
Getinge Clean Prion Detergent

According to Regulation (EC) No. 453/2010

Safety Data Sheet

GETINGE
GETINGE GROUP

6001615302_MSDS Prion detergent_EN_rev.A

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

1.1	Product Identifier Product form Trade name	Liquid Mixture GETINGE CLEAN PRION DETERGENT (PF-023)
1.2		Relevant identified uses of the substance or mixture and uses advised against.
1.2.1		Relevant identified uses. A prion deactivation enzymatic detergent biofilm-removal for cleaning medical instruments in washer disinfectors, ultrasonic baths and the manual cleaning of medical instruments. Suitable for use on water resistant surfaces such as stainless steel, ceramics, glass, plastics and soft metals.
1.2.2		Uses advised against. No additional information available.
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 Manufacturer: Novapharm Research Australia Pty Limited 3-11 Primrose Ave, Rosebery NSW 2018 Phone: (02) 9662 4033
1.4	Emergency telephone number:	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 New Zealand: +64 9929 1483

SECTION 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, P,S -phrases and Hazard- and EU Hazard-statements: see SECTION 15.2 and SECTION 16.
2.2	Label elements	Labelling according to Regulation (EC) No 1272/2008 [CLP] Hazard pictograms: None required Signal word: None required Danger: None Hazard statements: None Precautionary statements (CLP): P261 - Avoid breathing mist, spray, vapours. P262 - Do not get in eyes, on skin, or on clothing P281: Use personal protective equipment as required
2.3	Other hazards	Contains enzymes. May produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.1 Substance: Not applicable

3.2 Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Subtilisins (Protease)	CAS no. 9014-01-1 EC no. 232-752-2 EC Index no 647-012-00-8	<1%	Skin Irrit.2, H315 Eye Dam.1, H318 Resp.Sens.1, H334 STOT SE3, H335
Lipase (Triacyl glycerol)	CAS no. 9001-62-1 EC no. 232-619-9	<1%	Not classified
Lipase (Triacyl glycerol)	CAS no. 9000-90-2 EC no. 232-565-6 EC Index no. 647-015-00-4	<1%	Resp.Sens.1, H334
Cellulase	CAS no. 9012-54-8 EC no. 232-734-4 EC Index no. 647-002-00-3	<1%	Resp.Sens.1, H334
Ingredients determined not to be hazardous	NA	To 100%	-

Name	Product identifier	%	Classification according to Directive 67/548/EEC (DSD Classification)
Subtilisins (Protease)	CAS no. 9014-01-1 EC no. 232-752-2 EC Index no 647-012-00-8	<1%	Xi, R-37/38-41, R-42
Lipase (Triacyl glycerol)	CAS no. 9001-62-1 EC no. 232-619-9	<1%	Not classified
Amylase, α -	CAS no. 9000-90-2 EC no. 232-565-6 EC Index no. 647-015-00-4	<1%	R-42
Cellulase	CAS no. 9012-54-8 EC no. 232-734-4 EC Index no. 647-002-00-3	<1%	R-42
Ingredients determined not to be hazardous	NA	To 100%	-

SECTION 4: First Aid

4.1	Description of first aid measures	
	First - aid measures general:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
	First - aid measures after inhalation:	Remove patient to fresh air and keep at rest in a position comfortable for breathing. If not breathing, give artificial respiration. Get medical attention.
	First-aid measures after skin contact:	Remove contaminated clothing, wash skin with water and seek medical attention if symptoms occur.
	First-aid measures after eye contact:	Rinse with plenty of running water for at least 10 minutes. Seek medical attention if symptoms occur.
	First-aid measures after 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	
	Symptoms/injuries:	May cause eye and skin irritation.
	Symptoms/injuries after inhalation:	In case of repeated or prolonged exposure: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation.
	Symptoms/injuries after skin contact:	May cause skin irritation.

Symptoms/injuries after eye contact: May cause eye irritation.

Symptoms/injuries after ingestion: May cause gastrointestinal disturbance.

4.3 Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: Fire Fighting Measures

5.1 Extinguishing media Product is not combustible. Use extinguishing media appropriate for primary source of fire.

5.2 Special hazards arising from the substance or mixture Hazardous decomposition products may be released during prolonged heating: smoke, carbon monoxide and carbon dioxide.

5.3 Advice for firefighters: Advice for firefighters:

Protective equipment for firefighters: Use self- contained breathing apparatus. Do not enter fire area without proper protective equipment, including respiratory protection. Wear a self-contained breathing apparatus.

Other information: Hazardous decomposition products may be released during prolonged heating at temperatures exceeding 100C - smokes, carbon monoxide and dioxide.

SECTION 6: Accidental Release Measures

6.1	Personal precautions, protective equipment and emergency procedures General measures:	P281 - Use personal protective equipment as required. P261 - Avoid breathing mist, spray, vapours. P262 - Do not get in eyes, on skin, or on clothing.
6.1.1	For non-emergency personnel Protective equipment: Emergency procedures:	Wear protective gloves and eye/face protection. For further information refer to Section 8 "Exposure controls/personal protection". Stop leak if safe to do so. Evacuate unnecessary personnel.
6.1.2	For emergency responders Protective equipment: Emergency procedures:	Equip cleanup crew with protection equipment specified in Section 8. Ventilate area
6.2	Environmental precautions	Not applicable
6.3	Methods and material for containment and cleaning up	Methods for cleaning up: Avoid high pressure rinsing. Do not use cleaning methods that will generate aerosol. Spilled concentrate should be removed as soon as possible. Comply with applicable local, national and international regulation. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials. Residue may be washed down with water. Product may be flushed to a sanitary sewer with copious amounts of water, if in accordance with local, state or national legislation.
6.4	Reference to other sections	See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and Storage

7.1	Precautions for safe handling	<p>Precautions for safe handling:</p> <p>Working processes must be organized in a manner that prevents the inhalation of aerosols and mists or skin and eye contact. Product for hospital and professional use only. Read label and SDS before use. Provide good ventilation in process area to prevent buildup of vapour. Avoid all eye and skin contact and do not breathe vapour and mist. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.</p> <p>Hygiene measures:</p> <p>Take care for general good hygiene and housekeeping. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product.</p>
7.2	Conditions for safe storage, including any incompatibilities	<p>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.</p>
7.3	Specific end use(s)	<p>No additional information.</p>
	Directions:	
	For manual and automated cleaning:	<p>Dose: 1–5 ml/lit.</p> <p>Cleaning temp: 50–70 °C (Automated) or 30–50 °C (Manual. Always keep sharp instrument points inside basket to minimise risk of injuries).</p> <p>Time: >3 min.</p>
	For routine prion deactivation* (recommended for all instruments):	<p>Dose: 4–10 ml/lit.</p> <p>Cleaning temp: 60–70 °C</p> <p>Time: = 10 min.</p>
	For complete prion deactivation* (for high risk instruments):	<p>Dose: 4–10 ml/lit.</p> <p>Cleaning temp: 60–70 °C</p> <p>Time: = 30 min. Followed by autoclaving at ≥ 121 °C.</p>
		<p>*WHO recommends combining of at least two prion inactivating methods. Check material compatibility before use. Do not mix with other chemicals.</p>

SECTION 8: Exposure Control and Personal Protection

8.1 Control parameters

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

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

SECTION 9: Physical and chemical Properties

9.1 Information on basic physical and chemical properties

Appearance:	Blue liquid
Odour:	Faint odour
Odour threshold:	Not applicable
pH as supplied (typical):	7.6–8.5
Boiling point:	>100 °C
Melting point:	Not applicable
Flash point:	Not applicable
Evaporation rate:	Not applicable
Flammability:	Not applicable
Upper/lower flammability or explosive limits:	Not applicable
Auto-ignition temperature:	Not applicable
Explosive properties:	Not applicable
Oxidising properties:	Not applicable
Decomposition temperature:	None
Vapour pressure:	Not applicable
Vapour density:	No data
Relative density at 20 °C:	Not applicable
Solubility:	1.05 – 1.12
Partition coefficient:	Easily soluble in water
Viscosity:	n-octanol/water Not applicable
	Less than 10 cSt

9.2 Other information No additional information available.

SECTION 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. Storing at temp below -5 °C.
10.5	Incompatible materials	Incompatible with oxidising agents and acids.
10.6	Hazardous decomposition products	Does not decompose when used as intended.

SECTION 11: Toxicological Information

Eye contact:	Not classified Based on available data, the classification criteria are not met, no known significant effects or critical hazards.
Skin contact:	Not classified Based on available data, the classification criteria are not met. No known significant effects or critical hazards. May cause irritation in sensitized individuals.
Inhalation:	Not classified Based on available data, the classification criteria are not met. Not a hazard in normal use. Breathing spray mist may cause irritation.
Ingestion:	Not classified Based on available data, the classification criteria are not met. Exposure can cause nausea, headache and vomiting.
Respiratory/skin sensitisation:	Not classified Based on available data, the classification criteria are not met. May cause allergy reaction to sensitized individuals.
Long term:	Based on current knowledge, no long term effects are anticipated if used as recommended.
Germ cell mutagenicity:	Not classified Based on available data, the classification criteria are not met.
Carcinogenicity:	Not classified Based on available data, the classification criteria are not met.

Reproductive toxicity:	Not classified Based on available data, the classification criteria are not met.
Specific target organ toxicity (single exposure):	Not classified Based on available data, on criteria are not met.
Aspiration hazard:	Not classified Based on available data, the classification criteria are not met.
Potential Adverse human health effects and symptoms:	May be harmful if swallowed, in contact with skin and eyes and if inhaled.

SECTION 12: Ecological Information

12.1	Toxicity	Not classified as dangerous for the environment.
12.2	Persistence and degradability	Ingredients contained in this preparation comply with the biodegradability criteria of Regulation (EC) No 648/2004 on detergents.
12.3	Bioaccumulative potential	Unlikely
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.

SECTION 13: Disposal Considerations

Waste treatment methods

Disposal of unwanted product should be done in accordance with local, state or national legislation. Empty containers should be rinse with large quantity of water, and can be reused or recycled. Could be disposed of to landfill or incinerated where permitted. Avoid release to the environment.

SECTION 14: Transport Information

14.1 Transport Classification: Not Classified as Dangerous goods.

14.2 UN Number and shipping name: Not Classified

14.3 Transport Class: Not Classified

14.4 Packing Group: Not Classified

14.5 Environmental hazards: Not Classified

14.6 Special precautions for user

14.6.1 Overland Transport category (ADR): Non-hazardous

14.6.2 Transport by sea IMDG Class: Non-hazardous

14.6.3	Air transport ICAO/ IATA Class:	Non-hazardous
14.6.4	Inland waterway transport	No additional information available.
14.7	Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable

SECTION 15: Regulatory Information

15.1	Safety, health and environmental regula- tions/legislation specific for the sub- stance or mixture	<p>Contents according to (EC) regulation No.648/2004 on detergents: Anionic surfactants: 10–20% Nonionic surfactants: <10% Enzymes</p> <p>The formulation contains boron compounds at the combined level below the specific concentration limit of the relevant classification criteria as per (EC) No. 1272/2008.</p>
15.2	Chemical Safety Assessment	<p>Not classified as hazardous according to GHS classification.</p> <p>Not classified as hazardous according to CLP classification.</p> <p>Not classified as hazardous according to DSD classification</p> <p>Product safety phrases P261 - Avoid breathing mist, spray, vapours.</p> <p>P262 - Do not get in eyes, on skin, or on clothing.</p> <p>P281 - Use personal protective equipment as required.</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>P303+P361+P353 – If on skin (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.</p> <p>P312 – Call a POISON CENTER or doctor/physician if you feel unwell.</p> <p>P332+P313 - If skin irritation occurs: Get medical advice/attention.</p> <p>P410 - Protect from sunlight.</p> <p>P411 - Store at temperatures not exceeding 25 °C/77 °F.</p>

SECTION 16: Other Information

Definitions of Risk and Safety phrases in this document:

R-37	Irritating to respiratory system
R-38	Irritating to skin
R-41	Risk of serious damage to eyes
R-42	Risk of serious damage to eyes

Definition of Hazard statement codes:

H315	Causes skin irritation
H318	Causes serious eye damage
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation

"The information on this data sheet represents our current data and best opinion as to the proper use in handling of this product under normal conditions. Any use of the product which is not in conformance with this data sheet, which involves using the product, or otherwise that in accordance with instructions of use on product packaging is the responsibility of the user. If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact Novapharm Research Australia Pty Ltd, on +61 2 96624033.

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END

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GETINGE GROUP

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