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

1.1. Product identifier

Prontoderm Shower Gel

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture

For body decolonization including MDRO (MRE) by physical cleansing
[MDRO: Multi-Drug-Resistant-Organisms]

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name:	B. Braun Medical AG
Street:	Seesatz 17
Place:	CH-6204 Sempach
Responsible Department:	Zentrale Service-Bereiche / Logistik und Supply Chain Telephone: +49 (0) 5661 / 71-4422 E-Mail: logistics.service@bbraun.com Responsible for the safety data sheet: sds@gbk-ingelheim.de

Supplier

Company name:	B. Braun Melsungen AG
Street:	Carl-Braun-Straße 1
Place:	D-34212 Melsungen
Responsible Department:	Zentrale Service-Bereiche / Logistik und Supply Chain Telephone: +49 (0) 5661 / 71-4422 E-Mail: logistics.service@bbraun.com

1.4. Emergency telephone number: INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)
England and Wales: NHS Direct - 0845 4647; Scotland: NHS 24 - 08454 24 24 24

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture according to 1272/2008/EC

Hazard categories:
Hazardous to the aquatic environment: Aquatic Chronic 3
Hazard Statements:
Harmful to aquatic life with long lasting effects.

2.2. Label elements

Hazard statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

Special labelling of certain mixtures

EUH208 Contains Polyhexamethylene biguanide hydrochloride. May produce an allergic reaction.

Additional advice on labelling

This product is not subject to labeling obligation according to art. 1 (5) d) of Regulation (EC) no. 1272/2008 under the form of a medical product because it is used under body contact.

2.3. Other hazards

Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Viscous gel

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
27083-27-8	Polyhexamethylene biguanide hydrochloride			0,1 - < 0,25 %
		616-207-00-X		
	Carc. 2, Acute Tox. 4, STOT RE 1, Eye Dam. 1, Skin Sens. 1B, Aquatic Acute 1 (M-Factor = 10), Aquatic Chronic 1 (M-Factor = 10); H351 H302 H372 H318 H317 H400 H410			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information
Remove and wash contaminated clothing before re-use.
If you feel unwell, seek medical advice.

After inhalation
Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.
In the event of symptoms refer for medical treatment.

After contact with skin
Consult a doctor if skin irritation persists.

After contact with eyes
Rinse thoroughly with plenty of water, also under the eyelids.
If eye irritation persists, consult a specialist.

After ingestion
Rinse out mouth and give plenty of water to drink.
Seek medical treatment immediately.
Induce vomiting only upon the advice of a physician.

4.2. Most important symptoms and effects, both acute and delayed
Contact with eyes may cause irritation.

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media
Product does not burn, fire-extinguishing activities according to surrounding.

Unsuitable extinguishing media
Full water jet.

5.2. Special hazards arising from the substance or mixture
Fire may produce:
Irritant/corrosive, flammable as well as toxic distillation gases (carbonization gases).

5.3. Advice for firefighters
Use breathing apparatus with independent air supply.

Additional information
Cool containers at risk with water spray jet.
Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
In case of vapour formation use respirator.
Avoid contact with skin, eyes and clothing.
Ensure adequate ventilation.

6.2. Environmental precautions
Do not discharge into the drains/surface waters/ground water.

6.3. Methods and material for containment and cleaning up
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder).
Shovel into suitable container for disposal.

6.4. Reference to other sections
Observe protective instructions (see Sections 7 and 8).
Information for disposal see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling
Keep container tightly closed.
When using do not eat, drink or smoke.
Avoid contact with eyes.

Advice on protection against fire and explosion
No special protective measures against fire required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels
Keep only in original container.

Further information on storage conditions
Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

For body decolonization including MDRO (MRE) by physical cleansing 4
[MDRO: Multi-Drug-Resistant-Organisms]

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Protective and hygiene measures
When using do not eat, drink or smoke.
Avoid contact with the eyes.
Remove and wash contaminated clothing before re-use.
No special protective equipment required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Viscous
Colour:	Colourless
Odour:	Odourless
pH-Value (at 20 °C):	approx. 6,5

Changes in the physical state

Flash point:	n.a.
Lower explosion limits:	n.a.
Upper explosion limits:	
Ignition temperature:	n.a.
Density (at 20 °C):	approx. 1,0 g/cm³
Water solubility: (at 20 °C)	Miscible
Viscosity / dynamic: (at 25 °C)	approx. 30.000 mPa·s

9.2. Other information
No data available.

SECTION 10: Stability and reactivity

10.1. Reactivity
No decomposition if stored and applied as directed.

10.2. Chemical stability
Stable under normal conditions.

10.3. Possibility of hazardous reactions
No hazardous reactions known.

10.4. Conditions to avoid
To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials
No materials to be especially mentioned.

10.6. Hazardous decomposition products
No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity
Based on available data, the classification criteria are not met.
LD50/oral/rat: > 2000 mg/kg (Polyhexanide 20%)

Irritation and corrosivity
Based on available data, the classification criteria are not met.

Sensitising effects
Based on available data, the classification criteria are not met.

STOT-single exposure
Based on available data, the classification criteria are not met.

Severe effects after repeated or prolonged exposure
Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction
Based on available data, the classification criteria are not met.
Animal tests have shown that polyhexanide constitutes no carcinogenic or teratogenic risk to human being.

Aspiration hazard
Based on available data, the classification criteria are not met.

Specific effects in experiment on an animal
Not classified.

Additional information on tests
Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

Practical experience

Other observations
Contact with eyes may cause irritation.

SECTION 12: Ecological information

12.1. Toxicity
Ecological data are not available.
Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability
No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT substance.

12.6. Other adverse effects

Low hazard to waters.

Further information

Do not flush into surface water or sanitary sewer system.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.
Where possible recycling is preferred to disposal.

Waste disposal number of waste from residues/unused products

070699 WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics; wastes not otherwise specified

Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal.
Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.
Packaging that cannot be cleaned should be disposed of like the product.

SECTION 14: Transport information

Land transport (ADR/RID); Marine transport (IMDG); Air transport (ICAO); Inland waterways transport (ADN):

14.1. UN number:

No hazardous material as defined by the transport regulations.

14.2. UN proper shipping name:

No hazardous material as defined by the transport regulations.

14.3. Transport hazard class(es):

No hazardous material as defined by the transport regulations.

14.4. Packing group:

No hazardous material as defined by the transport regulations.

14.5. Environmental hazards

No hazardous material as defined by the transport regulations.

14.6. Special precautions for user

No hazardous material as defined by the transport regulations.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No hazardous material as defined by the transport regulations.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

2004/42/EC (VOC): 0 %

National regulatory information

Water contaminating class (D): 1 - slightly water contaminating

SECTION 16: Other information

Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route
RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses
ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure
IMDG = International Maritime Code for Dangerous Goods
IATA/ICAO = International Air Transport Association / International Civil Aviation Organization
MARPOL = International Convention for the Prevention of Pollution from Ships
IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals
REACH = Registration, Evaluation, Authorization and Restriction of Chemicals
CAS = Chemical Abstract Service
EN = European norm
ISO = International Organization for Standardization
DIN = Deutsche Industrie Norm
PBT = Persistent Bioaccumulative and Toxic
vPvB = Very Persistent and very Bio-accumulative

LD = Lethal dose
LC = Lethal concentration
EC = Effect concentration
IC = Median immobilisation concentration or median inhibitory concentration

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H351	Suspected of causing cancer.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
EUH208	Contains Polyhexamethylene biguanide hydrochloride. May produce an allergic reaction.

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities.
The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge.
The delivery specifications are contained in the corresponding product sheet.
This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.
(n.a. = not applicable; n.d. = not determined)

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)