., Whitehouse Station, USA, 1348 [redacted], published	N	-
A3.12/02	Riddick JA, Bunger WB & Sakano TK	1986	Organic solvents – physical properties and methods of purification. Volume II, 4th Ed., John Wiley & Sons, New York, 194-195 [redacted], published	N	-
A3.12/03	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A3.12/04	Sax NI	1984	Dangerous properties of industrial material. 6th Ed. Van Nostrand Reinhold Company, New York 2304 [redacted], published	N	-
A3.13/01	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A3.13/02	Vazquez G, Alvarez E & Navaza JM	1995	Surface tension of alcohol + water from 20 to 50 °C. J Chem Eng Data 40, 611-614, [redacted], published	N	-

A3.13/03	CRC	1992	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 72nd ed.. CRC Press Boca Raton, USA, 9p [redacted], published	N	-
A3.14	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A3.15/01	Sax NI	1984	Dangerous properties of industrial material. 6th Ed. Van Nostrand Reinhold Company, New York 2304 [redacted], published	N	-
A3.15/02	CRC	2001	Data for 1-Propanol. Handbook of chemistry and physics. Lide DR (ed.), 82th ed.. CRC Press Boca Raton, USA, 33p [redacted], published	N	-
A4.1	Council of Europe	2005	EUROPEAN PHARMACOPOEIA 5.0 Monograph Propanol. 01/2005: 2036 Corrected; p 2320-2321 [redacted], published	N	-
A4.2	BUA	1997	BUA Report 190 on 1-Propanol (in German), Editor: Beratergremium für umweltrelevante Altstoffe (BUA) der Gesellschaft Deutscher Chemiker, 197p [redacted], published	N	-
A4.2	WHO	1990	Environmental Health Criteria 102, 1-Propanol. IPCS, World Health Organization 1990 [redacted], published	N	-
A4.2b	NIOSH	1994	NIOSH Manual of Analytical Methods (NMAM), Fourth Edition, 8/15/94, Alcohols II, METHOD: 1401, Issue 2, 15 August 1994, 4p [redacted], published	N	-
A4.2c	BUA	1997	BUA Report 190 on 1-Propanol (in German), Editor: Beratergremium für umweltrelevante Altstoffe (BUA) der Gesellschaft Deutscher Chemiker, 197p [redacted], published	N	-

A4.2c	WHO	1990	Environmental Health Criteria 102, 1-Propanol. IPCS, World Health Organization 1990 [redacted], published	N	-
A4.2c	Iffland R, Balling P, Oehmichen M, Lieder F & Norpoth T	1989	Methanol, Isopropanol, n-Propanol - endogene Bildung unter Äthanoleinfluß? Blutalkohol 26, 87-97 [redacted], published	N	-
A4.2d	BUA	1997	BUA Report 190 on 1-Propanol (in German), Editor: Beratergremium für umweltrelevante Altstoffe (BUA) der Gesellschaft Deutscher Chemiker, 197p [redacted], published	N	-
A4.2d	WHO	1990	Environmental Health Criteria 102, 1-Propanol. IPCS, World Health Organization 1990 [redacted], published	N	-
A5.3/01	Kampf G & Ostermeyer C	2005	Efficacy of two distinct ethanol-based hand rubs for surgical hand disinfection – a controlled trial according to prEN 12791. BMC Infect. Dis. 5:17-21. [redacted], published	N	-
A5.3/02	Pullen W & van Klingeren B	1991	Vergelijkend onderzoek naar de desinfekterende werking van alcoholen in de Europese suspensie test. Rapport Nr. 358704003. RVVM, Bilthoven. [redacted], published	N	-
A5.3/03	Kampf G, Jarosch R & Rüden H	1997	Wirksamkeit alkoholischer Händedesinfektionsmittel gegenüber Methicillin-resistenten Staphylococcus aureus (MRSA). Der Chirurg. 68:264-270. [redacted], published	N	-
A5.3/04	Gehrke C, Steinmann J & Goroncy-Bermes P	2004	Inactivation of Feline Calicivirus, a surrogate of norovirus (formerly Norwalk-like viruses), by different types of alcohol in vitro and in vivo. J. Hosp. Inf. 56:49-55. [redacted], published	N	-
A5.3/05	Kurtz JB, Lee TW & Parsons AJ	1980	The action of alcohol on rotavirus, astrovirus and enterovirus. J. Hosp. Inf.1:321-325. [redacted], published	N	-

A6.1.1/01	[redacted]	1972	Aliphatic alcohols and alky esters: narcotic and lethal potencies to tadpoles and to rabbits. Ind Med Surg 41, 31 – 33 [redacted], published	N	-
A6.1.1/02	[redacted]	1954	Range-finding toxicity data. List V. Arch Ind Hyg Occup Med 10, 61 – 68 [redacted], published	N	-
A6.1.1/03	[redacted]	1964	A comparison of the toxicity of some allyl, propenyl and propyl compounds in the rat. Toxicol Appl Pharmacol 6, 378 – 387 [redacted], published	N	-
A6.1.1/04	[redacted]	1968	Estimation of the LD50 in Mol/kg. Proc Eur Soc Study Drug Tox 9, 276 - 278 [redacted], published	N	-
A6.1.1/05 Additional information	[redacted]	[redacted]	[redacted]	N	-
A6.1.2/01	[redacted]	1954	Range-finding toxicity data. List V. Arch Ind Hyg Occup Med 10, 61 – 68 [redacted], published	N	-
A6.1.3/01	[redacted]	1992	n-propyl alcohol (n-propanaol): Acute vapour inhalation toxicity tests in rats (Project Report 54-48; BRRC No. 90-13-40281). Bushy Run Research Center, Pennsylvania, 34 pp. (NTIS/OTS0537495)	N	-
A6.1.3/02	[redacted]	1954	Range-finding toxicity data. List V. Arch Ind Hyg Occup Med 10, 61 – 68 [redacted], published	N	-
A6.1.3/03 Additional information	[redacted]	[redacted]	[redacted]	N	-

A6.1.4/01	[redacted]	1982	Cutaneous reactions to lower aliphatic alcohols before and during disulfiram therapy. Arch Dermatol 118, 157-159 [redacted], published	N	-
A6.1.4/02	[redacted]	1954	Range-finding toxicity data. List V. Arch Ind Hyg Occup Med 10, 61 – 68 [redacted], published	N	-
A6.1.4/03	[redacted]	1954	Range-finding toxicity data. List V. Arch Ind Hyg Occup Med 10, 61 – 68 [redacted], published	N	-
A6.1.5/01	[redacted]	1986	Development and validation of an alternative dermal sensitization test: the mouse ear swelling test (MEST). Toxicol Appl Pharmacol 84, 93 - 114 [redacted], published	N	-
A6.1.5/02	[redacted]	1986	Development and validation of an alternative dermal sensitization test: the mouse ear swelling test (MEST). Toxicol Appl Pharmacol 84, 93 – 114 [redacted], published	N	-
A6.2/01	[redacted]	1979	Comparative effects of ethanol, n-propanol and isopropanol on lipid disposal by rat liver. Chem Biol Interact 26, 155 – 166 [redacted], published	N	-
A6.2/02	[redacted]	1985	Toxicokinetics of organic solvents. Scand J Work Environ Health (Suppl 1), 7 – 21 [redacted], published	N	-
A6.2/03	[redacted]	1979	Absorption, distribution and metabolism of propyl anthranilate. Toxicology 12, 75 – 87 [redacted], published	N	-
A6.2/04	[redacted]	1985	Differing effects of short-chain alcohols on body temperature and coordinated muscular activity in mice. Neuropharmacology 24, 83 – 89 [redacted], published	N	-

A6.2/05	[redacted]	1988	Teratogenicity of n-propanol and isopropanol administered at high inhalation concentrations to rats. Ff Chem Toxic 26, 247 - 254 [redacted], published	N	-
A6.2/06	Bonte W, Rüdell E, Sprung R, Frauenrath C, Blanke E, Kupilas G, Wochnik J & Zäh G	1981	Experimentelle Untersuchungen zum Nachweis geringer Dosen höherer aliphatischer Alkohole im Blut von Versuchsteilnehmern. Blutalkohol 18, 399 – 411 [redacted], published	N	-
A6.2/06	Bonte W, Sprung R, Rüdell E, Frauenrath C, Blanke E, Kupilas G, Wochnik J & Zäh G	1981	Experimentelle Untersuchungen zum Nachweis geringer Dosen höherer aliphatischer Alkohole im Urin von Versuchsteilnehmern. Blutalkohol 18, 412 – 426 [redacted], published	N	-
A6.2/07	Bilzer N, Schmutte P, Jehs M & Penners BM	1990	Kinetik aliphatischer Alkohole (Methanol, Propanol-1 und Isobutanol) bei Anwesenheit von Äthanol im menschlichen Körper. Blutalkohol 27, 385 – 409 [redacted], published	N	-
A6.2/08	Peschel O, Bauer MF, Gilg T & von Meyer L	1992	Veränderung von Begleitstoffanalysen durch perkutane Resorption propanolhaltiger Antiseptika. Blutalkohol 29, 172 – 184 [redacted], published	N	-
A6.2/09	Bieber N	2006	Absorption of alcohol from hand disinfection (Alkoholresorption nach Händedesinfektion) Dissertation Ernst-Moritz-Arndt-Universität Greifswald, Germany	N	
A6.3.3/01	[redacted]	[redacted]	n–Propyl Alcohol (n–propanol): Nine–Day Vapor Inhalation in Rats [redacted]	N	-
A6.3.3/02	[redacted]	[redacted]	Two Week Dose Range Finding Inhalation Study of 1- Propanol in Wistar (WU) – Rats [redacted]	Y	[redacted]

A6.4 Justification for non-submission	[redacted]	1994	Isopropanol 13-week vapor inhalation study in rats and mice with neurotoxicity evaluation in rats. Fundam Appl Toxicol 23, 421 – 428 [redacted], published	N	-
A6.4 Justification for non-submission	[redacted]	2005	Inert Reassessment – n-Propanol; CAS# 71-23-8. US Environmental Protection Agency. Washington, 18 pp.	N	-
A6.4.1/01	[redacted]	1974	Effects of chronic ingestion of some lower aliphatic alcohols in rats. Res Commun Chem Pathol Pharmacol 9, 177 - 180 [redacted], published	N	-
A6.4.3/01	[redacted]	[redacted]	13-Week Inhalation Toxicity Study of 1-Propanol in Wistar (WU) - Rats [redacted]	Y	[redacted]
A6.5 Justification for non-submission	[redacted]	1994	Isopropanol 13-week vapor inhalation study in rats and mice with neurotoxicity evaluation in rats. Fundam Appl Toxicol 23, 421 – 428 [redacted] published	N	-
A6.5 Justification for non-submission	[redacted]	1997	Isopropanol vapor inhalation oncogenicity study in Fischer 344 rats and CD-1 mice. Fundam Appl Toxicol 36, 95 – 111 [redacted], published	N	-
A6.6.1/01	Khudoley VV, Mizgireuv I & Pliss GB	1987	The study of mutagenic activity of carcinogens and other chemical agents with Salmonella typhimurium assays: Testing of 126 compounds. Arch Geschwulstforsch 57, 453 - 462 [redacted], published	N	-

A6.6.1/02	Stolzenberg SJ & Hine CH	1979	Mutagenicity of halogenated and oxygenated three-carbon compounds. J Toxicol Environ Health 5, 1149 – 1158 [redacted], published	N	-
A6.6.1/03	von der Hude W, Behm C, Guertler R & Basler A	1988	Evaluation of the SOS chromotest. Mutat Res 203, 81 – 94 [redacted], published	N	-
A6.6.3/01	[redacted]	[redacted]	Mutagenicity study of 1-propanol in mammalian cells (V79) in the in vitro gene mutation assay (HPRT Test). [redacted]	Y	[redacted]
A6.6.3/02	von der Hude W, Scheutwinkel M, Gramlich U, Fissler B & Basler A	1987	Genotoxicity of three-carbon compounds evaluated in the SCE test in vitro. Environ Mutagen 9, 401 - 410 [redacted], published	N	-
A6.6.4/01	[redacted]	[redacted]	1-Propanol - In vivo Comet Assay on Rat Liver, Stomach and Blood Cells Cells [redacted]	Y	[redacted]
A6.6.4	Basler A, von der Hude W & Scheutwinkel M	1987	Screening of the food additive propionic acid for genotoxic properties. Fd. Chem. Toxic. 25(4), 287-290 [redacted], published	N	-
A6.6.4	Bieber N	2006	Absorption of alcohol from hand disinfection (Alkoholresorption nach Händedesinfektion). Dissertation Ernst-Moritz-Arndt-Universität Greifswald, Germany, 93 p. [redacted], published	N	-
A6.6.4	Buszewicz G & Madro R	2002	In vitro co-metabolism of ethanol and cyclic ketones. Toxicology 177:207-213. [redacted], published	N	-
A6.6.4	Crabb DW, Matsumoto M, Chang D & You M	2004	Overview of the role of alcohol dehydrogenase and aldehyde dehydrogenase and their variants in the genesis of alcohol-related pathology. Proc. Nutr. Soc. 63, 49-63 [redacted], published	N	-

A6.6.4	Dalziel K & Dickinson FM	1966	The kinetics and mechanism of liver alcohol dehydrogenase with primary and secondary alcohols as substrates. Biochem. J. 100, 34-46 [redacted], published	N	-
A6.6.4	Paolini M, Sapigni E, Hrelia P, Scotti M, Morotti & Cantelli-Forti G	1991	Wide spectrum detection of precarcinogens in short-term bioassays by simultaneous superinduction of multiple forms of cytochrome P450 isoenzymes. Carcinogenesis 12:759-766. [redacted], published	N	-
A6.6.4	Teschke R, Hasumura Y & Lieber CS	1974	NADPH-dpendent oxidation of methanol, ethanol, propanol and butanol by hepatic microsomes. Biochem. Biophys. Res. Commun. 60:851-857. [redacted] published	N	-
A6.6.4	Teschke R, Hasumura Y & Lieber CS	1975	Hepatic microsomal alcohol-oxidizing system. J. Biol. Chem. 250:7397-7404. [redacted], published	N	-
A6.6.4	Vujasinovic M, Kocar M, Kramer K, Bunc M & Brvar M	2007	Poisoning with 1-propanol and 2-propanol. Human Exp. Toxicol. 26, 975-978 [redacted], published	N	-
A6.6.4	WHO	1990	International programme on chemical safety Environmental health criteria 102 1-propanol. World Health Organization, Geneva, Switzerland. Available online at http://www.inchem.org/documents/ehc/ehc/ehc102.htm [redacted], published	N	-
A6.6.4	WHO	1999	Evaluation of certain food additives and contaminants. 49th Report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO technical report series 884. World Health Organization, Geneva, Switzerland. Available online at http://whqlibdoc.who.int/trs/WHO_TRS_884.pdf. [redacted], published	N	-
A6.7 Justification for non-submission	[redacted]	1994	Isopropanol 13-week vapor inhalation study in rats and mice with neurotoxicity evaluation in rats. Fundam Appl Toxicol 23, 421 – 428 [redacted], published	N	-

A6.7 Justification for non-submission	[redacted]	1997	Isopropanol vapor inhalation oncogenicity study in Fischer 344 rats and CD-1 mice. Fundam Appl Toxicol 36, 95 – 111 [redacted], published	N	-
A6.7 Justification for non-submission	[redacted]	2005	Inert Reassessment – n-Propanol; CAS# 71-23-8. US Environmental Protection Agency. Washington, 18 pp.	N	-
A6.7/01	[redacted]	1975	Experimentelle Untersuchungen zur kanzerogenen Wirkung von Loesungsmitteln am Beispiel von Propanol-1, 2-Methylpropanol-1 und 3-Methylbutanol-1. Arch Geschwulstforsch 45, 19 – 24 [redacted], published	N	-
A6.8.1 Justification for non-submission	[redacted]	1994	Developmental toxicity evaluation of isopropanol by gavage in rats and rabbits. Fundam Appl Toxicol 22, 139 – 151 [redacted], published	N	-
A6.8.1/01	[redacted]	1988	Teratogenicity of n-propanol and isopropanol administered at high inhalation concentrations to rats. Ff Chem Toxic 26, 247 – 254 [redacted], published	N	-
A6.8.1/02	[redacted]	1985	Comparison of behavioural teratogenic effects of ethanol and N-propanol administered by inhalation to rats. Neurobehav Toxicol Teratol 7, 779 – 783 [redacted], published	N	-
A6.8.1/02	[redacted]	1989	Behavioral teratology investigation of propan-1-ol administered by inhalation to rats. Neurotoxicol Teratol 11, 153 – 159 [redacted], published	N	-

A6.8.2 Justification for non-submission	[redacted]	1995	Two-generation reproduction toxicity study with isopropanol in rats. J Appl Toxicol 15, 117 – 123 [redacted], published	N	-
A6.12	[redacted]	[redacted]	5th Periodic Safety Update Report for: Alcohol solutions for disinfection of intact skin [redacted]	Y	[redacted]
A6.12	[redacted]	[redacted]	Addendum Report 4 to 5th Periodic Safety Update Report for: Alcohol solutions for disinfection of intact skin [redacted]	Y	[redacted]
A6.12	[redacted]	[redacted]	Propanol (CAS 71-23-8). Master file for a biocidal substance. [redacted]	Y	[redacted]
A7.1.1.1.1 Justification for non-submission	Harris JC	1990	Rate of hydrolysis. In: Handbook of chemical property estimation methods (eds.: Lyman WJ, Reehl WF and Rosenblatt DH), American Chemical Society, Washington DC, 1990, pp. 7-1 – 7-48 [redacted], published	N	-
A7.1.1.1.2 Justification for non-submission	U.S. EPA	1998	Fate, Transport and Transformation Test Guidelines OPPTS 835.2210 “Direct Photolysis Rate in Water by Sunlight”. EPA 712-C-98-060, January 1998. [redacted], published	N	-
A7.1.1.2.1/01	Gerhold RM & Malany GW	1966	Structural determinants in the oxidation of aliphatic compounds by activated sludge. J Water Pollut Control Fed 38, 562-579 [redacted], published	N	-
A7.1.1.2.1/02	Gerike P & Gode P	1990	The biodegradability and inhibitory threshold concentration of some disinfectants. Chemosphere 2, 799-812 [redacted], published	N	-
A7.1.1.2.1/03	Price KS, Waggy GT & Conway RA	1974	Brine shrimp bioassay and seawater BOD of petrochemicals. J Water Pollut Control Fed 46, 63-77 [redacted], published	N	-

A7.1.1.2.3	Price KS, Waggy GT & Conway RA	1974	Brine shrimp bioassay and seawater BOD of petrochemicals. J Water Pollut Control Fed 46, 63-77 [redacted], published	N	-
A7.1.3 Justification for non-submission	[redacted]	[redacted]	Estimation of the distribution behaviour in the environment and the bioconcentration factors of propan-1-ol. [redacted]	N	-
A7.3.1/01	Atkinson R, Baulch DL, Cox RA, Crowley JN, Hampson RF, Hynes RG, Jenkin ME, Rossi MJ & Troe J	2006	Evaluated kinetic and photochemical data for atmospheric chemistry: Volume II – Reactions of organic species, IUPAC Subcommittee on Gas Kinetic Data Evaluation for Atmospheric Chemistry. In: Atmos Chem Phy 6, pp. 3723-3729 & 3816-3820 of 3625-4055 [redacted], published	N	-
A7.3.1/02	Overend R & Paraskevopoulos G	1978	Rates of OH radical reactions. 4. Reactions with methanol, ethanol, 1-propanol, and 2-propanol at 296K. J Phys Chem 82, 1329-1333 [redacted], published	N	-
A7.3.1/03	Wallington TJ & Kurylo MJ	1987	The gas phase reactions of hydroxyl radicals with a series of aliphatic alcohols over the temperature range 240-440K. Int J Chem Kinet 19, 1015-1023 [redacted], published	N	-
A7.4.1.1/01	[redacted]	1984	Acute Toxicities of Organic Chemicals to Fathead Minnows (Pimephales Promelas), Vol. I. Center for Lake Superior Environmental Studies, University of Wisconsin-Superior, USA, 1-14 and 65-68 [redacted], published	N	-
A7.4.1.1/02	[redacted]	1978	Ergebnisse der Untersuchung von 200 chemischen Verbindungen auf akute Fischtoxizität mit dem Goldorfentest. Z Wasser Abwasser-Forschung 11, 161-164 [redacted], published	N	-
A7.4.1.1/03	[redacted]	1979	The acute toxicity of 78 chemicals and pesticide formulations against two brackish water organisms, the bleak (Alburnus alburnus) and the harpacticoid Nitocra spinipes. Chemosphere 11/12, 843-851 [redacted] published	N	-

A7.4.1.1/03	[redacted]	1984	Molecular structure and aquatic toxicity – An example with C1-C13 aliphatic alcohols. Chemosphere 13, 613-622 [redacted], published	N	-
A7.4.1.1/04	[redacted]	1983	Comparison of the susceptibility of 22 freshwater species to 15 chemical compounds. I (Sub)acute toxicity tests. Aqua Toxicol 4, 113-128 [redacted], published	N	-
A7.4.1.1/05	[redacted]	1983	Comparison of the susceptibility of 22 freshwater species to 15 chemical compounds. I (Sub)acute toxicity tests. Aqua Toxicol 4, 113-128 [redacted], published	N	-
A7.4.1.1/06	[redacted]	1983	Comparison of the susceptibility of 22 freshwater species to 15 chemical compounds. I (Sub)acute toxicity tests. Aqua Toxicol 4, 113-128 [redacted], published	N	-
A7.4.1.2/01	Bringmann G & Kuehn R	1977	Befunde der Schadwirkung wassergefährdender Stoffe gegen Daphnia magna. Z Wasser Abwasser-Forsch 10, 161-166 (published) [redacted], published	N	-
A7.4.1.2/01	Bringmann G & Kuehn R	1982	Results of toxic action of water pollutants on Daphnia magna Straus tested by improved standardized procedure. Z Wasser Abwasser-Forsch 15, 1-6 (published) [redacted], published	N	-
A7.4.1.2/02	Kühn R, Pattard M, Pernak K-D & Winter A	1989	Results of the harmful effects of selected water pollutants (anilines, phenols, aliphatic compounds) to Daphnia magna. Wat Res 23, 495-499 (published) [redacted], published	N	-
A7.4.1.2/03	[redacted]	1979	The acute toxicity of 78 chemicals and pesticide formulations against two brackish water organisms, the bleak (Alburnus alburnus) and the harpacticoid Nitocra spinipes. Chemosphere 11/12, 843-851 [redacted] published	N	-
A7.4.1.2/03	[redacted]	1984	Molecular structure and aquatic toxicity – An example with C1-C13 aliphatic alcohols. Chemosphere 13, 613-622 [redacted], published	N	-

A7.4.1.2/04	Price KS, Waggy GT & Conway RA	1974	Brine shrimp bioassay and seawater BOD of petrochemicals. J Water Pollut Control Fed 46, 63-77 [redacted], published	N	-
A7.4.1.2/05	[redacted]	1983	Benthic macroinvertebrates and water quality assessment: some toxicological considerations. Aquatic Toxicol 4, 73-82 [redacted], published	N	-
A7.4.1.3/01	Bringmann G & Kuehn, R	1977	Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Bakterien (Pseudomonas putida) und Grünalgen (Scenedesmus quadricauda) im Zellvermehrungshemmtest. Z Wasser Abwasser Forsch 10, 87-98 [redacted], published	N	-
A7.4.1.3/01	Bringmann G & Kuehn R	1980	Comparison of the toxicity thresholds of water pollutants to bacteria, algae, and protozoa in the cell multiplication inhibition test. Water Res 14, 231-241 [redacted], published	N	-
A7.4.1.3/01	Bringmann G & Kuehn R	1978	Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Blaualgen (Microcystis aeruginosa) und Grünalgen (Scenedesmus quadricauda) im Zellvermehrungshemmtest. Vom Wasser 50, 45-60 [redacted] published	N	-
A7.4.1.3/02	Bringmann G & Kuehn R	1978	Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Blaualgen (Microcystis aeruginosa) und Grünalgen (Scenedesmus quadricauda) im Zellvermehrungshemmtest. Vom Wasser 50, 45-60 [redacted], published	N	-
A7.4.1.3/03	Slooff W, Canton JH & Hermens JLM	1983	Comparison of the susceptibility of 22 freshwater species to 15 chemical compounds. I (Sub)acute toxicity tests. Aqua Toxicol 4, 113-128 [redacted], published	N	-
A7.4.1.3/04	Slooff W, Canton JH & Hermens JLM	1983	Comparison of the susceptibility of 22 freshwater species to 15 chemical compounds. I (Sub)acute toxicity tests. Aqua Toxicol 4, 113-128 [redacted], published	N	-
A7.4.1.3/05	Slooff W, Canton JH & Hermens JLM	1983	Comparison of the susceptibility of 22 freshwater species to 15 chemical compounds. I (Sub)acute toxicity tests. Aqua Toxicol 4, 113-128 [redacted], published	N	-

A7.4.1.3/06	Hsieh SH, Tsai KP & Chen CY	2006	The combined toxic effects of nonpolar narcotic chemicals to Pseudokirchneriella subcapitata. Water Research 40, 1957-1964 [redacted]a, published	N	-
A7.4.1.3/07	Calamari D, Galassi S, Setti F & Vighi M	1983	Toxicity of selected chlorobenzenes to aquatic organisms. Chemosphere 12(2), 253-262 [redacted], published	N	-
A7.4.1.3/07	EC	2003	Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances (Parts I, II, III and IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market. European Commission 2003 [redacted], published	N	-
A7.4.1.3/07	ECOSAR	2004	ECOWin v0.99h: Ecosar Help-SAR neutral organics. 8p [redacted], published	N	-
A7.4.1.3/07	Galassi S, Vighi M	1981	Testing toxicity of volatile substances with algae. Chemosphere 10(10), 1123-1126 [redacted], published	N	-
A7.4.1.3/07	Verhaar HJM, Van Leeuwen CJ, Hermens JLM	1992	Classifying environmental pollutants. 1: Structure-activity relationships for prediction of aquatic toxicity. Chemosphere 25, 471-491 [redacted], published	N	-
A7.4.1.4/01	Blum DJM & Speece RE	1991	A database of chemical toxicity to environmental bacteria and its use in interspecies comparisons and correlations. J Water Pollut Control Fed 63, 198-207 [redacted], published	N	-
A7.4.1.4/02	Bringmann G & Kuehn, R	1977	Grenzwerte der Schadwirkung wassergefährdender Stoffe gegen Bakterien (Pseudomonas putida) und Grünalgen (Scenedesmus quadricauda) im Zellvermehrungshemmtest. Z Wasser Abwasser Forsch 10, 87-98 [redacted], published	N	-

A7.4.1.4/02	Bringmann G & Kühn R	1980	Comparison of the toxicity thresholds of water pollutants to bacteria, algae, and protozoa in the cell multiplication inhibition test. Water Res 14, 231-241 [redacted], published	N	-
A7.4.1.4/03	Gerike P & Gode P	1990	The biodegradability and inhibitory threshold concentration of some disinfectants. Chemosphere 2, 799-812 [redacted], published	N	-
A7.4.1.4/04	Klecka GM, Landi LP & Bodner KM	1985	Evaluation of the OECD Activated Sludge, Respiration Inhibition Test. Chemosphere 14, 1239-1251 [redacted], published	N	-
A7.4.2 Justification for non-submission	[redacted]	[redacted]	Estimation of the distribution behaviour in the environment and the bioconcentration factors of propan-1-ol. [redacted]	N	-
A7.4.3.2 Justification for non-submission	[redacted]	2003	European Union Risk Assessment Report: Propan-1-ol Environmental Part, CAS No.: 71-23-8, EINECS No.: 200-746-9. Series: 2nd Priority List Volume: 71. Joint Research Centre, Institute for Health and Consumer Protection, European Chemicals Bureau (ECB), 51pp, Draft of 19.08.2003 [redacted], published	N	-
A7.4.3.2 Justification for non-submission	[redacted]	2005	Scientific Committee on Health and Environmental Risks (SCHER), Opinion on “Risk Assessment Report on Propan-1-ol: Environmental Part”. Adopted by the SCHER during the 3rd plenary of 28 January 2005, 5p [redacted], published	N	-
A7.4.3.4 Justification for non-submission	[redacted]	2003	European Union Risk Assessment Report: Propan-1-ol Environmental Part, CAS No.: 71-23-8, EINECS No.: 200-746-9. Series: 2nd Priority List Volume: 71. Joint Research Centre, Institute for Health and Consumer Protection, European Chemicals Bureau (ECB), 51pp, Draft of 19.08.2003 [redacted], published	N	-
A7.4.3.4 Justification for non-submission	[redacted]	2005	Scientific Committee on Health and Environmental Risks (SCHER), Opinion on “Risk Assessment Report on Propan-1-ol: Environmental Part”. Adopted by the SCHER during the 3rd plenary of 28 January 2005, 5p [redacted], published	N	-

A7.5.5 Justification for non-submission	[redacted]	2007	Estimation of the distribution behaviour in the environment and the bioconcentration factors of propan-1-ol. [redacted]	N	-

Doc IIIB (PT 1)

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B5.11	Wille B	1976	Possibility of the development of resistance to disinfectants in microorganisms. Zbl. Bakt. Hyg., 1. Abt. Orig. B, 162:217-220 [redacted], published	N	-
B6.6	Bremmer, H. J.; Prud'homme de Lodder, L. C. H.; van Engelen, J. G. M.	2006	General Fact Sheet - Limiting conditions and reliability, ventilation, room size, body surface area. Updated version for ConsExpo 4. RIVM Report 320104002. [redacted], published	N	-
B6.6	Brunner A	2004	Neue Krankenhausrichtlinien in der Schweiz und in Deutschland: SWKI-Richtlinie 99-3 und VDI 2167, Blatt1, 2004 [redacted], published	N	-
B6.6	DGKH	2002	Deutsche Gesellschaft für Krankenhaushygiene. Leitlinienentwurf: Ausführung und Betrieb von raumlufttechnischen Anlagen (RLT-Analgen) in Krankenhäusern Hyg. + Med. 27 (3) 106-113 [redacted], published	N	-
B6.6	DIN 1946-4	2007	Raumlufttechnik- Teil 4: Raumlufttechnische Anlagen in Krankenhäusern. Deutschen Institut für Normung e.V. Berlin [redacted], published	N	-
B6.6	ECB	2000	Occupational exposure limits from: 1-Propanol IUCLID-Dataset, 6 p. [redacted], published	N	-
B6.6	Freijer JI, Cassee FR, van Bree L	1997	Modelling of particulate matter deposition in the human airways. RIVM report 624029001, Bilthoven [redacted], published	N	-
B6.6	KlimaPartner	2007	Technisches Handbuch für Luft- und Klimatechnik (published) [redacted], published	N	-

B6.6	The Engineering Tool Box	2005	Air Change Rates in some typical Rooms and Buildings (published) [redacted], published	N	-
B7.1	[redacted]	[redacted]	Estimation of the Environmental Concentrations and the Preliminary Environmental Risk Assessment of 1-Propanol applied biocidal products (PT 1, 2 and 4). [redacted]	Y	[redacted]
B7.1	Royal Haskoning	2004	Supplement to the methodology for risk evaluation of biocides. Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1), January 2004 [redacted], published	N	-

Doc IIIB (PT 2)

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B5.11	Wille B	1976	Possibility of the development of resistance to disinfectants in microorganisms. Zbl. Bakt. Hyg., 1. Abt. Orig. B, 162:217-220 [redacted], published	N	-
B6.6	Brunner A	2004	Neue Krankenhausrichtlinien in der Schweiz und in Deutschland: SWKI-Richtlinie 99-3 und VDI 2167, Blatt1, 2004 [redacted], published	N	-
B6.6	ECB	2000	Occupational exposure limits from: 1-Propanol IUCLID-Dataset, 6 p. [redacted], published	N	-
B6.6	TRGS 525	1998	Technische Regeln für Gefahrstoffe - Umgang mit Gefahrstoffen in Einrichtungen zur humanmedizinischen Versorgung Mai 1998 [redacted], published	N	-
B6.6	Freijer JI, Cassee FR, van Bree L	1997	Modelling of particulate matter deposition in the human airways. RIVM report 624029001, Bilthoven [redacted], published	N	-
B6.6	DGKH	2002	Deutsche Gesellschaft für Krankenhaushygiene. Leitlinienentwurf: Ausführung und Betrieb von raumlufttechnischen Anlagen (RLT-Analgen) in Krankenhäusern Hyg. + Med. 27 (3) 106-113 [redacted], published	N	-
B6.6	DIN 1946-4	2007	Raumlufttechnik- Teil 4: Raumlufttechnische Anlagen in Krankenhäusern. Deutschen Institut für Normung e.V. Berlin [redacted], published	N	-

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B6.6	Bremmer, H. J.; Prud'homme de Lodder, L. C. H.; van Engelen, J. G. M.	2006	General Fact Sheet - Limiting conditions and reliability, ventilation, room size, body surface area. Updated version for ConsExpo 4. RIVM Report 320104002. [redacted], published	N	-
B6.6	KlimaPartner	2007	Technisches Handbuch für Luft- und Klimatechnik (published) [redacted], published	N	-
B6.6	The Engineering Tool Box	2005	Air Change Rates in some typical Rooms and Buildings (published) [redacted], published	N	-
B7.1	[redacted]	[redacted]	Estimation of the Environmental Concentrations and the Preliminary Environmental Risk Assessment of 1-Propanol applied biocidal products (PT 1, 2 and 4). [redacted]	Y	[redacted]

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B5.11	Wille B	1976	Possibility of the development of resistance to disinfectants in microorganisms. Zbl. Bakt. Hyg., 1. Abt. Orig. B, 162:217-220 [redacted], published	N	-
B6.6	Freijer JI, Cassee FR, van Bree L	1997	Modelling of particulate matter deposition in the human airways. RIVM report 624029001, Bilthoven	N	-
B6.6	EC	2003	Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances (Parts I, II, III and IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market. European Commission 2003 [redacted], published	N	-
B6.6	ECB	2000	Occupational exposure limits from: 1-Propanol IUCLID-Dataset, 6 p. [redacted], published	N	-
B6.6	TRGS 525	1998	Technische Regeln für Gefahrstoffe - Umgang mit Gefahrstoffen in Einrichtungen zur humanmedizinischen Versorgung. Mai 1998, BArbBl. Heft 5/1998, 99-105 [redacted], published		
B6.6	Bremmer, H. J.; Prud'homme de Lodder, L. C. H.; van Engelen, J. G. M.	2006	General Fact Sheet - Limiting conditions and reliability, ventilation, room size, body surface area. Updated version for ConsExpo 4. RIVM Report 320104002. [redacted], published	N	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
B6.6	KlimaPartner	2007	Technisches Handbuch für Luft- und Klimatechnik (published) [redacted], published	N	
B6.6	The Engineering Tool Box	2005	Air Change Rates in some typical Rooms and Buildings (published) [redacted], published	N	
B7.1	[redacted]	[redacted]	Estimation of the Environmental Concentrations and the Preliminary Environmental Risk Assessment of 1-Propanol applied biocidal products (PT 1, 2 and 4). [redacted]	Y	[redacted]
B7.1	TRGS 525	1998	Technische Regeln für Gefahrstoffe 525: Gefahrstoffe in der humanmedizinischen Versorgung. BArbBl. Heft 5/1998, 99-105 [redacted], published	N	-