Getinge Clean

Prion Detergent

SECTION 1: Identification of the substance/mixture and company

1.1 Product identifier

Product name: **Prion Detergent**

Product form: Liquid Mixture

1.2 Product uses

Multi-enzyme cleaning detergent for the cleaning of medical and dental instents including flexible endoscope with Prion deactivation.

1.3 Supplier

Details of the supplier of the Safety Data Sheet.

Supplier:
Novapharm Research Australia Pty Limited,
3-11 Primrose Ave, Rosebery, NSW 2018, Australia
Phone: +61 2 9662 4033

1.4 Emergency telephone number

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

+61 417 217 473

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1

Classification according to GHS:
Reproductive Toxicity category 1

2.1.2

Classification according to Work Safe Australia:
Reproductive Toxicity category 1

2.1.3

Additional information:
For full text of Hazard-statements: see SECTION 16

2.2 Label elements

Labelling according to GHS.

Pictogram:	
Signal word:	DANGER

Hazard statements:

H360:	May damage fertility or the unborn child on ingestion.

Precautionary statements:

P202:	Do not handle until all safety precautions have been read and understood.
P261:	Avoid breathing mist, spray and vapours.
P262:	Do not get in eyes, on skin, or on clothing.
P280:	Wear protective gloves. Wear eye protection.
P308+P313:	IF exposed or concerned: Get medical advice/attention.
P405:	Store locked up.
P501:	Dispose of contents/container to an approved waste disposal plant.

2.3 Other hazards

Contains enzymes. May produce an allergic reaction on prolonged contact.

SECTION 3: Composition and information on ingredients

3.1 Substance

Not applicable.

3.2 Mixture

Material	Product identifier	%	Classification according GHS
Subtilisins (Protease)	CAS no. 9014-01-1 EC no. 232-752-2 EC Index no 647-012-00-8	0.1 – 0.2%	Skin Irrit.2, H315 Eye Dam.1, H318 Resp.Sens.1, H334 STOT SE3, H335 **Not classified at this concentration**
Lipase (Triacylglycerol)	CAS no. 9001-62-1 EC no. 232-619-9	0.001 – 0.002%	Not classified
Amylase, α	CAS no. 9000-90-2 EC no. 232-565-6 EC Index no. 647-015-00-4	0.05 -0.1%	Resp.Sens.1, H334 **Not classified at this concentration**
Cellulase	CAS no. 9012-54-8 EC no. 232-734-4 EC Index no. 647-002-00-3	0.001 – 0.002%	Resp.Sens.1, H334 **Not classified at this concentration**
Sodium tetraborate ecahydrate	CAS no 1303-96-4	2 - 4%	Repr. 1B., H360
Ingredients determined not to be hazardous	N/A	To 100%	-

SECTION 4: First aid

4.1 Description of 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).
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.
Skin contact:	Remove contaminated clothing, wash skin with water and seek medical attention if symptoms occur.
Eye contact:	Rinse with plenty of running water for at least 10 minutes. Seek medical attention if symptoms occur.
Swallowed:	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 damage fertility or the unborn child on ingestion.
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. May damage fertility or the unborn child.

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:

Exercise caution when fighting any chemical fire.

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 100°C - smokes, carbon monoxide and dioxide.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

General measures:
P280 - Wear protective gloves and eye/face protection, see section 8.
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:
Wear protective gloves and eye/face protection. For further information refer to Section 8 "Exposure controls/ personal protection".

Emergency procedures:
Stop leak if safe to do so. Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment:
Equip clean-up crew with protection equipment specified in Section 8.

Emergency procedures:
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

Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling:
Working processes must be organised 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.

Hygiene measures:
Take care for general good hygiene and housekeeping. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product.

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 oxidising agents. Store upright in original containers. Keep container closed when not in use. Storage temperature 5 – 25 °C.

7.3. Specific end use(s)

No additional information.

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 – 9.0
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:	None
Decomposition temperature:	Not applicable
Vapour pressure:	No data
Vapour density:	Not applicable
Relative density at 20 °C:	1.05 – 1.12
Solubility:	Easily soluble in water
Partition coefficient:	n-octanol/water Not applicable
Viscosity:	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.

10.5 Incompatible materials

Incompatible with oxidising agents and acids.

10.6 Hazardous decomposition products

Does not decompose when used as intended.

SECTION 11: Physical and chemical properties

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 sensitised 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 sensitised 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:	According to CLP Annex VI ATP17, may damage fertility or the unborn child on ingestion. Not classified in previous ATPs of CLP Annex VI. Chronic - Reproduction Animal feeding studies in rat, mouse and dog, at high doses, have demonstrated effects on fertility and testes. Studies in rat, mouse and rabbit, at high doses, demonstrate developmental effects on the foetus including foetal weight loss and minor skeletal variations. The doses administered were many times in excess of those which humans would normally be exposed to. While boron has been shown to adversely affect male reproduction in laboratory animals, there is no clear evidence of male reproductive effects attributable to boron in studies of highly exposed workers. An epidemiology study under the conditions of normal occupational exposure to borate dusts indicated no effect on fertility. Human epidemiological studies show no increase in pulmonary disease in occupational populations with chronic exposures to borate dusts. A study conducted in Turkey with boron exposed mine workers showed that mean blood concentrations of the high exposure group is ~6 times and ~9 times lower than those of the highest no effect level of boron in blood with regard to developmental and reprotoxic effects (respectively) in rats. With those findings, no unfavourable effects of boron exposure on reproductive indicators are observed in humans.
Specific target organ toxicity (single exposure):	Not classified Based on available data, the classification 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

13.1 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 regulations/legislation specific for the substance or mixture

Contents according to (EC) regulation No.648/2004 on detergents:
Anionic surfactants: 10-20%
Nonionic surfactants: <10%
Enzymes

15.2 Chemical Safety Assessment

May damage fertility or the unborn child. This classification was based on oral tox research study on mice. The diluted product in use is not classified as hazardous.

Product safety phrases:

P202	Do not handle until all safety precautions have been read and understood.
P261	Avoid breathing mist, spray, vapours.
P262	Do not get in eyes, on skin, or on clothing.
P280	Wear protective gloves. Wear eye protection.
P305+P351+P338	If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353	If on skin (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P405	Store locked up.
P410	Protect from sunlight.
P411	Store at temperatures not exceeding 25°C/77°F.
P501	Dispose of contents/container to an approved waste disposal plant.

SECTION 16: Other information

GHS Hazard statements on ingredients:

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.
H360	May damage fertility or the unborn child on ingestion.

Date of issue:
29/3/2023

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.

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