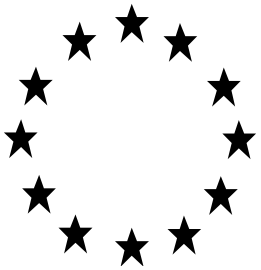
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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



Product family identifier in R4BP	AGMA IPA Product Family
Product type(s):	2 (Disinfectants and algaecides not intended for direct application to humans or animals)
Active ingredient(s):	Propan-2-ol
Case No. in R4BP	BC-HL057189-26
Asset No. in R4BP	DE-0026187-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	5.0-710 05/02.00013 710-05-02-00013-00-00-00-0000
Date	18.05.2021

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Disclaimer

The assessment of the biocidal product family has already been conducted by the former RefMS UK but was, however, not finalized before the withdrawal of UK from the EU and the transition of the application for authorization to the new RefMS DE. Therefore, several sections of the PAR were adopted and finalized by the RefMS DE.

1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the ready-to-use products within the product family “AGMA IPA Product Family” with the active substance propan-2-ol (70 % v/v) are used as a disinfectant (product-type 2) for hard surface disinfection in cleanrooms (wiping and spraying) by professional users.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.3.

A classification according to Regulation (EC) No 1272/2008[2] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the German Assessment Report for the approval of the active substance propan-2-ol including the “elements to be taken into account by Member States when authorising products” as requested by the German CA.
2. The specific provisions from Inclusion Directive for the active substance propan-2-ol (Commission Implementing Regulation (EU) 2015/407).

Approval of the active substance

[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

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

For products in product type 2:
The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Composition and formulation
The ready-to-use products within the biocidal product family “AGMA IPA Product Family” contain the active substance propan-2-ol.
Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.
No substance of concern has been identified.
Please refer to the confidential annex for detailed information.

Physical, chemical and technical properties
The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics
The product has to be classified because of identified physical-chemical hazard(s) (see chapter 2.3). However, this does not lead to an unacceptable risk for end users (please find more information in chapter 3.3).

Methods for detection and identification
Information on the analytical methods for the active substance is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms
The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.3. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

Since no relevant substance of concern has been identified the human health risk assessment for this product is based on the active substance.
There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3).
A human health risk assessment has been carried out for professional use of the product (see chapter 3.6) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to professional users, bystanders and residents. Regarding professional users health protection, there are no objections against the intended uses if the directions for use according to chapter 2.3 are followed.

Risk assessment for the environment

Since no relevant substance of concern has been identified the risk assessment for the environment for this product is based on the active substance.
There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3 and 3.8.5.6).
A risk assessment for the environment has been carried out for professional use of the product (see chapter 3.8) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable risk for the environment if the directions for use according to chapter 2.3 are followed.

Comparative Assessment

Since no candidate for substitution has been identified (see also chapter 2.2.5) a comparative assessment was not necessary.

2 Summary of the product family assessment

2.1 Administrative information (first information level)

2.1.1 Identifier in R4BP

AGMA IPA Product Family

2.1.2 Product type(s)

PT 2 (Disinfectants and algaecides not intended for direct application to humans or animals)

2.1.3 Manufacturer(s) of the product(s)

Name of manufacturer	AGMA Ltd
Address of manufacturer	Gemini Works, Haltwhistle, Northumberland, NE49 9HA, UK
Location of manufacturing sites	As above

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

Active substance	Propan-2-ol
Name of manufacturer	Ineos Solvents Germany GmbH
Address of manufacturer	Römerstraße 733, 47443 Moers, Germany
Location of manufacturing sites	As above

2.2 Composition and formulation (first information level)

2.2.1 Qualitative and quantitative information on the composition

Table 1

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

Refer to the confidential annex for further information. Note that for the sake of uniformity, the content of propan-2-ol (70%) in this PAR is given in (v/v) which is equal to 62.7% (w/w).

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

- According to the information provided the products in family contain no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?
  Yes ☐
  No ☒ (The technical equivalence of the active substance from the new source was established by ECHA, see asset number EU-0014281-000)

2.2.3 Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.

2.2.4 Information on the substance(s) of concern

No substance of concern was identified.

2.2.5 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.6 Type(s) of formulation

AL - Any other liquid (RTU)

2.3 Meta SPC(s) (second information level)

2.3.1 Meta SPC No. 01

2.3.1.1 Administrative information

2.3.1.1.1 Meta SPC identifier

01

2.3.1.1.2 Suffix to the authorisation number

01

2.3.1.1.3 Product type(s) of the products in the meta SPC

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

2.3.1.2 Composition and formulation of the products within the meta SPC

2.3.1.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Table 2

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

2.3.1.2.2 Type(s) of formulation of the products in the meta SPC

AL –any other liquid (RTU)
Other: Impregnated wipes

2.3.1.3 Classification and Labelling according to the Regulation (EC) 1272/2008 [3]

Besides the active substance propan-2-ol, the other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance propan-2-ol is based Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation).

Flam. Liq. 2	H225 Highly flammable liquid and vapour
Eye Irrit. 2	H319 Causes serious eye irritation
STOT SE3	H336 May cause drowsiness or dizziness

Classification of the products in the meta SPC pursuant to the Regulation (EC) 1272/2008 is required.

3 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.3.1.5 and if applicable to chapter 2.3.1.4.

Table 3

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Eye Irrit. 2	H319
Flam. Liq. 2	H225
STOT SE 3	H336

Table 4

Labelling	**Code**	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H319	Causes serious eye irritation
	H225	Highly flammable liquid and vapour
	H336	May cause drowsiness or dizziness
Supplemental hazard information	EUH066	Repeated exposure may cause skin dryness or cracking
Supplemental label elements	-	-
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P264	Wash hands thoroughly after handling.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P305+ P351+ P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337+ P313	IF eye irritation persists: Get medical advice/attention.
	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.

Labelling	Code	Pictogram / Wording
	P271	Use only outdoors or in a well-ventilated area.
	P304+ P340	IF INHALED: Remove victim to fresh air and Keep at rest in a position comfortable for breathing.
	P312	Call a POISON CENTER or doctor/physician if you feel unwell.
	P403 + P235	Store in a well ventilated place. Keep cool.
	P405	Store locked up.
	P501	Dispose of contents/container to..…
Note	-	Additional Labelling: EUH066: Repeated exposure may cause skin dryness or cracking. Both the active substance assessment report and the Biocidal Products Committee (BPC) opinion on the active substance propose this additional label, based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions. With the active substance, propan-2-ol, present at a concentration of 70 % (v/v) in the formulation, it is the opinion of the RefMS that the additional labelling phrase should be applied as a precautionary measure.

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.3.1.5.

Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.

It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

2.3.1.4 Use(s) of the products in the meta SPC appropriate for authorisation[4]

2.3.1.4.1 Use 1 appropriate for authorisation – Ready-to-use wipe for hard surface disinfection in cleanrooms

Product Type(s)	PT2

4 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

Where relevant, an exact description of the use	Disinfectants and algaecides not intended for direct application to humans or animals.
Target organism(s) (including development stage)	Bacteria Yeast Fungi
Field(s) of use	Disinfection of clean non-porous hard surfaces in cleanrooms - for transfer disinfection - as part of the rotational disinfectant regime - as part of a facility general, small and critical areas, and precision cleaning and disinfection regime in accordance with in-house documented, validated procedures
Application method(s)	Wiping
Application rate(s) and frequency	1 wipe for up to 0.1 m². The wipe should be replaced as frequently as needed to ensure complete wetting of the surface and to avoid transferring contaminants to other parts of the surface. Disinfection should be performed as and when required in accordance with cleanroom protocols. contact times: - 5 min for bacteria and yeast - 15 min for fungi
Category(ies) of users	Professional users
Pack sizes and packaging material	White laminate pouch; Packaging material: PET/PE

2.3.1.4.1.1 Use-specific instructions for use

See 2.3.1.5.1

2.3.1.4.1.2 Use-specific risk mitigation measures

See 2.3.1.5.2

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

See 2.3.1.5.3

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

See 2.3.1.5.4

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

See 2.3.1.5.5

2.3.1.5 General directions for use of the products in the meta SPC

2.3.1.5.1 Instructions for use

Only use on clean surfaces. Make sure to wet surfaces completely. Wipe the surface to be disinfected using unidirectional, overlapping strokes. Use a different, unused wipe surface area for each stroke (maximum of eight strokes). This can be done by unfolding and re-folding the wipe. Used wipes must be disposed in a closed container.

2.3.1.5.2 Risk mitigation measures

Avoid contact with eyes. The product must only be applied for disinfection of small surfaces. A ventilation rate of at least 20/h has to be ensured.

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

FIRST AID

IF INHALED: Remove person to fresh air and keep 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 CENTRE/doctor/… if you feel unwell. If eye irritation persists: Get medical advice/attention.

2.3.1.5.4 Instructions for safe disposal of the product and its packaging

None

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

Shelf life: 24 months. Storage requirement: Keep cool and away from heat. Keep away from frost.

2.3.1.5.6 Other information

Please be aware of the European reference value of 129.28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.

2.3.1.6 Individual products in the meta SPC(s) (third information level)

- Information on the specific composition of each individual product is provided in the confidential annex (chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

2.3.1.7 Packaging

Table 5

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Impregnated wipes contained in a pouch	20 x 29cm (10 wipes)	White laminate - PET/PE	Zip lock	Professional	Yes

2.3.2 Meta SPC No. 02

2.3.2.1 Administrative information

2.3.2.1.1 Meta SPC identifier

02

2.3.2.1.2 Suffix to the authorisation number

02

2.3.2.1.3 Product type(s) of the products in the meta SPC

PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals.

2.3.2.2 Composition and formulation of the products within the meta SPC

2.3.2.2.1 Qualitative and quantitative information on the composition of the products in the meta SPC

Table 6

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

2.3.2.2.2 Type(s) of formulation of the products in the meta SPC

AL - Any other liquid (RTU)

2.3.2.3 Classification and Labelling according to the Regulation (EC) 1272/2008 [5]

Besides the active substance propan-2-ol, the other components do not affect the classification of the biocidal product.

The current harmonised classification of the active substance propan-2-ol is based Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation).

Flam. Liq. 2	H225 Highly flammable liquid and vapour
Eye Irrit. 2	H319 Causes serious eye irritation
STOT SE3	H336 May cause drowsiness or dizziness

Classification of the products in the meta SPC pursuant to the Regulation (EC) 1272/2008 is required.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.3.2.5 and if applicable to chapter 2.3.2.4.

Table 7

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Eye Irrit. 2	H319
Flam. Liq. 2	H225
STOT SE 3	H336

5 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Table 8

Labelling	**Code**	**Pictogram / Wording**
	GHS02	
	GHS07	
Signal word	-	Danger
Hazard statements	H319	Causes serious eye irritation
	H225	Highly flammable liquid and vapour
	H336	May cause drowsiness or dizziness
Supplemental hazard information	EUH066	Repeated exposure may cause skin dryness or cracking
Supplemental label elements	-	-
Precautionary statements	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P233	Keep container tightly closed.
	P264	Wash hands thoroughly after handling.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P305+ P351+ P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337+ P313	IF eye irritation persists: Get medical advice/attention.
	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
	P271	Use only outdoors or in a well-ventilated area.
	P304+ P340	IF INHALED: Remove victim to fresh air and Keep at rest in a position comfortable for breathing.
	P312	Call a POISON CENTER or doctor/physician if you feel unwell.
	P403 + P235	Store in a well ventilated place. Keep cool.
	P405	Store locked up.
	P501	Dispose of contents/container to..…

Labelling	Code	Pictogram / Wording
Note	-	Additional Labelling: EUH066: Repeated exposure may cause skin dryness or cracking. Both the active substance assessment report and the Biocidal Products Committee (BPC) opinion on the active substance propose this additional label, based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions. With the active substance, propan-2-ol, present at a concentration of 70 % (v/v) in the formulation, it is the opinion of the RefMS that the additional labelling phrase should be applied as a precautionary measure.

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.3.2.5.

Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.

It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

2.3.2.4 Use(s) of the products in the meta SPC appropriate for authorisation[6]

2.3.2.4.1 Use 1 appropriate for authorisation – Ready-to-use spray for hard surface disinfection in cleanrooms

Product Type(s)	PT2
Where relevant, an exact description of the use	Disinfectants and algaecides not intended for direct application to humans or animals.
Target organism(s) (including development stage)	Bacteria Yeast Fungi
Field(s) of use	Disinfection of clean non-porous hard surfaces in cleanrooms - for transfer disinfection - as part of the rotational disinfectant regime

6 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

	- as part of a facility general, small and critical areas, and precision cleaning and disinfection regime in accordance with in-house documented, validated procedures
Application method(s)	Spraying
Application rate(s) and frequency	Disinfection should be performed as and when required in accordance with cleanroom protocols. Apply 5 actuations per 0.1 m^2 (to a maximum of 50 ml/m^2) and to allow the disinfectant to work. contact times: - 5 min for bacteria and yeast - 15 min for fungi After contact time, residual moisture may be removed with a sterile, dry cleanroom wipe. Alternatively, the area may be left to dry naturally before use.
Category(ies) of users	Professional users
Pack sizes and packaging material	5L container (HDPE), 1L trigger spray (HDPE), 500ml trigger spray (HDPE), 900 ml trigger spray (HDPE)

2.3.2.4.1.1 Use-specific instructions for use

See 2.3.2.5.1

2.3.2.4.1.2 Use-specific risk mitigation measures

See 2.3.2.5.2

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

See 2.3.2.5.3

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

See 2.3.2.5.4

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

See 2.3.2.5.5

2.3.2.5 General directions for use of the products in the meta SPC

2.3.2.5.1 Instructions for use

Only use on clean surfaces.

Make sure to wet surfaces completely.

Spray the product onto the surface to be disinfected.

For optimal application, keep container upright and hold at a distance of approximately 10-20 cm from the surface.

Always close the nozzle after use.

Used wipes must be disposed in a closed container.

2.3.2.5.2 Risk mitigation measures

Avoid contact with eyes.

The product must only be applied for disinfection of small surfaces.

For refilling a funnel must be applied.

The following personal risk mitigation measure can be considered for refilling procedure unless it can be replaced by technical and / or organisational measures:
The use of eye protection during refilling of the product is recommended.

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

FIRST AID

IF INHALED: Remove person to fresh air and keep 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 CENTRE/doctor/… if you feel unwell. If eye irritation persists: Get medical advice/attention.

2.3.2.5.4 Instructions for safe disposal of the product and its packaging

None

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

Shelf life: 24 months. Storage requirement: Keep cool and away from heat. Keep away from frost.

2.3.2.5.6 Other information

Please be aware of the European reference value of 129.28 mg/m³ for the active substance propan-2-ol (CAS No.: 67-63-0) which was used for the risk assessment for this product.

2.3.2.6 Individual products in the meta SPC(s) (third information level)

- Information on the specific composition of each individual product is provided in the confidential annex (chapter **Fehler! Verweisquelle konnte nicht gefunden werden.**).

2.3.2.7 Packaging

Table 9

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Trigger spray bottle	900 ml	HDPE bottle containing bung bag inside Bung bag: Coextruded five layer EVA/EVA/PVDC/EVA/EVA	Trigger device: PP-POM-LDPE-LLDPE	Professional	Yes

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Trigger spray bottle	500 – 1000 mL	HDPE bottle	Trigger device: PP Dip tube: PE	Professional	Yes
Container	5L	HDPE	HDPE cap	Professional	Yes

3 Assessment of the product family

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

Meta SPC	Use	PT	Where relevant, an exact description of the use	Target organism(s) (including development stage)	Field(s) of use	Application method(s)	Application rate(s) and frequency	Category(ies) of users	Pack sizes and packaging material
1	1	2	not relevant	bacteria, yeast and fungi	Indoor: Ready to use product for hard surface disinfection in cleanrooms, -For transfer disinfection, -As part of the rotational disinfectant regime. -As part of a facility general, small and critical areas, and precision cleaning and disinfection regime in accordance with in-house documented, validated procedures	Wiping: Wiping should be done in unidirectional, overlapping strokes, proceeding from the cleanest to the dirtiest areas. As wiping proceeds, wipers should be turned over / refolded to provide an unused surface area	The wipe should be replaced as frequently as needed to avoid transferring contaminants to other parts of the surface, and up to a maximum of eight strokes. Disinfection should be performed as and when required in accordance with cleanroom protocols. The area under application should be no more than 0.1 m^2. After application, to allow the disinfectant to work, leave the disinfected area for 5-minute dwell time for bacteria and yeast/15-minute dwell time for fungi. Always clean in accordance with cleanroom protocols.	Professional	White laminate pouch; Packaging material: PET/PE

2	1		not applicable		Indoor: Hard surface disinfection in cleanrooms. -For transfer disinfection. -As part of the rotational disinfectant regime. -As part of a facility general, small and critical areas, and precision cleaning and disinfection regime in accordance with in-house documented, validated procedures	Spraying: For optimal results keep container upright and spray at a distance of 10 cm to 20 cm	Apply 5 actuations per 0. 1m^2 (to a maximum of 50 ml/m^2) and to allow the disinfectant to work. Leave the disinfected area for 5-minute dwell time for bacteria and yeast/15-minute dwell time for fungi. After this time period any residual moisture may be removed with a sterile, dry, cleanroom wipe. Alternatively, the area may be left to dry naturally before use. Disinfection should be performed as and when required in accordance with cleanroom protocols.		5L container (HDPE), 1L trigger spray (HDPE), 500ml trigger spray (HDPE), 900 ml trigger spray (HDPE)

3.2 Physical, chemical and technical properties

Table 10: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual inspection	Both products (Sterile IPA 70%)	Liquid and impregnated wipes	Belussi, 2016 2016/75 AM
Colour at 20 °C and 101.3 kPa	Visual inspection		Transparent	
Odour at 20 °C and 101.3 kPa	Olfactory inspection		Alcoholic (as described on MSDS)	
pH	CIPAC Handbook J, MT 75.3S	Sterile IPA 70% in WFI Quality Water (900 ml trigger spray)	pH of 1 % dilution: T0 result from ambient storage: 5.69	Belussi, 2016 2016/78 AM
		Sterile IPA 70% in WFI Alcohol Wipes	pH of 1 % dilution: T0 result from ambient storage: 5.56	Belussi, 2016 2016/78 AM
		Bioburden Reduced Non-Sterile IPA 70% in WFI Quality Water (5 L container)	pH of 1 % dilution: T0 results from ambient storage: 5.99	Belussi, 2016 2016/79 AM
		Non-Sterile IPA 70% in WFI Quality Water (500ml trigger spray)	pH of 1 % dilution: T0 result from ambient storage: 6.81	Belussi, 2016 2016/80 AM

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td>Relative density / bulk density</td><td>CIPAC Hand-book F, MT 3</td><td>Sterile IPA 70% in WFI Quality Water (900 ml trigger spray)</td><td>T0 result from ambient storage: 0.878</td><td>Belussi, 2016

2016/78 AM</td></tr>
<tr><td></td><td></td><td>Bioburden Reduced Non-Sterile IPA 70% in WFI Quality Water</td><td>T0 result from ambient storage: 0.876</td><td>Belussi, 2016

2016/79 AM</td></tr>
<tr><td>Storage stability test – accelerated storage</td><td>CIPAC J/MT 46.3</td><td>Sterile IPA 70% in WFI Alcohol Wipes

Batch SZBF309BV</td><td><table><tr><td>@30°C</td><td>T0</td><td>T18weeks</td></tr><tr><td>Appear-ance</td><td colspan="2">No variation</td></tr><tr><td>Packaging</td><td colspan="2">No variation</td></tr><tr><td>Weight loss %</td><td>-</td><td>0.007%</td></tr><tr><td>pH 1%</td><td>5.68</td><td>5.24</td></tr><tr><td>ai content % v/v</td><td>69.3%</td><td>70.4%</td></tr></table></td><td>Belussi, 2016

2016/75 AM</td></tr>
<tr><td></td><td></td><td>Sterile IPA 70% in WFI Quality Water (900 ml trigger spray)

Batch SZBF1310V</td><td><table><tr><td>@30°C</td><td>T0</td><td>T18weeks</td></tr><tr><td>Appear-ance</td><td colspan="2">No variation</td></tr><tr><td>Packaging</td><td colspan="2">No variation</td></tr></table></td><td>Belussi, 2016

2016/77 AM</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>Weight loss %</td><td>-</td><td>0.55%</td></tr>
<tr><td>Relative density</td><td>0.878</td><td>0.875</td></tr>
<tr><td>pH 1%</td><td>5.69</td><td>5.88</td></tr>
<tr><td>ai content % v/v</td><td>69.6%</td><td>70.2%</td></tr>
</table>
</td><td></td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td></td><td>Sterile IPA 70% in WFI Alcohol Wipes

Batch 7394</td><td>
<table>
<tr><td>@30°C</td><td>T0</td><td>T24 months</td></tr>
<tr><td>Appear-ance</td><td colspan="2">No variation</td></tr>
<tr><td>Packaging</td><td colspan="2">No variation</td></tr>
<tr><td>Weight loss %</td><td>-</td><td>+0.01%</td></tr>
<tr><td>pH 1%</td><td>5.56</td><td>5.95</td></tr>
<tr><td>ai content % v/v</td><td>69.83%</td><td>71.43% (in-crease of 2.3%)</td></tr>
</table>
</td><td>Belussi, 2016

2016/76 AM</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td>Sterile IPA 70% in WFI Quality Water (900 ml trigger spray)

Batch 7332</td><td>
<table>
<tr><td>@30°C</td><td>T0</td><td>T24 months</td></tr>
<tr><td>Appear-ance</td><td colspan="2">No variation</td></tr>
<tr><td>Packaging</td><td colspan="2">No variation</td></tr>
<tr><td>Weight loss %</td><td>-</td><td>1.51%</td></tr>
<tr><td>Relative density</td><td>0.878</td><td>0.875</td></tr>
<tr><td>pH 1%</td><td>5.95</td><td>5.91</td></tr>
<tr><td>Spray rate</td><td>0.85g</td><td>0.88g</td></tr>
<tr><td>Particle size distri-butionDv (50) (MMAD)</td><td>111.3 µm</td><td>78.2 µm</td></tr>
<tr><td>Valve clog-ging</td><td>No clogging recorded</td><td>No clogging recorded</td></tr>
<tr><td>ai content % v/v</td><td>69.49%</td><td>70.74% (increase of 1.8%)</td></tr>
</table>
</td><td>Belussi, 2016

2016/78 AM</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td>Non-Sterile IPA 70% in WFI Quality Water (500ml trigger spray)

Batch 7394</td><td>
<table>
<tr><td>@30°C</td><td>T0</td><td>T24 months</td></tr>
<tr><td>Appear-ance</td><td colspan="2">No variation</td></tr>
<tr><td>Packaging</td><td colspan="2">No variation</td></tr>
<tr><td>Weight loss %</td><td>-</td><td>0.30%</td></tr>
<tr><td>pH 1%</td><td>6.81</td><td>7.00</td></tr>
<tr><td>Spray rate</td><td>0.90g</td><td>1.02g</td></tr>
<tr><td>Relative density</td><td>(no deter-mination in this test, value for 900mL trig-ger spray is 0.878)</td><td>0.877</td></tr>
<tr><td>Particle size distri-butionDv (50) (MMAD)</td><td>82.13µm</td><td>67.15µm</td></tr>
<tr><td>Valve clog-ging</td><td>No clogging recorded</td><td>No clogging recorded</td></tr>
</table>
</td><td>Belussi, 2016

2016/80 AM</td></tr>
</table>

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th colspan="3">Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>ai content % v/v</td><td>70.89%</td><td>70.89% (no change after 24 months)</td><td></td></tr>
<tr><td></td><td></td><td>Bioburden Reduced Non-Sterile IPA 70% in WFI Quality Water (5 L container)

Batch 7268 (6897)</td><td colspan="3">In progress

@30°C | T0 | T24 months
Appear-ance | No variation
Packaging | No variation
Weight loss % | - | 0.061%
Relative density | 0.876 | 0.874
pH 1% | 5.99 | 6.69
ai content % v/v | 69.41% | 71.32% (increase of 2.8%)</td><td>Belussi, 2016

2016/79 AM</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **low temperature stability test for liquids**		-	Product shall not be stored at temperatures < 0°C.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**		-	No direct exposure during storage because of packaging.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	The product labels should include a phrase stating they should not be stored at elevated temperatures. As the products consist of a significant amount of water, humidity does not effect them	-
Effects on content of the active substance and technical characteristics of the biocidal	-	-	-	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
product - **reactivity towards container material**				
Particle size distribution, content of dust/fines, attrition, friability	-	-	The MMAD values are included in the results for the long term stability test at ambient temperature.	-
Physical compatibility	-	All products in the BPF	The products included in the biocidal product family - AGMA IPA, are not intended to be used in conjunction with any other biocidal products.	IUCLID dossier section 3.6
Chemical compatibility	-	All products in the BPF	The products included in the biocidal product family - AGMA IPA, are not intended to be used in conjunction with any other biocidal products.	IUCLID dossier section 3.6
Surface tension	-	All products in the BPF	According to the guidance on information requirements a surface tension study should be provided for liquid biocidal products. A surface tension study on the wipes is therefore not applicable. The liquid products contain propan-2-ol at a concentration of 70% v/v. Substances are regarded as surface active if they show a	IUCLID dossier section 3.8

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			surface tension lower than 60 mN (as described in Method A5). Considering that propan-2-ol has a surface tension of 70.7 mN/m (c = 1g/L; T = 22 °C) as stated in the assessment report, then the liquid biocidal products are not considered to be surface active and therefore a study would be considered scientifically unjustified.	
Viscosity	-	All products in the BPF	According to the guidance on information requirements a viscosity study should be provided for liquid biocidal products. A viscosity study on the wipes is therefore not applicable. The liquid products contain propan-2-ol at a concentration of 70% v/v. Propan-2-ol is considered to be miscible with water (according to the assessment report). This means that it is extremely unlikely to exhibit the characteristics required to be an aspiration hazard, which tend to be more associated with non-polar organic compounds. Propan-2-ol is regarded as a polar organic compound. It can be predi-	IUCLID dossier section 3.9

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			cated that any IPA exposure would simply distribute itself in the available water in the body. It would not behave like known aspiration hazard solvents such as Toluene which is a non-polar, water insoluble solvent. Also viscosity was not considered relevant for propan-2-ol during active substance evaluation. Therefore a viscosity study is considered to be scientifically unjustified.	

Table 11

Conclusion on the physical, chemical and technical properties
Acceptable storage stability data and information on the relevant technical properties have been provided to support the product family. The pH value of a 1% dilution has been provided. In accordance with ECHA guidance the pH of the neat formulation should have been provided. However, as there is no safety or classification concern relating to pH, no corrosivity of the products while keeping the composition of the BPF in mind, these additional data have not been requested. The accelerated storage data for 18 weeks at 30 °C as well as the ambient temperature storage stability data are acceptable. The product appearance and packaging remain stable after both storage tests. The initial active substance content is within the FAO tolerance limits of ± 25 g/L. No significant decrease in active substance content has been reported. Therefore, a shelf life of 2 years is supported. The product labels should include a phrase stating they should not be stored under conditions of ≤ 0 °C (such as ‘protect from frost’).

3.3 Physical hazards and respective characteristics

Table 12: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	*Waiver*			According to Annex VI of Regulation (EC) No 1272/2008, propan-2-ol is not classified as explosive. The biocidal products contain 70% v/v propan-2-ol.	IUCLID dossier section 4.1
Flammable gases				Not applicable The parameter flammable gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas, this test does not need to be performed.	
Flammable aerosols				Not applicable The parameter flammable aerosols must be determined for biocidal products that are supplied as aerosols. Since the biocidal product is not an aerosol, this test does not need to be performed.	
Oxidising gases				Not applicable Study does not need to be conducted because products are liquids.	
Gases under pressure				Not applicable The parameter oxidising gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas, this test does not need to be performed.	

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Flammable liquids	*Waiver*		Flam. Liq. 2: H225 Calculation method acc. to 2.6.4.3.of Annex I, Part 2 of CLP-Regulation: Flash point: < 23 °C (calculated) Boiling point: 80.6 °C of azeotropic mixture (Gmehling and Rasmussen (1982l)	According to Annex VI of Regulation (EC) No 1272/2008, propan-2-ol is classified as a flammable liquid. The liquid biocidal products contain 70% v/v propan-2-ol. The biocidal products are classified as flammable.	IUCLID dossier section 4.2
Flammable solids				Not applicable The flammability has to be tested for solid biocidal products. Since the biocidal product is liquid, this test does not need to be performed.	
Self-reactive substances and mixtures				There are no ingredients with explosive or self-reactive properties present in the biocidal product. Therefore, the formulation is not self-reactive.	
Pyrophoric liquids				The study does not need to be conducted as based on experience in handling and use and the chemical structure of product contents, pyrophoric properties are not to be expected.	
Pyrophoric solids				Not applicable Test for pyrophoric properties of solid substances does need to be performed, because the biocidal product is liquid.	
Self-heating substances and mixtures				Not applicable The study does not need to be conducted as the biocidal product is liquid. A liquid shows not self-	

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
				heating behaviour if it is not absorbed on a large surface.	
Substances and mixtures which in contact with water emit flammable gases				Based on experience in handling and use and molecular structure of constituents, emission of flammable gases is not expected when the preparation comes in contact with water.	
Oxidising liquids	*Waiver*			According to Annex VI of Regulation (EC) No 1272/2008, propan-2-ol is not classified as oxidising. The liquid biocidal products contain 70% v/v propan-2-ol.	IUCLID dossier section 4.4
Oxidising solids				Not applicable The oxidising properties have to be determined for solid biocidal products. Since the biocidal product is liquid, this test does not need to be performed.	
Organic peroxides				Since the biocidal product is not an organic peroxide, the test does not need to be performed.	
Corrosive to metals			:	Not applicable. Not classified based on GHS/CLP criteria Study cannot be used for classification.	
Auto-ignition temperature (liquids and gases)	*Waiver*		According a report of the German PTB aqueous solutions of combustible liquids are exceptional, since water as incombustible substance shows an inerting effect in the	The auto-ignition temperature of a substance is the lowest temperature at which it will spontaneously ignite in normal atmosphere without an external source of ignition. The biocidal products contain 70% v/v propan-2-ol. Handbook data on propan-2-ol indicates that it has a high auto-ignition temperature >450°C. The presence of non-flammable additional co-formulants is likely to	IUCLID dossier section 4.17

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
			mixture (Hirsch, W., Brandes, E., Zündtemperaturen binärer Gemische bei erhöhten Ausgangsdrücken, PTB Braunschweig, 2005). Assuming the lowest available auto-ignition temperature of propan-2-ol (399 °C) as worst case is considered to be sufficiently protective for the usage of the product.	increase this temperature. A study is therefore considered scientifically unjustified.	
Relative self-ignition temperature for solids				Not applicable Study does not need to be conducted because products are liquids.	
Dust explosion hazard				Not applicable The dust explosion hazard must be determined for powders or biocidal products containing, or able to produce, dust. Since the biocidal product is liquid, this test does not need to be performed.	

Table 13

Conclusion on the physical hazards and respective characteristics
The evaluation was conducted to the liquid (AL) formulation of the AGMA IPA Product Family. Only the relevant hazard classes were listed in the table. Due to the physical state and composition of the products, the other hazard classes can be waived. Assuming the lowest available auto-ignition temperature of propan-2-ol (399 °C) as worst case is considered to be sufficiently protective for the usage of the products. The Biocidal products do not have any explosive, self-reactive or oxidising properties. Based on experience in production and handling it can be concluded that the product is not pyrophoric, does not evolve flammable gases in contact with water and is not considered as being corrosive to metals. Based on the available information on the substance properties a flashpoint below 20 °C can be calculated for a mixture of 70 % (v/v) propan-2 -ol and 30 % (v/v) water. The boiling point of the mixture is higher than 35 °C. Therefore, the biocidal product is classified as Flammable liquid, Category 2 based on GHS/CLP criteria.

3.4 Methods for detection and identification

Analytical methods for the active and impurities in the technical material

The source of the active substance is technically equivalent to that considered for BPR inclusion, therefore methods of analysis for the active substance and impurities have already been considered. No further consideration is required from a chemistry perspective.

Table 14

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Propan-2-ol (sterile alcohol trigger spray)	GC-FID	The method proved to be specific: the blank, the internal standard do not interfere with the peak associated with isopropanol (retention time of ~3.6 minutes)	0.55 – 1.65 mg/mL equivalent to 50-150 % of the nominal content n=5	~0.5 mg/mL [LOQ level](50% of nominal) 1 mg/ mL (100% of nominal) ~1.50 mg/mL (150% of nominal) N=2 for each level	100.0 – 100.8 % 100.7 – 101.2 % 101.0 – 101.6 %	100.4 % 100.8 % 101.3 %		n.a.	Abbiati, F (2016) Report No = S-2016-01090
Propan-2-ol (alcohol wipes)	GC-FID	The method proved to be specific: the blank, the internal standard do not interfere with the peak associated with isopropanol (retention time of ~3.6 minutes)	0.55 – 1.65 mg/mL equivalent to 50-150 % of the nominal content n=5	~0.5 mg/mL [LOQ level](50% of nominal 1 mg/ mL (100% of nominal)	104.2 – 104.3 % 102.7 – 103.0 % 100.8 – 101.3 %	104.26 % 102.89 % 101.05 %		n.a.	Meluso, A (2016) Report No = S-2016-01082

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
			R^2 = 1.0000	~1.50 mg/mL (150% of nominal) N=2 for each level					

The GC-FID method is validated in accordance with the BPR for the determination of propan-2-ol in both liquid and wipe formulations.

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

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

Table 15

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	no relevant residues expected	N/A	AR for PT1, PT2, PT4; LoEP (01/2015)
Drinking water	no relevant residues expected	N/A	AR for PT1, PT2, PT4; LoEP (01/2015)

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Surface water	no relevant residues expected	N/A	AR for PT1, PT2, PT4; LoEP (01/2015)
Air	propan-2-ol	3.2 mg/m³	$AEL_{acute/medium\text{-}term/long\ term}$:10.7 mg/kg bw/d (general population) AR for PT1, PT2, PT4; LoEP (01/2015)
Animal and human body fluids and tissues	no relevant residues	N/A	not classified as toxic or very toxic
Food of plant origin	no relevant residues expected	N/A	AR for PT1, PT2, PT4; LoEP (01/2015)
Food of animal origin	no relevant residues expected	N/A	AR for PT1, PT2, PT4; LoEP (01/2015)

Table 16:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
propan-2-ol	GC-FID, DB-5MS column	Confirmation by GC-MS possible	Calibration in solvent: 0.34 - 3.4 µg/mL R^2: 0.9983 matrix-matched calibration 0.50 - 12.56	Dry air (18 L sample volume) 49 mg/m³ / 6 98 mg/m³ / 6 197 mg/m³ / 6	99.2-101 102-103.6 102.7-104.9 102.1-	100.2 102.9 103.6	0.8 0.8 1.0	108 µg/m³ reported as reliable quantitation limit (it refers to the calibration data) 49 mg/m³ (it refers to the validated limit of 0.05 *	published OSHA method CAR DocIIIA, 4.2(b); 05/2009 OSHA, 1997

			mg/mL R^2:0.9998	491 mg/m³ / 6 983 mg/m³ / 6 1966 mg/m³ / 6 Air 21 °C, 80 % rel. humidity (18 L sample volume) 49 mg/m³ / 6 98 mg/m³ / 6 197 mg/m³ / 6 491 mg/m³ / 6 983 mg/m³ / 6 1966 mg/m³ / 6	104.8 103.2-104.3 102.6-104.6 101.1-103.4 102.3-104.5 102.5-104.4 104-106.1 103.3-105.3 103.1-107.3	103.2 103.7 103.8 102.5 103.3 103.4 104.8 104.5 105.4	1.1 0.3 0.7 1.0 0.9 0.7 0.8 0.7 1.7	OSHA target concentration of 983 mg/m³)	
propan-2-ol	GC-MS using DB-5 column, m/z 59 as quantifier and m/z 45 as qualifier	Confirmation not included, since for second fragment ion no validation data presented	0.025 - 7.4 mg/mL R^2:0.995 - 1.000	Air (considering maximum sample volume of 23.8 L of OSHA-method 9.4 mg/m³ / 5 93.8 mg/m³ / 5 250 mg/m³ / 4 750 mg/m³ / 5	 97.3-103 106-115 105-110 104-110	 99.2 111 107 107	 2.6 3.1 2.1 2.3	LOQ of the method is dependent on sampling volume: the lowest concentration of 0.025 mg/mL corresponds to 3.1 mg/m³ propan-2-ol in air at the maximum sampling volume of	DocIIIA, 4.1; 11/2015 Alcohol Task Force, 2015

								23.8 L in the OSHA method (9.4 mg/m³ - it refers to the validated QC-standard of 0.075 mg/mL and the supposed maximum sample volume of 23.8 L of OSHA-method)	

Table 17

Data waiving was acceptable for the following information requirements	
Information requirement	1. Soil 2. Water (including drinking water) and sediment 3. Animal and human body fluids and tissues 4. Analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant
Justification	For these matrices monitoring methods are deemed scientifically unjustified due to a lack of exposure, this has been agreed at EU level.

Table 18

Conclusion on the methods for detection and identification
A monitoring method for propan-2-ol residues in air has been evaluated and accepted at an EU level. Especially for workplace measurements, specific methods for workplaces should be taken into account (e.g. documentation in the „IFA-Arbeitsmappe" (no. 8415) or NIOSH documentation „ALCOHOLS I 1400"). Methods regarding substances of concern were not necessary.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

The "AGMA IPA product family" consists of two meta SPCs with ready-to-use spray and ready-to-use wipe products intended for professional use for the disinfection of clean, non-porous hard surfaces in cleanrooms (PT 2) with and without mechanical action, respectively:
- for general disinfection of small and critical areas
- for precision disinfection
- for transfer disinfection
- as part of the rotational disinfectant regime

No disinfection of large surfaces such as ceilings, walls and floors is intended.

Both the spray and the wipe contain 70% (v/v) propan-2-ol as active substance. The wipe is impregnated with the same liquid used in the spray.

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

The “AGMA IPA product family” is intended to have bactericidal, yeasticidal and fungicidal activity.

3.5.3 Effects on target organisms, including unacceptable suffering

The desired effect on target organisms is cell death through denaturation. No unacceptable suffering is expected as a result of the use of these products.

3.5.4 Mode of action, including time delay

Propan-2-ol exhibits an unspecific mechanism of effect. It affects the cell membrane causing alteration of membrane fluidity and leakage, enters the cytoplasm and destroys the inner structure of the cell molecules and of the cytoplasm’s proteins. This process (referred to as denaturation) and the enzymes’ coagulation leads to a loss of cellular activity resulting in the cell’s death.
Propan-2-ol rapidly inactivates the target microorganisms without time delay due to the unspecific mode of action (topical disinfectant). The time required for sufficient inactivation is strongly depending on the formulation, concentrations of propan-2-ol contained in the applied biocidal product, the type of target organisms and on the specific use conditions.
After thorough contact of the active substance with the target organisms, a continuous contact of the active substance with the target cells is not required since the initial contact already results in non-reversible damage of the cells, that triggers biological processes which ultimately kill the target organism.

3.5.5 Efficacy data

As the products of the “AGMA IPA product family” are intended to be applied for disinfection, they were tested in a tiered approach with quantitative suspension tests (phase 2, step 1 tests) and quantitative surface tests (phase 2, step 2 tests). All studies have been performed based on available EN standards. Experimental data is summarised in the following table

Table 19

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
PT 2 bactericidal	Surface disinfection (wiping)	Sterile Alcohol Wipes Batch: 7394	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541	EN 1276:2009	Quantitative suspension test Concentration: 80%, 50% and 25% Contact time: 5 min Temperature: 20 °C Soiling: 0.3 g/L bovine serum albumin (clean conditions) Test was performed on the liquid mechanically extracted from wipes by squeezing the wipe with a sterile syringe.	Results demonstrated >5 log reduction for bacteria at 50% product concentration in 5 min at 20 °C under clean conditions.	*S-2016-01165 AM*
PT 2 yeasticidal fungicidal	Surface disinfection (wiping)	Sterile Alcohol Wipes Batch: 7394	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis* (previously *A. niger*) ATCC 16404	EN 1650:2008 + A1:2013	Quantitative suspension test Concentration: 80%, 50% and 25% Contact time: 15 min Temperature: 20 °C	Results demonstrated >4 log reduction for yeast at 50% product concentration in 15 min at 20 °C under	*S-2016-01172 AM*

					Soiling: 0.3 g/L bovine serum albumin (clean conditions) Test was performed on the liquid mechanically extracted from wipes by squeezing the wipe with a sterile syringe.	clean conditions. Results demonstrated >4 log reduction for fungi at 80% product concentration in 15 min at 20 °C under clean conditions.	
PT 2 bactericidal yeasticidal	Surface disinfection (wiping)	Sterile Alcohol Wipes Batch: 7394	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Enterococcus hirae* ATCC 10541 *Candida albicans* ATCC 10231	EN 16615:2015	Quantitative surface test Concentration: RTU wipes Contact time: 5 min Temperature: 22.5 °C Soiling: 0.3 g/L bovine serum albumin (clean conditions)	Results demonstrated >5 log reduction for *P. aeruginosa* and *E. hirae* as well as >4 log reduction for *C. albicans* with RTU wipes in 5 min at 22.5 °C under clean conditions. Results did **not** demonstrate >5 log reduction for *S. aureus* with RTU wipes in	*S-2016-01987 AM*

						5 min at 22.5 °C under clean conditions (4.47 log reduction).	
PT 2 bactericidal	Surface disinfection (wiping)	Alcohol Wipes (impregnated with 70% IPA in WFI Quality Water) Batch: W2	*Staphylococcus aureus* ATCC 6538	EN 16615:2015	Quantitative surface test Concentration: RTU wipes Contact time: 5 min Temperature: 16-20 °C Soiling: 0.3 g/L bovine serum albumin (clean conditions)	Results demonstrated >5 log reduction for *S. aureus* with RTU wipes in 5 min at 16-20 °C under clean conditions.	*17561a*
PT 2 bactericidal	Surface disinfection (wiping)	Sterile IPA 70% in WFI Alcohol Wipes Batch: 8080	*Staphylococcus aureus* ATCC 6538	EN 16615:2015	Quantitative surface test Concentration: RTU wipes Contact time: 5 min Temperature: 22.5 °C Soiling: None	Results demonstrated >5 log reduction for *S. aureus* with RTU wipes in 5 min at 22.5 °C without soiling.	*S-2017-02965 AM* *supportive study*
PT 2 fungicidal	Surface disinfection (wiping)	Alcohol Wipes, impregnated with 70% IPA in WFI Quality Water	*Aspergillus brasiliensis* (previously *A. niger*) ATCC 16404	EN 13697:2015 + A1:2019	Quantitative surface test Concentration: 100%, 80% and 50%	Results demonstrated >3 log reduction for *A. brasiliensis*	*17560* *supportive study*

		Batch: W1			Contact time: 15 min Temperature: 18-25 °C Soiling: 0.3 g/L bovine serum albumin (clean conditions)	at 100% product concentration in 15 min at 18-25 °C under clean conditions.	
PT 2 bactericidal	Surface disinfection (spraying)	Sterile Alcohol Trigger Spray IPA Batch: 7332	*Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Escherichia coli* ATCC 10536	EN 1276:2009	Quantitative suspension test Concentration: 80%, 50% and 25% Contact time: 5 min Temperature: 20 °C Soiling: 0.3 g/L bovine serum albumin (clean conditions)	Results demonstrated >5 log reduction for bacteria at 50% product concentration in 5 min at 20 °C under clean conditions.	*S-2016-01166 AM*
PT 2 yeasticidal fungicidal	Surface disinfection (spraying)	AGMA 70% IPA in WFI Batch: WO 28911	*Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404	EN 1650:2008	Quantitative suspension test Concentration: 80% Contact time: 5 min Temperature: 20 °C Soiling: 0.3 g/L bovine serum albumin (clean conditions)	Results demonstrated >4 log reduction for yeast at 80% product concentration in 5 min at 20 °C under clean conditions.	*TRA-2011-060-01*

						Results did **not** demonstrate >4 log reduction for *A. niger* at 80% product concentration in 5 min at 20 °C under clean conditions (3.41 log reduction).	
PT 2 yeasticidal fungicidal	Surface disinfection (spraying)	Sterile Alcohol Trigger Spray IPA Batch: 7332	*Candida albicans* ATCC 10231 *Aspergillus brasiliensis (*previously *A. niger)* ATCC 16404	EN 1650:2008+A 1:2013	Quantitative suspension test Concentration: 80%, 50% and 25% Contact time: 15 min Temperature: 20 °C Soiling: 0.3 g/L bovine serum albumin (clean conditions)	Results demonstrated >4 log reduction for yeast at 50% product concentration in 15 min at 20 °C under clean conditions. Results demonstrated >4 log reduction for fungi at 80% product concentration in 15 min at 20 °C under	*S-2016-01168 AM*

						clean conditions.	
PT 2 bactericidal	Surface disinfection (spraying)	Sterile Alcohol Trigger Spray IPA Batch: 7332	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541	EN 13697:2015 (except for the interfering substances that were chosen in compliance with EN13697:2001)	Quantitative surface test Concentration: 100%, 50% and 25% Contact time: 5 min Temperature: 18-25 °C Soiling: 0.3 g/L bovine serum albumin (clean conditions)	Results demonstrated >4 log reduction for bacteria at 100% product concentration in 5 min at 18-25 °C under clean conditions.	*S-2016-01167 AM*
PT 2 bactericidal yeasticidal fungicidal	Surface disinfection (spraying)	AGMA 70% IPA in WFI Batch: WO 28911	*Escherichia coli* NCTC 10418 *Enterococcus hirae* NCIMB 8192 *Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* NCIMB 10421 *Candida albicans* ATCC 10231 *Aspergillus niger* ATCC 16404	EN 13697: 2001	Quantitative surface test Concentration: 100% Contact time: 5 min Temperature: 18-25 °C Soiling: 0.3 g/L bovine serum albumin (clean conditions)	Results demonstrated >4 log reduction for bacteria and yeast and >3 log reduction for fungi at 100% product concentration in 5 min at 18-25 °C under clean conditions.	*TRA-2011-062-01*

PT 2 fungicidal	Surface disinfection (spraying)	70% IPA in WFI Quality Water 900ml trigger Spray Batch: T1	*Aspergillus brasiliensis (*previously *A. niger)* ATCC 16404	EN 13697:2015 + A1:2019	Quantitative surface test Concentration: 100%, 80% and 50% Contact time: 15 min Temperature: 18-25 °C Soiling: 0.3 g/L bovine serum albumin (clean conditions)	Results demonstrated >3 log reduction for *A. brasiliensis* at 80% product concentration in 15 min at 18-25 °C under clean conditions.	*17559*

3.5.6 Occurrence of resistance and resistance management

Due to the unspecific mode of action of the active substance propan-2-ol, the development of resistance is not expected. A natural resistance against sporulated bacteria is known where propan-2-ol is ineffective at any concentration. Strategies such as alternate with other disinfectant active substances and avoidance of over frequent use are efficient standard practices and should be applied also to biocide uses of propan-2-ol, in order to prevent any potential development of resistance.

3.5.7 Known limitations

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

3.5.8 Evaluation of the label claims

In general, the following biocidal label claims are considered to be suitable for product labels of the AGMA IPA product family (non-biocidal label claims have not been evaluated):

Disinfection of clean, non-porous hard surfaces in cleanrooms by spraying/wiping (PT 2):
- Bactericidal, yeasticidal and fungicidal activity
- Required contact times: 5 min for bacteria and yeast, 15 min for fungi
- For use at room temperature

The following use-instructions have to be included to ensure efficacy:
- Make sure to wet surfaces completely.
- Only use on clean surfaces.

Contact times should always be stated on the label.

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

None of the products in the family is not intended to be used with other biocidal products.

3.5.10 Data waiving and conclusion

Table 20

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	

Table 21

Conclusion on the efficacy
Efficacy against bacteria: Two phase 2, step 1 tests according to EN 1276 were provided, one each for the spray and the wipe, which demonstrated the required log reduction for bacteria after a contact time of 5 min under clean condition for both test products. Two phase 2, step 2 tests according to EN 13697 were provided for the spray, which demonstrated the required log reduction for bacteria after a contact time of 5 min under clean condition. Two phase 2, step 2 tests according to EN 16615 were provided for the wipe, which (together) demonstrated the required log reduction for bacteria after a contact time of 5 min under clean condition. A third supportive phase 2, step 2 test according to EN 16615 was provided for the wipe, which demonstrated the required log reduction for *S. aureus* (which did not achieve the required log reduction in one of the other two EN 16615 studies) after a contact time of 5 min without soiling. **Efficacy against yeast:** A phase 2, step 1 test according to EN 1650 was provided for the spray, which demonstrated the required log reduction for yeast after a contact time of 5 min in clean condition. A phase 2, step 1 test according to EN 1650 was provided for the wipe with a contact time of 15 min, which demonstrated the required log reduction for yeast after a contact time of 15 min in clean condition. However, since the claimed contact time for yeast is 5 min, this study could not be taken into account for the assessment of the claimed use conditions. No phase 2, step 1 test according to EN 1650 with a contact time of 5 min was provided for the wipe. However, as the wipe is impregnated with the same liquid used in the spray and the comparison of corresponding studies for wipe and spray indicate that the solution extracted from the wipe shows a comparable or even higher log reduction in all cases, the test according to EN 1650 performed for the spray is acceptable as bridging study for the wipe. A phase 2, step 2 test according to EN 13697 was provided for the spray, which demonstrated the required log reduction for yeast after a contact time of 5 min under clean condition.

Conclusion on the efficacy
A phase 2, step 2 test according to EN 16615 was provided for the wipe, which demonstrated the required log reduction for yeast after a contact time of 5 min under clean condition. **Efficacy against fungi:** Two phase 2, step 1 tests according to EN 1650 were provided, one each for the spray and the wipe, which demonstrated the required log reduction for fungi after a contact time of 15 min under clean condition for both test products. Two phase 2, step 2 tests according to EN 13697 were provided for the spray, which demonstrated the required log reduction for fungi after a contact time of 5 and 15 min, respectively, under clean condition. A phase 2, step 2 test according to EN 16615 is not yet established for fungi. Therefore, no phase 2, step 2 test would be necessary for the wipe to claim fungicidal activity. However, a phase 2, step 2 test according to EN 13697 was provided for the wipe, which demonstrated the required log reduction for fungi after a contact time of 15 min under clean condition. **Overall conclusion:** The spray and wipe products of the AGMA IPA product family show sufficient bactericidal, yeasticidal and fungicidal activity under test conditions defined for disinfection of clean, non-porous hard surfaces in non-medical areas (cleanrooms) by spraying and wiping. - Bactericidal and yeasticidal - contact time 5 min - Fungicidal – contact time 15 min - use at room temperature To ensure the efficacy of the products, the following use conditions have to be indicated on the product label: - Make sure to wet surfaces completely. - Only use on clean surfaces.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 22

Propan-1-ol and Propan-2-ol	Value	Study	Safety factor
AEL acute/medium/long-term General population	10.7 mg/kg bw/d (31.25 ppm for 8 hours/d)	Human volunteer (Sethre et al., 2000a)	6.4
AEL acute/medium/long-term Professional workers	17.9 mg/kg bw/d (52.6 ppm for 8 hours/d)	Human volunteer (Sethre et al., 2000a)	3.8

Table 23

Propan-1-ol and Propan-2-ol	Value	Reference
Inhalative absorption	100 %	Assessment Report (RMS DE (2014))
Oral absorption	Nearly complete following oral, inhalation and intravenous exposure.	Slauter et al., 1994
Dermal absorption	See chapter 3.6.2.7	

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 24

Data waiving was acceptable for the following information requirements	
Information requirement	8.1.1. Skin corrosion or skin irritation
Justification	According to the Guidance on the Biocidal Products Regulation, Volume III: Human health, Part A: Information Requirements, testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active substance propan-2-ol as detailed

Data waiving was acceptable for the following information requirements	
	in the assessment report. Propan-2-ol is not considered to be irritating to skin. The other components of the biocidal products are not considered irritating. Testing is therefore scientifically unjustified.

Table 25

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	AGMA IPA product family is not corrosive or irritating to the skin.
Justification for the value/conclusion	Neither the active substance, propan-2-ol, nor any co-formulants are classified for skin corrosion and irritation.
Classification of the product according to CLP	AGMA IPA product family is not classified for skin corrosion or irritation.

3.6.2.2 Eye irritation

Table 26

Data waiving was acceptable for the following information requirements	
Information requirement	8.1.2. Eye irritation
Justification	According to the Guidance on the Biocidal Products Regulation, Volume III: Human health, Part A: Information Requirements, testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Propan-2-ol is classified as Eye.Irrit. 2 in accordance with Regulation (EC) No. 1272/2008. As the concentration of propan-2-ol in the products is above the generic concentration limit of 10 %, products are also classified as Eye. Irit. 2 and therefore a study is scientifically unjustified.

Table 27

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	AGMA IPA product family is classified for eye irritation (category 2).

Conclusion used in Risk Assessment – Eye irritation	
Justification for the value/conclusion	Specific test data on the formulation is not available. Therefore, classification by calculation was conducted according to Regulation (EC) No. 1272/2008 and the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.3.3, Annex I: Table 3.3.3 was followed. The active substance, propan-2-ol, is classified for Eye Irrit. 2 (H319). It is present in the products at a concentration of 70% (v/v), this is above the generic concentration limit triggering classification of the mixture as a category 2 eye irritant (≥ 10 %). Other co-formulants are not classified for eye irritation / eye damage.
Classification of the product according to CLP	AGMA IPA product family is classified for eye irritation (category 2), H319: Causes serious eye irritation.

3.6.2.3 Respiratory tract irritation

Table 28

Data waiving was acceptable for the following information requirements	
Information requirement	Annex III of BPR, point 8.7.1, “other endpoints”
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory irritation. Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008. AGMA IPA product family does not contain components classified for respiratory irritation in relevant concentrations.

Table 29

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	Based on intrinsic properties of individual components and their concentration in the formulation AGMA IPA product family is not irritating to the respiratory tract.
Classification of the product according to CLP	Classification for respiratory tract irritation is not required.

3.6.2.4 Skin sensitization

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.3.1. Skin sensitisation
Justification	According to the Guidance on the Biocidal Products Regulation, Volume III: Human health, Part A: Information Requirements, testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data are available for the active substance propan-2-ol as detailed in the assessment report. Propan-2-ol is not considered to be a skin sensitiser. The other components of the products are not considered skin sensitisers. Testing is therefore scientifically unjustified.

Table 31

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	AGMA IPA product family is not a skin sensitiser.
Justification for the value/conclusion	Neither the active substance nor any co-formulants are classified for skin sensitisation.
Classification of the product according to CLP	AGMA IPA product family is not classified for skin sensitisation.

3.6.2.5 Respiratory sensitization (ADS)

Table 32

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal products of this family or its components are not available.

Table 33

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	No concerns regarding this endpoint
Justification for the value/conclusion	Neither the active substance nor any co-formulants are classified for respiratory sensitisation.
Classification of the product according to CLP	AGMA IPA product family is not classified for respiratory sensitisation.

3.6.2.6 Acute toxicity

3.6.2.6.1 Acute toxicity by oral route

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.1. By oral route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health, “testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data are available for the active substance propan-2-ol as detailed in the assessment report. (LD50 = 4400 mg/kg bw). Also for other components the LD50 is far above 2000 mg/kg bw. Based on the available information the biocidal products in the family do not need to be classified for acute oral toxicity and a study would be considered scientifically unjustified.

Table 35

Value used in the Risk Assessment – Acute oral toxicity	
Value	AGMA IPA product family is not acutely toxic via the oral route.
Justification for the selected value	Neither the active substance nor any co-formulants are classified for acute oral toxicity.
Classification of the product according to CLP	AGMA IPA product family is not classified for acute toxicity via the oral route.

3.6.2.6.2 Acute toxicity by inhalation

Table 36

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health, “testing on the product/mixture does not need to be conducted if: — there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data are available for the active substance propan-2-ol as detailed in the assessment report. (LC50 = 17100 mg/kg bw (47.5 mg/L air for 8 h; whole body vapour)). Also the other components are not classified for acute inhalation toxicity. Based on the available information the biocidal products in the family do not need to be classified for acute inhalation toxicity and a study would be considered scientifically unjustified.

Table 37

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	AGMA IPA product family is not acutely toxic via the inhalation route.
Justification for the selected value	Neither the active substance nor any co-formulants are classified for acute inhalation toxicity.
Classification of the product according to CLP	AGMA IPA product family is not classified for acute toxicity via the inhalation route.

3.6.2.6.3 Acute toxicity by dermal route

Table 38

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.3. By dermal route
Justification	According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health, “testing on the product/mixture does not need to be conducted if: —

Data waiving was acceptable for the following information requirements	
	there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Data is available for the active substance propan-2-ol as detailed in the assessment report. (rabbit: 12900 mg/kg bw).). Also the other components are not classified for acute dermal toxicity.. Based on the available information the biocidal products in the family do not need to be classified for acute dermal toxicity and a study would be considered scientifically unjustified.

Table 39

Value used in the Risk Assessment – Acute dermal toxicity	
Value	AGMA IPA product family is not acutely toxic via the dermal route.
Justification for the selected value	Neither the active substance nor any co-formulants are classified for acute dermal toxicity.
Classification of the product according to CLP	AGMA IPA product family is not classified for acute toxicity via the dermal route.

3.6.2.7 Information on dermal absorption

Table 40

Data waiving was acceptable for the following information requirements	
Information requirement	8.6. Information on dermal absorption
Justification	Point 8.6 of Annex III to the BPR states that information on dermal absorption is required when exposure occurs to the biocidal product and the assessment of this endpoint should proceed using a tiered approach. The guidance on the approach to dermal absorption assessment for biocidal products authorisation (CA-July13-Doc.6.2.b – Final) specifies the following: Step 1) If available, use of data on the specific formulation is recommended. Step 2) If data on the specific formulation is not available, the applicant in consultation with the evaluating CA, could use either: 2.a) A default value for a first worst-case exposure estimate from the EFSA Guidance on Dermal Absorption…. Or 2.b) Data from the Assessment Report for Annex I inclusion or for product authorisation provided that conditions 1 and 2 are met: 1. It is justified that the formulations presented in dermal absorption studies submitted for Annex I inclusion or for product authorisation have a similar composition as compared to the BP to be authorised. 2. The applicant holds a letter of access (LoA) from the data owner of the dermal absorption study which is relevant for the BP to be authorised. According to the Assessment Report for propan-2-ol and the disseminated active substance dossier, the dermal absorption and transdermal flux rate were derived from an in vivo study in rats investigated under occlusive conditions using a 70% (w/w) aqueous solution of propan-2-ol. The IPA biocidal products are a 62.7% (w/w) aqueous solution of propan-2-ol. Therefore, the only difference between the two formulations is a slight variation in the content of propan-2-ol. However, it is considered that this would have a negligible effect on the dermal absorption of the propan-2-ol. The only other component of the formulations are water and wipe material, which will have no effect on the dermal absorption of chemicals, the dermal absorption of the formulations and the active itself will essentially be the same. Furthermore, the applicant holds a letter of ownership to the data submitted as part of the active substance review program and therefore can legally refer to the information submitted on propan-2-ol. For the reasons stated above, the performance of an in vitro or in vivo dermal absorption test on the biocidal product is considered scientifically unjustified and dermal absorption

Data waiving was acceptable for the following information requirements	
	data available in the Assessment Report for propan-2-ol is considered applicable to the Agma biocidal product family.

Table 41

Value(s) used in the Risk Assessment – Dermal absorption	
Substance exposure scenario(s)	All scenarios with dermal contact Concentration propan-2-ol: 70 % (v/v)
Value(s)	0.85 mg/cm^2/h (transdermal flux rate)
Justification for the selected value(s)	Read-across of the dermal absorption data from the propan-2-ol Assessment Report for '70 % (w/w) propan-2-ol in aqueous solution'. The dermal absorption value is based on *in vivo* dermal absorption rates for male and female rats. The tested formulation was a model formulation consisting of the active substance and water; this is sufficiently similar to the product family to enable read-across of these data. Reference: Assessment Report, Propan-2-ol, Product-type 1 (Human hydiene biocidal products), 13 January 2015, Germany.

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

Classification and labelling of the product is based on the classification and labelling of the active substance only, at a concentration of 70% (v/v) in the product. Co-formulants do not drive the classification and labelling of this product. Therefore, AGMA IPA product family does not contain substances of concern.

3.6.2.9 Available toxicological data relating to a mixture

Not relevant.

3.6.2.10 Other

AGMA IPA product family is classified for STOT SE 3, H336: May cause drowsiness or dizziness.

Specific test data on the formulation is not available, therefore, classification by calculation was conducted according to the Guidance on the Application of the CLP Criteria (Version 4.1 – June 2015); Section 3.8.3, Annex I: 3.8.3.4.5. was followed. The active substance, propan-2-ol, is classified for STOT-SE 3 (H336).

It is present in the product at a concentration of 70 % (v/v), this is above the generic concentration limit triggering classification of the mixture as category 3 (≥ 20 %).

Additional Labelling:
EUH066: Repeated exposure may cause skin dryness or cracking.
Both the active substance assessment report and the Biocidal Products Committee (BPC) opinion on the active substance propose this additional label, based on local skin effects and reactions that have been described for human individuals exposed to formulations containing propan-2-ol or to propan-2-ol dilutions. With the active substance, propan-2-ol, present at a concentration of 70 % (v/v) in the formulation, it is the opinion of the RefMS that the additional labelling phrase should be applied as a precautionary measure.

Endocrine disrupting properties

The biocidal product does not contain any components listed for ED properties on the SVHC list or the Endocrine disruptor assessment list of the ECHA.

3.6.2.11 Summary of effects assessment

Table 42

Endpoint	Brief description
Skin corrosion and irritation	Based on the intrinsic properties of the single components. Not corrosive or irritating to the skin. Repeated exposure may cause skin dryness or cracking. Labelling with EU066 is required.
Eye irritation	Based on the intrinsic properties of the single components. Irritating to the eyes (Eye Irrit. 2, H319).
Respiratory tract irritation	Based on the intrinsic properties of the single components. Not irritating to the respiratory tract (not classified).
Skin sensitisation	Based on the intrinsic properties of the single components. Not skin-sensitising.
Respiratory sensitization (ADS)	Based on the known intrinsic properties of the single components. Not sensitising to the respiratory tract.
Acute toxicity by oral route	Based on the known intrinsic properties of the single components. No acute toxicity via the oral route.
Acute toxicity by inhalation	Based on the known intrinsic properties of the single components. No acute toxicity via the inhalation route.
Acute toxicity by dermal route	Based on the known intrinsic properties of the single components. No acute toxicity via the dermal route.

Endpoint	Brief description
Information on dermal absorption	Based on dermal absorption data from Boatman et al. (1998). Flux rate: 0.85 mg/cm^2/h.
Available toxicological data relating to non-active substance(s)	Substances of concern were not identified.
Available toxicological data relating to a mixture	Not required.
Other relevant information	Based on the intrinsic properties of the active substance also the biocidal product is classified with STOT SE 3, H336 (May cause drowsiness or dizziness).

3.6.3 Exposure assessment

AGMA IPA is biocidal product family which is based on propan-2-ol as active substance. It is used for disinfection of small surfaces in cleanrooms.

Intended uses of the product family		
Product category	**Use**	**Application rate**
Meta-SPC 1: Ready-to-use disinfectant impregnated wipe	Professional surface disinfectant for use in cleanrooms (excluding for use on walls, floors and ceilings)	212 ml/m²
Meta-SPC 2: Ready-to-use disinfectant spray		50 ml/m²

The biocidal product is marketed in different packages:

- Meta-SPC 1: White laminate pouch; Packaging material: PET/PE
- Meta-SPC 2: 5 L container (HDPE), 1 L trigger spray (HDPE), 500 ml trigger spray (HDPE), 900 ml trigger spray (HDPE)

The exposure to the a.s. is assessed separately for the different applications and is described in individual subsections of the current section. The exposure assessment is usually based on the harmonised document “Biocides Human Health Exposure methodology (BHHEM, October 2015, version 1) which includes details from the TNsG 2002 (Technical Notes for Guidance) updated where relevant with the corresponding parts from HEEG/HEAdhoc opinions (Human Exposure Expert Group / Ad hoc Working Group Human Exposure) or the TNsG 2007.

In Annex 4.3.1, the details of the exposure calculations to the a.s. for the professional user are laid out.

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

Table 43

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

Summary table: relevant paths of human exposure							
Expo-sure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Indus-trial use	**Profes-sional use**	**Non-profes-sional use**	**Indus-trial use**	**Profes-sional use**	**General public**	**Via food**
Oral	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 44

Summary table: scenarios			
Scenario number	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure Description of scenario**	**Exposed group (e.g. professionals, non-professionals, by-standers)**
1.	Small surface disinfection in cleanrooms with rtu wipes	Primary exposure: a professional performs routine disinfection of small surfaces by using a rtu wipe. Secondary exposure is also covered by this scenario.	Professional
2.	Small surface disinfection in cleanrooms by trigger spraying and wiping	Primary exposure: a professional performs routine disinfection of small surfaces by spraying and subsequent wiping. Secondary exposure is also covered by this scenario.	Professional

3.6.3.1.1 Professional exposure

- **<u>Scenario 1</u> - Small surface disinfection in cleanrooms with RTU wipes**

The exposure assessment of small surface disinfection in cleanrooms is based on the approach described in the CAR for propan-2-ol. Alcohol based ready to use (RTU) products are applied for rapid in between disinfection of small surfaces, e.g. prior to a new task to remove potential contamination e.g. of biomaterial from the previous task. The assessment is based on the Recommendation no. 15 of the BPC Ad hoc Working Group on Human Exposure “Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger sprayer”.

The products of meta-SPC 1 (AGMA IPA) are ready-to-use surface disinfectant wipes.

The disinfectant is used in cleanrooms.

The scenario covers rapid disinfection of small surfaces in technically ventilated rooms such as cleanrooms. It is assumed that a staff person in a cleanroom carries out 10 small surface disinfections per day. According to the CAR for propan-2-ol, alcoholic disinfection of small surfaces of approx. 0.5 m² is commonly performed in laboratories prior to every new task to remove potential contamination e.g. of biomaterial from a previous task. As a realistic worst case scenario, it is assumed that one person disinfects its working bench every 45 minutes in a small room and that the person does not leave the room in between (realistic worst-case assumption).

Dermal exposure
During the application phase dermal exposure can be expected when the biocidal product is distributed by wiping with a wipe in one hand. So it can be assumed that the area of one palm is exposed to the biocidal product during the application procedure. The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5.
For informational purpose, dermal exposure is calculated based on the 75th percentile value of the model BEAT small scale wiping (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).

Inhalation exposure
Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol at room temperature. A calculation of the inhalation exposure for the professional user to the a.s. is carried out using the consumer exposure model ConsExpo Web “Inhalation exposure to vapour - evaporation model” which is applicable to assess the volatile part of the active substance.

Exposure to the eyes

The ready-to-use wipes are impregnated with the disinfectant liquid. The application liquid evaporates rapidly and no residues on the skin are available for a possible hand to eye contact.

Secondary exposure

Dermal exposure of a professional bystander in the same room is not expected, due to the high vapour pressure of the active substance the product quickly evaporates from the treated surface. It is possible that inhalation exposure occurs to a professional bystander who is present in the laboratory where the disinfection of a small surface is carried out. Secondary inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 45

Details of Scenario 1: Small surface disinfection in cleanrooms with rtu wipes	
Parameter	**Value**
Concentration of a.s. propan-2-ol in b.p.	70 % (v/v)
Density of the b.p.	0.878 g/cm³
Number of surface disinfections per day	10
Exposed skin area (one palm)	205 cm²
Application duration per disinfection	1 min
Application rate	212 ml/m²*
Temperature (room)	25 °C
ConsExpo Web parameters	
Room volume	55 m³
Ventilation rate	Tier 1: 8/h Tier 2: 20/h
Surface area = Area disinfected	0.5 m²
Product amount per application	93.1 g (106 ml)*
Exposure duration (of one application)	45 min
Mode of release	Evaporation

* Corresponds to 18.64 g b.p. per wipe (information from the applicant), assuming that one wipe is used per 0.1 m² and that the product is completely wrung out of the wipe (worst case).

Calculations for Scenario 1

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 47. For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR. For risk characterisation, see chapter 3.6.4.5.

Further information and considerations on scenario 1

A risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is therefore required. The Tier 2 refinement was calculated taking a ventilation rate of 20/h into account (instead of 8/h).

Used ready-to-use wipes have to be discarded into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from the used ready-to-use wipes.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). Local risk assessment indicated no risk for eye irritation. Nevertheless, contact to the eyes should be avoided.

- **<u>Scenario 2 -</u> Small surface disinfection in cleanrooms by spraying and wiping**

The exposure assessment of small surface disinfection in cleanrooms is based on the approach described in the CAR for propan-2-ol. Alcohol based ready to use (RTU) products are applied for rapid in between disinfection of small surfaces, e.g. prior to a new task to remove potential contamination e.g. of biomaterial from the previous task. The assessment is based on the Recommendation no. 15 of the BPC Ad hoc Working Group on Human Exposure “Harmonisation of PT2 small surface disinfection exposure scenarios for biocidal products containing highly volatile active substances by RTU wipes and trigger sprayer”.

The product of meta-SPC 2 (AGMA IPA) is a ready-to-use surface disinfectant spray which is used in cleanrooms.

For disinfection of small surfaces the application liquid is sprayed from a hand-held bottle onto the surface to be treated or onto a wipe. Finally, the surface to be disinfected is wiped off. This scenario also takes into account that the biocidal product is transferred from a larger packaging (> 1 L) to a smaller bottle (refilling of empty hand-held bottle; equals mixing and loading).

The scenario covers rapid disinfection of small surfaces in technically ventilated rooms such as cleanrooms. It is assumed that a staff person in a laboratory carries out 10 small surface disinfections per day. According to the CAR for propan-2-ol, alcoholic disinfection of small surfaces of approx. 0.5 m² is commonly performed in laboratories prior to every new task to remove potential contamination e.g. of biomaterial from a previous task. As a realistic worst case scenario, it is assumed that one person disinfects its working bench every 45 minutes in a small room and that the person does not leave the room in between (realistic worst-case assumption).

Dermal exposure

During the loading phase (refilling), exposure of the palm of one hand is expected during manual refilling of trigger spray bottles, due to spilled quantities on the outside. For informational purpose, dermal exposure is also calculated based on “Mixing and loading model 4” (BHHEM 2015 and TNsG on Human Exposure, recommendation of Human Exposure Expert Group HEEG).
During the application phase dermal exposure can be expected when the biocidal product is distributed by wiping with a wipe e.g. a single use paper towel in one hand. So it can be assumed that the area of one palm is exposed to the biocidal product during the application procedure.
The dermal exposure is calculated via the dermal flux, for details please refer to chapter 3.6.4.5.
For informational purpose, dermal exposure is calculated based on the 75th percentile value of the model BEAT small scale wiping (Hughson G.W., Aitken R.J. (2004) Determination of Dermal Exposures During Mixing, Spraying and Wiping Activities. Annals of Occupational Hygiene (48) 245-256).

Inhalation exposure
Inhalation of vapour of propan-2-ol is assumed arising from evaporation of the a.s. during the manual refilling of the b.p. from a bigger vessel into a trigger spray bottle.
It is assumed that the procedure is carried out in a small room. The modelled scenario includes a 10 min exposure phase for the loading activity and a 470 min non-exposure period. Calculation of inhalation exposure to the a.s. is carried out using the near field model of the Advanced REACH Tool 1.5 (ART) which assesses inhalation exposure to vapour during decanting. It is further assumed that the relatively small size of the opening of the canister and of the bottle reduces contact between the b.p. and adjacent air.
Exposure to vapour occurs during the application phase due to the high vapour pressure of the active substance propan-2-ol at room temperature. A calculation of the inhalation exposure for the professional user to the a.s. is carried out using the consumer exposure model ConsExpo Web “Inhalation exposure to vapour - evaporation model” which is applicable to assess the volatile part of the active substance.

Exposure to the eyes
Accidental splashes to the eyes cannot be excluded during manual refiling. Even if local effects for eye irritation are taken into account via the AEL according to the CAR of propan-2-ol, it is assumed that possible eye irritation on a daily basis should be avoided. Therefore, wearing of eye protection is recommended for this task.
For the treatment of small surfaces e.g. work benches, a small amount of the application liquid is directly applied to the surface from a short distance, so that exposure to the eyes is not expected. Moreover, the application liquid evaporates rapidly and no residues on the skin are available for a possible hand to eye contact.

Secondary exposure
Dermal exposure of a professional bystander in the same room is not expected, due to the high vapour pressure of the active substance the product quickly evaporates from the treated surface. It is possible

that inhalation exposure occurs to a professional bystander who is present in the laboratory where the disinfection of a small surface is carried out. Secondary inhalation exposure will be in the same order of magnitude or lower as for the operator.

Table 46

Details of Scenario 2: Small surface disinfection in cleanrooms by spraying and wiping	
Parameter	**Value**
Concentration of a.s. propan-2-ol in b.p.	70 % (v/v)
Density of the b.p.	0.878 g/cm³
Number of surface disinfections per day	10
Exposed skin area (one palm)	205 cm²
Application duration	1 min
Application rate	50 ml/m²
Temperature (room)	25 °C
ConsExpo Web parameters	
Room volume	55 m³
Ventilation rate	Tier 1: 8/h Tier 2: 20/h
Surface area = Area disinfected	0.5 m²
Product amount per application	21,95 g (25 ml)
Exposure duration (of one application)	45 min
Mode of release	Evaporation
Advanced Reach Tool (ART) 1.5 parameters	
Room size	Any size workroom
Ventilation rate	Only good natural ventilation
Exposure duration per day	10 min
Non-exposure period	470 min
Activity class	Falling liquids
Situation	Transfer of liquid product with flow of 0.1-1 l/minute
Containment level	Handling that reduces contact between product and adjacent air
Loading type	Splash loading

Calculations for Scenario 2

The results of the calculation for potential/actual inhalation and dermal exposure (Tier 1 and Tier 2) are summarised in Table 46.For details of the calculation of dermal and inhalation exposure, please refer to Annex 4.3.1 of this PAR. For risk characterisation, see chapter 3.6.4.5

Further information and considerations on scenario 2

Since no risk was identified resulting from the quantitative risk assessment in Tier 1, a refined exposure assessment is not required. For informational purposes, a Tier 2 refinement was calculated taking a ventilation rate of 20/h into account (instead of 8/h).

Used wipes have to be discarded into a closable container to prevent secondary inhalation exposure to the a.s. which evaporates from the used wipes.

The classification of the b.p requires additional assessment of local risks (see chapter 3.6.4.5: Risk for professional users). Local risk assessment indicated a risk for eye irritation. For disinfection of small surfaces by professional users the product is usually applied from a short distance on the surface in downwards direction so that exposure to the eyes is not expected. Nevertheless, contact to the eyes should be avoided. Accidental splashes to the eyes cannot be excluded during manual decanting, thus, eye protection is recommended.

- **Summary of professional exposure**

The following tables give an overview of the assessed exposure values. The exposure data include all phases of application. In Table 47 the estimated external inhalation exposure and external dermal exposure are listed. In Annex 4.3.1 the external and internal exposure values are available for the scenarios.

Table 47

Summary table: estimated exposure from professional uses. For Tier 2, only measures that have not yet been considered for Tier 1 are indicated.				
Exposure scenario	**Use no. (Product type)**	**Tier/PPE**	**a.s.: propan-2-ol**	
			Estimated external inhalation exposure [mg/m³]	**Estimated external dermal exposure [mg/day]**
Scenario 1: Small surface disinfection in cleanrooms with rtu wipes	1 (Meta-SPC: 1; PT02)	Tier 1: • Ventilation rate: 8/h	159.38	1178.08
		Tier 2: • Ventilation rate: 20/h	63.75	1178.08
Scenario 2: Small surface disinfection in cleanrooms by spraying and wiping	1 (Meta-SPC: 2; PT02)	Tier 1: • Ventilation rate: 8/h	39.21	1453.34
		Tier 2: • Ventilation rate: 20/h	16.71	1453.34

- **Combined scenarios**

A combination of exposure scenarios is not applicable for the intended uses.

3.6.3.1.2 Non-professional exposure

AGMA IPA product family is intended for use by professional users only.

3.6.3.1.3 Secondary exposure of the general public

AGMA IPA product family are intended to be used in controlled professional environments (e.g. clean-rooms) where members of the general public (e.g. children) will be excluded from entry. As such no general public exposure is foreseen.

3.6.3.2 Dietary exposure

AGMA IPA Product family is not intended for use in areas where exposure to food, drinking water or livestock is foreseen.

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

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Aggregated exposure

Not applicable.

3.6.3.5 Summary of exposure assessment

Table 48

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1. Small surface disinfection in cleanrooms with rtu wipes	Professional user	Tier 1: ventilation rate 8/h Tier 2: ventilation rate 20/h	Tier 1: 27.0 mg a.s./kg bw/day Tier 2: 11.1 mg a.s./kg bw/day
2. Small surface disinfection in cleanrooms by spraying and wiping	Professinal user	Tier 1: ventilation rate 8/h Tier 2: n.a.	Tier 1: 7.0 mg a.s./kg bw/day Tier 2: n.a.

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in Table 49.

Table 49

Reference values to be used in Risk Characterisation

Reference values of the active substances propan-1-ol and propan-2-ol					
Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
AELacute/medium-term/long-term General population	Human volunteer study (Sethre et al. 2000a)	NOAEC – 200 ppm.	6.4	-	10.7 mg/kg bw/d (31.25 ppm for 8 hours/d)
AELacute/medium-term/long-term Professional workers	Human volunteer study (Sethre et al. 2000a)	NOAEC – 200 ppm. LOAEL 400 ppm for acute systemic (neurological) effects (over 8 hours),	3.8 for intraspecies variability within the population (comprising age groups	-	17.9 mg/kg bw/d (52.6 ppm for 8 hours/d)

		based on the deterioration of postural balance.	from 5 to 75 years of age)		
ARfD	Not necessary, no residues in food expected				
ADI	Not necessary, no residues in food expected				
Dermal absorption	Boatman et al., 1998				Absorption rate (transdermal flux) in rat study: 0.85 mg/cm²/h for aqueous solution containing 70 % propan-2-ol (by weight) Since the model formulation consists only of the active substance and water; this is sufficiently similar to the product family) and water toxicological properties can be derived from data provided for the active substance.
Inhalative absorption	Assessment-Report (RMS DE (2014))				100 %
Oral absorption	Slauter et al., 1994				Nearly complete following oral, inhalation and intravenous exposure.
Professional User					
Reference value for inhalation (proposed OEL)	2-year inhalation rat	-	-	-	200 ppm
Note on local effects	The $AEC_{acute/medium/long-term}$ is assumed to also sufficiently cover local irritant effects in the eyes/airways.				
Reference: Assessment Report, Propan-2-ol, PT 2 (Private area and public health area disinfectants and other biocidal products), 13 January 2015, Germany. Assessment Report, Propan-2-ol, PT 1 (Human hygiene biocidal products), 13 January 2015, Germany.					

3.6.4.2 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.6.4.3 Endocrine disrupting properties

The biocidal product does not contain any components listed for ED properties on the SVHC list or the Endocrine disruptor assessment list of the ECHA.

3.6.4.4 Risk for industrial users

No industrial applications are intended.

3.6.4.5 Risk for professional users

The biocidal product family Agma IPA comprises two meta SPCs. An overview of the applications applied for the two meta SPCs is given in Table 48 in chapter 3.6.3.5. All members of the biocidal product family contain propan-2-ol (CAS 67-63-0) as active substance.

The occupational risk assessment for the biocidal products covered by both meta SPC takes into account systemic and local effects of the active substance propan-2-ol. The risk assessment is based on the internal reference value (AEL).

Systemic effects – quantitative

Active substance propan-2-ol

The primary toxic effect of the active substance propan-2-ol is acute central nervous system (CNS) depression. The AEC derived for professionals is assumed to also sufficiently cover local irritant effects in the eyes/airways. The AEC corresponds to the systemic/internal reference dose AEL. The quantitative risk characterisation for professional users takes into account dermal and inhalation exposure to propan-2-ol resulting from use of the biocidal product family Agma IPA.

Details of risk characterisation

Reference values

The systemic reference value $AEL_{long\text{-}term}$ of 17.9 mg propan-2-ol/kg bw/d is used.

Calculation of total uptake and AEL exhaustion (%)

For inhalation route 100 % is assumed as default absorption for the active substance propan-2-ol.

The calculation of the dermal uptake significantly depends on the methodology used for the calculation of dermal absorption. Due to the rapid evaporation of propan-2-ol, data on dermal flux (0.85 mg/cm²/h) instead of data on the percentage of dermal absorption is used for the calculation of the dermal uptake. Application time/day and exposed skin area are shown in Table 45 and Table 46 (see chapter 3.6.3.1.1).

The inhalation uptake and dermal uptake referring to the active substance propan-2-ol resulting from use of the biocidal product family Agma IPA are determined according to the following equations:

Inhalation uptake (mg/kg bw/d) = inhalation exposure to propan-2-ol (mg/m³) x 10 m³/d breathing volume / 60 kg body weight / 100 % x 100 % inhalation absorption

Dermal uptake (mg/kg bw/d) based on flux = dermal flux rate 0.85 mg/cm²/h x exposed skin area (205 cm²) x application time/day (meta SPC1: 10 min; meta SPC2: 10.5 min) / 60 kg body weight

The summation of inhalation uptake and dermal uptake within a scenario gives the total uptake.

A risk for professional users referring to the active substance propan-2-ol resulting from the use of the biocidal product family Agma IPA is unlikely if the AEL exhaustion (%) for each scenario is below the value of 100 %.
Table 50 gives a detailed overview of the risk assessment results referring to the active substance propan-2-ol in the biocidal product family. It is noted that for clarity reasons all values are rounded to an appropriate number of decimal places in
Table 50. However, the underlying calculations are based on unrounded values.

As shown in
Table 50 for the scenarios in meta SPC 2, small surface disinfection in cleanrooms by trigger spraying and wiping‘ a risk for the professional user is unlikely already in Tier 1. By contrast, for the scenarios in meta SPC 1 ‚Small surface disinfection in cleanrooms with rtu wipes‘ inacceptable risks are identified after Tier 1 consideration. However, when additional risk mitigation measures are implemented a risk for the professional user is unlikely in Tier 2.

Table 50: Overview of detailed risk assessment results referring to the active substance propan-2-ol in the biocidal product family Agma IPA

Scenario		**AEL** long-term mg/kg bw/d	**Estimated inhalation uptake** mg/kg bw/d	**Estimated dermal uptake based on dermal flux** mg/kg bw/d	**Estimated total uptake** mg/kg bw/d	**Estimated total uptake / AEL** AEL exhaustion %	**Acceptable** (yes/no)
	Tier 1	17.9	26.6	0.5	27.0	151	No

Meta SPC 1: Small surface disinfection in cleanrooms with rtu wipes	Tier 2	17.9	10.6	0.5	11.1	62	Yes
Meta SPC 2: Small surface disinfection in cleanrooms by trigger spraying and wiping	Tier 1	17.9	6.5	0.5	7.0	39	Yes

Conclusion

Based on the risk assessment of the active substance propan-2-ol via the inhalation and dermal route, a risk for professional users resulting from both uses is unlikely at the latest after Tier 2 consideration. Regarding occupational safety, there are no objections against the uses taking into account the provisions described in chapter 3.6.3.1.1 of this PAR.

Local effects – qualitative

The local toxicity profiles of the active substance propan-2-ol is considered. The substance leads to the classification of the biocidal product family Agma IPA with Eye Irrit 2, H319 (Causes serious eye irritation) and labelling with EUH066.

The qualitative risk assessment for local effects takes into account the concentrated biocidal product. The Table 51 gives an overview of the relevant classifications for the qualitative risk assessment for local effects of biocidal product family Agma IPA. Furthermore, the allocated hazard categories according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) are plotted against the respective classification.

Table 51: Relevant classification and resulting hazard categories (meta SPC 1 and 2)

b.p. concentration in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)
100%	Eye Irrit 2, H319 EUH066	low

Concluding qualitatively on the acceptability of risk, the acceptable maximum frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) the following tables are prepared to carry out the qualitative

risk assessment for local effects regarding contact with the skin and eyes of the biocidal product family Agma IPA for the intended uses. With the proposed risk mitigation measures the reduction of dermal and eye contact minimises the anticipated health risk to an acceptable level for the intended uses and for secondary exposure.

Table 52: Summary of qualitative conclusions for local risk assessment for scenario ‘Small surface disinfection in cleanrooms with rtu-wipes’ in meta SPC 1

Task, uses, processes	Concentration b.p. (max.)	Local effects in terms of C&L	Hazard category	Potential degree of exposure	Necessary RMM & PPE for acceptable risk
Small surface disinfection in cleanrooms with rtu-wipes	100%	Eye Irrit. 2 (H319), EUH066	Low	Eyes: contact not expected Skin: exposure expected	Technical Measure: -/- Organisational measure: 1) PPE: -/- Other: - Labelling: "Avoid contact to eyes."

1) At the workplace a good standard of occupational hygiene is assumed

Table 53: Summary of qualitative conclusions for local risk assessment for scenario ‘Small surface disinfection in cleanrooms by trigger spraying and wiping’ in meta SPC 2

Task, uses, processes	Concentration b.p. (max.)	Local effects in terms of C&L	Hazard category	Potential degree of exposure	Necessary RMM & PPE for acceptable risk

Loading of spray bottle (refilling)	100%	Eye Irrit. 2 (H319), EUH066	Low	Eyes: contact not expected Skin: exposure expected	Technical Measure: - Use of a funnel for refilling Organisational measure: 1) PPE: - Eye protection (just recommended due to the reversibility of the local effect) Other: - Labelling: "Avoid contact to eyes."
Small surface disinfection in cleanrooms by trigger spraying and wiping	100%	Eye Irrit. 2 (H319), EUH066	Low	Eyes: contact not expected Skin: exposure expected	Technical Measure: -/- Organisational measure: 1) PPE: -/- Other: - Labelling: "Avoid contact to eyes."

[1)] At the workplace a good standard of occupational hygiene is assumed

Conclusion

Concerning the irritating properties of the biocidal product family Agma IPA, exposure should be minimised with risk mitigation measures. If the proposed risk mitigation measures are implemented, the intended uses do not lead to concern for professional users.

Overall conclusion

In summary, a risk for professional users resulting from the use of the biocidal product family Agma IPA is unlikely for the intended uses in meta SPC 1 ‚Small surface disinfection in cleanrooms with rtu wipes', in meta SPC 2 ‚Small surface disinfection in cleanrooms by trigger spraying and wiping'. Risk mitigation measures described in chapter 2.3 have to be taken into account in order to ensure a safe use of the biocidal product family Agma IPA.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.6 Risk for non-professional users

AGMA IPA product family are intended to be used in controlled professional environments e.g. cleanrooms which members of the general public e.g. children will be excluded from entry.

3.6.4.7 Risk for the general public

AGMA IPA product family is intended to be used in controlled professional environments e.g. cleanrooms which members of the general public e.g. children will be excluded from entry.

3.6.4.8 Risk for consumers via residues in food

AGMA IPA Product family is not intended for use in areas where exposure to food, drinking water or livestock is foreseen.

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

Risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product is not required as the product contains only the active substance propan-2-ol and no substances of concern.

3.6.4.10 Summary of risk characterisation

3.6.4.10.1 Summary of risk characterisation for industrial user

No industrial applications are intended.

3.6.4.10.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product family Agma IPA is unlikely for the intended uses in meta SPC 1 ‚Small surface disinfection in cleanrooms with rtu wipes', in meta SPC 2 ‚Small surface disinfection in cleanrooms by trigger spraying and wiping' (see Table 50, Table 52 and Table 53). Risk mitigation measures described in chapter 2.3.1.5 and 2.3.2.5 have to be taken into account in order to ensure safe use of the biocidal product family Agma IPA.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.7 Risk assessment for animal health

AGMA IPA Product family is not intended for use in areas where pets or livestock animals are present.

3.8 Risk assessment for the environment

3.8.1 General information

AGMA IPA Product family are products used in cleanrooms only (hard surface disinfection with impregnated wipes and by spraying). The products are available ready-to-use (RTU) and each contains 70 % (v/v) propan-2-ol as the active substance. The application rate to surfaces is 50 ml/m^2 via the liquid trigger spray use or one wipe per 0.1 m^2.

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

3.8.2 Effects assessment

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

Aquatic = 2.82 mg a.s./L

Sediment = 2.41 mg/kg ww sediment

Sewage = 10 mg/L

Soil = 0.496 mg/kg ww soil

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

The active substance propan-2-ol has a harmonised classification, but is not classified according to environmental hazards and no substance of concern is contained in the biocidal product. Therefore, no classification according to environmental hazards is required for the b.p.

Further Ecotoxicological studies

Data waiving	
Information requirement	Further Ecotoxicological studies
Justification	No additional data are required.

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

Data waiving	
Information requirement	Effects on other non-target organisms.
Justification	No additional data are required.

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

Data waiving	
Information requirement	Supervised trials.
Justification	No additional data are required.

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

Data waiving	
Information require-ment	Acceptance by ingestion.
Justification	No additional data are required.

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

No additional data are required.

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

AGMA IPA Product family are applied indoors to hard surfaces in industrial areas; no direct exposure of soil or surface waters is expected.

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

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

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

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

AGMA IPA Product family products are not intended for spraying on a large scale near surface waters. Consequently, overspray studies are not required.

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

AGMA IPA Product family products are not intended for spraying on a large scale near surface waters. Consequently, overspray studies are not required.

3.8.2.1 Mixture toxicity

The product contains only one active substance and no substances of concern. Therefore, no assessment of mixture toxicity is necessary.

3.8.2.2 Aquatic compartment (including sediment and STP)

The active substance propan-2-ol is practically non-toxic to aquatic organisms. The lowest acute effect value for fish is the 96 h LC50 of 8692 mg a.s./L (*Pimephales promelas*) and for invertebrates a 48 h EC_{50} value of 2285 mg a.s./L for *Daphnia magna* was estimated.
The toxicity to algae (*Pseudokirchneriella subspicata*) is also very low (E_rC_{50} = 10500 mg/L).
The estimation of long-term effects is limited to studies on invertebrates (*Daphnia magna*) and algae and the lowest chronic effect value is a 16 d NOEC of 141 mg/L determined for Propan-2-ol the endpoint growth. A $PNEC_{water}$ of 2.82 mg/L was derived from the available studies considering an assessment factor of 50.
Studies on sediment dwelling organisms are not available and are not necessary for the intended use. By using equilibrium partitioning method, a $PNEC_{sediment}$ of 2.41 mg/kg ww could be estimated, based on $PNEC_{water}$.

Inhibition of microbial activity (STP)
In a test on the respiration inhibition of activated sludge conducted according to OECD 209 guideline, the EC_{50} was calculated to be >1000 mg a.s./L nominal. For the risk assessment an EC_{50} value of 1000 mg/ L will be used as a worst case.
Considering an assessment factor of 100 to the EC50 of the respiration inhibition test a $PNEC_{microorganisms, STP}$ of 10 mg/L was derived.

3.8.2.3 Terrestrial compartment (including groundwater)

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-2-ol are scientifically not justified.
Based on $PNEC_{water}$ a $PNEC_{soil}$ of 0.496 mg/kg ww was derived by using equilibrium partitioning method.

3.8.2.4 Atmosphere

For the air compartment ecotoxicological data on animal species are not available and methods for determination of effects of chemicals on species arising from atmospheric contamination have not yet been fully developed. Therefore, no quantitative estimation of $PNEC_{air}$ for the active substance is possible.

3.8.2.5 Non-compartment specific effects

Not necessary.

3.8.2.5.1 Further ecotoxicological studies

No further data is available.

3.8.2.6 Summary of effects assessment

Table 54

Summary table on calculated PNEC values	
Compartment	**PNEC**
Fresh water	2.82 mg a.s./L
Sediment	2.41 mg/kg ww
STP	10 mg/L
Soil	0.496 mg/kg ww soil

3.8.3 Fate and behaviour

Biodegradation

Based on a test on ready biodegradability according to OECD 301 C (“modified MITI test (I)”), the a.s. propan-2-ol was shown to be readily biodegradable. Since according to the guideline, the 10-day window criterion is not applicable to the test and the pass levels are met after 14 days, propan-2-ol is classified as “readily biodegradable”.
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-2-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-2-ol has no chromophore. In addition, for propan-2-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 inaccessible for direct photodegradation in sunlight.

The vapour pressure of propan-2-ol at 25°C is 57.8 hPa and direct evaporation is expected, consequently. The Henry’s law constant (0.82 Pa ´ m3 mol-1 at 25°C) indicates moderate volatility from water. Propan-2-ol present in the atmosphere will react with photo-chemically produced OH and NO3 radicals. The half-life of propan-2-ol in the troposphere was estimated to be 3.1 days considering a global 24-hours mean OH-radical concentration of 5 ´ 105 OH radicals cm-3.

Distribution and Mobility
Experimentally derived soil sorption coefficients are not available. A KOC of 1.1 L/kg can be estimated based on the generally accepted model PCKOCWIN v1.66. In addition, the KOC was estimated according to a QSAR model described in EU TGD on Risk Assessment, Part III, chapter 4.3 (2003). Based on a log KOW of 0.05 and the QSAR for alcohols, the KOC was calculated to 3.3 L/kg. This KOC is used for the environmental exposure assessment.

Therefore, propan-2-ol is expected to exhibit only a weak adsorption in soils and sediments indicating a very high mobility of propan-2-ol in soil and a very low geoaccumulation potential. Adsorption of relevant amounts of propan-2-ol on soils and sediments is not expected.
The hydrosphere as well as the atmosphere is the target compartment due to calculations applying the fugacity model (Level 1) according to Mackay (1991). The results demonstrate that propan-2-ol is preferentially distributed to water (77.8 %) and air (22.1%) in an equilibrium atmosphere. The exact distribution between air and water in a nonequilibrium atmosphere is not known.

The distribution in the sewage treatment plant using the SimpleTreat 3.0-model (a rate constant of 1 h^{-1} for STP was concluded since propan-2-ol is ready biodegradable) results in release fractions to air 0.3 %, water 12.5 %, sludge 0 % and degraded fraction 87.1 %.

3.8.3.1 Bioconcentration

Based on the physicochemical properties an approximate estimation of the bioconcentration factors (BCFs) can be calculated according to TGD (EC 2003). Applying the experimentally derived log KOW of 0.05 results in a BCF_{Fish} of 0.22 L/kg ww and a $BCF_{Earthworm}$ of 0.85 L/kg ww. Consequently, the aquatic and terrestrial bioaccumulation potential of propan-2-ol can be assumed as low.

In consequence of the log KOW < 3 and the low estimated BCF values, experimental studies are not required. Furthermore, no other indicators point to an intrinsic potential for bioconcentration. The surface tension, for instance, is 70.7 mN/m and thus, lies above the trigger value of ≤ 50 mN/m for surface active substances.

With regard to the low estimated BCF values in aquatic and terrestrial indicator species, propan-2-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.

3.8.4 Exposure assessment

3.8.4.1 General information

AGMA IPA Product family are ready-to-use, alcoholic disinfectant products containing 70 % v/v propan-2-ol which are intended to be used as industrial area disinfectants: Product Type 2 (PT 2). Their use is restricted to routine hard surface disinfection in cleanrooms only (hard surface disinfection with impregnated wipes and by spraying).

These products are used in strictly controlled, occupational settings where all members of the public will be excluded. The products are applied to surfaces as such (i.e. undiluted) and no post-application rinsing of surfaces is required.

The products in this family are intended for professional use only and are provided ready-to-use and therefore no mixing and loading is required. It was agreed at Ad hoc Working Group Environmental Exposure (AHEE-2) in December 2018 that an exposure assessment is not required for a RTU wipe product

containing a volatile a.s. (propan-2-ol) that is not rinsed from the surface. Therefore, no exposure assessment was conducted for Scenario 1 (wipes) and so the emissions estimation has focussed on the use of the spray product (Scenario 2).

Table 55

Assessed PT	PT 2
Assessed scenarios	"PT 2-industrial areas" (emission scenario for calculating the releases of disinfectants used in industrial areas).
ESD(s) used	Emission Scenario Document for product Type 2: Private and public health area disinfectants and other biocidal products, JCR 2011
Approach	Scenario 2: average consumption based
Distribution in the environment	Calculated based on Guidance BPR IV ENV B + C (2017) and Technical Agreements for Biocides (TAB), version 2.1 December 2019; ENV-A5
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	All Intended Uses: Production: No Formulation No Use: Yes Service life: No
Remarks	None

3.8.4.2 Fate and distribution in exposed environmental compartments

Table 56

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Soil**	**Ground-water**	**Air**	**Other**
Scenario 2	yes (indirect)	yes (indirect)	no	no	yes	not relevant	not relevant	yes	no

Parameters which describe the fate and distribution of propan-2-ol in the environment are summarised in Table 57 and are based on the LoEP of propan-2-ol (AR 2014, RefMS DE).

Table 57

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	60.09	g/ mol	Assessment report 2015

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	**Value**	**Unit**	**Remarks**
Melting point	-89.5	°C	Assessment report 2015
Boiling point	82.5	°C	Assessment report 2015
Vapour pressure at 25°C (12 °C)	5780 (2302)	Pa	Assessment report 2015
Water solubility at 25 °C	1	kg/L	Assessment report 2015
Log Octanol/water partition coefficient	0.05	Log 10	Assessment report 2015
Organic carbon/water partition coefficient (KOC)	3.3	L/kg	Assessment report 2015
Henry's Law Constant at 25 °C (12 °C)	0.80 (0.383)	Pa/ m^3/ mol	Assessment report 2015
Rate constant for degradation in air	3.1	days	Assessment report 2015
Biodegradability	Readily biodegradable	N/A	Assessment report 2015
DT_{50} for biodegradation in surface water	15	d (at 12ºC)	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.4, table 5
DT_{50} for hydrolysis in surface water	no hydrolysis	d or hr (at 12ºC /pH)	Assessment report 2015
DT_{50} for photolysis in surface water	not applicable	d or hr	Assessment report 2015
DT_{50} for degradation in soil	30	d (at 12ºC)	Default value, BPR Guidance Vol. IV Part B + C (2017), chapter 2.3.6.5, table 6

The distribution in the sewage treatment plant is calculated using SimpleTreat v.4.0. This results in release fractions to air of 0.27 %, water 7.96%, sludge < 0.1 % (0.03 %) and degraded fraction 91.74 %. As the distribution in sewage sludge for propan-2-ol is < 0.1 % further environmental exposure assessment via sludge application on agricultural land was considered not relevant for several biocidal products containing propan-2-ol as a.s..

Table 58

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	Scenario 2	
Air	0.2736	calculated using SimpleTreat v4.0
Water	7.956	
Sludge	0.0309	

Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
	Scenario 2	
Degraded in STP	91.74	

3.8.4.3 Local emission estimation for relevant environmental compartments

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

The local release to wastewater was calculated based on the application rate of the biocidal product of 50 mL/ m^2 and a concentration of active substance in the product of 62.7 % (w/w) propan-2-ol.

Based on the product containing 62.7 % (w/w) propan-2-ol and a density of the biocidal product of 878 g/L the content of active substance in the biocidal product is 550.5 g/L (878 g/L * 62.7 % (w/w)).

During the environmental risk assessment of the active substance propan-2-ol, it was assumed that 90% of the a.s. is released to air and 10% of the a.s. is released to water. According to the BPC opinion of propan-2-ol, the distribution between water and air should be re-evaluated in the frame of product authorisation. In case of the ready-to-use (RTU) product AGMA IPA Product family containing 70% v/v propan-2-ol, the disinfection is finished when the treated surface completely dried, aka the product has evaporated completely. This is facilitated by the relatively high vapour pressure of propan-2-ol. Nearly the whole amount of substance applied is released to indoor air, which is emitted to the local outside air without deposition indoors. However, partial releases to waste water – via leakages or rinse off – cannot be excluded for liquid products. Therefore, for the environmental risk assessment of the biocidal product family AGMA IPA, the distribution used during the assessment of the active substance is maintained since it is plausible that the main emission path will be via air. The fraction released to wastewater was therefore set to 0.1 to derive the release to wastewater and the release to air calculated from this value (i.e. ($Elocal_{water}$ x 10) x 0.9).

It was agreed in the TAB version 2.1 (ENV 46) for PT 2 that the treated area for a RTU product should be reduced to 25 m^2 (when product is applied by means of trigger spray or wipes). This surface area of 25 m^2 takes account for several applications per day. Therefore, the default application (Nappl) does not need to be changed, even for several applications per day of the RTU product (TAB 2.1, ENV 46).

All other parameters used were defaults (number of applications per day and fraction of substance disintegrated during or after application (before release to the sewage system)).

Table 59

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2: emission scenario for calculating the releases of disinfectants used in industrial areas (chapter 2.1.4.1, table 2, Environmental Emission Scenario for PT 2 (JRC, 2011))			
Application rate of biocidal product (Vform)	0.05	L/m²	Based on 50 ml/ m² application rate
Concentration of active substance in the product (Cform)	550.5	g/L	Calculated based on products composed of 70% v/v propan-2-ol
Surface area to be disinfected ($AREA_{surface}$)	25	m^2	Default value
Number of application per day (Nappl)	1	d^{-1}	Default value
Fraction of substance disintegrated during or after application (before release to the sewer system) (F_{dis})	0	-	Default value
Fraction released to wastewater (F_{water})	0.1	-	Assessment report 2015
Fraction released to air (F_{air})	0.9	-	Assessment report 2015

Calculations for Scenario 2

Local release to wastewater ($Elocal_{water}$):

$Elocal_{water}$ = Vform • Cform • $AREA_{surface}$ • Nappl • (1 - F_{dis}) • F_{water} / 1000 = **0.07 kg/d**

Local release to air ($Elocal_{air}$):

$Elocal_{air}$ = Vform • Cform • $AREA_{surface}$ • Nappl • (1 - F_{dis}) • F_{air} / 1000 = **0.62 kg/d**

3.8.4.4 Non-compartment specific effects

- **Primary poisoning**

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

- **Secondary poisoning**

According to the CAR of propan-2-ol (2014), the relevance of a risk characterisation for secondary poisoning is not applicable for propan-2-ol. Due to its physical properties propan-2-ol has a low potential for bioaccumulation in the terrestrial and in the aquatic food chain.

3.8.4.5 Resulting local emission to relevant environmental compartments

Table 60

Compartment	Local emission ($Elocal_{compartment}$) [kg/d]	Remarks
Wastewater	0.07	
Freshwater	-	
Freshwater sediment	-	
Seawater	-	
Seawater sediment	-	
STP	-	
Soil	-	
Groundwater	-	
Air	0.62	
Other	-	

3.8.4.6 Calculated PEC values

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols used in small-scale applications, there is no need for a risk assessment of the subsequent environmental compartments following the release path via air (see also TAB v. 2.1, ENV-A5, 2019). Therefore, no PEC_{soil} and PEC_{GW} values were calculated for the biocidal product.

The estimation of the local PECs for the aquatic compartment includes PECs for sewage treatment plant (STP), surface water and sediment:

- PEC_{STP} (= C_{local_eff}) according to equation 41, chapter 2.3.6.7, Guidance BPR IV ENV B + C (2017);
- $PEC_{local\_surfacewater}$ according to equation 51, chapter 2.3.7.3.1, Guidance BPR IV ENV B + C (2017);
- $PEC_{local\_sediment}$ according to equation 53, chapter 2.3.7.4, Guidance BPR IV ENV B + C (2017).

According to the proposed use of b.p. the interval between two releases is shorter than one month and therefore, the effluent concentration is representative for the exposure of microorganisms in STP. Thus,

- $PEC_{STP} = C_{local\_eff}$ referring to equation 41, chapter 2.3.6.7, Guidance BPR IV ENV B + C (2017).

The local PEC values from all intended uses are presented in Table 61 and are used for the environmental risk assessment.

Based on the non-adsorptive properties of propan-2-ol, the distribution in the STP results in a zero concentration of propan-2-ol in the sewage sludge. However, because propan-2-ol is highly volatile it will be emitted to soil indirectly by wet and dry deposition ($DEPTtotal_{ann}$), which is calculated according to the OPS model in the Guidance BPR IV ENV B + C (2017). The groundwater exposure occurs after wet and dry aerial deposition on soil. In accordance to WG ENV IV 2019 and TAB 2.1 ENV A-5 no PEC_{soil} and PEC_{GW} values were calculated for the biocidal product AGMA IPA product family.

Table 61

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/m³]	**[mg/l]**	**[mg/kg$_{wwt}$]**	**[mg/l]**	**[mg/kg$_{wwt}$]**	**[mg/m³]**	**[µg/l]**	**[mg/m³]**
Scenario 2	2.74E-06	2.74E-04	2.34E-04	-	-	Not relevant	Not relevant	1.72E-04

3.8.4.7 Aggregated exposure (combined for relevant emission sources)

According to the “Decision tree on need for estimation of aggregated exposure” the requirement for aggregated exposure estimations was checked for the biocidal product family AGMA IPA containing propan-2-ol as active substance.

The active substance propan-2-ol is also evaluated in the frame of other regulatory areas (e.g. REACH). According to OECD SIDS Dossier of the HPV chemical Isopropanol (1997) most propan-2-ol goes into the solvent market either directly or via conversion to acetone or one of acetone’s derivates. Propan-2-ol’s major solvents uses include inks, coatings, cosmetics and pharmaceuticals. Small percentages are used for esters and as rubbing alcohol. The total European production volume of propan-2-ol in 1995 was reported to be 619000 tons (OECD 1997). According to the provided tonnage information only a small fraction (< 10 %) of the total tonnage produced is used as biocidal active substance. Therefore, no aggregated exposure assessment for propan-2-ol has to be performed as the biocidal uses of propan-2-ol is less than 10 % of the total tonnage produced.

But according to the decision tree (Figure 1) it must be also examined whether specific biocidal emission patterns are available. The main (only) emission pathway for propan-2-ol is through a STP; but this emission route is not limited to biocidal products. Specific biocidal emission patterns are not identified. Therefore, according to the decision tree it is not required to perform an aggregated exposure estimation.

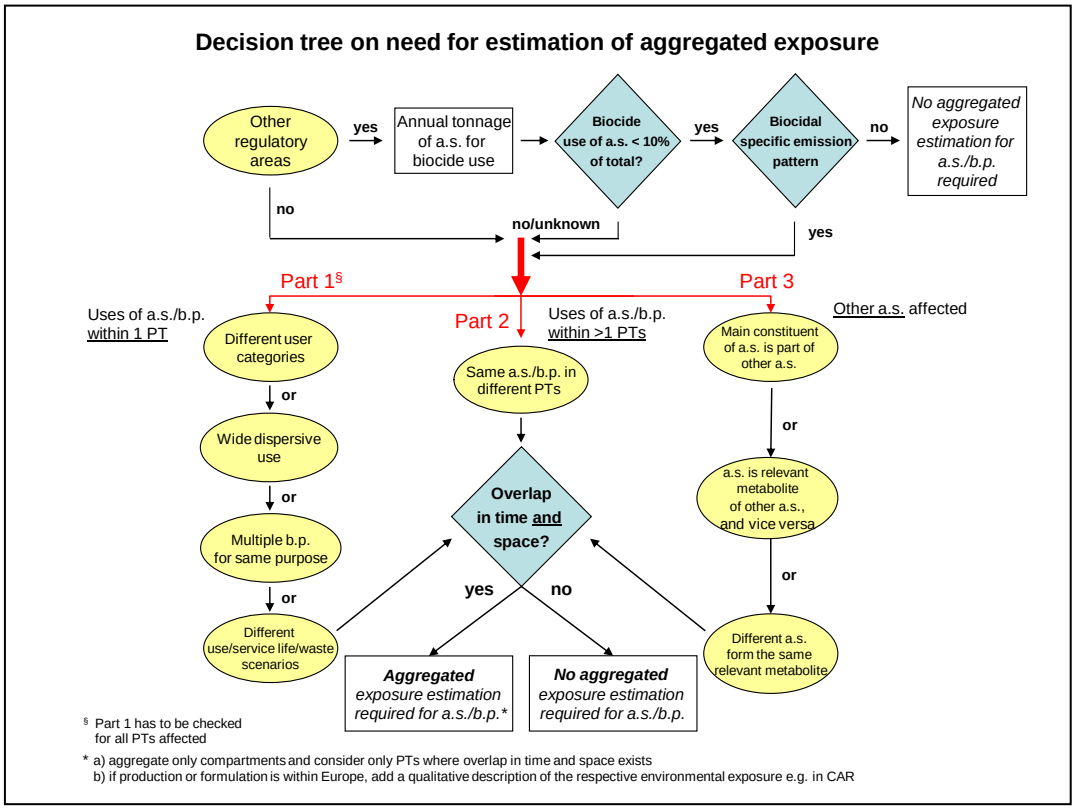

Figure 1: Decision tree on the need for estimation of aggregated exposure

3.8.5 Risk characterisation

Summary table of PNEC values		
Compartment	**PNEC**	**Units**
STP	10	mg/L
Surface Water	2.82	mg/L
Sediment	2.41	mg/kg_{wwt}
Soil	0.496	mg/kg_{wwt}

3.8.5.1 Aquatic compartment (sediment and STP)

Table 62

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{seased}$**
Scenario 2	9.70E-05	9.71E-05	-	-

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

- **Sewage treatment plant (STP)**

Table 63

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 2	2.74E-04

Conclusion. As the PEC/PNEC ratios for the STP are below the trigger value of 1 for the estimated scenario, no risk to the STP is indicated.

3.8.5.2 Terrestrial compartment (Soil/Groundwater)

During the WG ENV IV 2019 it was agreed that for products containing volatile alcohols used in small-scale applications, there is no need for a risk assessment of the subsequent environmental compartments following the release path via air (see also TAB v. 2.1, ENV-A5, 2019). Therefore, no PEC_{soil} and PEC_{GW} values were calculated for the biocidal product. As a consequence, no $PEC_{soil}/PNEC_{soil}$ was calculated and no PEC_{GW} was compared to the groundwater trigger value.

3.8.5.3 Atmosphere

No hazard is identified for the air compartment and so no PEC/PNEC ratio is derived.

3.8.5.4 Non-compartment specific

- **Primary poisoning**

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

- **Secondary poisoning**

According to the CAR of propan-2-ol (2014), the relevance of a risk characterisation for secondary poisoning is not applicable for propan-2-ol. Due to its physical properties propan-2-ol has a low potential for bioaccumulation in the terrestrial and in the aquatic food chain (see chapter 3.8.2.5).

Therefore, no risk for primary or secondary poisoning is assumed.

3.8.5.5 PBT assessment

The conclusions from the PBT assessment do not differ from the results of the PBT assessment, which was performed within the frame of the evaluation of the active substance propan-2-ol.
Accordingly, propan-2-ol fulfil neither the PBT- nor the vP/vB-criteria.

3.8.5.6 Endocrine disrupting properties

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

In summary, there is no indication for endocrine disrupting properties of the biocidal product.

3.8.5.7 Summary of risk characterisation

Table 64

Summary table on calculated PEC/PNEC values						
	PEC/ $PNEC_{STP}$	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**	**PEC/ $PNEC_{seawater}$**	**PEC/ $PNEC_{seased}$**	**PEC/ $PNEC_{soil}$**
Scenario 2	2.74E-04	9.70E-05	9.71E-05	-	-	-

Overall conclusion on the risk assessment for the environment

This assessment has followed the agreements made within the propan-2-ol CAR and assumed a 90 % loss to air and 10 % loss to drain following application.

The proposed application rate of 50 mL/ m^2 has been used in risk assessment for spray application (the RefMS also notes that a maximum application rate of 50 mL/ m^2 was also considered in the propan-2-ol CAR).
A separate assessment for the wipes has not been carried out for this product as it has been agreed at AHEE-2 that this is not necessary (for a volatile a.s.).

Even making a number of worst case assumptions in the calculation of the emissions- acceptable levels of risk to the environment have been demonstrated for the proposed uses of the RTU trigger spray product and following use of the RTU wipes.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

No candidate for substitution was identified (see chapter 2.2.5), hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product family

4.1.1 List of studies for the products in meta SPC No. 01

Table 65

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.4.1	Accelerated stability study for 18 weeks at 30°C on the test item 'sterile alcohol wipes'	Belussi, C	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
2	3.4.1	Shelf life stability study for 24 months at 25°C on the test item „sterile alcohol wipes"	Belussi, C	2019	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
3	5	Method validation for the quantification of the active ingredient isopropanol in the test item "sterile alcohol wipes"	Meluso, A	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
4	6.7	Suspension bactericidal effectiveness on sterile alcohol wipes	Brambilla, L	2016	Agma Limited Gemini Works, Haltwhistle, Northumberland Ne49 9ha United Kingdom

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
5	6.7	Suspension fungicidal effectiveness on sterile alcohol wipes ipa	Brambilla, L	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
6	6.7	Surface bactericidal effectiveness on sterile alcohol wipes	Brambilla, L	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
7	6.7	Surface fungicidal effectiveness on sterile alcohol wipes	Brambilla, L	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
8	6.7	Bactericidal and Yeasticidal Activity on Non-Porous Surface with Mechanical Action Employing Wipes in Medical Area in Clean Conditions on Sterile Alcohol Wipes	Carloni, C	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
9	6.7	Bactericidal activity against Staphylococcus aureus on non-porous surface with mechanical action employing wipes in medical area in no soiling conditions on sterile IPA 70% in WFI alcohol wipes	Carluccio, S	2017	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
10	6.7	Test Report for BS EN 13697:2015+A1:2019 (Wipes)	Mellors, D	2020	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
11	6.7	Report for BS EN 16615:2015	Mellors, D	2020	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom

4.1.2 List of studies for the products in meta SPC No. 02

Table 66

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.4.1	Accelerated stability study for 18 weeks at 30°C on the test item sterile alcohol trigger spray IPA	Belussi, C	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
2	3.4.1	Shelf life stability study at 25°c for 24 months on the test item “sterile alcohol trigger spray ipa”	Belussi, C	2019	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
3	3.4.1	Shelf-life stability study at 25°c for 24 months on the test item “non-sterile ipa 70% triggers”	Belussi, C	2019	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
4	3.4.1	Shelf life stability study at 25°c for 24 months on the test item “ipa 70% in wei 5l (filtered)”	Belussi, C	2019	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
5	5	Method set up and validation for the determination of the active ingredient isopropanol in the test item “sterile alcohol trigger spray ipa”	Abbiati, F	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
6	6.7	Suspension bactericidal effectiveness on sterile alcohol trigger spray ipa	Brambilla, L	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
7	6.7	Suspension fungicidal effectiveness on sterile alcohol trigger spray ipa	Brambilla, L	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
8	6.7	Surface Bactericidal Effectiveness on Sterile Alcohol Trigger Spray IPA	Brambilla, L	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
9	6.7	Surface fungicidal effectiveness on sterile alcohol trigger spray ipa	Brambilla, L	2016	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
10	6.7	Test Report for BS EN 13697:2015+A1:2019 (Trigger Spray)	Mellors, D	2020	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
11	6.7	EN1650 (2008) - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics (Phase 2 / Step 1)	Duxbury, H	2011	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom
12	6.7	Microbiological Analysis based on EN13697(2001) - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas (Phase 2/Step 2)	Duxbury, H	2011	Agma Limited, Gemini Works, Haltwhistle, Northumberland, Ne49 9ha, United Kingdom

4.2 List of studies for the active substance(s)

No new information on the active substance was submitted within the application.

4.2.1 Propan-2-ol

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval (respectively the inclusion into Annex I of Directive 98/8/EC[7]) of the active substance propan-2-ol for use in product-type 2. Please, refer to the corresponding Assessment Report for a reference list.

7 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Safety for professional users

4.3.2 Output tables from environmental exposure assessment tools

PEC_{air}

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

$$Estp_{air} = Fstp_{air} \times Elocal_{water}$$

$$Clocal_{air} = \max\ (Elocal_{air}, Estp_{air}) \times Cstd_{air}$$

Where:

$Fstp_{air}$ = 0.003

$Cstd_{air}$ = 2.78E-04 mg/ m^3 (default value)

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

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

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

$$Fass_{aer} = \frac{CONjunge \times SURF_{aer}}{VP + CONjunge \times SURF_{aer}}$$

Hence $Fass_{aer}$ = 4.34E-08

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

$$DEPtotal = (Elocal_{air} + Estp_{air}) \times (Fass_{aer} \times DEPstd_{aer} + (1 - Fass_{aer}) \times DEPstd_{gas})$$

$$DEPtotal_{ann} = DEPtotal \times \frac{Temission}{365}$$

Where:
$DEPstd_{air}$ = 1.00E-02
$DEPstd_{gas}$ = 4.00E-04

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

	$Elocal_{water}$ (kg/ d)	**$ESTP_{air}$ (kg/ d)**	**$Elocal_{air}$ (kg/ d)**	**$Clocal_{air}$ (kg/ d)**	**DEP*total* (mg/m²/d)**
Scenario 1	1.39	4.16E-03	12.5	3.47E-03	5.00E-03
Scenario 2	2.78	8.33E-03	25.0	6.94E-03	9.99E-03

The aerial deposition flux per kg of soil, D_{air} is then derived from the total deposition flux ($DEPtotal_{ann}$) and is used in the calculation of PEC_{soil}.

$$D_{air} = \frac{DEPtotal_{ann}}{DEPTH_{soil} \times RHO_{soil}}$$

	Ecosystem and arable crops Dair (kg/ d)	Grassland Dair (kg/ d)
Scenario 1	1.47E-05	2.94E-05
Scenario 2	2.94E-05	5.88E-05

PEC_{STP} and $PEC_{surface\ water}$ (and $PEC_{sediment}$)

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

$$Clocal_{eff} = Clocal_{inf} \times Fstp_{water}$$

$$Clocal_{water} = \frac{Clocal_{eff}}{\left(1 + Kp_{susp} \times SUSP_{water} \times 10^{-6}\right) \times DILUTION}$$

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

	$(Clocal_{eff})$ PEC_{stp} (mg/l)
Scenario 1	8.67E-02
Scenario 2	1.73E-01

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

Parameters	Nomenclature	Value	Unit	Origin
Fraction directed to water by STP (Simpletreat)	$Fstp_{water}$	0.125	[-]	Input
Weight fraction organic carbon in suspended solids	Foc_{susp}	0.1		Default
Partition coefficient organic carbon - water	Koc	3.30	l/kg	Input
Partition coefficient solid – water in suspended matter	Kp_{susp}	0.330		Default
Concentration of suspended matter	$SUSP_{water}$	15	mg/l	Default
	DILUTION	10		Default
$PEC_{surface\ water}$	**$Clocal_{water}$**		**mg/l**	**Output**
Scenario 1		8.67E-03	mg/l	Output
Scenario 2		1.73E-02	mg/l	Output

PEC_{soil} and $PEC_{groundwater}$

Calculation of soil removal rate constants

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

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

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

$$k = k_{volat} + k_{leach} + kbio_{soil}$$

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

$$\frac{1}{k_{volati}} = \left(\frac{1}{kasl_{air} \times \frac{K_{air-water}}{K_{soil-water}}} + \frac{1}{kasl_{soil,air}} \right) \times DEPTH_i$$

Where:

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

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

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

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

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

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

$$\mathrm{K}_{air-water} = \frac{HENRY}{R \times TEMP}$$

Where:

HENRY = Henry's law constant [$Pa/m^3/mol^{-1}$] (0.8 at 25°C corrected to 0.383 at 12°C using equation 25 Volume IV Parts B + C 2017 as HENRY was derived experimentally)

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

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

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

Where:

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

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

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

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

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

As the mixing depth for soil varies between the different soil types, two values for kvolat can be calculated;

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

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

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

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

$$Cdep_{soil\ 10}(0) = \frac{D_{air}}{k} - \frac{D_{air}}{k} \times e^{-365 \times 10 \times k}$$

	Ecosystem and arable crop $Cdep_{soil10}$ (0) (mg /kg)	**Grassland $Cdep_{soil10}$ (0) (mg /kg)**
Scenario 1	3.42E-04	4.67E-04
Scenario 2	6.83E-04	9.34E-04

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

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

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

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

	PECsoil		
	Ecosystem 30 days (mg /kg)	**Arable 180 days (mg /kg)**	**Grassland 180 days (mg /kg)**
Scenario 1	3.42E-04	3.42E-04	4.67E-04
Scenario 2	6.83E-04	6.83E-04	9.34E-04

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

$$PEClocal_{soil,\ porewater} = \frac{(PEClocal_{soil} \times RHOsoil)}{(K_{soil-water} \times 1000)}$$

	$PEClocal_{soil,\ porewater}$ (µg / l)
Scenario 1	1.94
Scenario 2	3.88

Calculation of $kasl_{soil}$

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