

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

DESINTOP SF

Product type(s)

PT02: Disinfectants and algacides not intended for direct application to humans or animals

PT04: Food and feed area

Authorisation number: ES/APP(NA)-2024-02/04-00931

R4BP asset number: ES-0032365-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	DESINTOP SF
---------------	-------------

1.2. Authorisation holder

Name and address of the authorisation holder	Name	IMARK-HOSPITAL, S.L.
	Address	Ctra Ajalvir a Torrejón, Km. 3,300. Pol. Ind. Conmar nave 10 28864 Ajalvir Spain
Authorisation number	ES/APP(NA)-2024-02/04-00931	
<i>R4BP asset number</i>	ES-0032365-0000	
Date of the authorisation	16/04/2024	
Expiry date of the authorisation	16/04/2029	

1.3. Manufacturer(s) of the product

Name of manufacturer	IMARK HOSPITALS, S.L.
Address of manufacturer	CR Torrejón-Ajalvir, km. 3.3, Pol. Ind Conmar, Naves 10 y 12 28864 Ajalvir Spain
Location of manufacturing sites	IMARK HOSPITALS, S.L. site 1 CR Torrejón-Ajalvir, km. 3.3, Pol. Ind Conmar, Naves 10 y 12 28864 Ajalvir Spain

1.4. Manufacturer(s) of the active substance(s)

Active substance	Glutaral (glutaraldehído)
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch strasse 38 67056 Ludwigshafen Germany
Location of manufacturing sites	BASF SE site 1 Carl-Bosch strasse 38 67056 Ludwigshafen Germany

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Glutaral (glutaraldehído)		active substance	111-30-8	203-856-5	2

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	<p>H315: Causes skin irritation.</p> <p>H319: Causes serious eye irritation.</p> <p>H317: May cause an allergic skin reaction.</p> <p>H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p> <p>H335: May cause respiratory irritation.</p>
Precautionary statements	<p>P261: Avoid breathing dust.</p> <p>P261: Avoid breathing fume.</p> <p>P261: Avoid breathing gas.</p> <p>P261: Avoid breathing mist.</p> <p>P261: Avoid breathing vapours.</p> <p>P261: Avoid breathing spray.</p> <p>P271: Use only outdoors or in a well-ventilated area.</p> <p>P272: Contaminated work clothing should not be allowed out of the workplace.</p> <p>P280: Wear water.</p> <p>P284: [In case of inadequate ventilation] wear respiratory protection.</p> <p>P403+P233: Store in a well-ventilated place. Keep container tightly closed.</p> <p>P405: Store locked up.</p> <p>P264: Wash con agua thoroughly after handling.</p> <p>P302+P352: IF ON SKIN: Wash with plenty of POISON CENTER/doctor/....</p> <p>P362+P364: Take off contaminated clothing and wash it before reuse.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P337+P313: If eye irritation persists: Get medical advice.</p> <p>P333+P313: If skin irritation or rash occurs: Get medical advice/attention.</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p>

P342+P311: If experiencing respiratory symptoms:
Call a POISON CENTER/doctor/...

P312: Call a POISON CENTER/doctor/... if you feel
unwell.

P501: Dispose of contents to container as hazardous
waste to a registered establishment or undertaking, in
accordance with current regulations..

4. AUTHORISED USE(S)

4.1. Use description

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

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	Disinfectants and algaecides not intended for direct application to humans or animals
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Fungi Development stage: no data
Field(s) of use	indoor use Surface Disinfection in Hospitals and in Industrial Areas: Cleanrooms. Indoor use
Application method(s)	Method: fogging Detailed description: Room diffusion. Fogging of surfaces.
Application rate(s) and frequency	Application rate: Dose rate: 5.63 ml/m ³ . Distribution time: Aprox 0.4L/10 minutes. Thermonebuliser works at temperatures of 20°C - 30°C. The droplet size is between 0.2 and 0.4 µm. Dilution (%): Dilution (%) 0 Number and timing of application: <u>Dose rate</u> : 5.63 ml/m ³ . <u>Distribution time</u> : Aprox 0.4L/10 minutes. Thermonebuliser works at temperatures of 20°C - 30°C. The <u>droplet size</u> is between 0.2 and 0.4 µm.
Category(ies) of users	professional
Pack sizes and packaging material	Jerry can 10 L HDPE

4.1.1. Use-specific instructions

See section in General directions for use

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

See section in General directions for use

4.1.4. 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 in General directions for use

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

See section in General directions for use

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

See section in General directions for use

4.2. Use description

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

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	Surface disinfection in food and feed industrial areas. Indoor use.
Target organism(s) (including development stage)	Common name: Fungi Development stage: no data Common name: Bacteria Development stage: no data
Field(s) of use	indoor use Surface Disinfection in food and feed industrial Areas: Cleanrooms. Indoor use
Application method(s)	Method: fogging Detailed description: Room diffusion. Fogging of surfaces.
Application rate(s) and frequency	Application rate: Dose rate: 5.63 ml/m ³ . Distribution time: Aprox 0.4L/10 minutes. Thermonebuliser works at temperatures of 20°C - 30°C. 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. Dilution (%): Dilution (%) 0 Number and timing of application: <u>Dose rate</u> : 5.63 ml/m ³ . <u>Distribution time</u> : Aprox 0.4L/10 minutes. Thermonebuliser works at temperatures of 20°C - 30°C. The <u>droplet size</u> is between 0.2 and 0.4 µm. Ready to use product. <u>Frequency of application</u> : weekly or monthly depending on the protocols of the applicator.

Category(ies) of users	professional
Pack sizes and packaging material	Jerry can 10 L HDPE

4.2.1. Use-specific instructions

See section General Directions for use

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

See section General Directions for use

4.2.4. 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 General Directions for use

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

See section General Directions for use

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

See section General Directions for use

5. GENERAL DIRECTIONS FOR USE¹

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.
- The product must be used in a device with the technical parameters:

- Thermonebulizer device
- Droplet size: 0.2-0.4µm
- Diffusion rate: approx 0.4L/10 minutes.

- The room must maintain a temperature of 20°C and RH of 56%.
- Room size: 30-150 m³

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 m³. The maximum concentration reached in treated room is 113 mg of active substance/m³.

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-life of glutaraldehyd 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 equipment.

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 select the day, working time and frequency of operation.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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.

5.2. Risk mitigation measures

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.

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.

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.

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.

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.