
According to: Regulation (EC) No. 453/2010

SECTION 1: Identification of the substance/mixture and company

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| 1.1 | Product Identifier Product form Trade name | Liquid Mixture GETINGE CLEAN MANUAL PLUS |
| 1.2 | Product Uses | Relevant identified uses of the substance or mixture and uses advised against. |
| 1.2.1 | | Relevant identified 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. |
| 1.2.2 | | Uses advised against. No additional information available. |
| 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 New Zealand: Getinge Australia (NZ Branch) Unit 4, 10 Cryers Road East Tamaki, Auckland Botany 2163 New Zealand Phone: +64 927 290 393 |
| | Manufacturer | Novapharm Research Australia Pty Limited 3-11 Primrose Ave, Rosebery NSW 2018 Phone: +61 29662 4033 |
| 1.4 | Emergency telephone number | For emergency event of spillage, inhalation or ingestion of products, please contact the emergency hotline: EU: +44 (0) 123 523 96 70 Australia: +61 280 144 558 Japan: +81 345 789 341 China: +86 105 100 30 39 Middle East: +44 (0) 123 523 96 71 New Zealand: +64 992 914 83 |

SECTION 2: Hazards identification

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| 2.1 | Classification of the mixture | Classification of the substance or mixture. |
| 2.1.1 | | Classification according to GHS, Regulation (EC) No 1272/2008 [CLP] Eye irritant category 2. |
| 2.1.3 | Additional information | For full text of H, P, -phrases and Hazard and EU Hazard- statements: see SECTION 15 and SECTION 16. |
| 2.2 | Label elements | Labelling according to GHS Regulation (EC) No 1272/2008 [CLP] Hazard pictograms: |



Signal word: Warning

Hazard statements:

H319 Causes serious eye irritation

Precautionary pictograms:



Precautionary statements (CLP):

P261 Avoid breathing mist, spray and vapours.

P280 Wear gloves and eye protection.

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| 2.3 | Other Hazards | Contains enzymes. May produce an allergic reaction. |
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SECTION 3: Composition/information on ingredients

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| 3.1 | Substance | Not applicable |
| 3.2 | Mixture | |

| Material | CAS number | Level | GHS/CLP (EC) No. 1272/2008 Classification |
|---|------------|---------|--|
| Alkoxyated 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 Halal Kosher | 57-55-6 | 1–5% | Not classified at this concentration |
| Protease as pure enzyme protein | 9014-01-1 | 0.1–1% | Skin Irrit. 2, H315 Eye Dam. 1, H318 Resp. Sens. 1, H334 STOT SE 3, H335 Not classified at this concentration |
| Lipase as pure enzyme protein | 9001-62-1 | 0.1–1% | Not classified at this concentration |
| Endocellulase as pure enzyme protein | 9012-54-8 | 0.1–1% | Resp. Sens. 1, H334 Not classified at this concentration |
| Alpha-amylase as pure enzyme protein | 9000-90-2 | 0.1–1% | Resp. Sens. 1, H334 Not classified at this concentration |
| C37H34N2Na2O9S3 Blue Dye CI 42090 | 3844-45-9 | <0.01% | Not classified at this concentration |
| 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
- 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 from contaminated area. Move to fresh air, rest patient. If required, seek medical advice.
- First-aid measures after skin contact: Remove contaminated clothing. Rinse skin with plenty of water.
- First-aid measures after 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.
- First-aid measures after 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
- 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

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| 5.1 | Extinguishing media | Product is non-flammable. Will not promote combustion. Use extinguishing media appropriate for primary source of fire. |
| 5.2 | Special hazards arising from the 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 °C - smokes, carbon monoxide and dioxide. |

SECTION 6: Accidental release measures

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| 6.1 | Personal precautions, protective equipment and emergency procedures | P280 Wear gloves and eye protection. P261 Avoid breathing mist, spray, vapours. P262 Do not get in eyes, on skin, or on clothing. |
| | General measures: | |
| 6.1.1 | For nonemergency 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 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. Exposure controls and personal protection. |

SECTION 7: Handling and storage

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| 7.1 | Precautions for safe handling | <p>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.</p> <p>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.</p> |
| 7.2 | Conditions for safe storage, including any incompatibilities | <p>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.</p> |
| 7.3 | Specific end use(s) Directions: For manual and ultrasonic cleaning: | <p>No additional information.</p> <p>Dose: 2–20 ml/lt. Cleaning temp: 25–45 °C (Manual) or 45–60 °C (Ultrasonic). Always keep sharp instrument points inside basket to minimise risk of injuries. Time: 2–10 min.</p> |

SECTION 8: Exposure controls/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

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| 9.1 | Information on basic physical and chemical properties | Appearance: | A clear to slightly hazy 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: | Non-flammable |
| | | Evaporation rate: | Not applicable |
| | | Flammability: | Not applicable |
| | | Upper/lower flammability or explosive limits: | Not applicable |
| | | Auto-ignition temperature: | Not applicable |
| | | Explosive properties: Oxidising | Not applicable |
| | | Properties: Decomposition | Not applicable |
| | | Temperature: Vapour pressure: | None |
| | | Vapour density: | Not available |
| | | 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

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| 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 anions which can affect the product efficacy. |
| 10.6 | Hazardous decomposition products | Does not decompose when used as intended. |

SECTION 11: Toxicological information

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| 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 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. May cause eye irritation. May cause allergic reaction when in contact with unprotected skin and if inhaled. |

SECTION 12: Ecological information

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| 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

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| 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. |
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SECTION 14: Transport information

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| 14.1 | UN number | Not Classified as Dangerous goods. |
| 14.2 | UN proper 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): | Not classified |
| 14.6.2 | Transport by sea IMDG Class: | Not classified |
| 14.6.3 | Air transport ICAO/ IATA Class: | Not classified |
| 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

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|------|---|---|
| 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 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. |
| 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 CENTER 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

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| Definition of Hazard statement codes: | H360FD May damage fertility. May damage the unborn child. H315 Causes skin irritation H319 Causes serious eye irritation H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled H335 May cause respiratory irritation H318 Causes serious eye damage H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects. "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. Date of revision: 13 April 2016 END |
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