



Safety Data Sheet

according to Regulation (EC) No 1907/2006

THERMOSHIELD FLEX

Revision date: 16.11.2023

Product code: 00320-0378-GHS

Page 1 of 9

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

1.1. Product identifier

THERMOSHIELD FLEX

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

Use of the substance/mixture

Cleaning agents for medical devices

1.3. Details of the supplier of the safety data sheet

Company name:	Dr. Schumacher GmbH	
Street:	Am Roggenfeld 3	
Place:	34323 Malsfeld / DEUTSCHLAND	
Telephone:	+49 (0) 5664/9496-0	Telefax: +49 (0) 5664/8444
E-mail:	post@schumacher-online.com	
Internet:	www.schumacher-online.com	
Responsible Department:	Responsible for the safety data sheet: sds@gbk-ingelheim.de	

1.4. Emergency telephone number:

INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)
In England and Wales: NHS 111 In Scotland: NHS 24 - dial 111

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous in accordance with GB CLP Regulation.

2.2. Label elements

Regulation (EC) No. 1272/2008

Special labelling of certain mixtures

EUH208	Contains Subtilisin. May produce an allergic reaction.
EUH210	Safety data sheet available on request.

2.3. Other hazards

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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Aqueous solution

Safety Data Sheet

according to Regulation (EC) No 1907/2006

THERMOSHIELD FLEX

Revision date: 16.11.2023

Product code: 00320-0378-GHS

Page 2 of 9

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
9014-01-1	Subtilisin			< 1 %
	232-752-2	647-012-00-8	01-2119480434-38	
	Acute Tox. 4, Skin Irrit. 2, Eye Dam. 1, Resp. Sens. 1, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 2; H302 H315 H318 H334 H335 H400 H411			

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

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
9014-01-1	232-752-2	Subtilisin	< 1 %
	oral: ATE = 500 mg/kg		

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

Remove contaminated soaked clothing immediately.
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

Wash hands with water as a precaution.
Consult a doctor if skin irritation persists.

After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
If eye irritation persists, consult a specialist.

After ingestion

Do not provoke vomiting. Consult physician. Attention in case of vomiting - acute danger of suffocating, produced by foaming ingredients. Rinse mouth. Make drink some glasses of water. The decision whether to provoke vomiting is to be taken by a physician.

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

Contact with eyes or skin may cause irritation.
May cause sensitization of susceptible persons by skin contact.
Watch out. Beware, hazard of foam aspiration.

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



THERMOSHIELD FLEX

Revision date: 16.11.2023

Product code: 00320-0378-GHS

Page 3 of 9

5.2. Special hazards arising from the substance or mixture

Fire may produce:
carbon monoxide (CO), carbon dioxide (CO₂) and nitrogen oxides (NO_x)

5.3. Advice for firefighters

Use breathing apparatus with independent air supply.
Protective suit.

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

General advice

Ensure adequate ventilation.
Keep away noninvolved persons.

For non-emergency personnel

Do not breathe vapours.
Avoid contact with skin, eyes and clothing.

For emergency responders

In case of vapour formation use respirator.
Use personal protective clothing.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

For containment

Prevent spread over a wide area (e.g. by containment or oil barriers).

For 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.
Avoid contact with skin, eyes and clothing.

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 container tightly closed in a dry, cool and well-ventilated place.

Hints on joint storage

No materials to be especially mentioned.

Further information on storage conditions

Keep away from food, drink and animal feeding stuffs.

7.3. Specific end use(s)

**THERMOSHIELD FLEX**

Revision date: 16.11.2023

Product code: 00320-0378-GHS

Page 4 of 9

Cleaning agents for medical devices

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
57-55-6	Propane-1,2-diol, particulates	-	10		TWA (8 h)	WEL
9014-01-1	Subtilisins (Bacillus subtilis Carlsberg)	-	0.00004		TWA (8 h)	WEL

8.2. Exposure controls**Appropriate engineering controls**

Ensure adequate ventilation, especially in confined areas.

Protective and hygiene measures

Wash hands before breaks and immediately after handling the product.

When using do not eat, drink or smoke.

Take off immediately all contaminated clothing.

Avoid contact with skin, eyes and clothing.

Eye/face protection

Tightly fitting goggles (EN 166).

Eye wash bottle with pure water (EN 15154).

Hand protection

Chemical protective gloves made of nitrile, layer thickness at least 0.1 mm, breakthrough time (wearing time) approx. 240 minutes or gloves with the same protective effect.

This recommendation is based exclusively on the chemical compatibility and the test according to EN 374-1 Type A/B under laboratory conditions.

Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves.

Skin protection

Long sleeved clothing (DIN EN ISO 6530)

Respiratory protection

No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state:	Liquid
Colour:	Yellowish
Odour:	Mild

Test method

pH-Value:	10 - 11 (Concentrate)
-----------	-----------------------

Changes in the physical state

Melting point/freezing point:	n.d.
Boiling point or initial boiling point and boiling range:	n.d.
Sublimation point:	n.a.
Softening point:	n.d.
Flash point:	n.a.
Sustaining combustion:	Not sustaining combustion

**THERMOSHIELD FLEX**

Revision date: 16.11.2023

Product code: 00320-0378-GHS

Page 5 of 9

Flammability

Solid/liquid: n.a.

Explosive properties

The product is not explosive.

Lower explosion limits: n.a.

Upper explosion limits: n.a.

Auto-ignition temperature: n.a.

Self-ignition temperature

Solid: n.a.

Gas: n.a.

Decomposition temperature: n.d.

Oxidizing properties

Not oxidising.

Vapour pressure: n.d.

Density (at 20 °C): 1,014 g/cm³

Bulk density: n.a.

Water solubility:
(at 20 °C) Miscible**Solubility in other solvents**

n.d.

Partition coefficient n-octanol/water: n.d.

Viscosity / dynamic:
(at 20 °C) n.d.

Viscosity / kinematic: n.d.

Flow time: n.d.

Relative vapour density: n.d.

Evaporation rate: n.d.

Solvent separation test: 0 %

Solvent content: < 15 %

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.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

THERMOSHIELD FLEX

Revision date: 16.11.2023

Product code: 00320-0378-GHS

Page 6 of 9

Fire may produce:

Carbon monoxide (CO), carbon dioxide (CO₂) and nitrogen oxides (NO_x)

SECTION 11: Toxicological information

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

Acute toxicity

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

No toxicological data available.

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.

Contains Subtilisin. May produce an allergic reaction.

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

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

STOT-repeated exposure

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

Aspiration hazard

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

Additional information on tests

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

11.2. Information on other hazards

Endocrine disrupting properties

No data available.

Other information

Contact with eyes or skin may cause irritation.

Watch out. Beware, hazard of foam aspiration.

SECTION 12: Ecological information

12.1. Toxicity

Ecological data are not available.

12.2. Persistence and degradability

The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer.

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to UK REACH.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

Low hazard to waters.

Safety Data Sheet

according to Regulation (EC) No 1907/2006

THERMOSHIELD FLEX

Revision date: 16.11.2023

Product code: 00320-0378-GHS

Page 7 of 9

Further information

Do not flush into surface water or sanitary sewer system.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Can be incinerated, when in compliance with local regulations.

Where possible recycling is preferred to disposal.

List of Wastes Code - 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)

<u>14.1. UN number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

<u>14.1. UN number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

<u>14.1. UN number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number:</u>	No dangerous good in sense of this transport regulation.
<u>14.2. UN proper shipping name:</u>	No dangerous good in sense of this transport regulation.
<u>14.3. Transport hazard class(es):</u>	No dangerous good in sense of this transport regulation.
<u>14.4. Packing group:</u>	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory information

Safety Data Sheet

according to Regulation (EC) No 1907/2006

THERMOSHIELD FLEX

Revision date: 16.11.2023

Product code: 00320-0378-GHS

Page 8 of 9

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

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 75

Directive 2004/42/EC on VOC in
paints and varnishes: < 15 %

Information according to Directive
2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water hazard class (D): 1 - slightly hazardous to water

15.2. Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

Changes

Changes in section: 8, 9

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. |
| H315 | Causes skin irritation. |
| H318 | Causes serious eye damage. |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H335 | May cause respiratory irritation. |
| H400 | Very toxic to aquatic life. |
| H411 | Toxic to aquatic life with long lasting effects. |



Safety Data Sheet

according to Regulation (EC) No 1907/2006

THERMOSHIELD FLEX

Revision date: 16.11.2023

Product code: 00320-0378-GHS

Page 9 of 9

EUH208 Contains Subtilisin. May produce an allergic reaction.
EUH210 Safety data sheet available on request.

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.

The provision of the safety data sheet does not automatically guarantee the marketability of the product.
(n.a. = not applicable; n.d. = not determined)

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