

Getinge Clean Manual Plus

SECTION 1: Identification of the substance/mixture and company

1.1 Product identifier

Product code: Name: PF-126 Getinge Clean Manual Plus

1.2 Product uses

A quadruple enzymatic detergent with powerful cleaning and sanitizing action. For use in ultrasonic and manual cleaning of all medical devices including flexible endoscopes.

1.3 Supplier

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: www.getinge.com E-mail: info@getinge.com

| Supplier Australia: |
|---------------------------|
| Getinge Australia Pty Ltd |
| 1/160 Lytton Road |
| Morningside, QLD 4170 |
| Australia |
| Phone: 1800 438 464 |
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1.4 Emergency telephone number

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

EU: +44 1235 239670 Australia: +61 2 8014 4558 Japan: +81 3 4578 9341 China: +86 512 8090 3042 Middle East: +44 1235 239671 New Zealand: +64 9 929 1483

SECTION 2: Hazards identification (undiluted product)

2.1 Classification of the substance or mixture

According to 1272/2008

Health hazards:

Eye irritant category 2.

For full text of H, P, -phrases and Hazard and EU Hazardstatements: see Section 15 and 16.

2.2 Label elements

According to 1272/2008

Warning



| H319 | Causes serious eye irritation. |
|------|--|
| P261 | Avoid breathing mist, spray and vapours. |
| P280 | Wear gloves and eye protection. |

2.3 Other hazards

Contains enzymes. May produce an allergic reaction.

SECTION 3: Composition/information on ingredients

| Material | CAS number | Level | Hazards (see section 16) |
|-------------------------|------------|---------|---------------------------------------|
| Alkoxylated alcohol | 68937-66-6 | 1-5 % | Not classified at this concentration. |
| Boracic acid | 10043-35-3 | <0.5% | Repr. 1B, H360FD |
| | | | Not classified at this concentration. |
| Propylene Glycol | 57-55-6 | 1–5% | Not classified at this concentration. |
| Halal Kosher | | | |
| Protease as pure enzyme | 9014-01-1 | 0.1–1% | Skin Irrit. 2, H315 |
| protein | | | Eye Dam. 1, H318 |
| | | | Resp.Sens. 1, H334 |
| | | | STOT SE 3, H335 |
| | | | Not classified at this concentration. |
| Lipase as pure enzyme | 9001-62-1 | 0.1–1% | Not classified at this concentration. |
| protein | | | |
| Endocellulase as pure | 9012-54-8 | 0.1–1% | Resp. Sens. 1, H334 |
| enzyme protein | | | Not classified at this concentration. |
| Alpha-amylase as pure | 9000-90-2 | 0.1–1% | Resp. Sens. 1, H334 |
| enzyme protein | | | Not classified at this concentration. |
| C37H34N2Na2O9S3 Blue | 3844-45-9 | <0.01% | Not classified at this concentration. |
| Dye CI 42090 | | | |
| Benzalkonium chloride | 85409-22-9 | 1–5% | Eye Irrit. 2, H319 |
| | | | Aquatic Acute 1, H400 |
| | | | Aquatic chronic 1, H410 |
| Water | 7732-18-5 | To 100% | - |

SECTION 4: First aid measures

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 from contaminated area. Move to fresh air, rest patient. If required, seek medical advice. |
| Skin contact: | Remove contaminated clothing. Rinse skin with plenty of water. |
| Eye contact: | Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing. If eye irritation persists get medical advice/attention. |
| Ingestion: | Immediately rinse mouth and drink plenty of water. Seek medical attention if symptoms persist. |

4.2 Most important symptoms and effects, both acute and delayed

| Inhalation: | In case of repeated or prolonged exposure: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation. |
|---------------|---|
| Skin contact: | May cause skin irritation. |
| Eye contact: | May cause eye irritation. |
| Ingestion: | May cause gastrointestinal disturbance. |

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Fire fighting measures

Flammability hazard: Product is non-flammable. Will not promote combustion.

5.1 Extinguishing media

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

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 $^{\circ}$ C - smokes, carbon monoxide and dioxide.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

General measures: P280 - Wear gloves and eye protection. P261 - Avoid breathing mist, spray, vapours. P262 - Do not get in eyes, on skin, or on clothing.

6.1.1 For nonemergency personnel

Protective equipment: Wear protective gloves and eye/face protection. For further information refer to section 8. Emergency procedures: Stop leak if safe to do so. Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment: Equip cleanup crew with protection equipment specified in section 8. Emergency procedures: Ventilate area.

6.2 Environmental precautions

P273 - Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Place inert absorbent such as vermiculite, sand or dirt into material. Mop up the remaining material.

6.4 Reference to other sections

See section 8.

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

7.3 Product uses

Do not use in automated washers.

Always keep sharp instrument points inside basket to minimise risk of injuries.

Manual process:

Dose 2–20 ml of Manual Plus per litre of warm water (25–45 °C). Stir well. Submerge instruments in bath for 2–10 min. Brush if necessary. For optimal results discard at least every 2-3 hours.

Ultrasonic process:

Dose 2–20 ml of Manual Plus per litre of water (35–60 °C). Run ultrasonic bath for 2–10 min. For optimal results discard occasionally or at least every 8 hours.

SECTION 8: Exposure controls and personal protection

8.1 Control parameters

Workplace exposure limits: Subtilisins 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 vapours, mist or droplets. 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:

P273 - Avoid release to environment.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| Appearance: | A clear to slightly hazy blue liquid |
|--|--------------------------------------|
| Odour: | Faint odour |
| Odour threshold: | N/A |
| pH as supplied (typical): | 7.6–8.5 |
| Boiling point: | 100 °C |
| Melting point: | N/A |
| Flash point: | Non-flammable |
| Evaporation rate: | N/A |
| Flammability: | N/A |
| Upper/lower flammability or explosive limits: | N/A |
| Auto-ignition temperature: | N/A |
| Explosive properties: | N/A |
| Oxidising properties: | N/A |
| Decomposition temperature: | N/A |
| Vapour pressure: | Not available |
| Vapour density: | No data |
| Relative density at 20 °C: | 1.05–1.12 g/ml |
| Solubility: | Soluble in water |
| Partition coefficient: | Not available |
| Viscosity: | Not available |

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 $^\circ\text{C}).$

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 anions which can affect the product efficacy.

10.6 Hazardous decomposition products

Does not decompose when used as intended.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

| Eye contact: | H319 - Causes serious eye irritation. |
|--|---|
| 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 | Not classified. |
| exposure): | 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. May cause eye irritation. May cause allergic reaction when in contact with unprotected skin and if inhaled. |

SECTION 12: Ecological information

12.1 Toxicity

P273 - Avoid release to the environment.An ingredient of this preparation - Benzalkonium chloride is classified.Aquatic Acute 1. H400 - Very toxic to aquatic life.Aquatic Chronic 1. H410 - Very toxic to aquatic life with long lasting effects.

12.2 Persistence and degradability

Ingredients 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 contents/container in accordance with local/regional regulation. Dispose of via sewerage only ensuring the concentrated formulation does not enter waterways.

SECTION 14: Transport information

14.1 UN number

Not classified as dangerous goods.

14.2 UN proper shipping name

Not classified.

14.3 Transport hazard class(es)

Not classified.

14.4 Packing group

Not classified.

14.5 Environmental hazards

Not classified.

14.6 Special precautions for user

Overland Transport category (ADR): Not classified. Transport by sea IMDG Class: Not classified. Air transport ICAO/IATA Class: Not classified. Inland waterway transport: No additional information available.

14.7 Transport in bulk according to Annex II of MARPOL 7 3/78 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 Regulation (EC) No. 648/2004 on detergents:

Anionic surfactants: 10–20 %

Nonionic surfactants: <10 %

Enzymes

The formulation contains boron compounds at the combined level below the specific concentration limit of the relevant classification criteria as per Regulation (EC) No. 1272/2008.

15.2 Chemical safety assessment

Classified as hazardous according to GHS classification:

H319 - Causes serious eye irritation

Product safety phrases:

| P261 | Avoid breathing mist, spray, vapours. |
|--------------------|--|
| P262 | Do not get in eyes, on skin, or on clothing. |
| P280 | Wear gloves and 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 centre or doctor/physician if you feel unwell. |
| P332 + P313 | If skin irritation occurs: Get medical advice/attention. |
| P410 | Protect from sunlight. |
| P411 | Store at temperatures not exceeding 25 °C/77 °F. |
| | |

SECTION 16: Other information

Hazard statements relating to ingredients (see section 3).

| H315 | Causes skin irritation. |
|--------|--|
| H318 | Causes serious eye damage. |
| H319 | Causes serious eye irritation. |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H335 | May cause respiratory irritation. |
| H360FD | May damage fertility. May damage the unborn child. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |

Date of issue: 2019-02-27

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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