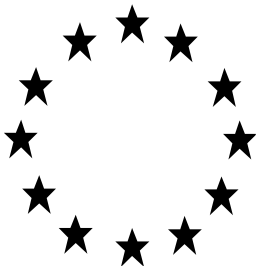
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



DESINTOP SF

Product types 2 and 4

Active substance: Glutaraldehyde

Case Number in R4BP: BC-TY072826-87

Evaluating Competent Authority: Spain

Date: April 2024

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1 CONCLUSION

The overall conclusion is that the biocidal product DESINTOP SF meets the conditions laid down in article 19 (1) of regulation EU No 528/2012 and therefore can be authorised for the uses specified in the Summary of Product Characteristics (SPC).

The use of Glutaraldehyde as active biocidal substance in product formulations to surface disinfection in Hospitals and industrial areas (PT2) and surface disinfection in food and feed industrial areas (PT4) for professional use only.

Explanatory note (only for Spain authorisation):
The conclusions reached in this PAR, which affect the category of "Professional", if appropriate, will be applicable to Trained Professional users at the Spanish level.
Therefore, regarding the category of authorized users, **ES CA will apply article 37 according to the BPR.**

APCP
The physico-chemical properties and the safety relevant physico-chemical properties have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.
The required validated analytical method are available.
The justification considering method requirement for detection of glutaraldehyde in soil, in animal tissues and in food or feedstuffs have been accepted.
It can be concluded that data on the physical, chemical and technical properties of the biocidal product are sufficient for authorization.

Efficacy

Efficacy studies were provided to substantiate two uses:

Use # 1: Surface disinfection in Hospitals and industrial areas (PT2)
Use # 2: Surface disinfection in food and feed industrial areas (PT4)

The product DESINTOP SF has proved efficacy as disinfectant against bacteria, yeasts and fungi. The Glutaraldehyde based disinfectant is intended to be used as ready for use product and may be applied in clean rooms, laboratories, in sanitation areas, in medical practices, and in pharmaceutical, and cosmetic industry. The ready for use solutions are usually fogged in closed rooms, where the presence of workers is forbidden.

Human Health

The assessment of the risks for human health for the biocidal product DESINTOP SF was carried out for the active substance (Glutaraldehyde (2%)) only as no substance of concern was identified.

Taking into consideration the currently legal harmonized classification and labelling of the active substance, the active substance Glutaraldehyde is a candidate for substitution in accordance with Article 10(1)(b) of BPR due to classification according to Regulation (EC) No 1272/2008 as a respiratory sensitiser. Consequently, a comparative assessment has been performed as part of the evaluation of this application.

Regarding Exposure assessment and Risk characterisation

After evaluating the exposure and characterizing the risk to human health of the biocidal product according to the pattern of use requested by the applicant, the conclusions for each scenario are:

Summary table risk assessment for human health			
Nº	**Scenario**	**Conclusion**	**Exposed group**
1.	Manual loading[1] and connecting to fogging device.	A **safe** situation has been identified for loading of the VHP machines..	Professional users
2.	Fogging application[4].	A **safe** situation has been identified for disinfection of dry surfaces in enclosed areas.	Professional users
3	Cleaning and Maintenance of the fogging device	A **safe** situation has been identified for maintenance of the VHP machines (e.g. manual cleaning, technical incidents or repair).	Professional users
4	Re-entry in the treated room	A **safe** situation has been identified for re-entry adult in the treated room	Professional users
5	Re-entry in the treated room	A **safe** situation has been identified for re-entry toddler in the treated room	General public

All scenarios resulted in acceptable risk. In addition, risk assessment for consumers via residues in food and animal health is not foreseen from the intended uses of the biocidal product.

Explanatory note (only for Spain authorisation):
According to national legislation, in Spain there are three user categories:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (P): professionals that use the biocidal products in the context of their profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
- Non-professional users (NP): users who are not professionals and that apply the biocidal product in the context of their private life (Note: this user has not been claimed by the applicant for this product).

The conclusions reached in this PAR, which affect the category of "Professional", if appropriate, will be applicable to Trained profesional user at the Spanish level. Therefore, regarding the category of authorized users, **ES CA will apply article 37 according to BPR.**

Environment:

Based on this risk assessment and available data, no unacceptable risk to the environment has been identified for the product "DESINTOP SF", when is applied according to the intended uses.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country (if relevant)
DESINTOP SF	Spain

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	IMARK HOSPITAL, S.L.
	Address	Ctra Ajalvir-Torrejón, km. 3.300. Pol Ind. Conmar Nave 10 y 12 28864-Ajalvir (Madrid) Spain
Authorisation number	ES/APP(NA)-2024-02/04-00931	
Date of the authorisation	16/04/2024	
Expiry date of the authorisation	16/04/2029	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	IMARK HOSPITAL, S.L.
Address of manufacturer	Ctra Ajalvir-Torrejón, km. 3.300. Pol Ind. Conmar Nave 10 y 12 28864-Ajalvir (Madrid) Spain
Location of manufacturing sites	Ctra Ajalvir-Torrejón, km. 3.300. Pol Ind. Conmar Nave 10 y 12 28864-Ajalvir (Madrid) Spain

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

Active substance	1,5-Pentanedial
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch-Str. 38 67056 Ludwigshafen Germany
Location of manufacturing sites	Carl-Bosch-Str. 38 67056 Ludwigshafen Germany

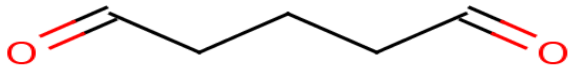
2.1.2 Product composition and formulation

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

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

Yes ☒
No ☐

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Glutaraldehyde, Glutaral
IUPAC or EC name	1,5-Pentanedial
EC number	203-856-5
CAS number	111-30-8
Index number in Annex VI of CLP	---
Minimum purity / content	95%
Structural formula	

2.1.2.2 Candidate(s) for substitution

Taking into consideration the currently legal harmonized classification and labelling of the active substance, the active substance Glutaraldehyde is a candidate for substitution in accordance with Article 10(1)(b) of BPR due to classification according to Regulation (EC) No 1272/2008 as a respiratory sensitiser. Consequently, a comparative assessment has been performed as part of the evaluation of this application.

Despite this substance is considered as candidate for substitution, today, glutaraldehyde has no alternative in specific applications where virucidal and sporicidal activities are necessary, with the exception of oxidants, which are corrosive for many materials and incompatible with some materials used for TP2, TP3 and TP4 applications (metals such as galvanized steel, aluminum, etc..). Especially for veterinary and livestock applications, glutaraldehyde is difficult to replace.

Nevertheless, as the active substance glutaraldehyde is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for either national or Union authorisation.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Glutaraldehyde	1,5-Pentanedial	Active substance	111-30-8	203-856-5	2.0* (technical)
-	-	Non-active substance	-	-	-

*Miminum purity of glutaraldehyde is 95%, therefore glutaraldehyde (pure) content is 1.9%

2.1.2.4 Information on technical equivalence

The source of 1,5-Pentanedial active substance supplied by BASF SE is the known source from the BPD/BPR process for the active substance 1,5-Pentanedial. Therefore, this source is not a technical equivalence

2.1.2.5 Information on the substance(s) of concern

No substances of concern regarding human health were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)). Consequently, only the active substance(s) was addressed in the human health risk assessment.

2.1.2.6 Type of formulation

AL- Any other liquid

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Skin irritation 2 ; H315 Eye irritation 2; H319 Skin sensitiser 1; H317 Respiratory sensitiser 1; H334 Specific Target Organ Toxic (STOT SE) 3; H335 Aquatic chronic 3; H412
Labelling	
Signal words	Danger
Hazard statements	H315: Causes skin irritation H319: Causes serious eye irritation H317: May cause an allergic skin reaction H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled H335: May cause respiratory irritation
Precautionary statements	P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P280: Wear protective gloves/protective clothing/eye protection/face protection. P271:Use only outdoors or in a well-ventilated area. P272: Contaminated work clothing should not be allowed out of the workplace. P284: Wear respiratory protection. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P264: Wash … thoroughly after handling. P302+P352: IF ON SKIN: Wash with plenty of water/… P362+P364: Take off contaminated clothing and wash it before reuse 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. P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor/… P312: Call a POISON CENTRE/ doctor/… if you feel unwell. <u>Professional</u> P501: Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations.
Note	

2.1.4 Authorised use(s)

2.1.4.1 Use description 1

Table 1. Use 1 – Professional: Surface Disinfection in Hospitals and in industrial areas (PT2)

Product Type	2
Where relevant, an exact description of the authorised use	Disinfectants and algaecides not intended for direct application to humans or animals
Target organism (including development stage)	Bacteria and fungi
Field of use	Surface Disinfection in Hospitals and in Industrial Areas: Cleanrooms. Indoor use
Application method(s)	Room diffusion. Fogging of surfaces.
Application rate(s) and frequency	Dose rate: 5.63 ml/m^3. Distribution time: Aprox 0.4L/10 minutes. Thermonebuliser works at temperatures of 20ºC - 30ºC. The droplet size is between 0.2 and 0.4 µm.
Category(ies) of users	Professional*
Pack sizes and packaging material	Jerry can 10 L HDPE

** Category of users at Spanish level: TRAINED PROFESSIONAL (ES CA will apply article 37)*

2.1.4.1.1 Use-specific instructions for use

See section 5.1

2.1.4.1.2 Use-specific risk mitigation measures

See section 5.2

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

See section 5.3

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

See section 5.4

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

See section 5.5

2.1.4.2 Use description 2

Table 2. Use 2 – Professional: Surface Disinfection in food and feed industrial areas (PT4)

Product Type	4
Where relevant, an exact description of the authorised use	Surface disinfection in food and feed industrial areas. Indoor use.
Target organism (including development stage)	Bacteria and fungi
Field of use	Surface Disinfection in food and feed industrial Areas: Cleanrooms. Indoor use
Application method(s)	Room diffusion. Fogging of surfaces.
Application rate(s) and frequency	Dose rate: 5.63 ml/m^3. Distribution time: Aprox 0.4L/10 minutes. Thermonebuliser works at temperatures of 20ºC - 30ºC. The droplet size is between 0.2 and 0.4 µm. Ready to use product. Frequency of application: weekly or monthly depending on the protocols of the applicator.
Category(ies) of users	Professional*
Pack sizes and packaging material	Jerry can HDPE 10 L

** Category of users at Spanish level: TRAINED PROFESSIONAL (ES CA will apply article 37)*

2.1.4.2.1 Use-specific instructions for use

See section 2.1.5.1

2.1.4.2.2 Use-specific risk mitigation measures

See sction 2.1.5.2

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

- Only professional user.
- Allow the total distribution of the product (the distribution time will depend on the size of the room) and maintain a minimum contact time of 10 minutes.
- Aeration time of at least 30 minutes.
- Surfaces need to be cleaned and rinsed before using the product.
- The product must be used in a device with the technical paremetres:
    - Thermonebulizer device
    - Droplet size: 0.2-0.4µm
    - Difussion rate: aprox 0.4L/10 minutes.
- The room must maintain a temperature of 20º C and RH of 56%.
- Room size: 30-150 m^3

The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter.
In case there are methods available for chemical monitoring besides biological validation chemical validation should be performed.

Apply without diluting fogging during a contact time of 14 minutes/100 m^3. The maximum concentration reached in treated room is 113 mg of active substance/m^3.
Before using the product, it is necessary that the surface is perfectly clean and rinsed.
Ventilate properly before come into the room.
Disinfection will be performed by qualified personnel. For security reasons, 24 hours in the absence of people is required, ventilated properly until all the equipments and facilities are completely dry before re-entering. As the half-live of Glutaraldehyde is 8.2 hours, the concentration after the safety period can be considered negligible.

Before using the product read the label carefully. Do not mix with other chemical products. Incompatible with organic matter, anionic detergents, ammonia derivatives, hypochlorite, anionic substances and alkaline products.

Avoid the presence of residues of the product in treated surfaces and equipments.

Application by professional staff:
Direct insertion in fogging device:
1- Introduce the jerry-can into the fogging device, by hand.
2- Program and connect the fogging device.
3- Leave the room.
4- For security reasons avoid re-entry before 24h from application.

The fogging device can be used in Manual or Automatic way.
Manual operation:

Following the Menu sequence, the machine can be used for an established time:
- Select "Time": time in minutes of operation.
- Select "Resis": switch it on for thermo-nebulisation. Don't switch it on for cold fogging.
- In case of thermo-nebulisation, introduce the time of heating (in seconds)
- Evacuation time: minimum of 60 seconds

Once evacuation time is over, the apparatus starts the operation.

Automatic operation:
This mode allows to selct the day, working time and frequency of operation.

Manual filling:
Open the device cover
Fill carefully the internal container until the maximum level mark
Close the device. Check that it is correctly tight
Switch on the device: establish the operation time.

2.1.5.2 Risk mitigation measures

RECOMMENDED METHODS AND PRECAUTIONS CONCERNING HANDLING AND TRANSPORT

Handling
General precautions: it is recommended handling in an area that has pollution control barriers in case of spilled, and have absorbent material in the proximities of the product.

Technical recommendations for the prevention of fires and explosions: Non-flammable product under normal conditions of storage, handling and use.

Technical recommendations to prevent ergonomic and toxicological risks: Do not eat, drink or smoke in work areas; wash your hands after each use, and take off clothing and contaminated protective equipment before entering eating areas.

Technical recommendations to prevent environmental risks: it is recommended handling within an area that has pollution control barriers if spilled and has absorbent material in the proximities.

Transport
This product is not regulated for its transport (ADR/RIP/IMDG/IATA).

ENGINEERING MEASURES:
General ventilation is recommended. Use general ventilation with local exhaust ventilation.

PERSONAL PROTECTIVE EQUIPMENT
GENERAL ADVICE
The use and choice of personal protection equipment is related to the hazard of the product, the workplace and the way the product is handled. In general, we recommend as a minimum precaution that safety glasses with side-shields and workclothes protecting arms, legs and body be used. In addition any person visiting an area where this product is handled should at least wear safety glasses with side-shields.

EYE/FACE PROTECTION
When handling this product, the use of splash chemical goggles is recommended. The applicable European standard can be found in EN 166.

SKIN PROTECTION
When handling this product, the use of chemical gauntlets is recommended. The choice of work glove depends on work conditions and what chemicals are handled. The applicable European standard can be found in EN 374. Wear standard protective clothing. The applicable European standard can be found in EN ISO 20345.

RESPIRATORY PROTECTION
Not required for the foreseen scenarios.

The recommended resistance management strategy is:

- Vary the products used.
- Alternate treatment regimes.
- Monitor occurrence of resistance.

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.
If symptoms: Call 112/ambulance for medical assistance.
If no symptoms: Call a POISON CENTRE or a doctor.

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

IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.

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

EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT IN CASE OF ACCIDENT:

It is recommended handling within an area that has pollution control barriers in case of spilling, and have absorbent material in the proximities. Under the community legislation of environmental protection, it is recommended to prevent spillage of both the product and its packaging to the environment.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations

Code the waste according to Decision 2014/955 / EU.

Do not release to soil, ground, surface water or any kind of sewer.

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

Shelf-life: 12 months
Keep out of direct sunlight and frost.
Keep always in the original package
Keep away from sources of ignition. Avoid sources of heat, radiation, static electricity and contact with food.

2.1.6 Other information

ONLY for SPAIN:
In order to adapt the category of authorized users to its national legislation, ES CA will apply Art 37 of the BPR. Definitions (Users in Spain):

- Trained professional: pest control operators, having received specific training in biocides according to the national legislation in force.

In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:

1. The hazardousness of the product under evaluation.
2. The use being requested.
3. The frequency of use.
4. Complexity of control measures.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Jerry can	10 L	HDPE	HDPE	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Not applicable.

2.1.8.2 Access to documentation

The applicant IMARK HOSPITAL, S.L. has submitted a letter of access for the active substance included in biocidal product submitted; BASF SE as owner of data dossiers for 1,5-Pentanedial active substance.

2.2 Assessment of the biocidal product

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

Use # 1 – Trained Professional: Surface Disinfection in Hospitals and in industrial areas[1]

Product Type(s)	2
Where relevant, an exact description of the authorised use	Disinfectants and algaecides not intended for direct application to humans or animals.
Target organism (including development stage)	**Bacteria:** Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae, Escherichia coli **Fungi:** Candida albicans, Aspergillus niger
Field of use	Surface Disinfection in Hospitals and in Industrial Areas: Cleanrooms. Indoor use
Application method(s)	Room diffusion. Fogging of surfaces
Application rate(s) and frequency	The product application ratio is about 10 min/100 m3 of room volume daily, weekly or monthly depending on the protocols of the applicator. Rate application: 2L/h. Thermonebuliser works at temperatures below 30ºC. The product is stable at this temperature. The droplet size is between 0.2 and 0.4 µm.
Category(ies) of user(s)	Trained Professional
Pack sizes and packaging material	Please see the relevant section.

Use # 1 – Trained Professional: Surface Disinfection in Hospitals and in industrial areas[2]

Product Type(s)	4
Where relevant, an exact description of the authorised use	Surface disinfection in food and feed industrial areas. Indoor use.
Target organism (including development stage)	**Bacteria:** Staphylococcus aureus, Pseudomonas aeruginosa, Enterococcus hirae, Escherichia coli **Fungi:** Candida albicans, Aspergillus niger
Field of use	Surface disinfection in food industry: disinfection of equipment, utensils, containers, food processing surfaces, etc.
Application method(s)	Room diffusion. Fogging of surfaces
Application rate(s) and frequency	The product application ratio is about 10 min/100 m3 of room volume daily, weekly or monthly

1 Copy this section as many times as necessary (one table per use).

2 Copy this section as many times as necessary (one table per use).

	depending on the protocols of the applicator. Rate application: 2L/h. Thermonebuliser works at temperatures below 30ºC. The product is stable at this temperature. The droplet size is between 0.2 and 0.4 µm.
Category(ies) of user(s)	Trained Professional
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	DESINTOP SF (Glutaraldehyde= 2%) Batch:P02F0700	Liquid	CoA Desintop SF P02F0700 V2
	CIPAC MT 46.3	Test formulation2.5% w/w Glutaraldehyde Batch:53573	Liquid	PR055.01-16
Colour at 20 °C and 101.3 kPa	Visual	DESINTOP SF (Glutaraldehyde= 2%) Batch:P02F0700	Not coloured	CoA Desintop SF P02F0700 V2
	CIPAC MT 46.3	Test formulation2.5% w/w Glutaraldehyde Batch:53573	Not coloured	PR055.01-16
Odour at 20 °C and 101.3 kPa	Visual	DESINTOP SF (Glutaraldehyde= 2%) Batch:P02F0700	Characteristic	CoA Desintop SF P02F0700 V2
	CIPAC MT 46.3	Test formulation2.5% w/w Glutaraldehyde Batch:53573	Characteristic	PR055.01-16
Acidity / alkalinity	Not performed .The range of pH falls between 4 and 6			
pH	Internal method	DESINTOP SF (Glutaraldehyde= 2%) Batch:P02F0700	Ph (20ºC)=4.87 Ph(1%sol.20ºC)=5.79	NºDoc A-016; CoA Desintop SF P02F0700 V2
Relative density / bulk density	Internal method	DESINTOP SF (Glutaraldehyde= 2%) Batch:P02F0700	1.0274 g/cm^3 (20ºC)	CoA Desintop SF P02F0700 V2
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Test formulation2.5% w/w Glutaraldehyde Batch:53573	Test conditions:30ºC,18 weeks . After 18 weeks the active substance content meets the acceptance criteria, glutaraldehyde loss is < 8%.	PR055.01-16

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**	GIFAP (Croplife International) monograph No.17	Test formulation2.0% w/w Glutaraldehyde Batch:19102021	Conditions:at 20-30ºC t=0; 2.1% (w/w) t=3 months; 2.0% (w/w) t= 6 months; 2.2% (w/w) t= 12 months; 2.1% (w/w)	Report nº:PR011.002-21
Storage stability test – **low temperature stability test for liquids**	-	-	Not performed. It is considered to be scientifically justified to omit this study on the basis that the product labels state: *Protect from frost.*	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	The product is stable at normal storage conditions. Opaque packaging. According with the experience of the registrant, effects of light in the product stability are not expected. The product should be stored in darkness at room temperature.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	This endpoint falls in the scope of test for storage stability of the product. The product is not affected by temperature and humidity if stored at room temperature. The temperature range for storage is from 5 to 30 ºC.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	This endpoint falls in the scope of test for storage stability of the product.			
Wettability	Not applicable for this type of product.			
Suspensibility, spontaneity and dispersion stability	Not applicable for this type of product.			
Wet sieve analysis and dry sieve test	Not applicable for this type of product.			
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable for this type of product.			
Disintegration time	Not applicable for this type of product.			
Particle size distribution, content of dust/fines, attrition, friability	Not applicable for this type of product.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Persistent foaming	Not applicable for this type of product.			
Flowability/Pourability/Dustability	Not applicable for this type of product.			
Burning rate — smoke generators	Not applicable for this type of product.			
Burning completeness — smoke generators	Not applicable for this type of product.			
Composition of smoke — smoke generators	Not applicable for this type of product.			
Spraying pattern — aerosols	Not applicable for this type of product.			
Physical compatibility	The product is applied as such. Mixture with other products must be avoided.			
Chemical compatibility	The product is applied as such. Mixture with other products must be avoided.			
Degree of dissolution and dilution stability	Not applicable for this type of product.			
Surface tension	OECD 115 Du Nouy ring method	DESINTOP SF (Glutaraldehyde= 2%) Batch:P02F0700	57.3 mN/m	BIOCHEMIZE Report nº:110883
Viscosity	OECD 114 rotational viscosimeter Brookfield	DESINTOP SF (Glutaraldehyde= 2%) Batch:P02F0700	20°C dynamic viscosity (in mPa s)= 12.5 cP 40°C dynamic viscosity (in mPa s)= 7.5 cP	CoA Desintop SF P02F0700 V2

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

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.

For the accelerated storage stability, a read-across from test results for a representative product from the same applicant is proposed. This product, has a very similar composition to the product evaluated in this report. Both products consist of the same formulation. The difference between these products is that the product evaluated in this report, contains a higher content of glutaraldehyde as an active substance. The tested product has a higher active substance content (2.5%) of the product evaluated and can be considered representative for biocidal product. Hence, the read-across is considered acceptable by the rMS.

Justification for read-across can be found in the confidential PAR.

Results show that the product is stable after 12 months at ambient temperature when stored in a opaque plastic can (commercial packaging material).

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive properties.The product is not classified as explosive. None of their components has been classified as explosive.			
Flammable gases	The product is a liquid solution. Therefore, this endpoint is scientifically unjustified.			
Flammable aerosols	The product is a liquid solution. Therefore, this endpoint is scientifically unjustified.			
Oxidising gases	The product is a liquid solution. Therefore, this endpoint is scientifically unjustified.			
Gases under pressure	The product is a liquid solution. Therefore, this endpoint is scientifically unjustified.			
Flammable liquids	Método específico según OPPTS 830.6315/ ASTM/ EU Method A.9 o similar	DESINTOP SF (Glutaraldehyde=2%) Lote P02F0700	The product has a flash point of 168.3 ºC ,therefore the product is not classified as flammable and further studies are not required.	Biochemize,Report number 111662
Flammable solids	The product is a liquid solution. Therefore, this endpoint is scientifically unjustified.			
Self-reactive substances and mixtures	The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties and hence, the classification procedure does not need to be applied.			
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, (i.e. the liquid is known to be stable at room temperature for prolonged periods of time (days). Therefore, a classification as pyrophoric liquid is considered not necessary.			
Pyrophoric solids	The product is a liquid solution. Therefore, this endpoint is scientifically unjustified.			
Self-heating substances and mixtures	Waiver	-	According to the guidance on the application of the CLP criteria, self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			method is not applicable to liquids. Therefore liquids are not classified as self-heating.	
Substances and mixtures which in contact with water emit flammable gases	Waiver	-	The biocidal product does not contain metals or metalloids, therefore testing this endpoint is scientifically not justified.	-
Oxidising liquids	Waiver	-	Glutaraldehyde has no chemical groups indicating oxidising properties. This statement agrees with the recommendations of appendix 6 in the Manual of Tests and criteria of the United Nations.	-
Oxidising solids	Since the biocidal product is liquid, this test does not need to be performed.			
Organic peroxides	Since the biocidal product contains no organic peroxide, the test does not need to be performed.			
Corrosive to metals	UN Test Methods C.1.Part III, subsection 37.4	DESINTOP SF (Glutaraldehyde=2%) Lote P02F0700	No corrosion attack was occurred after 168 hours of exposure at the temperature of 55ºC and the loss mass was lower than 0.39%.	A.Cuetos Info Nº: 111662
Auto-ignition temperatures of products (liquids and gases)	The study does not need to be conducted because the substance is a liquid non flammable in air, e.g. no flash point up to 200°C The auto-ignition temperature of the product is comprised between 204 and 395ºC (20 Ethyldiglycol and 395 glutaral)			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Relative self-ignition temperature for solids	The product is a liquid solution. Therefore, this endpoint is scientifically unjustified.			
Dust explosion hazard	The product is a liquid solution. Therefore, this endpoint is scientifically unjustified.			

Conclusion on the physical hazards and respective characteristics of the product
Desintop SF has no oxidizing, no organic peroxides and explosive properties. The flash point of the product was >99º·C, therefore the product does not need to be classified as 'flammable liquid'. Hence, the product does not require classification under Regulation (EC) No 1272/2008 for physical hazards.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Glutaraldehyde	GC-FID	Three solutions are injected in triplicate /9	0,10 to 3,54 mg/ml R^2=0.999 n=(3x2)	No interference	98.0-101.8	1532	1.51	-	Report PR055-16

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the respective active substance's CAR for further methods									

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the respective active substance's CAR for further methods									

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Please refer to the respective active substance's CAR for further methods

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the respective active substance's CAR for further methods									

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Please refer to the respective active substance's CAR for further methods									

Conclusion on the methods for detection and identificationof the product
Impurities of the active substance were not determined. As per ATSDR (Agency for toxic substances and Disease Registry, USA), analytical methods for monitoring glutahraldehyde residues in soil, air and water is as follows: - SOIL: No methods for determining glutaraldehyde concentrations in soil were located, but it is unlikely that this would be an important environmental medium for glutaraldehyde as it is rapidly degraded in soil, possibly by bacteria. - AIR: GC-FID with several detection limit. - WATER: GC/MS The methods for detection and identification of the product falls under the expected.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The product DESINTOP SF is used to disinfect surfaces, equipment and furniture in medical or industrial areas (PT2), and in food and feed areas (PT4). The product is applied through automated airbone system, using a device with specific characteristics. It is exclusive for its application by professional user.

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

The product DESINTOP SF is intended for disinfection of non-porous surfaces against bacteria, yeasts and fungi according to EN 13727, EN 13624 and EN 17272 standards.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Not applicable.

2.2.5.4 Mode of action, including time delay

Glutaraldehyde acts on proteins by denaturation and on nucleic acids by alkylation (the reaction is irreversible on nucleic acids). The reaction occurs rapidly with receptive nucleotides and the equilibrium shifts towards hydroxymethylation. This action is pH-dependent, working better at alkaline pH but the solution is less stable in such conditions, the molecule is polymerised and the disinfectant activity decreases.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)						
Test substance	**Field of use envisaged**	**Test organisms**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
DESINTOP SF (2% glutaraldehyde)	Disinfection of hard surfaces PT2 and PT4	Bacteria: - *Pseudomonas aeruginosa* - *Staphylococcus aureus* - *Escherichia coli* - *Enterococcus hirae*.	UNE-EN 1276 (2,1)	Dirty conditions: 3g/l bovine albumin. Dilution: 80% Contact time: 5 minutes Temperature: 20ºC. The test cannot be validated since it has only been carried out at one concentration	Redution of ≥5 log for all target organisms	Test report: 303429 (2006)
DESINTOP SF (2% glutaraldehyde)	Disinfection of hard surfaces PT2 and PT4	Fungi: - *Candida albicans* *-Aspergilus brasiliensis*	UNE-EN 1650 (2,1)	Dirty conditions: 3g/l bovine albumin. Dilution: 80% Contact time: 15 minutes Temperature: 20ºC. The test cannot be validated since it has only been carried out at one concentration	Redution of ≥4 log for all target organisms.	Test report: 303429 (2006)
DESINTOP SF (2% glutaraldehyde)	Disinfection of hard surfaces PT2 and PT4	*Candida albicans* *Aspergilus brasiliensis*.	UNE-EN 13624:2014 (2,1)	Dirty conditions: 3g/l bovine albumin + 3ml/l bovine erythrocytes Concentration tested: 80%, 40% and 20% Contact time: 15 minutes Temperature: 20ºC ± 1°C	**R (80%) = ≥4** **R (40%) = ≥4** **R (20%) = ≥4** **R (80%) = ≥4** R (40%) **=** ≤4 R (20%) = ≤4	Test report: 210052663 (2021)
DESINTOP SF (2% glutaraldehyde)	Disinfection of hard surfaces PT2 and PT4	*Candida albicans*	UNE-EN 13624:2014 (2,1)	Dirty conditions: 3g/l bovine albumin + 3ml/l bovine erythrocytes Concentration tested: 40% ,20% and 8% Contact time: 5 minutes Temperature: 20ºC ± 1°C.	**R (40%) = ≥4** **R (20%) = ≥4** R (8%) = ≤4	Test report: 210048996 (2021)
DESINTOP SF (2% glutaraldehyde.		*Pseudomonas aeruginosa*		Dirty conditions: 3g/l bovine albumin + 3ml/l bovine erythrocytes	**R (20%) = ≥5** **R (8%) = ≥5** R (4%) = ≤5	Test report: 210052664 (2021)

2 years storage)	Disinfection of hard surfaces PT2 and PT4	*Stahylococcus aureus*	UNE-EN 13727:2012+A2:2015 (2,1)	Concentration tested: 20%. 8% and 4% Contact time: 5 minutes Temperature: 20ºC ± 1°C	**R (20%) = ≥5** **R (8%) = ≥5** R (4%) = ≤5	
		Enterococcus hirae			**R (20%) = ≥5** **R (8%) = ≥5** R (4%) = ≤5	
DESINTOP SF (2% glutaraldehyde)	Disinfection of hard surfaces PT2 and PT4	*Pseudomona aeruginosa*	UNE-EN 13727:2012+A2:2015 (2,1)	Dirty conditions: 3g/l bovine albumin + 3ml/l bovine erythrocytes Concentration tested: 20%. 8% and 4% Contact time: 5 minutes Temperature: 20ºC.	**R (20%) = ≥5** **R (8%) = ≥5** R (4%) = ≤5	Test report: 210048994 (2021)
		Staphylococcus aureus			**R (20%) = ≥5** **R (8%) = ≥5** R (4%) = ≤5	
		Enterococcus hirae			**R (20%) = ≥5** **R (8%) = =5** R (4%) = ≤5	
DESINTOP SF (Glutardehyde 2%)	Room disinfection with vaporice biocide.	*Candida albicanss*	NF EN 17272:2020 (semi-field test)	Thermonebulizer device: Aerobrumer type H digital, manufacturer: Jose collado, sa serial number 8410 TA Room size: 74 m^3 Concentration tested: Pure. (ready to use). Droplet size: 0.2-0.4 µm. Clean conditions: 0.3g/l bovine albumin. Clean conditions for fragile microorganisms 0.3 g/L of bovine albumin and skimmed milk diluted 1/20. Temperature:21ºC RH=56% ADC time: 10 minutes. Dose rate: 5.63ml product/m^3 Distribution time: 0.41 liters in 10 minutes. Amount of product used: 416.5ml Aeration time: 30 minutes from the end of the ADC time. Total surface/volume ratio: 0.35 m^{-1}	**R(100%)= ≥6**	Test report: D/21/B0370 (2021)
		Aspergilus brassiliensis			**R(100%)= ≥5**	
		*Staphylococcus aureus (*distribution test*)*			**R(100%)= ≥7** In all test-carriers (8)	

DESINTOP SF (Glutardehyde 2%)	Room disinfection with vaporice biocide.	*Pseudomona aeruginosa*	NF EN 17272:2020 (semi-field test)	Thermonebulizer device: Aerobrumer type H digital, manufacturer: Jose collado, sa serial number 8410 TA Room size: 74 m^3 Concentration tested: Pure. (ready to use). Droplet size: 0.2-0.4 µm. Clean conditions: 0.3g/l bovine albumin. Clean conditions for fragile microorganisms: 0.3 g/L of bovine albumin and skimmed milk diluted 1/20. Temperature:21ºC RH=56% ADC time: 10 minutes. Dose rate: 5.63ml product/m^3 Distribution time: 0.41 liters in 10 minutes. Amount of product used: 416.5ml Aeration time: 30 minutes from the end of the ADC time. Total surface/volume ratio: 0.35 m^{-1}	**R(100%)= ≥6**	Test report: D/21/B0369 (2021)
		Staphylococcus aureus			**R(100%)= ≥7**	
		Enterococcus hirae			**R(100%)= ≥6**	
		Escherichia coli			**R(100%)= ≥6**	
		Escherichia coli K12			**R(100%)= ≥6**	
		Staphylococus aureus (Distribution test)			**R(100%)= ≥7** In all test-carriers (8)	
DESINTOP SF (Glutardehyde 2%)	Room disinfection with vaporice biocide.	*Acinetobacter baumannii*	NF EN 17272:2020 (semi-field test)	Thermonebulizer device: Aerobrumer type H digital, manufacturer: Jose collado, sa serial number 8410 TA Room size: 74 m^3 Concentration tested: Pure. (ready to use). Droplet size: 0.2-0.4 µm. Clean conditions: 0.3g/l bovine albumin. Clean conditions for fragile microorganisms: 0.3 g/L of bovine albumin and skimmed milk diluted 1/20. Temperature:21ºC RH=56%	**R(100%)= ≥6**	Test report: D/22/B0260 (2022) Presented in the same document as report: D/21/B0369 (2021)
		Staphylococus aureus (Distribution test)			**R(100%)= ≥7** In all test-carriers (8)	

				ADC time: 10 minutes. Dose rate: 5.63ml product/m^3 Distribution time: 0.41 liters in 10 minutes. Amount of product used: 416.5ml Aeration time: 30 minutes from the end of the ADC time. Total surface/volume ratio: 0.35 m^{-1}		
DESINTOP SF (Glutardehyde 2%)	Disinfection of hard surfaces PT2 and PT4	*Escherichia coli* (K12 NCTC 10538 = CECT 433) *Escherichia coli* (CECT 405 = ATCC 10536)	UNE-EN 13727:2012+A2:2015 (2,1)	Dirty conditions: 3g/l bovine albumin + 3ml/l bovine erythrocytes Concentration tested: 20%. 8% and 4% Contact time: 5 minutes Temperature: 20ºC ± 1°C	**R (8%) = ≥5** **R (4%) = ≥5** R (2%) = ≤5	Test report: 220049278 (2022)

Conclusion on the efficacy of the product

DESINTOP SF has been claimed for general disinfection PT2 included health care and for disinfectant of food and feed areas, PT4. The application method is automated airborne disifection process. Exclusively for professional users.
According to the efficacy guideline for general application in hospitals (PT2) the product has to be at least effective against bacteria and yeast. In the same way as with those products intended to food and feed areas disinfectants. (PT4).
The applicant has provided 8 trials to prove the efficacy of the family product. Studies carried out according to EN 1650 and EN1276 are not accepted since only one concentration has been used for these tests. However, when claiming the use also in hospitals, the trials provided according to standards UNE EN 13624: 2014 and UNE-EN 13727: 2012 + A2: 2015, are a worse case, according to note 5 of appendix 4. These tests can also be considered a worst case for PT4 products.
The product is claimed for disinfection of hard surfaces using a airborne diffused biocide, therefore, according to the guide, they must provide semi-field tests according to the NF T 72-281 standard. Currently this standard has been transposed to European standards (EN 17272: 2020).

According to suspension tests (2.1), the product has demonstrated efficacy disinfectión under these conditions:

Bacteria:	**Yeast**:	**Fungus:**
T=20ºC	T=20ºC	T=20ºC
Time of contact: 5 minutes.	Time of contact: 5 minutes.	Time of contact: 15 minutes.
Dilution: 8%	Dilution: 20%	Dilution: 80%
Dirty conditions	Dirty conditions	Dirty conditions.

According to semi-field test, the product has demonstrated efficacy disinfection under these conditions:

Bacteria/yeast/fungus:
T=21ºC
Time of contact: 10 minutes.
Dilution: 100%
Dose rate: 5.63ml product/m^3
Clean conditions.
Non-porous surface.

According to the point 8 and 11 of Efficacy Technical Agrements of Biocidas (2018), an advice regarding biological and/or chemical validation should be inlucided:
"The user shall always carry out a microbiological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room", if applicable) with the devices to be used, after which a protocol for disinfection of these rooms can be made and used thereafter..
In case there are methods available for chemical monitoring besides biological validation chemical validation should be performed.

The standard not only validates the efficacy of the product but also the device that is used. Therefore the technical characteristics of the device must be included within the SPC.
Technical paremetres:

- Thermonebulizer device
- Dropled size: 0.2-0.4µm

- Room size: 30-150 m^3
- Temperature ~20ºC
- RH~56%
- Dose rate: 5.63ml/m^3
- Distribution time: aprox 0.4L/10 minutes.

The product has not demonstrated long-term stability in storage tests, but the Applicant has provided bactericidal efficacy tests, Phase 2 Step 1, with the product stored for 2 years. (Point 12 of the TAB). Trials show that the product remains effective.

According to the TAB point 14, for professional users in the food industry, the target organism may differ between applications and product lines, and therefore the contact time and dose can be separated by different target organisms. However, the semi-field test has been demonstrated under the same conditions for both bacteria and yeast / fungi, so there are no differences in applications or product lines. Therefore, it does not makes sense in this case to separate the contact time and the dose rate.

2.2.5.6 Occurrence of resistance and resistance management

Resistance to glutaraldehyde in certain mycobacteria strains has been reported in hospitals for a use which is outside the scope of regulation (EU) No 528/2012. The cell surface of the resistant strains has been modified so that there are no or few sensitive reaction sites for glutaraldehyde. Resistant strains have grown in surgical equipment, e.g. endoscopes. Resistance against glutaraldehyde has been associated with improper uses of the disinfectant on dirty endoscopes and use of non-sterile water to rinse disinfected equipment. At industry, resistance development may thus be theoretically possible, but despite of use for decades no observations of resistance development has been made in industrial applications.
The recommended resistance management strategy is:

- Vary the products used.
- Alternate treatment regimes.
- Monitor occurrence of resistance.

2.2.5.7 Known limitations

Not applicable.

2.2.5.8 Evaluation of the label claims

Efficacy data support claims that DESINTOP SF is an effective disinfectant against bacteria, yeasts and fungi according to:

The product has shown acceptable efficacy as a disinfectant against bacteria, yeasts and fungi in medical and industrial areas (PT 2) as well as in food and feed handling areas (PT 4) under clean conditions and in non-porous surfaces.
The application method is through a thermonebulizer device with these characteristics:

- Droplet size: 0.2-0.4µm
- Room size: 30-150 m^3
- Temperature ~20ºc
- RH~56%
- Dose rate: 5.63ml/m^3

- Distribution time: approx 0.4l/10 minutes.

The minimum contact time is 10 minutes and aeration is carried out at 30 minutes of contact time.

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

Not applicable.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Causes skin irritation
Justification for the value/conclusion	The biocidal product DESINTOP SF is classified following Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008. The active substance Glutaraldehyde is classified as Skin Corr. 1B and present at concentrations above the generic concentration limit for category 2 (Skin Corr. 1 ≥ 5%; Skin Irrit. 2 1%≤C<5%). None of the other substances listed in the formulation are classified as skin irritant/corrosive. Therefore, according to CLP Regulation, DESINTOP SF must be classified as Skin Irrit. 2 category, H315.
Classification of the product according to CLP	Skin irritation category 2; H315: Causes skin irritation

Data waiving	
Information requirement	Skin irritation study
Justification	Testing on the product 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 Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Therefore, based on the classification of the active substance and co-formulants, the biocidal product DESINTOP SF is classified as Skin irritation. 2; H315 and no further studies are needed with the formulated product.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye irritation

Justification for the value/conclusion	The biocidal product DESINTOP SF is classified following Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008. The active substance Glutaraldehyde is classified as Skin Corr. 1B and present at concentrations above the generic concentration limit required for classification as category 2 (Eye Dam. 1 C≥3%; Eye Irrit. 2 1%≤C<3%). None of the other substances listed in the formulation are classified as eye irritant/damage. Therefore, according to CLP Regulation DESINTOP SF must be classified as Eye Irrit. 2 category, H319.
Classification of the product according to CLP	Eye irritation category 2; H319: Causes serious eye irritation.

Data waiving	
Information requirement	Eye irritation study
Justification	No data on eye irritation related to the product has been submitted, however testing on the product 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 Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Therefore, based on the classification of the active substance and co-formulants, the biocidal product DESINTOP SF is classified as Eye irritation. 2; H319 and no further studies are needed with the formulated product.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	May cause respiratory irritation.
Justification for the conclusion	The biocidal product DESINTOP SF is classified following Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008. The active substance Glutaraldehyde is classified as STOT SE 3 and present at concentrations above the specific concentration limit (STOT SE 3 0.5%≤C<5%). None of the other substances listed in the formulation are classified for this risk category. Therefore, according to CLP Regulation, DESINTOP SF must be classified as STOT SE 3 category, H335.
Classification of the product according to CLP	Specific Target Organ Toxic (STOT SE) category 3; H335: May cause respiratory irritation.

Data waiving

Information requirement	Respiratory tract irritation data
Justification	No data on respiratory tract irritation is submitted. However, 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 Regulation (EC) Nº 1272/2008 (CLP Regulation). Therefore, based on the classification of the active substance and co-formulants, the biocidal product DESINTOP SF is classified as respiratory tract irritant Specific Target Organ Toxic (STOT SE) category 3; H335 and no further studies are needed with the formulated product.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	May cause an allergenic skin reaction
Justification for the value/conclusion	The biocidal product DESINTOP SF is classified following Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008. The active substance Glutaraldehyde is classified as Skin Sens. 1A and present at concentrations above the generic concentration limit (Skin Sens. 1 C≥0,1%). None of the other substances listed in the formulation are classified as skin sensitisers. Therefore, according to CLP Regulation, DESINTOP SF must be classified as Skin Sens. 1 category, H317.
Classification of the product according to CLP	Skin Sens. category 1; H317: May cause an allergenic skin reaction.

Data waiving	
Information requirement	Skin sensitisation study
Justification	Testing on the product does not need to be conducted if the data available on each of the components in the mixture is sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Therefore, based on the classification of the active substance and co-formulants, the biocidal product DESINTOP SF is classified as Skin Sens. category 1.; H317 and no further studies are needed with the formulated product.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Justification for the value/conclusion	The biocidal product DESINTOP SF is classified following Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008.

	The active substance Glutaraldehyde is classified as Resp. Sens. 1 and present at concentrations above the generic concentration limit (Resp. Sens. 1 C≥1%). None of the other substances listed in the formulation are classified as respiratory sensitiser. Therefore, according to CLP Regulation, DESINTOP SF must be classified as Resp. Sens. 1 category; H314.
Classification of the product according to CLP	Resp. Sens. category 1; H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Data waiving	
Information requirement	Respiratory sensitization data
Justification	No data on the respiratory sensitisation of the biocidal product family has been submitted. However, 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 Regulation (EC) Nº 1272/2008 (CLP Regulation). Therefore, based on the classification of the active substance and co-formulants, biocidal product DESINTOP SF is classified as Resp. Sens. category 1.;H334 and no further studies with the formulated product are needed.

Acute toxicity

The assessment of the acute toxicological properties of DESINTOP SF is derived from the classification of the active substance and co-formulants as agreed in the Annex VI of the CLP regulation or, when not available, as agreed in the Classification and Labelling notification at ECHA. This information is included in their safety data sheets. For confidentiality reasons, the names and percentages of co-formulants are disclosed in PAR confidential annex document.

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values (ATE_{mix}):

$$\frac{100}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

or

$$\frac{100 - (\sum C_{unknown} if > 10\%)}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

where:
C_i = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients
ATE_i = Acute Toxicity Estimate of ingredient i.

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	The calculated acute oral toxicity ATEmix is greater than 2000 mg/kg bw.
Justification for the selected value	The biocidal product DESINTOP SF is classified according to the calculation method set in Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008. The active substance Glutaraldehyde is classified as acute toxic category 3 for the oral route. None of the other substances listed in the formulation of DESINTOP SF are classified as acute toxic for the oral route. The formula detailed in the guidance Annex I: 3.1.3.6.1 was used and the ATEmix determined as > 2000 mg/kg. The LD50(rat) value used in the calculation is 77 mg/kg bw (Glutaraldehyde CAR, Finland eCA). The calculated ATEmix is greater than the generic concentration limit of 2000 mg/kg bw. Therefore, the mixture does not need to be classified for acute oral toxicity.
Classification of the product according to CLP	Not classified.

Data waiving	
Information requirement	Acute oral toxicity
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing. 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 Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Therefore, based on the classification of the active substance and co-formulants, the biocidal product family biocidal product DESINTOP SF is not classified for acute oral toxicity.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	The calculated acute inhalation toxicity ATEmix is 14.00 mg/l.
Justification for the selected value	The biocidal product DESINTOP SF is classified according to the calculation method set in Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008. The active substance Glutaraldehyde is classified as acute toxic category 3 for the inhalation route. None of the other substances listed in the formulation of DESINTOP SF are classified as acute toxic for the oral route.

	The formula detailed in the guidance Annex I: 3.1.3.6.1 was used and the ATEmix determined as a value of 14 mg/l (dust/mist). Given the active substance's experimentally obtained acute toxicity values and classification (GHS category 2), an acute toxicity LC50 value of 0.28mg/l (Glutaraldehyde CAR, eCA Finland, worst case scenario, rat, female) was used in the calculations. The calculated ATEmix is not enough to trigger product classification (Acute toxicity, inhalation, dust/mist, category 4: 1.0<ATE≤5.0 mg/l). Therefore, the mixture should not be classified acute inhalation toxicity category.
Classification of the product according to CLP	Not classified.

Data waiving	
Information requirement	Acute inhalation toxicity
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing. 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 Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Therefore, based on the classification of the active substance and co-formulants, the biocidal product DESINTOP SF is classified as acute inhalation toxicity category 4; H332 and no further studies are needed with the formulated product.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not classified.
Justification for the selected value	The biocidal product DESINTOP SF is classified according to the calculation method set in Guidance on the Application of the CLP Criteria, Guidance to Regulation (EC) No 1272/2008. Neither the active substance nor any of the co-formulants are classified for acute dermal toxicity. Therefore, DESINTOP SF is not classified for this hazard category.
Classification of the product according to CLP	Not classified.

Data waiving	
Information requirement	Acute dermal toxicity
Justification	No vertebrate studies have been performed with the formulated product in order to avoid unnecessary testing. 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 Regulation (EC) Nº 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected. Therefore, based on the classification of the active substance and co-formulants, the biocidal product DESINTOP SF is not classified for acute dermal toxicity.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Glutaraldehyde
Value(s)*	70%
Justification	There is no experimental data available on the dermal absorption of DESINTOP SF since no study has been conducted thus far. As a result, risk assessment calculations for human exposure have been made according to the EFSA guidance on dermal absorption (EFSA Journal 2017;15(6):4873, 60 pp.) using a default value of 70% dermal absorption for this product. According to Guidance on dermal absorption (EFSA), if special formulation types are not contained in the data set and cannot be grouped with the proposed categories the worst-case default values should be adopted (solvent based + other). Thus, a default dermal absorption value of 70% may be applied for (in use) dilutions of organic solvent formulated or in other types of formulations (Any other liquid: cold/hot fogging). Reference: Guidance on dermal absorption (2017, EFSA)

For this product the applicant proposed to use the dermal absorption value of 10% established in the Glutaraldehyde CAR for the reference product PROTECTOL GDA (Finland, 2014). DESINTOP SF is not sufficiently similar to the reference formulation to allow the dermal absorption data on the reference formulation to be read-across. Glutaraldehyde content is significantly lower in the evaluated product DESINTOP SF when compared with the reference product PROTECTOL GDA, which is relevant given that lower active substance content relates with higher dermal absorption rates.

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

No substances of concern regarding human health were identified as none of the non-active substances fulfils the criteria as specified in the guidance (Guidance on the BPR: Volume III Human Health (Parts B+C)). Consequently, only the active substance(s) was addressed in the human health risk assessment.

Endocrine disruption

Assessment of the ED properties of the active substances:

The biocidal product contains only one active substance. Assessment report of Glutaraldehyde indicate "*Glutaraldehyde is not included in the priority list of substances for further evaluation of their role in endocrine disruption established within the Community Strategy for Endocrine Disrupters (COM (1999) 706, COM (2001) 262). Available evidence at this time indicates that glutaraldehyde does not have endocrine-disrupting properties*

(classification criteria specified in Art. 5(3) are not met, no effects on endocrine organs and/or reproduction were observed in standard toxicity studies to raise a concern for potential endocrine disruption).”

Assessment of the ED properties of non-active substances (co-formulants):

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), none of them are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, ES eCA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the Glutaraldehyde assessment report data provided, there is no indication of concern regarding the ED properties of the substances used in the biocidal product DESINTOP SF.

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

Available toxicological data relating to a mixture

Not relevant.

Other

Not relevant.

2.2.6.2 Exposure assessment

The product DESINTOP SF is a PT2 and PT4 biocidal product containing 2.0 (w/w) of glutaraldehyde formulated as a solvent based product intended to be used as ready to use (i.e. without dilution) surface disinfectant by either cold fogging or thermo-nebulization. The product is packaged in a jerry can of 10 liters, that is charged into the diffusion device.

The application of the product (i.e. disinfection of surfaces by room diffusion) is carried out in the absence of personnel. A mandatory waiting period of 24 hours before re-entering the room is set. Ventilation is compulsory. Cleaning is not foreseen after application.

The product is intended to be used by professional users.

Explanatory note (only for Spain authorisation):
According to national legislation, in Spain there are three user categories:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (P): professionals that use the biocidal products in the context of their profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.

- Non-professional users (NP): users who are not professionals and that apply the biocidal product in the context of their private life (Note: this user has not been claimed by the applicant for this product).

The conclusions reached in this PAR, which affect the category of "Professional", will be applicable to Trained profesional users at the Spanish level. Therefore, regarding the category of authorized users, **ES CA will apply article 37 according to BPR.**

The exposure assessment has been carried out in accordance with the Glutaraldehyde Assessment Report for products types 2, 3, 4, 6, 11 and 12 (CAR, Finland 2014).
In addition, the products belonging to this family contain only one substance is classified regarding human toxicity: - 1,5-Pentanedial (Glutaraldehyde).

The product DESINTOP SF also cointain 2-(2-ethoxyethoxy)ethanol, which is not classified.

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

The product DESINTOP SF is applied by fogging with blower pump (fogging device). The use of the products is by professionals only.

No difference between cold and hot fogging is considered regarding exposure. The operation of loading and connecting the fogging device is similar for both, cold and hot applications.

Both inhalation and dermal exposure for professional users and general population (toddler as worst case) have been considered to assess the human exposure, in case of professional because the re-entry to the treated area will be for working purposes. In case general population, it is focused on visitors of hospital facilities.

As it has already been stated the application of the product DESINTOP SF is by fogging in a empty of people room.

For secondary exposure, the rentry in treated areas is considered.

Since the product is used as a PT4, contamination of the food could be expected and therefore a dietary assessment could in theory be triggered out. Regarding secondary exposure via food, glutaraldehyde is very reactive with for example proteins, as has been demonstrated in the metabolism studies and no residues remain. Therefore, glutaraldehyde is not expected to be present in food, and an ADI is not derived.

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[2]**
Inhalation	No	Yes	n.a.	n.a	Yes	Yes	No
Dermal	No	Yes	n.a.	n.a	Yes	Yes	No
Oral	No	No[1]	n.a.	n.a	No	Yes	No

1- Oral exposure should be negligible for professional

2- Please see the section dedicated to dietary exposure for further information

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Manual loading[1] and connecting to fogging device.	Primary exposure: Inhalation and dermal route. Loading the 10L Jerry can into the fogging device[4].	Professionals*
2.	Fogging application[3].	Primary exposure- Dermal and inhalation route Automated application by a fogging device [2]	Professionals*
3	Cleaning and Maintenance of the fogging device	Primary exposure: Inhalation and Dermal route. The worker could be exposed to the dry residues of the product when those activities are performed. This exposure should be residual.	Professionals*
4	Re-entry in the treated room	Primary exposure: Inhalation and Dermal route. To assess this scenario it was considered, although it is secondary exposure, the approach of re-entry of an adult as worst-case. The re-entry is defined after 24h application. Dermal contact with treated surfaces and inhalation exposure	Professionals*
5	Re-entry in the treated room	Secondary exposure: Inhalation and Dermal route. Dermal contact with treated surfaces, inhalation exposure and hand to mouth contact (oral route)	General public

*According to the Spanish legislation: Trained professionals.

1- The product is a RTU product so the mixing and loading phase is included in this scenario

2- This scenario is included in other to properly characterize the use of the product but since the application i.e. surface disinfection will be automatically carried out in absence of personnel no exposure is expected during the application operation the presence of people in the contaminated room is not allowed.

3- No difference between cold and hot fogging is considered regarding exposure since the application takes place in the absence of the applicator. The operation of loading and connecting the fogging device is similar for both, cold and hot, applonly ications

4- The assays have been carried out by using the fogging device FORTEX AIR. The applicant cannot guarantee that in the event that other fogging device are used, the loading of tank will be not be performed manually, although the loading phase is described on the use description.

Industrial exposure

DESINTOP SF biocidal Product is not intended for industrial users.

Professional exposure.

Scenario 1: Loading and connecting to fogging device

Description of Scenario 1

The biocidal product is a ready to use product, so no mixing step will be required.
Regarding the primary exposure, the relevant scenario is the operation of loading the 10L jerry can into the device. This application takes place indoors. The user could be exposed to the vapors generated since the Glutaraldehyde is volatile and, in an extremely conservative approach, to the splashes of the product.
Exposure was calculated using ConsExpo web (exposure to vapour – evaporation; direct contact - constant rate)
The approach developed using ConsExpo considers a release area of 20 cm^2 as a default value. In this case this is a worst case, because the 10L jerry can involve a release area of 10 cm^2 (ø = 3.5 cm). A task duration of 5 minutes has been considered. It is assumed that this task is performed 1 time per week.
The bottle has a maximum volume of 10L, so, assuming that the whole amount of the container content is used (10L) this would equal to 10.000 g with [declared density ≤1,0390 kg/m^3 (Cleaning fact sheet), density of 1 is assumed] Considering that exposure by inhalation takes place around the professional, a room volume of 1 m^3 has been chosen equivalent to the user breathing zone.
For the assessing the exposure during the manual loading of biocidal product into the equipment bucket, a concentration of 2.0 % is considered for active substance.
In Tier 2 PPE (gloves) are considered.

	Parameters[1]	Value
Tier 1	Concentration of a.s in the product[1]	2.0% (w/w)
	Task duration[2]	5 minutes
	Product amount	10.000 grams
	Release area[3]	20 cm^2
	Room volumen[4]	1 m^3
	Vapour pressure[5]	44 Pa, 20 °C
	Emission duration (hours)[2]	24 h
	Ventilation rate	0.6/h
	Inhalation absorption	100%
	Exposed dermal area (2 hands)	820 cm2
	Dermal absorption	70%
	Contact rate (according to TNSG 2002, p 142)	0.43 mg/min
	Release duration	0.5 min (splashes duration)
Tier 2[2]	Gloves	5%
	Contact rate	0.02 mg/min: 0.43 mg/min x 0.05 (protection of gloves of 95%) = 0.02 mg/min

[1] Applicants data
[2] Expert judgement
[3] Opening diameter corresponding to a 20 l bottler
[4] Cleaning FactSheet (ConsExpo)
[5] CAR active substance

Calculations for Scenario 1

Systemic effects

Summary table: estimated systemic exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg a.s./kg/day)**	**Estimated dermal uptake (mg a.s./kg/day)**	**Estimated oral uptake (mg a.s./kg/day)**	**Estimated total uptake (mg a.s./kg/day)**
Scenario 1	Tier 1: Without gloves	$1.5x10^{-5}$	$5.02x10^{-5}$		$6.52x10^{-5}$
Scenario 1	Tier 2: With gloves	$1.5x10^{-5}$	$2.33x10^{-6}$		$1.74x10^{-5}$

Calculations in Annex 3.2

Further information and considerations on scenario [1]

According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as sensitizer to skin (H317), irritant to eye (H319), irritant to skin (H315 and sensiziter to inhalation (H334). Therefore, as AECs have been set for the active substance, quantitative and qualitative assessment of local effects will be performed in Risk Characterisation Section according to Guidance on the BPR Volume III Human Health-Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Quantitative local effects

Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg a.s./m³)**	**Estimated dermal concentration (ppm)**
Scenario 1	Tier 1: Without gloves	$3.01x10^{-5}$	$7.17x10^{-5}$

Scenario 2: Fogging application - Automated application by a diffuser desvice

Description of Scenario 2
Automated application of the product by a diffuser desvice. The application takes place in absence of personnel so no exposure is foreseen. The exposure during fogging application is considered negligible.

Calculations for Scenario 2

The exposure during this task is considered negligible.

Scenario 3: Cleaning and maintenance activities of the fogging device

Description of Scenario 3		
The worker could be exposed to the dry residues of the product when those activities are performed. The exposure due to dry residues of glutaraldehyde should be negligible and it is in any case below the exposure of acenario 1 so the calculations for this scenarios could be omitted. Exposure has been developed using ConsExpo web (evaporation, constant rate). In an extreme worst case situation, the applicant was submitted consexpo based calculations considering that the volume involved in this operation is not more than 1 m^3; the product release area is less than 20 cm^2 (as a default value) and, the residual amount considered as worst-case after use of 1 g (expert judgement). The evaluating competent authority agrees that any maintenance or cleaning activity is more likely to be performed with the internal tank empty. The operation takes place once a week. For dermal calculation is assumed the dermal absorption default value of 70%, accoding to EFSA Guidance on Dermal absorption. For Tier 2, is assumed gloves with a 95% of protection.		
	Parameters[1]	Value
Tier 1	Concentration of a.s in the product[1]	2.0% (w/w)
	Task duration[2]	10 minutes
	Product amount[6]	1 grams (the maintenance takes place with the device empty)
	Release area[3]	0.002 m^2
	Room volumen[4]	1 m3
	Vapour pressure[5]	44 Pa, 20 °C
	Emission duration (min)[2]	5 minute
	Ventilation rate	0.5/h
	Exposed area (2 hands)	820 cm^2
	Dermal absorption rate	70%
	Inhalation rate	100%
	Contact rate (dermal)	0.0043 the maintenance takes place with the device empty. So a factor of 100 is applied to the TNSG value for mixing and loading
	Release duration	1 min (splashes duration)
Tier 2[2]	Gloves	5%
	Contact rate	0.002 mg/min: 0.0043 mg/min x 0.05 (protection of gloves of 95%) = 0.0002 mg/min

[1] Applicants data
[2] Expert judgement
[3] Opening diameter corresponding to a 20 l bottler
[4] Cleaning FactSheet (ConsExpo)
[5] CAR active substance
[6] This exposure should be residual. As per ConsExpo, the volume involved in this operation is not more than 1 m3; the product release area is less than 20 cm2 (as a default value) and, the residual amount

considered as worst-case after use of 1 g. This value is used to assess both inhalation and dermal exposure.

Calculations for Scenario 3

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 3	Tier 1: Without gloves	$4.41x10^{-5}$	$1.0x10^{-6}$		$4.5x10^{-5}$
Scenario 3	Tier 2: With gloves	$4.41x10^{-5}$	$4.67x10^{-8}$		$4.42x10^{-5}$

Calculations in Annex 3.2

Further information and considerations on scenario [3]

According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as sensitizer to skin (H317), irritant to eye (H319) and sensiziter to inhalation (H334). Therefore, as AECs have been set for the active substance, quantitative and qualitative assessment of local effects will be performed in Risk Characterisation Section according to Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Quantitative local effects

Exposure scenario	**Tier/PPE**	**Estimated inhalation concentration (mg a.s./m^3)**	**Estimated dermal concentration (ppm)**
Scenario 3	Tier 1: Without gloves	$8.83x10^{-5}$	$1.43x10^{-5}$

Scenario 4: Re-entry in the treated room by the professional user room post application

Description of Scenario 4

Re-entry in the treated room by the professional user takes place 24 hours after treatment. Previously to allow the entrance the room is strongly ventilated.
An adult enters the treated room being potentially exposed to the volatized residues and dermally due when touching the dry residues. After 24 hours of waiting period, and taking into consideration that:
Regarding the air concentration, a waiting period of 24 hours is set.
According to the ratio of application (5.63mL/1m^3), considering the maximum time of application of 14 minutes (flow:0.4L/h=40 mL/min) and the maximum concentration of 2.0%, the maximum minconcentration of active substance reached in the room is 113 mg/m^3. Therefore, the concentration on air should be below the AEC and inhalation AEC after reentry period (24 h).
To conclude that this exposure should be residual, the worst-case premises is a very low ventilation rate of 0.6 per hour. As per ConsExpo, the exposure should be residual, due to the air concentration of the active substance will be lower than AEL (0.0106 mg/m^3).
The dermal exposure should be overestimated since tha CAR does not contain data on dermal absorption of the dry residues, and therefore a 70% absorption is considered.

For ConsExpo calculation is assumed:

- The product is applied during 14 min.
- Volume: 100 m^3
- The room is closed, no ventilation is considered. Then the maximum concentration of active substance reachable is 113mg/m^3 (ConsExpo-inhalation-exposure to vapour-constante rate. See graphic below):

  0.563 L x 10 min/0.4L (40 mL/min) = 14 min
  14 min x 40 mL/min = 560 g prod emitted in the 100 m^3 room
  560 g prod/100 m^3 x 2.0 g a.s/100 g prod x 10^3 mg/1g = 113 mg a.s/m^3

- The room keeps closed 24 hours. During this period a rate of 0.6/h is considered to simulate abatement:
  6.3x10^{-5} mg as/m^3 (ConsExpo-inhalation-evaporation-exposure to vapour-intantaneous release. See graphic below) x 100 m^3 x 1g/1000 mg x 100 g prod/2 g as = 3.15x10^{-4} g prod after 24 hours.
- After above steps, people can come into the room. 6/h rate is applied (default for public commercial place. Conservative value) in ConsExpo-inhalation-exposure to vapour-instantaneous release and dermal-direct contact-rubbing off)

	Parameters	Value
Tier 1: inhalation	Concentration of active substance	2.0%
	Exposure duration	8 h
	Product amount	560 g after 14 minutes application. 3.15x10^{-4} g after 24 hours* (see graphs below and calculations in section 3.2)
	Room volume	100 m^3

	Ventilation rate	0 h^{-1} during release 0.6 h^{-1} during application 6 h^{-1} when re-entry
Tier 1: dermal	Exposed area (2 hands)	410 cm^2
	Weight fraction substance	2%
	Contact time	1 h
	Contacted surface	1 m^2 surface of utensils/tools/forniture touched with hands
	Transfer coeficient	0.78 m^2 /h (From Heeg 12 recomendation)
	Dislodgeable amount**	$4.2x10^{-7}$ g/m^2
	Absorption fraction	0.7

*Product amount: $6.3x10^{-5}$ mg as/m^3 x 100 m^3 x 1g/1000 mg x 100 g prod/2 g as = **$3.15x10^{-4}$ g** prod
Dislodgeable amount: The concentration of substance after 24 hours is $6.3x10^{-5}$ mg as/m^3 (ConsExpo), which is equivalent to $3.15x10^{-4}$ g product/m^3. We consider a surface of 33 m^2 (100 m^3 of volume and 3 m hight). We suppose that all the all the product falls in the surface: $3.15x10^{-4}$ g prod/33 m^2 = $9.5x10^{-6}$ g prod/m^2. We also consider a decrease due to the half-live of 8.2 h (calculated for 24 hours): $9.5x10^{-6}$ g prod/m^2 x 0.25 = $2.4x10^{-6}$ g prod/m^2. According to TNSG 2002, for dislodgeable fraction for various surfaces types is 18%. Then: $2.4x10^{-6}$ g prod/m^2 x 0.18 = **$4.2x10^{-7}$ g/m^2

Taking into consideration the concentration of DESINTOF SF (2.0%) and a very low ventilation rate value (0.6/h), the graph below shows that, a re-entry period of 24 hours to get an air concentration of glutaraldehyde lower than AEL (0.0106 mg/m^3). As graphic below shows, the AEL value is achieved after 24h time, we recommend 3 hours more as safety time to assure a lower value than AEL.

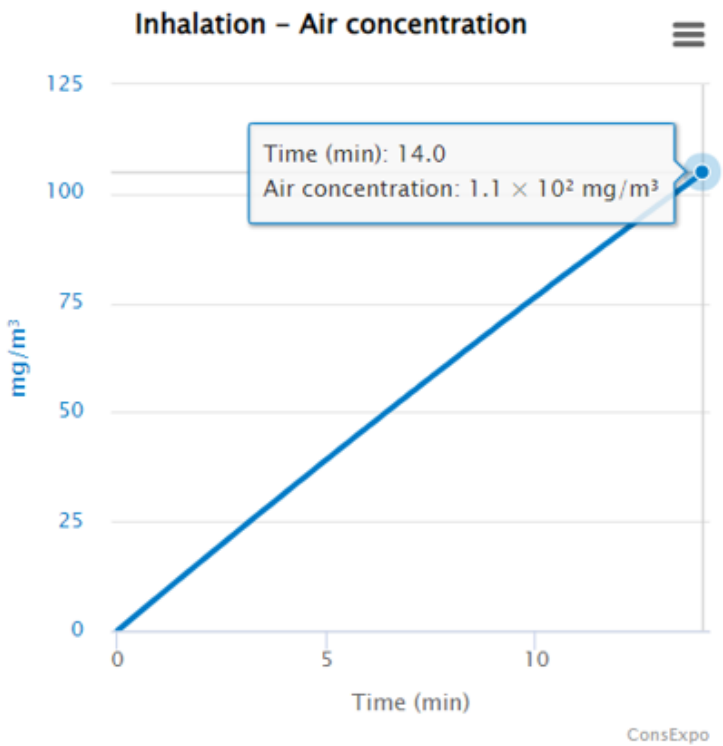
Calculations for Scenario 4

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 4	Tier 1	2.2×10^{-7}	$7.6 \times 10^{-}8$		3.0×10^{-7}

Calculations in Annex 3.2

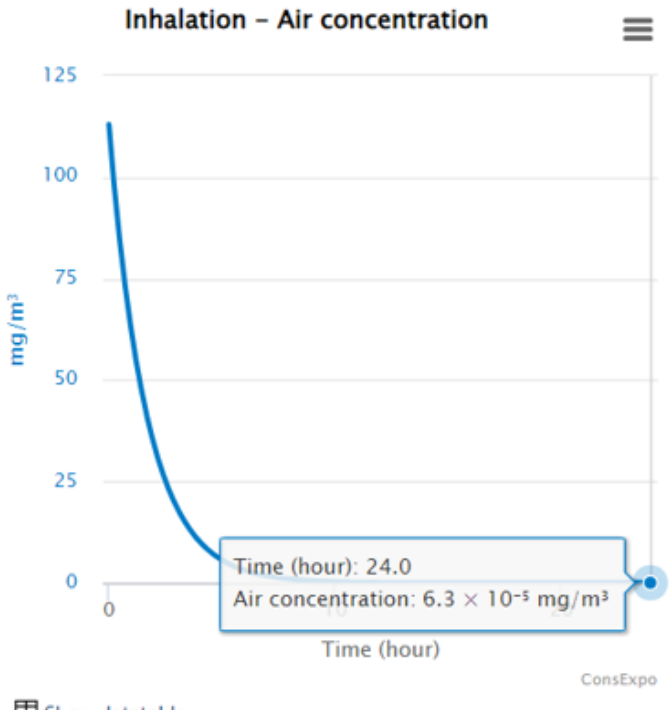
Further information and considerations on scenario [4]

1. Máximum concentration reached in closed room after application (14 minutes). Consexpo web. Inhalation-exposure to vapour-constate rate



1.13 x 10^2 mg as/m3 x 100 m3 x 1g/1000 mg x 100 g prod/2 g as = 560 g

2. Decrease of concentration (24 hours).



6.3x10^{-5} mg as/m^3 x 100 m^3 x 1g/1000 mg x 100 g prod/2 g as = 3.15x10^{-4} g prod

Decrease of concentration after 11.5 hours closed room. Despite the room is closed, a 0.6 ventilation rate is considered, since is a decrease of product concentration is produced by its own action.

3. Fogging Re entry time. Strong ventilation in closed room for 30 minutes.

Open room: workers/general population exposure when re-entering in treated room.

See graphs and calculation in Annex 3.2

Combined scenarios

Combined scenarios is possible since scenario 1, 3 and 4 can be carried out for the same operator.

Systemic effects

Summary table: combined systemic exposure from professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 1, 3 and 4 Tier 1	$5.9x10^{-5}$	$5.2x10^{-5}$	-	$1.1x10^{-4}$
Scenarios 1, 3 and 4 Tier 2	$5.9x10^{-5}$	$3.1x10^{-6}$	-	$6.2x10^{-5}$

Non-professional exposure

Not applicable.

General public exposure

Scenario 5: Re-entry in the treated room by general public

Description of Scenario [5]
Secondary exposure: Inhalation and dermal, toddler Re-entry takes place 24 hours after treatment. Previously to allow the entrance the room is strongly ventilated. Even if the majority of the rooms intended to be disinfected by the products under evaluation would not be accesible for children or general public, it is posible that a toddler might enter into the treated room of a hospital. To assess this scenario, it was considered he approach of re-entry of toddler as worst-case of general population. The re-entry is defined after 24h application. To conclude that this exposure should be residual, the worst-case premises is a very low ventilation rate of 0.6 per hour. As per ConsExpo, the exposure should be residual, due to the air concentration of the active substance will be lower than AEL (0.0106 mg/m^3). The dermal exposure should be overestimated since tha CAR does not contain data on dermal absorption of the dry residues, and therefore a 70% absorption is considered For ConsExpo calculation is assumed: - The product is applied during 14 min.

- Volume: 100 m^3
- The room is closed, no ventilation is considered. Then the maximum concentration of active substance reachable is 113 mg/m^3 (see graphs and calculations in section 3.2):

  0.563 L x 10 min/0.4L = 14 min

  14 min x 40 mL/min = 560 g prod emitted in the 100 m^3 room

  560 g prod/100 m^3 x 2.0 g a.s/100 g prod x 10^3 mg/1g = 113 mg a.s/m^3

- The room keeps closed 24 hours. During this period a rate of 0.6/h is considered to simulate abatement.

After above steps, people can come into the room. 6/h rate is applied (default for public commercial place. Conservative value)

Calculations and graphics can be found in section 3.2

	Parameters[1]	Value
Tier 1: inhalation	Concentration of active substance	2%
	Exposure duration	2 h (in medical area for instance)
	Product amount	560 g after 14 minutes application. $3.15x10^{-4}$ g after 24 hours (see graphs and calculations in section 3.2)*
	Room volume	100 m^3
	Ventilation rate	0 h^{-1} during release 0.6 h^{-1} during application 6 h^{-1} when re-entry
	Vapour pressure	44 Pa
Tier 1: dermal	Exposed area (2 hands)	230 cm^2 (palms)
	Weight fraction substance	2%
	Contact time	30 min (time spended touching surfaces)
	Contacted surface	1 m^2 surface of utensils/tools/forniture touched with hands
	Transfer coeficient	0.21 m^2/h (From Heeg 12 recomendation)
	Dislodgeable amount**	$4.2x10^{-7}$ g/m^2
	Dermal absorption	70%

*Product amount: $6.3x10^{-5}$ mg as/m^3 x 100 m^3 x 1g/1000 mg x 100 g prod/2 g as = $3.15x10^{-4}$ g prod

**Dislodgeable amount: The concentration of substance after 24 hours is $6.3x10^{-5}$ mg as/m^3 (ConsExpo), which is equivalent to $3.15x10^{-4}$ g product/m^3. We consider a surface of 33 m^2 (100 m^3 of volume and 3 m hight). We suppose that all the all the product falls in the surface: $3.15x10^{-4}$ g prod/33 m^2 = $9.5x10^{-6}$ g prod/m^2. We also consider a decrease due to the half-live of 8.2 h (calculated for 24 hours): $9.5x10^{-6}$ g prod/m^2 x 0.25 = $2.4x10^{-6}$ g prod/m^2. According to TNSG 2002, for dislodgeable fraction for various surfaces types is 18%. Then: $2.4x10^{-6}$ g prod/m^2 x 0.18 = $4.2x10^{-7}$ g/m^2

Calculations for Scenario [5]

Summary table: estimated exposure from different uses				
Exposure scenario	**Tier/ PPE**	**Inhalation**	**Dermal (mg/kg bw/d)**	**Total intake (mg/kg bw/d)**
Reentry Tier 1: no PPE	no	$2.2x10^{-7}$	$1.0x10^{-8}$	$2.3x10^{-7}$

Further information and considerations on scenario [5]

Fogging Re entry time. Strong ventilation in closed room for 30 minutes.

Open room: workers/general population exposure when re-entering in treated room.

See graphs and calculation in Annex 3.2

Monitoring data

Not appicable

Dietary exposure

Food, drinking water and livestock exposure of the biocidal product can be excluded when applied according to the recommended uses. Due to its chemical nature, the active ingredient glutaraldehyde is very reactive with for example proteins, as has been demonstrated in the metabolism studies and no residues remain. Therefore, glutaraldehyde is not expected to be present in food, and an ADI is not derived.

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

The potential exposure of industrial workers during the production and formulation of the b.p. is addressed under REACH and not repeated under Regulation (EU) 528/2012 (BPR), as the manufacturing is not exclusively for biocidal purposes. The risk assessments performed have focused on the use of the product once formulated and the potential exposure to both humans and the environment.

Aggregated exposure

Not considered. Aggregated exposure is very unlikely

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/d)**
1	Professional	Tier 1: no gloves	$6.5x10^{-5}$
		Tier 2: gloves	$1.7x10^{-5}$
3.	Professional	Tier 1: no gloves.	$4.5x10^{-5}$
		Tier 2: gloves	$4.4x10^{-5}$
4.	Professional	Tier 1: no gloves	$3.0x10^{-7}$
5.	Toddler	Tier 1: no gloves	$2.3x10^{-7}$
Combined 1,3 and 4	Professional	Tier 1: no gloves	$1.1x10^{-4}$
		Tier 2: gloves	$6.2x10^{-5}$

2.2.6.3 Risk characterisation for human health

The applicant intends to use as toxicological reference value a theoretical value obtained from the DNEL (6.25 mg/kgbw/d x 1 d/24h x 1h/1.37= 0.2 mg/m3), this approach is not admissible.

From the Assessment Report of Glutaraldehyde, the following AEL/AEC values are taken into account:

Reference values to be used in Risk Characterisation (from CAR)

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
AELshort-term	Threshold nasal chemestetic detection	1.6 mg/m^3	3.2		0.5 mg/m^3
AELmedium-term	2-year inhalation mouse	0.255 mg/m^3	2.5x3.2x3		0.0106 mg/m^3
AELlong-term			2.5x3.2x3		0.0106 mg/m^3
AEL systemic	carcinogenicity	3.5 mg/kg bw/d	10x10	0.4	$1.4x10^{-2}$ mg/kg bw/d
ARfD	Rabbit teratogenicity study	15 mg/kg bw/d	25		0.60 mg/kg bw/day
ADI	Not derived, because glutaraldehyde is not expected to be present in food				

Maximum residue limits or equivalent

No data

Specific reference value for groundwater

No data

Risk for industrial users

Not applicable

Risk for professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1	1	3.5	$1.4x10^{-2}$	$6.5x10^{-5}$	0.46	yes
	2	3.5	$1.4x10^{-2}$	$1.7x10^{-5}$	0.21	yes
3	1	3.5	$1.4x10^{-2}$	$4.5x10^{-5}$	0.32	yes
	2	3.5	$1.4x10^{-2}$	$4.4x10^{-5}$	0.31	yes
4	1	3.5	$1.4x10^{-2}$	$3.3x10^{-7}$	0.0024	yes

Combined scenarios.

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1, 3 and 4	1	3.5	$1.4x10^{-2}$	$1.1x10^{-4}$	0.79	yes
	2	3.5	$1.4x10^{-2}$	$6.1x10^{-5}$	0.44	yes

Local effects

According to the criteria of the Regulation 1272/2008, the biocidal product is proposed to be classified as sensitizer to skin (H317), irritant to eye (H319), irritant to skin (H315 and sensiziter to inhalation (H334). Therefore, as AECs have been set for the active substance, quantitative and qualitative assessment of local effects will be performed in Risk Characterisation Section according to Guidance on the BPR Volume III Human Health-Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017).

Quantitative local risk assessments

Inhalation acute local:

Task/ Scenario	Tier	Systemic NOAEL mg/ m^3	AEL mg/m^3	Estimated uptake mg/m^3	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1	1	1.6	0.5	$3x10^{-5}$	$6.0x10^{-3}$	yes
2	1	1.6	0.5	-	-	
3	1	1.6	0.5	$8.9x10^{-5}$	$1.8x10^{-2}$	yes
4	1	1.6	0.5	$4.4x10^{-7}$	$2.3x10^{-7}$	yes

Conclusion

When the inhalation exposures are compared to the $AEC_{inhalation}$ of 0.5 mg/m^3, the risk is also considered acceptable for all scenarios

Qualitative local risk assessments

Local exposure is assessed following the qualitative risk characterisation steps showed in the Guidance on the BPR: Volume III parts B+C.

Hazard classification	**Hazard statement**	
Eye Irritation 2	H319	Causes serious eye irritation

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Conclusion**
Low	Eye Irrit.2	---	2-4	Professional	Manual loading and connecting to fogging device	Ocular	Few minutes per day or less	Low	Minimisation of splashes and spills: 1. Supervision by management about the effectiveness of RMM; 2. Training of staff on good practices; 3. Good standard of personal hygiene; 4. Avoidance of contact with contaminated tools and objects; 5. PPE: Gloves.	The manual loading must be done slowly in order to avoid any splashes and spills. Considering that these recommendations can be followed during these tasks, the risk is acceptable according to RMMs.
Low	Eye Irrit.2	---	2-4	Professional	Fogging application with an automatic device	Ocular	Less than few minutes per day	Low	1. Staff should leave the room to be treated just before starting the process; 2. Training of staff on good practices; 3. Before re-entering a safety period of 24 hours should be implemented;	Considering that these recommendations, the risk is acceptable.

									4. Before coming into the room, ventilation is compulsory, until facilities and equipment are fully dry.	
Low	Eye Irrit.2	---	2-4	Professional	Maintenance: Cleaning and maintenance operations of the fogging device	Ocular	Few minutes per day or less	Low	Minimisation of splashes and spills: 1. Supervision by management about the effectiveness of RMM; 2. Training of staff on good practices; 3. Good standard of personal hygiene; 4. Avoidance of contact with contaminated tools and objects; 5. PPE: Gloves.	The manual loading must be done slowly in order to avoid any splashes and spills. Considering that these recommendations can be followed during these tasks, the risk is acceptable according to RMMs.
Low	Eye Irrit.2	---	2-4	Professional	Re-entry in the treated room	Ocular	Less than few minutes per day	Low	Human exposure of product is almost negligible: 1. Good standard of general ventilation; 2. Training of staff on good practices: Respecting of 24 hours safety period.	Considering that these recommendations can be followed during these tasks, the risk is acceptable.

									3. Good standard of personal hygiene.	

Conclusion
As the Estimated exposure/AEC (%) ratio is less than 100, the risk is acceptable. Also, the local exposure assessed shows that by implementing the relevant measures, this risk is under control.

Risk for non-professional users

Not applicable

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
5	1		$1.4x10^{-2}$	$8.4x10^{-7}$	$5.9x10^{-3}$	yes

Local effects

Quantitative local risk assessments

Inhalation acute local:

Task/ Scenario	Tier	AEL mg/m^3	Estimated uptake mg/m^3	Estimated uptake/ AEL (%)	Acceptable (yes/no)
5	1	0.5	$2.7x10^{-7}$	$5.4x10^{-5}$	yes

Qualitative local risk assessments

Hazard			Exposure							Risk
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM & PPE**	**Conclusion**
Low	Eye Irrit.2	---	2-4	General public	Re-entry in the treated room	Ocular	Less than few minutes per day	Low	Human exposure of product is almost negligible: 4. Good standard of general ventilation 5. Respecting of 24 hours safety period. 6. Good standard of personal hygiene.	Considering that these recommendations can be followed during these tasks, the risk is acceptable.

Risk for consumers via residues in food

Glutaraldehyde is very reactive with for example proteins, as has been demonstrated in the metabolism studies and no residues remain. Therefore, glutaraldehyde is not expected to be present in food, and an ADI is not derived.

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

Not applicable.

2.2.7 Risk assessment for animal health

Food, drinking water or livestock exposure of glutaraldehyde can be excluded when applied according to the recommended uses. Therefore, no unacceptable risk to animal health needs to be expected

2.2.8 Risk assessment for the environment

ES - CA

Please notice that the risk assessment for the environment (section 2.2.8) is reported as provided by the applicant. The ES- CA position is presented in **green evaluation boxes**.

2.2.8.1 Effects assessment on the environment

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

The biocidal DESINTOP SF has only a substance, the biocidal active substance, glutaraldehyde, classified as toxic for the environment. The concentration of glutaraldehyde in the product is 2.0% and does not give a classification of toxicity regarding the environment, the environmental risk is assessed.

The data source for calculations is the assessment report of the active substance.

Glutaraldehyde is highly hydrophilic and lipophobic substance. It is non-ionisable and fully soluble in water. Glutaraldehyde is volatile, but does not easily evaporate from water. Glutaraldehyde is subject to rapid photochemical degradation in air with a half-life of 8.2 h. Glutaraldehyde is readily biodegradable and has a potential to biodegrade in the marine environment, but it is hydrolytically and photolytically stable under environmental relevant conditions.

Glutaraldehyde is not expected to bioaccumulate in aquatic or terrestrial organisms based on the low log octanol/water partition coefficient (-0.33, -0.36). Taken into account the low bioaccumulation potential and ready biodegradation there is no need to further testing or risk assessment of secondary poisoning.

Summary of PNEC values:

Glutaraldehyde:

PNEC	Unit	Value
$PNEC_{STP}$	mg/L	0.51
$PNEC_{WATER}$	mg/L	0.0025
$PNEC_{SOIL}$	mg/kg ww	0.184
$PNEC_{GROUDWATER}$	mg/L	0.0001

Further Ecotoxicological studies
No data available

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
No data available

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

No data available
Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No data available

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

No data available

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

Glutaraldehyde is not expected to bioaccumulate in aquatic or terrestrial organisms based on the low log octanol/water partition coefficient (-0.33, -0.36). Data from Assessment Report of Glutaraldehyde.

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

No data available

Leaching behaviour (ADS)

Not applicable

Testing for distribution and dissipation in soil (ADS)

No data available

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

No data available

Testing for distribution and dissipation in air (ADS)

No data available

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

No data available

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

No data available

ES-CA:

Environmental classification of the product

Harmonised environmental classification of the active substances

The environmental classification of the active substances is the following:

Classification for the active substance			
Active substance	**Env. Classification**	**M-Factor**	**Concentration of a.s. in the product (%)**
Glutaraldehyde (1)	H400, H411	M = 1	2.0

(1) Current entry in Annex VI, CLP Regulation, ATP 9.

Environmental classification of the substance(s) of concern

The biocidal product does not contain substances which influence the environmental classification.

Environmental classification of the biocidal product

Classification for the biocidal product
Classification: Not classified

PBT-assessment:

According to the AR of Glutaraldehyde (2014), glutaraldehyde is readily biodegradable substance, has a low bioaccumulation potential (Log Kow -0.33) and does not have any NOEC less than 0.01 mg/l. It is concluded that Glutaraldehyde is not a PBT or vPvB substance.

ED-assesssment:

According to the AR of Glutaraldehyde (2014) available evidence at this time indicates that glutaraldehyde does not have endocrine-disrupting properties (classification criteria specified in Art. 5(3) are not met, no effects on endocrine organs and/or reproduction were observed in standard toxicity studies to raise a concern for potential endocrine disruption).

2.2.8.2 Exposure assessment

DESINTOP SF is applied for disinfection of hard surfaces in food feed industry (PT4) and hospitals, cleanrooms and industrial areas (PT2) by professional workers. The application is by fogging inside the contaminated room and the product is applied as such, not diluted.

After application no rinsing is performed: the treated surfaces are let to dry out during a safety period of time, 24 hours, before the presence of people inside the treated room is allowes again. Due to the high reactivity of glutaraldehyde, after this period of time, the presence of glutaraldehyde is negligible.

Only one substance is considered for calculation: the active substance, glutaraldehyde.

General information

Assessed PT	*PT 2: Disinfectants and algaecides not intended for direct application to humans or animals* *PT4: Surface disinfection in food and feed industrial areas. Indoor use.*
Assessed scenarios	*Scenario 1: Application and service life*
Sources and calculation guidelines	*Technical Agreements for Biocides Environment (ENV) Version 2.1, December 2019* *Guidance on biocidal products regulation: Volume IV Environment - Assessment and Evaluation - Part B+C version 2.0 – October 2017*

Emission estimation

Only the scenario of application is considered. There is not a mixing and loading step before the applcation. The original bottle with the product is connected to the diffuser device. This scenario includes PT2 and PT4 application since the product is applied in the same way and ratios for both types.

To develop the scenario room volume from *Technical Agreements for Biocides Environment (ENV) Version 2.1, December 2019,* has been considered:

PT2: 4000 m^3 (Default volume for industrial premises in PT 2 when applying the biocidal product by e.g. vaporizing or fogging (PT 2))

PT4: 6000 m^3 (Large kitchen)

Calculations are carried out takig the application rate, which is 10 min/100 m^3, and considering the concentration of 2%.

Scenario 1: Application

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Application			
Applied amount per treatment	6.7	*g*	The concentration of active substance is 2.0%, the flow of application is 2L/60 min and the application takes place during 10 min: 2L/60 min x 10 min x 1000 g prod/1L x 2.0 g a.s/100 g prod = 6.7 g a.s/application (The density of the product is assumed as 1 g/mL)
Active substance applied (concentration)	0.067	*g/m³*	
Concentration of active substance in the product (maximum)	2.0	*% (w/w)*	

Fate and distribution in exposed environmental compartments

	Fresh-water.	**Fresh-water sediment**	**Sea-water**	**Sea-water sediment**	**STP**	**Air**	**Soil**	**Ground water**
Scenario 1	X				X		X	X

Input parameters for calculation of fate and distribution in the environment.

Input	**Value**	**Units**	**Remark**
Scenarios 1, 2, 3 and 4			
Molecular weight	100	g/mol	---
Melting point	-0.18	ºC	---
Boiling point	101.5	ºC	---
Vapour pressure (25ºC)	0.44	hPa	---

Water solubility (20ºC)	>513	g/L	---
Log octanol/water partition coefficient (logKow)	-0.33		---
Organic carbon/water partition coefficient (Koc)	326	L/kg	---
Henry's Law Constant (20ºC)	0.0086	Pa m^3/mol	---
Biodegradability	Readily biodegradable		---
Rate constant for STP	4.95	h^{-1}	---
DT_{50} for biodegradation in surface water	5	day	---
DT_{50} for hydrolysis in surface water	102-394	day	25ºC
DT_{50} for photolysis in surface water	195	day	25ºC
DT_{50} for degradation in soil	Not available	h	---
DT_{50} for degradation in air	8.2	h	---

Calculated fate and distribution in the STP

Compartment	Percentage	Remarks
Air	0	**---**
Water	2.65	**---**
Sludge	0.04	**---**
Degraded in STP	97.31	**---**

Calculated PEC values

Summary of calculated PEC's PT 2

PEC	Unit	Value
PEC_{STP}	mg/L	$3.9x10^{-3}$
PEC_{WATER}	mg/L	$3.9x10^{-4}$
PEC_{SOIL}	mg/kg ww	$8.2x10^{-5}$
$PEC_{GROUDWATER}$	mg/L	$1.4x10^{-5}$

Summary of calculated PEC's PT 4

PEC	Unit	Value
PEC_{STP}	mg/L	$6x10^{-3}$
PEC_{WATER}	mg/L	$6x10^{-4}$
PEC_{SOIL}	mg/kg ww	$1.2x10^{-4}$
$PEC_{GROUDWATER}$	mg/L	$2x10^{-5}$

ES-CA:

The environmental exposure assessment of DESINTOP SF, was assessed in accordance with the Guidance on the Biocidal Products Regulation (Volume IV Environment, version 2.0, October 2017) and the technical agreements for biocides (TAB, Version 2.1, December 2019). This assessment was likewise performed following the recommendations of the Emission Scenarios Documents for PT2 and PT4.

Assessed PT	PT 2 and 4
Assessed scenarios	• Scenario 1 "Disinfectant in large scale- Industrial areas - fogging" • Scenario 2 "Disinfectant used for sanitary purposes in hospitals – consumption-fogging" • Scenario 3 "Disinfectant used for sanitary purposes in hospitals – tonnage-fogging" • Scenario 4 "Disinfection in large scale - catering kitchens and canteens - fogging "
ESD(s) used	ESD PT2: Private and public health area disinfectants and other biocidal products, 2001 and 2011 ESD PT4: Disinfectants used in food and feed areas, 2011
Approach	Scenario 1: Average consumption Scenario 2: Average consumption Scenario 3: tonnage Scenario 4: Average consumption
Distribution in the environment	Estimated according to: • Guidance on the Biocidal Products Regulation, Vol. IV. Env., Part B Risk Assessment (active substances), October 2017. • Assessment report: Glutaraldehyde, September 2014. • EUSES 2.2.
Groundwater simulation	NO
Life cycle steps assessed	Scenario 1: product use Scenario 2: product use Scenario 3: product use Scenario 4: product use
Remarks	-

USE 1. PT 2: Disinfection of cleanrooms in hospitals and industrial areas

The emission scenario submitted for PT2 (Scenario1) by the applicant considered the default room volume for fooging in PT2 (discussed and agreed at WG-I-2017). But this room volume is **only applied for industrial premises** in biotechnology plants, production plants for pharmaceuticals, cosmetics or toiletries or production plants for computers. According, to the intended use of this product, the surface areas to be disinfected are Cleanrooms in Hospitals and Industrial Areas, so the disinfection in the hospital sector (Scenario 2 and 3) is covered by the emission scenario for sanitary purposes in hospitals (RIVM 2001).

It must be taken into account that this product will evaporate completely (diffuse air emissions) and not reach the sewer, therefore this intended use is not included in the emission scenarios for PT2. But, ES-CA has considered this scenario as the worst-case.

Scenario 1: Cleanrooms in industrial areas

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Application			
Application rate of product (Vform)	5.63	*ml/m³*	According to efficacy of the product
Concentration of substance in the product (Cform)	20	*g/L*	*S*
Surface area treated	4000	*m³*	(TAB v2.1, ENV 52)
Number of applications per day (Nappl)	1	-	
Fraction released to waste-water [Fwater]	1	-	Default value
Output	**Value**	**Unit**	**Remarks**
Local release to wastewater	0.450	*kg/d*	

Scenario 2: Cleanrooms in hospitals (Consumption-fogging).

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Application			
Type of application	Sanitary purposes		S
Concentration of substance in the product (Cform)	20	*g/L*	*S*
Fraction released to wastewater (sanitary purposes)	0.55	-	Default value
Amount of water with substance (sanitary purposes)	25	l/d	Default value
Output	**Value**	**Unit**	**Remarks**
Local release to wastewater	0.275	*kg/d*	

Scenario 3: Cleanrooms in hospitals (Tonnage-fogging)

Please note that no tonnage-based scenario was proposed by the applicant. The emission scenario for calculating the releases of disinfectants used for sanitary purposes based on the annual tonnage (Scenario 3) was carried out by ES-CA and it is included as Confidential Annex.

Break-even point

Based on the local emission from the consumption based approach a regional tonnage equivalent (break-even point) can be calculated. If the consumption based break-even point is larger than the regional tonnage, then the local emission from the consumption based approach should be used for further environmental exposure and risk assessment. In the case of DESINTOP SF, for the environmental exposure and risk assessment, the emission based on consumption is greater and therefore the on that it has been used.

USE 2. PT4 Disinfection in large scale - catering kitchens and canteens - fogging

The scenario provided estimates the emission from the disinfection of surfaces (floors, walls, working areas or other surfaces) in large-scale catering kitchens and canteens with a maximum room volume of 6000m^3.

Scenario 4: Food and feed areas

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Application			
Application rate of product (Vform)	5.63	*ml/m^3*	According to efficacy of the product
Concentration of substance in the product (Cform)	20	*g/L*	*S*
Surface area treated	6000	*m^3*	(TAB v2.1, ENV 66)
Number of applications per day (Nappl)	1	-	
Fraction released to waste-water [Fwater]	1	-	Default value
Output	**Value**	**Unit**	**Remarks**
Local release to wastewater	0.678	*kg/d*	

Local emission resulted from use 1 and 2

The local emission to wastewater for PT2 scenario was of 0.450 kg/d in industrial areas, 0.275kg/d in hospitals and for PT4 was 0.678 kg/d.

Fate and distribution in exposed environmental compartments

For the local emission scenarios, the primary receiving compartment is the STP, after entering the STP, the active substance will distribute to the different environmental compartments. The fate and distribution of glutaraldehyde in the exposed environmental compartments were calculated via EUSES 2.2.

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water*	Seawater sediment**	STP	Air	Soil	Ground-water	Other
Scenario 1	+	+	+	+	++	+	+	+	-
Scenario 2	+	+	+	+	++	+	+	+	-
Scenario 3	+	+	+	+	++	+	+	+	-
Scenario 4	+	+	+	+	++	+	+	+	-

* covered by the assessment of freshwater
** covered by the assessment of the freshwater compartment

In EUSES 2.2. these scenarios were implemented. So, ES - CA carried out the risk assessment using EUSES 2.2. and the following table shows some of the input parameters considered in the environmental assessment:

Input parameters (only set values) for calculating the fate and distribution in the environment [Glutaraldehyde]			
Input	**Value**	**Unit**	**Remarks**
Molecular mass	100.11	g/mol	LoE
Melting point	-18ºC	°C	LoE
Boiling point	101.5ºC at 987.4 hPa	°C	LoE
Vapour pressure	44	Pa at 20ºC	LoE
Water solubility	≥513000 at 21ºC	mg/l	LoE
Log Octanol/water partition coefficient	-0.33	Log 10	LoE
Henry's Law Constant	0.0086	$Pa/m^3/mol$ (25ºC)	LoE
Biodegradability	Readily biodegradable		
Rate constant for degradation in air	Although there is a photo-oxidative degradation in air (DT_{50}= 8.2 hours). Fate and behaviour in air is not regarded relevant because there is no relevant release of the compound to the air compartment.	hours	LoE
Organic carbon/water partition coefficient (Koc)	326	L/kg	
Rate constant for STP (at 15 °C)	2.9	h^{-1}	[-]

Rate constant for biodegradation in surface water	0.56	d^{-1}	at 12ºC
Rate constant for hydrolysis in surface water	6 x 10^{-4}	d^{-1}	at 12ºC / pH 7
Rate constant for photolysis in surface water	4 x 10^{-3}	d^{-1}	at 12ºC / pH 7
DT_{50} for degradation in soil (12 °C)	30	d	Default value for readily biodegradable substances according to ECHA-Guidance (2017) BPR, Vol. IV, ENV – Parts B+C

The distribution of glutaraldehyde in the STP is based on calculations with SimpleTreat 4.0 (EUSES 2.2) considering its physical-chemical properties and information provided in the glutaraldehyde Assessment Report for PT2, 3, 4, 6, 11, 12 (Finland, September 2014) and considering the experimentally derived rate constant of 2.9 h^{-1} (at 15 °C) for the STP.

The outputs for glutaraldehyde were the following:

Calculated fate and distribution in the STP Simple Treat 4.0 [Glutaraldehyde]		
Compartment	Percentage [%]	Remarks
Air	1.32E-03	
Water	2.85	
Primary settle	2.82	
Surplus sludge	0.04	
Degraded in STP	94.29	

According to the glutaraldehyde Assessment Report for PT2, 3, 4, 6, 11, 12 (Finland, September 2014) a risk assessment for the sediment compartment is not required since glutaraldehyde has log K_{OC} – and log K_{OW}-values below 3 and is readily biodegradable. Furthermore, the toxicity of glutaraldehyde to sediment dwelling organisms has not been studied. Thus, neither PEC-values nor PEC/PNEC-ratios are provided for the sediment compartment.
There are no relevant metabolites of glutaraldehyde that need to be considered in the environmental risk assessment.

PEC	**Unit**	**Scenario 1 (PT2)**	**Scenario 2 (PT2)**	**Scenario 4 (PT4)**
PECair	mg/m^3	1.36x10^{-9}	8.29x10^{-10}	2.04x10^{-9}
PEC_{STP}	mg/L	6.41x10^{-3}	3.91x10^{-3}	9.65x10^{-3}
PEC_{WATER}	mg/L	6.41x10^{-4}	3.91x10^{-4}	9.65x10^{-4}
PEC_{SOIL}	mg/kg ww	1.67x10^{-2}	1.02x10^{-2}	2.52x10^{-2}

$PEC_{GROUNDWATER}$	mg/L	$9.26x10^{-4}$	$5.66x10^{-4}$	$1.39x10^{-3}$

*Scenario 3 see Confidential Annex

Primary and secondary poisoning

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

Secondary poisoning

Glutaraldehyde is not expected to bioaccumulate in aquatic or terrestrial organisms based on the low log octanol/water partition coefficient (-0.33, -0.36). Taken into account the low bioaccumulation potential and ready biodegradation there is no need to further testing or risk assessment of secondary poisoning.

2.2.8.3 Risk characterisation

Glutataraldehyde: PT2

Predicted No Effect Concentrations (*):

PNEC	Unit	Value
$PNEC_{STP}$	mg/L	0.51
$PNEC_{WATER}$	mg/L	0.0025
$PNEC_{SOIL}$	mg/kg ww	0.184
$PNEC_{GROUDWATER}$	mg/L	0.0001

(*): Data from the active substance, glutaraldehyde, assessment report

Summary of calculated PEC's

PEC	Unit	Value
PEC_{STP}	mg/L	$3.9x10^{-3}$
PEC_{WATER}	mg/L	$3.9x10^{-4}$
PEC_{SOIL}	mg/kg ww	$8.2x10^{-5}$
$PEC_{GROUDWATER}$	mg/L	$1.4x10^{-5}$

PEC/PNEC ratios

Scenario	PEC/PNEC STP	PEC/PNEC Water	PEC/PNEC Soil	PEC/PNEC Groundwater
PT 2	$7.6x10^{-3}$	0.16	$4.5x10^{-4}$	0.14

PEC/PNEC Values lower than 1 indicates that the risk is under control

Conclusion:

PT-2:

Based on the tabulated values above, the Glutaraldehyde based disinfectants are intended to be used as ready for use products and are mainly applied as prophylactic disinfectant in clean rooms, laboratories, in sanitation areas, in medical practices and in pharmaceutical and cosmetic industry.

Acceptable risk is identified in surface water, STP, soil and groundwater compartments. It should be taken into account that the application of the product is on sealed and paved facilities, therefore the releases of the product to environment are very unlikely.
In case of unintentional spills may reach the facility drain, it is not expected any non-acceptable risk for environment in accordance with the PEC/PNEC ratios for STP compartment showed on above table.

Glutaradehyde is employed as a broad-spectrum biocide for the disinfection of surfaces, inanimate objects and materials equipment in private, public health and industrial areas within the PT2 for professional without any impact for the environment.

PT4:

Glutataraldehyde: PT4

Predicted No Effect Concentrations (*):

PNEC	Unit	Value
$PNEC_{STP}$	mg/L	0.51
$PNEC_{WATER}$	mg/L	0.0025
$PNEC_{SOIL}$	mg/kg ww	0.184
$PNEC_{GROUDWATER}$	mg/L	0.0001

(*): Data from the active substance, glutaraldehyde, assessment report

Summary of calculated PEC's

PEC	Unit	Value
PEC_{STP}	mg/L	$6x10^{-3}$
PEC_{WATER}	mg/L	$6x10^{-4}$
PEC_{SOIL}	mg/kg ww	$1.2x10^{-4}$
$PEC_{GROUDWATER}$	mg/L	$2x10^{-5}$

PEC/PNEC ratios

Scenario	PEC/PNEC STP	PEC/PNEC Water	PEC/PNEC Soil	PEC/PNEC Groundwater
PT4 application	0.012	0.24	$6.5x10^{-4}$	0.2

PEC/PNEC Values lower than 1 indicates that the risk is under control

PT-4:
Based on the values tabulated above, the application fot PT4 does not have impact for the environment.

Based on the tabulated values above, the Glutaraldehyde based disinfectants are intended to be used as ready for use products and are mainly applied as prophylactic disinfectan in food and feed industry.

Acceptable risk is identified in surface water, STP, groundwater and soil compartments. It should be taken into account that the application of the product is on sealed and paved facilities, therefore the releases of the product to environment are very unlikely.

In case of unintentional spills may reach the facility drain, it is not expected any non-acceptable risk for the environment in accordance with the PEC/PNEC ratios for the STP compartment shown on the above table.

ES-CA:

The corrected PEC/PNECs values weres summary in the following table:

PT 2

Scenario	PEC/PNEC STP	PEC/PNEC Water	PEC/PNEC Soil	PEC(µg/L) Groundwater
Scenario 1 (PT2)	0.01	0.26	0.09	**0.93**
Scenario 2 (PT2)	0.01	0.16	0.06	**0.57**

Scenario 3 see Confidential Annex

PT 4

Scenario	PEC/PNEC STP	PEC/PNEC Water	PEC/PNEC Soil	PEC(µg/L) Groundwater
Scenario 4 (PT4)	0.02	0.39	0.14	**1.39**

Conclusion: PEC/ PNEC ratios for the STP, water and soil compartments are below the value of 1 for all scenarios indicating an acceptable level of risk for all proposed uses. However, for groundwater, the concentration is greater than the drinking water threshold trigger value of 0.1 µg/ L in all scenarios.

However, a Tier-2 can be applied in the risk assessment. According to Assessment Report, the adsorption/desorption experiment in soil provided evidence of reactions with soil organic matter during the adsorption phase. As Glutaraldehyde reacted with the soil matrix, it was not available in the desorption experiment. Therefore, in Tier 2 the concentration in dry sewage sludge in EUSES is set to 0 and no emission via land application of sewage sludge was considered

The recalculated PEC-values for terrestrial compartment including groundwater were summarized in the following table:

Compartment	Unit	PEC Scenario 1 (PT2)	PEC Scenario 2 (PT2)	PEC Scenario 4 (PT4)	PEC/PNEC Scenario 1 (PT2)	PEC/PNEC Scenario 2 (PT2)	PEC/PNEC Scenario 4 (PT4)
SOIL	mg/kg ww	$3.06x10^{-10}$	$1.87x10^{-10}$	$4.61x10^{-10}$	0.00	0.00	0.00
GROUNDWATER	mg/L	$5.22x10^{-11}$	$3.19x10^{-11}$	$7.86x10^{-11}$	0.00	0.00	0.00

Aggregated Risk Assessment

The identified scenario for Glutaraldehyde application as both PT-2 and PT-4 could be relevant for cumulative risk assessment. The emission point is STP compartment.

Generally the emissions of non-dispersive uses as industrial use is, are not relevant for cumulative assessment, since it is unlikely that the emissions end up into the same compartment (STP).

Overall conclusion on the risk assessment for the environment of the product
Concerning the environmental impact, the PEC/PNEC ratios of STP, water, groundwater and soil compartments are less than one. The DESINTOP SF does not pose any unacceptable risk to the environment if it is used for disinfection of industrial areas PT2 and PT4.

ES-CA:

Mixture toxicity

As the biocidal product contains only one active substance, and no substances of concern an assessment of mixture toxicity is not required.

Aggregated exposure (combined for relevant emmission sources)

Glutaraldehyde is used in a number of biocidal PTs (2, 3, 4, 6, 11 and 12) and has a number of other non-biocidal uses. An aggregated exposure assessment was performed in the CAR (2014).

It must be taken into account that for this product will evaporate completely (diffuse air emissions) and not reach the environment. So, ES-CA has considered that an aggregated exposure estimated is not necessary.

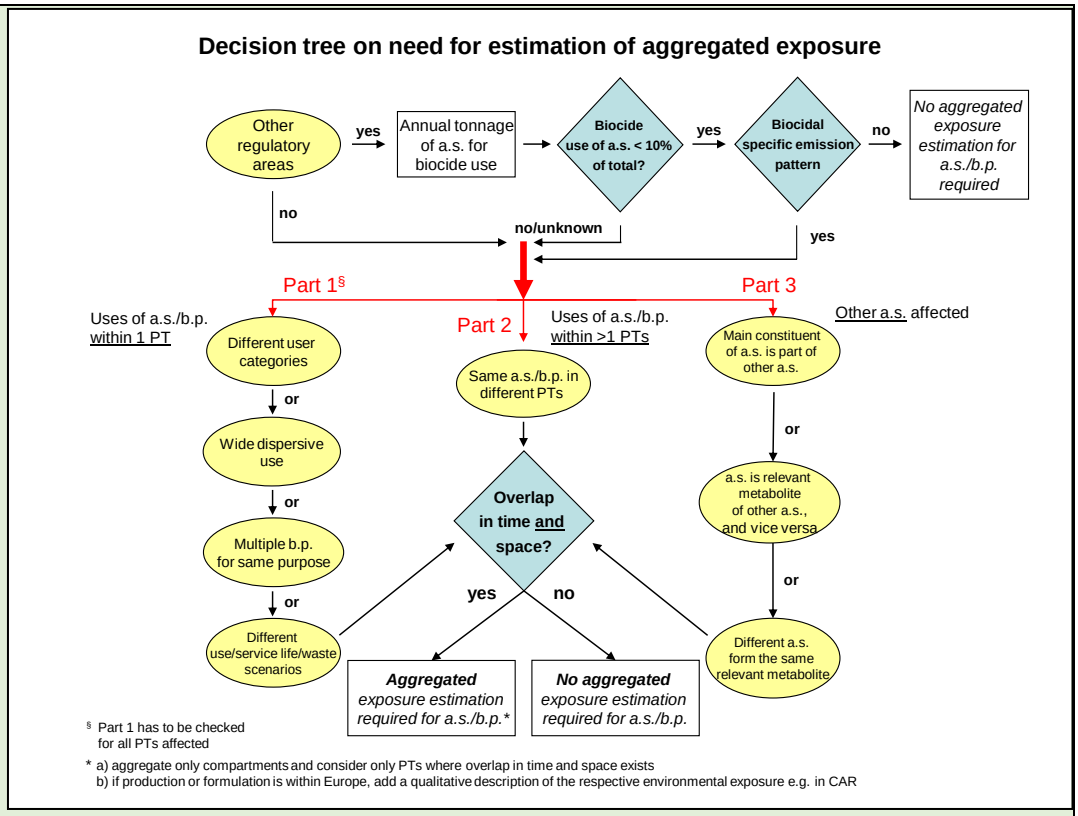


Figure 1: Decision tree on the need for estimation of aggregated exposure

Overall conclusion on the risk assessment for the environment of the product
Therefore, as an overall conclusion, the ES-CA would propose that acceptable levels of risk to the environment have been demonstrated for all proposed uses of this product family.

2.2.9 Measures to protect man, animals and the environment

See risk mitigation measures for authorized uses

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

The spanish competent authority has been processing an application for a biocidal product, DESINTOP SF, which contains Glutaraldehyde as active substance, being said active substance the reason why this comparative evaluation is made.
Currently, glutaraldehyde is regarded as candidate for substitution. Glutaraldehyde has a harmonized classification in accordance with Regulation (EC) No 1272/2008 as Resp. Sens. 1, H334, therefore glutaraldehyde fulfils the criteria according to Article 10.1(b) of the Biocidal Products Regulation (EU) No 528/2012 (BPR) and should be regarded as a candidate for substitution. Therefore, in line with Article 23 (1) of the Biocides Regulation, the Spanish

CA has conducted a comparative assessment for the product DESINTOP SF according to the "Technical Guidance Note on comparative assessment of biocidal products" as agreed upon by the Member States on the 55th meeting of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012 (document: CA-May15-Doc.4.3.a - Final - TNG on comparative assessment.doc).

2.2.11.1 Screening phase

The product DESINTOP SF has been only compared with alternative products authorized in Spain under the Directive 98/8/EC or Regulation (EU) No 528/2012. In accordance with the "Technical Guidance Note on comparative assessment of biocidal products" CA-May 15-Doc.4.3.a-Final, the existing products placed on the market of Spain according to the national systems operating during the transitional period have been excluded from the comparison.

2.2.11.2 Tier IA

According to the information available in R4BP3 on January 2023, in Spain 85 PT2, PT4 products have been authorized. These products are based in 8 notified active substances: lactic acid, hydrogen peroxide, peracetic acid, propan-2-ol, ethanol, D-pentose and D-glucose, oligomeric, C8 and C10 alkyl glycosides, Decanamide, N,N-dimethyl-, mixt. with N,N-dimethyloctanamide, sulphuric acid, D-glucopyranose.

In accordance with the guidance document, during the screening phase it shall be checked whether chemical diversity of the active substances and product type/ mode of action combinations in authorized biocidal products (BP) is adequate to minimize the occurrence of resistance in the target organisms.

Only active substances that can be used via fogging and are effective against a wide range of microorganism are considered eligible alternatives. Taking into consideration that one of the target species of DESINTOP SF is *E.coli*, and that this microorganism is known for developing resistance to molecular oxidation, which is the main mode of action for hydrogen peroxide, there is no adequate chemical diversity for disinfection by fogging products against a this range of microorganism by professional users in line with Article 23(3)(b) and the technical guidance note on comparative assessment.

The Spanish CA has checked whether the chemical diversity of the available active substances/ mode action within the identified alternative biocidal products can be considered adequate to minimise the occurrence of resistance in the target harmful organism. Even though there are a variety of active substances that could be considered PT2,PT4 alternatives, when taking into consideration the application method and wide range of target species the chemical diversity cannot we guaranteed without the active substance glutaraldehyde.

2.2.11.3 Overall conclusion

The Spanish CA concludes that there is no adequate is no adequate chemical diversity for disinfection by fogging products against a wide range of microorganism by professional users in the line with Article 23(3)(b) and the technical guidance note on comparative assessment. The comparative assessment is finalised at this stage. The product DESINTOP SF is authorised for a period not to exceed 5 years in accordance with Article 23 (6) of BPR.

3 ANNEXES[3]

3.1 List of studies for the biocidal product

Section No. (IUCLID dossier)	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
3.1 3.4	[redacted]	[redacted]	Title: Estudio de Estabilidad acelerada Test facility: Laboratorio Microbios S.L Study code: PR055.01-16 Data protection claimed → Yes
3.2 3.3 3.9	[redacted]	[redacted]	Title: Análisis fisicoquimico Test facility: Imark Study code: CoA Desintop SF P02F0700 V2 Data protection claimed → Yes,
3.4	[redacted]	[redacted]	Title: Estudio de Estabilidad a Largo Plazo. Determinacion de Glutaraldehido mediante GG en formulación acuosa Test facility: Microbios Study code: PR011.002-21 Data protection claimed → Yes,
3.8	[redacted]	[redacted]	Title: Certificado de análisis Test facility: BIOCHEMIZE Study code: Report nº:110883 Data protection claimed → Yes
4.6 4.16	[redacted]	[redacted]	Title: Certificado de análisis Test facility: BIOCHEMIZE Study code: Report number 111662 Data protection claimed → Yes
5.1	[redacted]	[redacted]	Title: Informe de validación del método analítico Test facility: LABORATORIO MICROBIOS SL Study code: PR055-16 Data protection claimed → Yes
6.7	[redacted]	[redacted]	Title: Actividad Bactericida UNE EN 1276 Y Fungicida UNE EN 1650 Test facility: Tecnodial, S.A. Study code: Report number 303429 Data protection claimed → Yes
6.7	[redacted]	[redacted]	Title: Desinfección por vía aérea de habitaciones mediante procesos automatizados. Determinación de la actividad bactericida con el producto "Desintop SF" para PT2 área médica y PT4. Test facility: IVAMI Study code: Report number D/21/B0369 Data protection claimed → Yes
6.7	[redacted]	[redacted]	Title: Valoración de actividad levuricida para desinfección de superficies según UNE-EN 13624: 2014 Test facility: Laboratorio Control Microbiológico y

[3] When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Section No. (IUCLID dossier)	Author(s)	Year	Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published
			químico. Study code: Report number 210048996 Data protection claimed → Yes
6.7	[redacted]	[redacted]	Title: Valoración de actividad levuricida para desinfección de superficies según UNE-EN 13727: A1:2012+ A2:2015 Test facility: Laboratorio Control Microbiológico y químico. Study code: Report number 210048994 Data protection claimed → Yes
6.7	[redacted]	[redacted]	Title: Desinfección por vía aérea de habitaciones mediante procesos automatizados. Determinación de la actividad fungicida con el producto "Desintop SF" para productos PT2 para área médica y PT4. Test facility: IVAMI Study code: Report number D21/B0370 Data protection claimed → Yes
6.7	[redacted]	[redacted]	Title: Valoración de actividad bactericida para desinfección de superficies según UNE-EN 13727: A1:2012+ A2:2015 Test facility: Laboratorio Control Microbiológico y químico. Study code: Report number 210052664 Data protection claimed → Yes
6.7	[redacted]	[redacted]	Title: Valoración de actividad fungicida para desinfección de superficies según UNE-EN 13624:2014 Test facility: Laboratorio Control Microbiológico y químico. Study code: Report number 210052663 Data protection claimed → Yes
6.7	[redacted]	[redacted]	Title: Valoración de actividad bactericida para desinfección de superficies según UNE-EN 13727: A1:2012+ A2:2015 Test facility: Laboratorio Control Microbiológico y químico. Study code: Report number 220049278 Data protection claimed → Yes
6.7	[redacted]	[redacted]	Title: Desinfección por vía aérea de habitaciones mediante procesos automatizados. Determinación de la actividad bactericida para el sector salud humana con el producto Desintop SF. NF EN 17272: 2020 Test facility: IVAMI Study code: Report number D/22/B0260 y D/21/B0369 Data protection claimed → Yes

3.2 Output tables from exposure assessment tools

HUMAN HEALTH:
ConsExpo reports:

Substance	Glutaraldehyde
CAS number	111-30-8
Molecular weight	100 g/mol
logKow	-0.33 10Log
Product	DESINTOP SF
Weight fraction substance	2 %
Body weight	60 kg

Scenario 1: Manual loading and connecting to fogging device. Professional

Input:
Inhalation:

Frequency	1 per week
Exposure model	Exposure to vapour - Evaporation
Exposure duration	5 minute
Molecular weight matrix	28.8 g/mol
Amount of dilution used (*)	10000g
Weight fraction substance	2%
Room volume (*)	1 m^3 (around operator)
Ventilation rate	0.5 per hour
Inhalation rate	1.25 m^3/h
Application temperature	20 ºC
Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coeficient	10 m/h
Release área model	Constant
Release area (*)	0.002 m^2
Emission duration	5 minute
Absorption fraction	100 %

(*) These inputs parameters are considered representatives as worst-case.
10000 g are the quantity of the product in 10L Jerrycan.
1m^3 is the volume around the operator head.
20cm^2 is the opening area of the jerrycan. Exposure duration 5 min is the period that the professional is opening the jerring can and connect it to the fogging device.

Dermal:
Tier 1: Without gloves:

Exposure model	Direct contact – Constant rate
Exposed area	820 m^2
Weight fraction substance	2%
Contact rate	0.43 mg/min
Release duration	0.5 min
Absorption fraction	70 %

Tier 2: With gloves:

Exposure model	Direct contact – Constant rate
Exposed area	820 m^2
Weight fraction substance	2%
Contact rate	0.02 mg/min

Release duration	0.5 min
Absorption fraction	70 %

Output:
Inhalation:

Mean event concentration	$8.7x10^{-3}$ mg/m^3
Peak concentration (TWA 15 min)	$8.7x10^{-3}$ mg/m^3
Mean concentration on day of exposure	$3.0x10^{-5}$ mg/m^3
Year average concentration	$4.3x10^{-6}$ mg/m^3
External event dose	$1.5x10^{-5}$ mg/kg bw
External dose on day of exposure	$1.5x10^{-5}$ mg/kg bw

Dermal:
Tier 1: Without gloves:

Dermal load	$5.2x10^{-6}$ mg/cm^2
External event dose	$7.2x10^{-5}$ mg/ kg bw
External dose on day of exposure	$7.2x10^{-5}$ mg/ kg bw
Internal event dose	$5x10^{-5}$ mg/kg bw
Internal dose on day of exposure	$5x10^{-5}$ mg/kg bw/day
Internal year average dose	$7.2x10^{-6}$ mg/kg bw/day

Tier 2: With gloves:

Dermal load	$2.4x10^{-7}$ mg/cm^2
External event dose	$3.3x10^{-6}$ mg/ kg bw
External dose on day of exposure	$3.3x10^{-6}$ mg/ kg bw
Internal event dose	$2.3x10^{-6}$ mg/kg bw
Internal dose on day of exposure	$2.3x10^{-6}$ mg/kg bw/day
Internal year average dose	$3.3x10^{-7}$ mg/kg bw/day

Scenario 2: Fogging application. Professional
During the application operation the presence of people in the contaminated room is not allowed.

Scenario 3: Cleaning and Maintenance of the fogging device. Professional.

The user could be exposed to the dry residues of the product when activities such as cleaning or maintenance are performed. This exposure should be residual.

Input:
Inhalation:

Frequency	1 per week
Exposure model	Exposure to vapour - Evaporation
Exposure duration	10 minute
Molecular weight matrix	28.8 g/mol
Amount of dilution used(*)	1 g
Weight fraction substance	2%
Room volume	1 m^3 (around operator)
Ventilation rate (**)	0.5 per hour
Inhalation rate	1.25 m^3/h
Application temperature	20 ºC

Vapour pressure	44 Pa
Molecular weight	100 g/mol
Mass transfer coeficient	10 m/h
Release área model	Constant
Release area	0.002 m^2
Emission duration	5 minute

(*)This exposure should be residual. As per ConsExpo, the volume involved in this operation is not more than 1 m^3; the product release area is less than 10 cm^2 (as a default value) and, the residual amount considered as worst-case after use of 10 g. This value is used to assess both inhalation and dermal exposure.
(**)0.5 per hour is considered a worst-case value of ventilation rate, due to a very low rate.

Dermal:
Tier 1: Without gloves:

Exposure model	Direct contact – Constant rate
Exposed area	820 m^2
Weight fraction substance	2%
Contact rate	0.0043 mg/min
Release duration	1 minute
Absorption fraction	70%

Tier 2: With gloves:

Exposure model	Direct contact – Constant rate
Exposed area	820 m^2
Weight fraction substance	2%
Contact rate	0.0002 mg/min
Release duration	1 minute
Absorption fraction	70%

Output:
Inhalation:

Mean event concentration	$1.3x10^{-2}$ mg/m^3
Peak concentration (TWA 15 min)	$1.3x10^{-2}$ mg/m^3
Mean concentration on day of exposure	$8.9x10^{-5}$ mg/m^3
Year average concentration	$1.3x10^{-5}$ mg/m^3
External event dose	$4.4x10^{-5}$ mg/kg bw
External dose on day of exposure	$4.4x10^{-5}$ mg/kg bw

Dermal:
Tier 1: Without gloves:

Dermal load	$1.05x10^{-7}$ mg/cm^2
External event dose	$1.4x10^{-6}$ mg/ kg bw
External dose on day of exposure	$1.4x10^{-6}$ mg/ kg bw
Internal event dose	$1.0x10^{-6}$ mg/kg bw
Internal dose on day of exposure	$1.0x10^{-6}$ mg/kg bw/day
Internal year average dose	$1.4x10^{-7}$ mg/kg bw/day

Tier 2: With gloves:

Dermal load	$4.9x10^{-9}$ mg/cm^2
External event dose	$6.7x10^{-8}$ mg/ kg bw

External dose on day of exposure	$6.7x10^{-8}$ mg/ kg bw
Internal event dose	$4.7x10^{-8}$ mg/kg bw
Internal dose on day of exposure	$4.7x10^{-8}$ mg/kg bw/day
Internal year average dose	$6.7x10^{-9}$ mg/kg bw/day

Scenario 4: Re-entry in the treated room. Professional

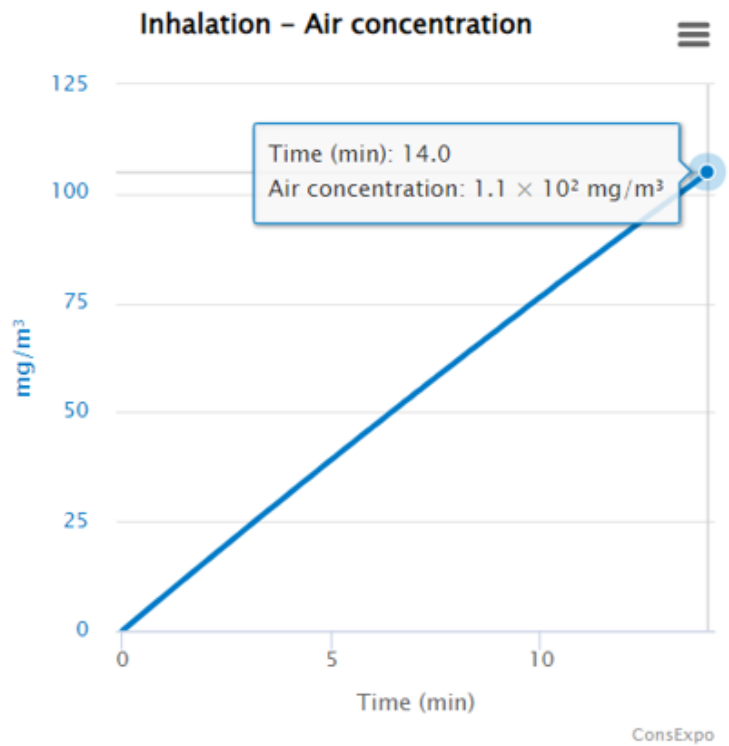
Calculation involves 4 steps:

1- Calculation of concentration reached in closed room after application (14 minutes).
2- Decrease of concentration after 11.5 hours, closed room. Despite the room is closed, a 0.6 ventilation rate is considered, since is a decrease of product concentration is produced by its own action
3- Strong ventilation in closed room for 30 minutes
4- Open room: workers/general population exposure when re-entering in treated room.

1- Máximum concentration reached: 113 mg as/m^3

Inhalation:
Input

Frequency	1 per day
Exposure model	Exposure to vapour – Contant rate
Exposure duration	14 minutes
Amount of dilution used	560 g
Weight fraction substance	2 %
Room volume	100 m^3
Ventilation rate	0 per hour
Inhalation rate	1.25 m^3/h

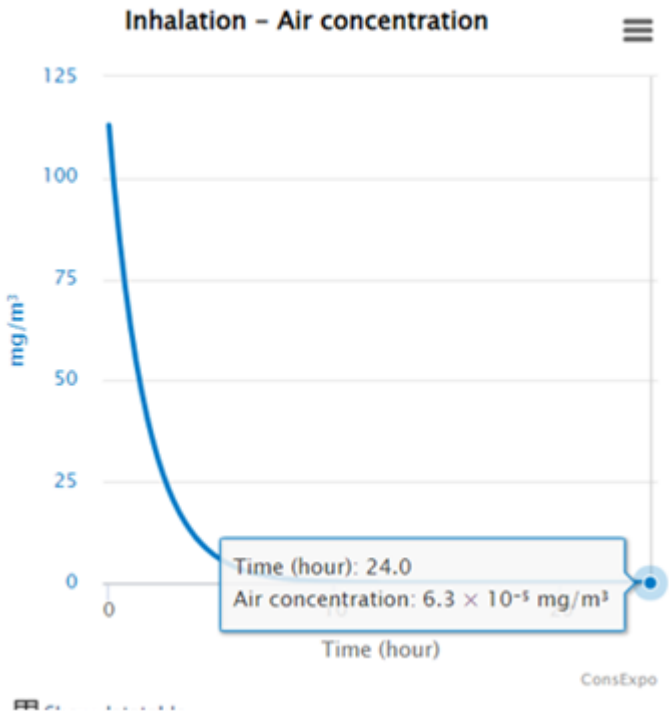


1.$\overline{13}$ x 10^2 mg as/m^3 x 100 m^3 x 1g/1000 mg x 100 g prod/2 g as = 560 g

2- Decrease of concentration. 24h

Inhalation:
Input

Frequency	1 per day
Exposure model	Exposure to vapour – Instantaneous release
Exposure duration	24 hours
Amount of dilution used	560 g
Weight fraction substance	2 %
Room volume	100 m^3
Ventilation rate	0.6 per hour
Inhalation rate	1.25 m^3/h



6.3x10^{-5} mg as/m^3 x 100 m^3 x 1g/1000 mg x 100 g prod/2 g as = 3.15x10^{-4} g prod

3 . Fogging Re entry time

Inhalation:
Input:

Frequency	1 per week
Exposure model	Exposure to vapour – Instantaneous release
Exposure duration	8 hour
Molecular weight matrix	---
Amount of dilution used	3.15x10^{-4} g
Weight fraction substance	2%
Room volume	100 m^3
Ventilation rate	6 per hour
Inhalation rate	1.25 m^3/h
Application temperature	20 ºC
Vapour pressure	44 Pa
Molecular weight	100 g/mol

Dermal:
Input
Tier 1: Without gloves:

Exposure model	Direct contact – Rubbing off
Exposed area	410 m^2
Weight fraction substance	2%
Transfer coefficient	0.78 m^2 /h
Dislodgeable amount	4.7x10^{-7} g/m^2(calculated)

Contact time	1 h
Contacted surface	1 m^2
Absorption fraction	0.7

Output:
Inhalation:

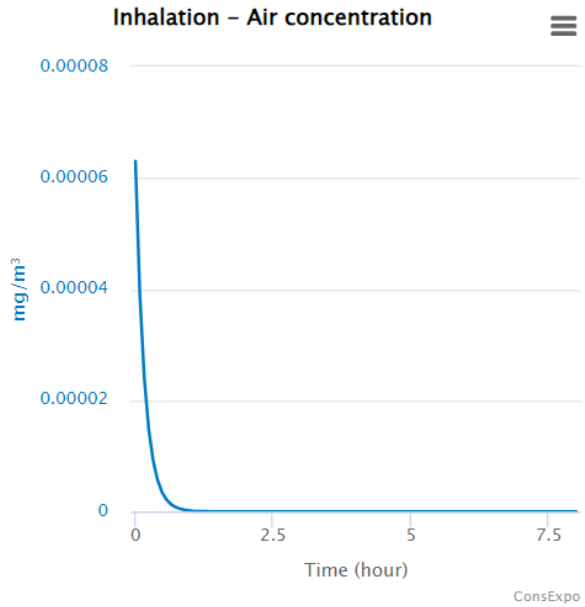
Mean event concentration	7.8 mg/m^3
Peak concentration (TWA 15 min)	$1x10^2$ mg/m^3
Mean concentration on day of exposure	7.8 mg/m^3
Year average concentration	1.1 mg/m^3
External event dose	3.9 mg/kg bw
External dose on day of exposure	3.9 mg/kg bw
Year average dose	3.9 mg/kg bw

Output:
Dermal:
Tier 1: Without gloves:

Dermal load	1.6×10^{-8} mg/cm^2
External event dose	$1.1x10^{-7}$ mg/ kg bw
External dose on day of exposure	$1.1x10^{-7}$ mg/ kg bw
Internal event dose	$7.6x10^{-8}$ mg/kg bw
Internal dose on day of exposure	$7.6x10^{-8}$ mg/kg bw/day
Internal year average dose	$1.1x10^{-8}$ mg/kg bw/d

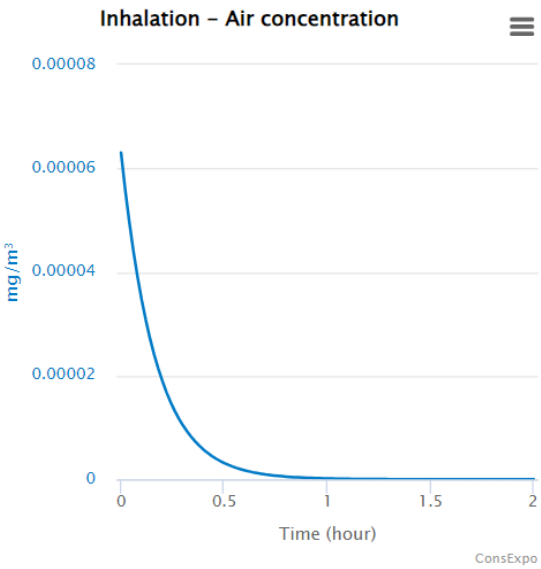
Fogging Re entry time. Strong ventilation in closed room for 30 minutes.

Open room: workers/general population exposure when re-entering in treated room



Scenario 5: Re-entry in the treated room. General public (toddler)

Fogging Re entry time. Strong ventilation in closed room for 30 minutes. Open room: workers/general population exposure when re-entering in treated room.



Re-entry in the treated room
Inhalation:
Input:

Frequency	1 per week
Exposure model	Exposure to vapour – Instantaneous release
Exposure duration	2h
Molecular weight matrix	-
Amount of dilution used	$3.15x10^{-4}$ g
Weight fraction substance	2%
Room volume	100 m^3
Ventilation rate	6 per hour
Inhalation rate	1.25 m^3/h
Application temperature	20 ºC
Vapour pressure	44 Pa
Molecular weight	100 g/mol

Dermal:

Exposure model	Direct contact – Rubbing off
Exposed area	230 m^2
Weight fraction substance	2%
Transfer coefficient	0.21 m^2/h
Dislodgeable amount	$4.7x10^{-7}$ g/m^2 (calculated)
Contact time	30 minute
Contacted surface	1 m^2
Absorption fraction	0.7

Output:
Inhalation:

Mean event concentration	$5.2x10^{-6}$ mg/m^3
Peak concentration (TWA 15 min)	$3.3x10^{-5}$ mg/m^3
Mean concentration on day of exposure	$4.4x10^{-7}$ mg/m^3
Year average concentration	$6.2x10^{-8}$ mg/m^3
External event dose	$2.2x10^{-7}$ mg/kg bw

External dose on day of exposure	$2.2x10^{-7}$ mg/kg bw

Dermal:

Dermal load	$3.8x10^{-9}$ mg/cm^2
External event dose	$1.5x10^{-8}$ mg/ kg bw
External dose on day of exposure	$1.5x10^{-8}$ mg/ kg bw
Internal event dose	$1.5x10^{-8}$ mg/kg bw
Internal dose on day of exposure	$1.0x10^{-9}$ mg/kg bw/day

3.3 New information on the active substance

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3.4 Residue behaviour

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3.5 Summaries of the efficacy studies (B.5.10.1-xx)[4]

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3.6 Confidential annex

See annex Confidential

3.7 Other

[4] If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.