

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 30/07/2026 Version: 1.0

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

1.1. Product identifier

Product form	: Article
PRODUCT NAME	: BACTIGRAS Dressing
Product code	: 66003650, 66003661, 66333661, 66337457, 7456, 7457, 7461, 66007505, 66987457, 66987461, 66267457, 66267461, 86300401, 36361355, 86300403, 66803157, 66807719, 66807717
Type of product	: Medical devices
Product group	: Consumer use

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

Relevant identified uses

Intended for general public	
Main use category	: Professional use, Consumer use
Use of the substance/mixture	: Medicinal Use Antiseptic wound contact layer.
Function or use category	: Consumer uses: Private households (= general public = consumers), Pharmaceuticals

1.3. Details of the supplier of the safety data sheet

Supplier

Smith & Nephew Medical Ltd
101 Hessle Road
HU3 2BN Hull, East Ridings of Yorkshire
T +44 (0) 1482 225181
<https://www.smith-nephew.com/en/contact-us#general>

REACH Legal Entity

Smith & Nephew Operation B.V.
Bloemlaan 2
2132 NP Hoofddorp
Netherlands

1.4. Emergency telephone number

Emergency number	: 999 (UK) or 112 (EU) - 24 Hours, +1-703-527-3887 (Chemtrec 24 Hours)
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SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazardous to the aquatic environment – Chronic Hazard, H412
Category 3
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Signal word (CLP)	: -
Hazard statements (CLP)	: H412 - Harmful to aquatic life with long lasting effects.
Precautionary statements (CLP)	: P102 - Keep out of reach of children. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Child-resistant fastening	: Not applicable
Tactile warning	: Not applicable

2.3. Other hazards

Contains no PBT and/or vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
White Soft Paraffin BP substance with national workplace exposure limit(s) (NL)	CAS-No.: 8009-03-8 EC-No.: 232-373-2 EC Index-No.: 649-254-00-X	≥ 80	Not classified
CHLORHEXIDINE DIACETATE BP	CAS-No.: 56-95-1 EC-No.: 200-302-4	≥ 0.1 – < 1	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Adverse effects not expected from this product. Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Not expected to present a significant skin hazard under anticipated conditions of normal use.
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	: Ingestion is not considered a potential route of exposure.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact	: Not expected to present a significant skin hazard under anticipated conditions of normal use.
Symptoms/effects after eye contact	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after ingestion	: Ingestion is not considered a potential route of exposure.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Dry powder. Alcohol-resistant foam. Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Will ignite if exposed to intensive heat.
Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions	: Do not enter fire area without proper protective equipment, including respiratory protection.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.
Other information	: Do not release runoff from fire to drains or watercourses.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. For further information refer to section 8: "Exposure controls/personal protection". Eliminate ignition sources. Ensure adequate ventilation, especially in confined areas.

For non-emergency personnel

Protective equipment : Do not attempt to take action without suitable protective equipment.
Emergency procedures : Avoid contact with eyes.

For emergency responders

Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
Hygiene measures : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Store in a dry, well ventilated place away from sources of heat, ignition and direct sunlight.
Storage conditions : Store in a dry, cool place.
Storage temperature : < 25 °C
Heat and ignition sources : No flames, no sparks. Eliminate all sources of ignition.
Packaging materials : Keep only in original container.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Personal protection equipment

Personal protective equipment:
Avoid all unnecessary exposure.

Eye and face protection

Eye protection:
Not required for normal conditions of use

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Skin protection

Hand protection:

Not required for normal conditions of use

Respiratory protection

Respiratory protection:

Not required for normal conditions of use

Environmental exposure controls

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Not available
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Non-reactive under normal conditions of use.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

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10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizing agents.

10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. Nitrogen oxides. hydrogen chloride.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

White Soft Paraffin BP (8009-03-8)

LD50 oral	> 2000 mg/kg bodyweight
LD50 dermal	> 2000 mg/kg bodyweight

Skin corrosion/irritation : Not classified
Additional information : Based on available data, the classification criteria are not met
Serious eye damage/irritation : Not classified
Respiratory or skin sensitisation : Not classified
Additional information : Based on available data, the classification criteria are not met
Germ cell mutagenicity : Not classified
Additional information : Based on available data, the classification criteria are not met
Carcinogenicity : Not classified
Additional information : Based on available data, the classification criteria are not met
Reproductive toxicity : Not classified
Additional information : Based on available data, the classification criteria are not met
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified
Additional information : Based on available data, the classification criteria are not met
Aspiration hazard : Not classified
Additional information : Based on available data, the classification criteria are not met

11.2. Information on other hazards

Other information

Potential adverse human health effects and symptoms : Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

BACTIGRAS Dressing

Persistence and degradability	Not established.
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White Soft Paraffin BP (8009-03-8)

Persistence and degradability	Rapidly degradable
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CHLORHEXIDINE DIACETATE BP (56-95-1)

Persistence and degradability	Rapidly degradable
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12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

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Other information	Avoid release to the environment.
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Ecological waste information	: Avoid release to the environment.
HP Code	: HP14 - "Ecotoxic:" waste which presents or may present immediate or delayed risks for one or more sectors of the environment

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated for transport				
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

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14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (2024/590)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 2024/590 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

National regulations

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

France

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
H302	Harmful if swallowed.
H318	Causes serious eye damage.
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.

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.