

Material Safety Data Sheet

MIS Detergent

1: Identification of the substance/mixture and of the company undertaken

1.1 Product identifier

Name: Getinge Clean MIS Detergent (PF-094)

Order no: 6001069200

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

A biofilm-removal enzymatic detergent for use in washer disinfectors, ultrasonic baths and the manual cleaning of medical devices. Specially formulated to clean complex minimally invasive surgical instruments. Suitable for use on water resistant surfaces such as stainless steel, ceramics, glass, plastics and soft metals.

1.3 Details of the supplier of the Safety Data Sheet

Supplier:

Getinge Disinfection AB, Ljungadalsgatan 11, Box 1505, SE-351 15 Växjö, Sweden Phone: +46 (0)10 335 98 00 Web: http://www.getinge.com

E-mail: info@getinge.com

1.4 Emergency telephone number

For emergency event of spillage, inhalation or ingestion of products, please contact the emergency hotline:

EU: +44 (0) 1235 239 670 Australia: +61 2801 44558 Japan: +81 345 789 341 China: +86 10 5100 3039

Middle East: +44 (0) 1235 239 671

2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP]

Not classified as hazardous.

2.1.2 Classification according to Directive 67/548/EEC (see SECTION 16 for full text of risk phrases) Not classified as hazardous.

2.1.3 Additional information:

For full text of R-phrases and Hazard- and EU Hazard-statements: see SECTION 15 and SECTION 16

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms:

Signal word:

Danger:

None

None

None

Hazard statements:

None

2.3 Other hazards

Contains enzymes. May produce an allergic reaction.



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3: Composition/information on ingredients

Material CAS number Level Hazards (see section 16)

No hazardous ingredients at reporting threshold.

4: First aid measures

4.1 Description of first aid measures

Eye contact: Rinse with plenty of running water for at least 10 minutes. Seek medical

attention if symptoms occur.

Skin contact: Remove contaminated clothing, wash skin with water and seek medical

attention if symptoms occur.

Inhalation: Remove to fresh air.

Seek medical attention if symptoms occur.

Ingestion: Do not induce vomiting. If conscious, give water to rinse mouth and one or two

glasses of water to drink. Contact a doctor or a Poisons Information Centre.

4.2 Most important symptoms and effects, both acute and delayed

Unknown

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically

5: Fire fighting measures

Not applicable

6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment.

6.2 Environmental precautions

Not applicable

6.3 Methods and material for containment and cleaning up

Absorb spill with inert material. Spill area should be flushed with water to sewer (avoid high pressure rinsing). Do not use cleaning methods that generate aerosol. Spilled concentrate should be removed as soon as possible to avoid drying and formation of dust. Rinse with excess water.



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7: Handling and storage

Shelf life: 36 months from the manufacturing date.

7.1 Precautions for safe handling

Working processes must be organized in a manner that prevents the inhalation of aerosols and mists or skin and eye contact.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry place protected from frost heat and direct sunlight away from acids and strong oxidizing agents. Store upright in original containers. Keep container closed when not in use. Storage temperature 5 – 25 °C.

7.3 Specific end use(s)

Not applicable

8: **Exposure controls/personal protection**

8.1 **Control parameters**

Workplace exposure limits Borate ion: 1 mg/m³ 1 mg/m³ WEL 8 hour TWA 0.04 µg/m³ WEL 8 hour TWA Subtilisin 0.06 µg/m³ WEL 8 hour TWA Cellulase 0.06 μg/m³ WEL 8 hour TWA Lipase 0.06 μg/m³ WEL 8 hour TWA Amylase

8.2 **Exposure controls**

These measures are recommended on the basis of common application methods and may not be appropriate to all potential applications of the product. The user is responsible for carrying out a full risk assessment for their specific processes and systems of work.

Eye protection: Wear eye protection to EN 166 1F if splashing is likely.

Hand protection: Wear nitrile or neoprene gloves. Exact choice of glove depends on specific

risk assessments.

Body protection: As necessary to prevent contact.

Respiratory

protection: Use in a well ventilated area. Avoid breathing vapour or spray. Wear a respirator

if necessary.

Other protection: N/A

Personal protective equipment:





Exact PPE requirements should be determined from a specific risk assessment of the processes being carried out.

Environmental protection: N/A



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9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:

Odour:

Odour threshold:

Paint odour

Not applicable

7.6 – 9.0

Boiling point:

Melting point:

Not applicable

Not applicable

Flash point:

Flash point:

Not applicable

Evaporation rate:

Not applicable

Not applicable

Not applicable

Upper/lower flammability or

explosive limits: Not applicable
Auto-ignition temperature: Not applicable
Explosive properties: Not applicable

Oxidising properties: None

Decomposition temperature
Vapour pressure:

Vapour density:

Relative density at 20 °C:

Not applicable
Not applicable
1.05 – 1.12

Solubility: Easily soluble in water

Partition coefficient: n-octanol/water Not applicable

Viscosity: Less than 10 cSt

10: Stability and reactivity

10.1 Reactivity

Not reactive

10.2 Chemical stability

The mixture is stable at normal ambient temperature (5 – 25 °C).

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Storing at temp above +25 °C.

10.5 Incompatible materials

Incompatible with oxidising agents and acids.

10.6 Hazardous decomposition products

Does not decompose when used as intended.



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11: Toxicological information

Eye contact: No known significant effects or critical hazards.

Skin contact: No known significant effects or critical hazards. May cause irritation in

sensitized individuals.

Inhalation: Not a hazard in normal use. Breathing spray mist may cause irritation.

Ingestion: Exposure can cause nausea, headache and vomiting.

Long term: Based on current knowledge, no long term effects are anticipated if

used as recommended

12: Ecological information

12.1 Toxicity

Not classified as dangerous for the environment.

12.2 Persistence and degradability

Excipients contained in this preparation comply with the biodegradability criteria laid down in Regulation (EC) No 648/2004 on detergents.

12.3 Bioaccumulative potential

Unknown

12.4 Mobility in soil

Unknown

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed as PBT or vPvB.

12.6 Other adverse effects

No other adverse effects are anticipated.

13: Disposal considerations

Waste treatment methods

Disposal of unwanted product should be done in accordance with local, state or national legislation. Do not reuse product containers. Empty containers are 100% recyclable. Could be disposed of to landfill or incinerated where permitted.

14: Transport information

Transport Classification: Not Classified UN Number: Not Classified Transport Class: Not Classified Packing Group: Not Classified



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15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Contents according to (EC) regulation No.648/2004 on detergents:

Anionic surfactants: <10% Nonionic surfactants: <10%

Enzymes Preservative

15.2 Chemical Safety Assessment

Product safety phrases

S24/25 Avoid contact with skin and eyes.

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S28 After contact with skin, wash immediately with plenty of water.

16: Other information

R phrases relating to ingredients (see section 3).

None allocated

This product should be stored, handled and used in accordance with good industrial practice and in conformity with legal regulations. The information in this data sheet is based on the present state of our knowledge and is intended to describe products from the point of view of safety requirements and thus should not be construed as guaranteeing specific properties. It is for users to satisfy themselves of the suitability of this product for their own applications.

Always consult and follow manufacturer's recommendations for the reprocessing of medical devices as per EN ISO 17664.

In accordance with COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Annex II.