

Getinge Clean

Prion Detergent

An enzymatic detergent for the deactivation of M1000-prions - the infectious agents of protein misfolding diseases such as Creutzfeldt Jacob Disease. The Getinge Clean Prion Detergent works by unfolding and cleaving prion proteins down to small peptide fragments, thus effectively inactivating the infectivity of the misfolded proteins.

The product has been rigorously tested against both animal and human prion strains selected for their resistance to common prion deactivation methods. The Getinge Clean Prion Detergent demonstrated superior prion deactivation compared to the WHO-recommended protocols (soaking in 1M NaOH for 1 hour and autoclaving at 134 °C for 18 min).

Getinge Clean Prion Detergent is compatible with all common instrument surfaces, stainless steel, ceramic, glass, plastic, rubber and soft metals such as aluminum. It is intended to be used in automated washer disinfectors, ultrasonic baths and manual cleaning procedures.



Directions for use

Always refer to the Safety Data Sheet and check material compatibility before use. Do not mix with other chemicals.

- 1. For instrument cleaning** (Routine instrument reprocessing). Dosage 3 to 5mL/litre. Temp: 55°C - 65°C.
Recommended contact time: Min 5 minutes.
- 2. For combined cleaning and greater than 2log reduction of prion titre***
Dosage: 4 to 10mL/litre. Temp: 60°C - 65°C Contact time: Min 10 minutes. Rinse well, follow by autoclaving when possible to achieve combined >4log reduction in prion titre.
- 3. For combined cleaning and complete deactivation of prions***
Dosage: 4 to 10mL/litre. Temp 60°C-65°C Contact time: Min 30 minutes. Rinse well. Autoclave: at least 20 minutes at 121°C to achieve complete M1000 prion deactivation.

*World Health Organisation recommends combination of at least two prion inactivating methods. Avoid heating detergent solutions above 70°C as enzymes are deactivated above this temperature.

Symbols



Getinge's range of detergents have been developed, tested and validated on Getinge washers to consistently meet ISO 15883 standards for cleaning efficacy of medical devices.

Ingredients

Protease, lipase, amylase and cellulase enzymes, surfactants, sequestering agents, corrosion inhibitors and sodium tetraborate decahydrate 2-4%.

Technical data

- **Specific gravity (20 °C):** 1.1
- **pH as supplied (typical):** 7.6 – 8.5
- **pH in 5ml /litre (typical):** 8 – 9.0
- **Viscosity (concentrate, 25 °C):** <10 cSt

Storage information

Store locked up, in a cool, dry place protected from frost, heat and direct sunlight away from corrosive chemicals and strong oxidising agents. Store upright in original containers. Keep container closed when not in use. Optimum storage temperature 15 – 20 °C.

Shelf life

24 months from the manufacturing date.

Safety and handling

Refer to Safety Data Sheet.

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

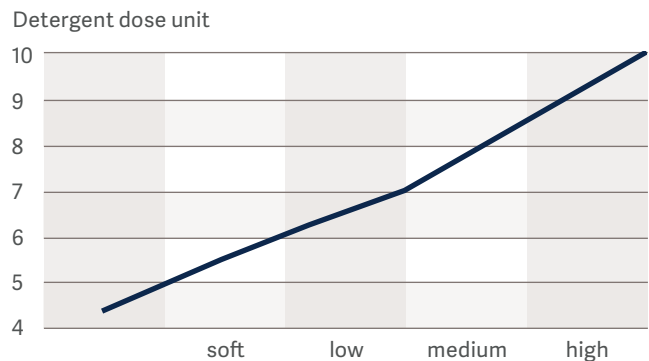
CE Mark

Conforms to the European directive 93/42/EEC, Annex 1 concerning medical devices.

Environmental awareness

Fully biodegradable formulation and recyclable packaging.

Water hardness and detergent dosing



Note: Water hardness is only one factor that influences the amount of detergent to be dosed.

Other factors to be considered include:

- Duration of cleaning cycle
- Temperature
- Soil type, amount and condition e.g. dry
- Materials compatibility












Service

For technical support in regards to appropriate detergent dosing and optimisation of your cleaning processes, please contact your local Getinge representative.



Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Contains enzymes. May produce an allergic reaction
Cleaning and prionocidal efficacy is not guaranteed if the mix is reused.

	Aluminum	Anodized aluminium	Titanium	Non ferrous metals	Machrome plated	Stainless steel	Glass	Ceramics	Rubber	Plastic
 Getinge Clean Pre-treatment Foam	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
 Getinge Clean Manual Pro +	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
 Getinge Clean Enzymatic Plus	✓	✓	✓	✓	✓	✓	✓	✓	✓	M
 Getinge Clean Universal Detergent	M	M	M	M	✓	✓	✓	✓	✓	M
 Getinge Clean Prion Detergent	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
 Getinge Clean Neutralizer	M	M	✓	✓	✓	✓	✓	✓	M	M
 Getinge Clean Neutralizer Plus	-	-	M	M	M	✓	✓	M	M	M
 Getinge Clean Instrument Lubricant	✓	✓	✓	✓	✓	✓	-	-	-	-
 Getinge Clean Instrument Lubricant Plus	✓	✓	✓	✓	✓	✓	-	-	-	-
 Getinge Clean Rinse Aid	✓	✓	✓	✓	✓	✓	✓	✓	M	M
 Getinge Clean Chamber Foam	-	-	-	-	-	✓	-	-	-	-

✓ = The product is suitable for the material

- = The product is not suitable for the material

M = Pay special attention to the guidelines from the instruments/items manufacturer

This chart is only a guideline and information on the reprocessing of medical devices from the manufacturer according to EN ISO 17664 must always be followed.


Ordering information

Product Description	Order Number
Getinge Clean Prion Detergent 205L	6001600203

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