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SECTION 1: Identification of the substance/mixture and of the company/undertaking

Product identifier

Trade name

PRESEPT ™ Disinfectant Tablets

PRESEPT ™ Disinfectant Granules

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses of the substance or mixture

disinfectant

1.3 Details of the supplier of the safety data sheet

Address

Advanced Sterilization Products a division of Johnson & Johnson Medical Ltd. Pinewood Campus, Nine Mile Ride

Wokingham, Berkshire, UK

Telephone no. +44 (0)1344 871081 +44 (0)1344 871171 Fax no.

Information provided by / telephone

Technical Queries: +44 (0)1344 871081; UK Freephone: 0800 864060

Advice on Safety Data Sheet

contact@medgb.jnj.com

1.4 **Emergency telephone number**

01865 407333

SECTION 2: Hazards identification

Classification of the substance or mixture

Classification in accordance with Directive 67/548/EEC or 1999/45/EC

O; R8 R31

Xi; R36/37 N; R50/53

Classification information

Classification and labelling on the basis of results obtained from toxicological examinations.

2.2 Label elements

Labelling according to Directive 1999/45/EC

Hazard symbols







RG40 3EW

environment

R phrases

Contact with combustible material may cause fire.

31 Contact with acids liberates toxic gas. 36/37 Irritating to eyes and respiratory system.

50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic

environment.

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S phrases

2 Keep out of the reach of children.

8 Keep container dry.

24/25 Avoid contact with skin and eyes.

26 In case of contact with eyes, rinse immediately with plenty of water and seek medical

advice.

41 In case of fire and/or explosion do not breathe fumes.

61 Avoid release to the environment. Refer to special instructions/ Safety data sheets.

2.3 Other hazards

PBT assessment

The product is not considered to be a PBT.

vPvB assessment

The product is not considered to be a vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable. The product is not a substance.

3.2 Mixtures

Chemical characterization

Alkaline aqueous solution of amine with wetting and sequestering agents.

Hazardous ingredients

No	Substance name		Additional information		
	CAS / EC / Index /	Classification 67/548/EEC	Concentration	%-b.w.	
	REACH no				
1	troclosene sodium				
	2893-78-9	E; R2	50.00	%-b.w.	
	220-767-7	O; R8			
	613-030-00-X	Xn; R22			
	-	R31			
		Xi; R36/37			
		N; R50/53			
2	adipic-acid-				
	124-04-9	Xi; R36	22.50	%-b.w.	
	204-673-3				
	607-144-00-9				
	-				

Full Text for all R-phrases: pls. see section 16

No	Note	Specific concentration limits
1	G	R31: C >= 10%
		R22: C >= 10%
		R36/37: C >= 10%

Full text for the notes: pls. see section 16 "Notes relating to the identification, classification and labelling of substances ((EC) No 1272/2008, Annex VI)".

SECTION 4: First aid measures

4.1 Description of first aid measures

General information

In case of accident or if you feel unwell, seek medical advice immediately. Remove contaminated, soaked clothing immediately and dispose of safely.

After inhalation

Remove affected person from the immediate area. Ensure supply of fresh air. In case of breathing difficulties give oxygen.

After skin contact

Wash off immediately with soap and water. Consult a doctor if skin irritation persists.

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After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Seek medical assistance.

After ingestion

Seek medical advice immediately. Rinse mouth thoroughly with water. Drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

No data available.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Carbon dioxide; Water spray jet

Unsuitable extinguishing media

No data available.

5.2 Special hazards arising from the substance or mixture

In the event of fire, the following can be released: Carbon dioxide (CO2); Carbon monoxide (CO); Nitrogen oxides (NOx); chlorine compounds

5.3 Advice for firefighters

Product itself does not burn. Adapt extinguisher and fire-fighting measures to fire in the environment. Cool endangered containers with water spray jet. Fire-fighting operations, rescue and clearing work under effect of combustion and smoulder gases just may be done with breathing apparatus. Wear protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Refer to protective measures listed in sections 7 and 8. Ensure adequate ventilation. Avoid dust formation.

For emergency responders

No data available. Personal protective equipment (PPE) - see Section 8.

6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

6.3 Methods and material for containment and cleaning up

Take up mechanically. When picked up, treat material as prescribed under heading "Disposal considerations".

6.4 Reference to other sections

No data available.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Avoid the formation and deposition of dust. Provide good ventilation of working area (local exhaust ventilation, if necessary). Avoid contact with skin and eyes.

General protective and hygiene measures

Do not eat, drink or smoke during work time. Keep away from foodstuffs and beverages. Wash hands before breaks and after work. Provide eye wash fountain in work area. Do not inhale dust.

Advice on protection against fire and explosion

No special measures necessary.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Keep container tightly closed and dry in a cool, well-ventilated place.

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Requirements for storage rooms and vessels

Store product in closed containers.

Advice on storage assembly

Do not store together with: Acids; Alkalis; Reducing agents

7.3 Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No parameters available for monitoring.

8.2 Exposure controls

Appropriate engineering controls

No data available.

Personal protective equipment

Respiratory protection

If workplace exposure limits are exceeded, a respiration protection approved for this particular job must be worn. In case of dust formation, take appropriate measures for breathing protection in the event workplace threshold values are not specified.

Eye / face protection

Safety glasses (EN 166)

Hand protection

In case of intensive contact, wear protective gloves (EN 374). Sufficient protection is given wearing suitable protective gloves checked according to i.e. EN 374, in the event of risk of skin contact with the product. Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties). Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves. Protective gloves shall be replaced immediately when physically damaged or worn. Design operations thus to avoid permanent use of protective gloves.

Appropriate Material nitrile
Appropriate Material PVC

Other

Normal chemical work clothing.

Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form/Colour						
Tablets; granules						
white						
Odour						
amine-like						
Odour threshold						
No data available						
pH value						
Value	5.5	-	6.5			
Boiling point / boiling range						
No data available						
Melting point / melting range						
No data available						
Decomposition point / decomposition range						
Value	225	-	250	°C		

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Flash point

No data available

Auto-ignition temperature

No data available

Oxidising properties

No data available

Explosive properties

No data available

Flammability (solid, gas)

No data available

Lower flammability or explosive limits

No data available

Upper flammability or explosive limits

No data available

Vapour pressure

No data available

Vapour density

No data available

Evaporation rate

No data available

Relative density

No data available

Density

Value appr. 1.0

Solubility in water

Value>250g/lRemarkssoluble

Solubility(ies)

No data available

Partition coefficient: n-octanol/water

No data available

Viscosity

No data available

9.2 Other information

Other information

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

No data available.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Heat: Moisture

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10.5 Incompatible materials

Acids; Alkalis; Reducing agents

10.6 Hazardous decomposition products

Nitrous oxides (NOx); Amines; Chlorine compounds

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity			
LD50	>	2000	mg/kg
Species	rat		
Source	Manufacturer		

Acute dermal toxicity

No data available

Acute inhalational toxicity

No data available

Skin corrosion/irritation			
Source	Manufacturer		
Evaluation	non-irritant non-irritant		

Serious eye damage/irritation

Source Manufacturer Evaluation irritant

Respiratory tract irritation

Source Manufacturer Evaluation irritant

Respiratory or skin sensitisation

Route of exposure	Skin
Source	Manufacturer
Evaluation	non-sensitizing

Germ cell mutagenicity

No data available

Reproduction toxicity

No data available

Carcinogenicity

No data available

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Aspiration hazard

No data available

Other information

Exercise customary precautions when handling chemicals.

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SECTION 12: Ecological information

12.1 Toxicity

Fish toxicity		
No data available		

Daphnia toxicity No data available

Algae toxicity No data available

Bacteria toxicity No data available

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Results of PBT and vPvB assessment				
PBT assessment	The product is not considered to be a PBT.			
vPvB assessment	The product is not considered to be a vPvB.			

12.6 Other adverse effects

No data available.

12.7 Other information

ar other information				
Other information				
Ecological data are not available.				
Do not allow to enter soil, waterways or waste water canal.				

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Allocation of a waste code number, according to the European Waste Catalogue, should be carried out in agreement with the regional waste disposal company.

Packaging

Residuals must be removed from packaging and when emptied completely disposed of in accordance with the regulations for waste removal. Incompletely emptied packaging must be disposed of in the form of disposal specified by the regional disposer.

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SECTION 14: Transport information

14.1 Transport ADR/RID/ADN

The product is not subject to ADR/RID/ADN regulations.

14.2 Transport IMDG

The product is not subject to IMDG regulations.

14.3 Transport ICAO-TI / IATA

The product is not subject to ICAO-TI / IATA regulations.

14.4 Other information

Independent tests, carried out by TNO Prins Mauritis Laboratory, according to United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria, third revised edition, test O.1. has demonstrated that these products are not oxidising for transport.

Furthermore, based on a bridging formula from section 2.9 of the UN Model Regulations 2011 the tablet mixture is not characterized as an acute aquatic hazard.

14.5 Environmental hazards

Information on environmental hazards, if relevant, pls. see 14.1 - 14.3.

14.6 Special precautions for user

No data available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture <u>EU regulations</u>

Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

Remarks

Annex I, part 2, category 3

15.2 Chemical safety assessment

No data available.

SECTION 16: Other information

Sources of key data used to compile the data sheet:

EC Directive 67/548/EC resp. 1999/45/EC as amended in each case.

Regulation (EC) No 1907/2006 (REACH), 1272/2008 (CLP) as amended in each case.

EC Directives 2000/39/EC, 2006/15/EC, 2009/161/EC

National Threshold Limit Values of the corresponding countries as amended in each case.

Transport regulations according to ADR, RID, IMDG, IATA as amended in each case.

The data sources used to determine physical, toxic and ecotoxic data, are indicated directly in the corresponding chapter

Full text of the R-, H- and EUH- phrases drawn up in sections 2 and 3 (provided not already drawn up in these sections)

R2 Risk of explosion by shock, friction, fire or other sources of ignition.

R22 Harmful if swallowed. R36 Irritating to eyes.

Notes relating to the identification, classification and labelling of substances and mixtures ((EC) No 1272/2008, Annex VI)

This substance may be marketed in an explosive form in which case it must be evaluated

using the appropriate test methods. The classification and labelling provided shall reflect

the explosive properties.

EC safety data sheet

ADVANCED STERILIZATION PRODUCTS

a Johnson Johnson company

Trade name: PRESEPT ™ Disinfectant Tablets

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Department issuing safety data sheet

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This information is based on our present state of knowledge and experience.

The security data sheet describes products with a view to the security requirements.

However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.