

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
Commission Regulation (EU) 2020/878

THERMOSHIELD® FLEX

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	15.12.2025	100000000136	Date of first issue: 15.12.2025
			Country / Language : DE / EN

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

1.1 Product identifier

Product name : THERMOSHIELD® FLEX

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

Use of the Sub- : Cleaning agent for the chemothermic treatment of medical
stance/Mixture devices in cleaning and disinfection devices

1.3 Details of the supplier of the safety data sheet

Company : Dr. Schumacher GmbH
Am Roggenfeld 3
34323 Malsfeld

Telephone : +49 566494960

Telefax : +49 56648444

E-mail address of person : sds.sap-ehs@schumacher-online.com
responsible for the SDS

1.4 Emergency telephone number

INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

No labeling elements required.

Additional Labelling

EUH208 Contains subtilisin. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
subtilisin	9014-01-1 232-752-2 647-012-00-8 01-2119480434-38	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Resp. Sens. 1; H334 STOT SE 3; H335 (Lungs) Aquatic Acute 1; H400 Aquatic Chronic 2; H411 Acute toxicity estimate Acute oral toxicity: 1.800 mg/kg	>= 0,1 - < 0,25

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

- | | | |
|-------------------------|---|---|
| General advice | : | Take off immediately all contaminated clothing.
If you feel unwell, seek medical advice (show the label where possible). |
| If inhaled | : | Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.
If symptoms persist, call a physician. |
| In case of skin contact | : | Wash with water and soap as a precaution.
If skin irritation persists, call a physician. |
| In case of eye contact | : | Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
If eye irritation persists, consult a specialist. |
| If swallowed | : | DO NOT induce vomiting unless directed to do so by a physician or poison control center.
Rinse mouth.
Obtain medical attention. |

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|------------------------|
| Treatment | : | Treat symptomatically. |
|-----------|---|------------------------|
-

SECTION 5: Firefighting measures

5.1 Extinguishing media

- | | | |
|--------------------------------|---|--|
| Suitable extinguishing media | : | The product itself does not burn.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Unsuitable extinguishing media | : | High volume water jet |

5.2 Special hazards arising from the substance or mixture

- | | | |
|-------------------------------|---|--|
| Hazardous combustion products | : | No hazardous combustion products are known |
|-------------------------------|---|--|

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5.3 Advice for firefighters

Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if necessary.
Further information	:	Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Ensure adequate ventilation.
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6.2 Environmental precautions

Environmental precautions	:	If the product contaminates rivers and lakes or drains inform respective authorities.
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6.3 Methods and material for containment and cleaning up

Methods for cleaning up	:	Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.
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6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.
Advice on protection against fire and explosion	:	Normal measures for preventive fire protection.
Hygiene measures	:	General industrial hygiene practice.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Electrical installations / working materials must comply with the technological safety standards.
Advice on common storage	:	No materials to be especially mentioned.
Storage class (TRGS 510)	:	12

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Further information on storage stability : No decomposition if stored and applied as directed.

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment

Eye/face protection	: Safety glasses with side-shields conforming to EN166
Hand protection	
Material	: 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.
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: No personal respiratory protective equipment normally required.
Protective measures	: Avoid contact with skin.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	: liquid
Colour	: yellow
Odour	: odourless
Melting point/range	: not determined
Boiling point/boiling range	: not determined
Upper explosion limit / Upper flammability limit	: not determined

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Lower explosion limit / Lower
flammability limit : not determined

Flash point : not determined

pH : 10

Viscosity
Viscosity, kinematic : not determined

Solubility(ies)
Water solubility : not determined

Partition coefficient: n-
octanol/water : No data available

Vapour pressure : not determined

Density : 1,014 g/cm³ (20 °C)

Relative vapour density : not determined

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

Hazardous reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : Strong acids and oxidizing agents

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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

Acute toxicity

Not classified based on available information.

Components:

subtilisin:

Acute oral toxicity : LD50 (Rat, male and female): 1.800 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

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11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Further information

Product:

Remarks : Inhalation of aerosol or skin contact may cause sensitisation of susceptible persons.

SECTION 12: Ecological information

12.1 Toxicity

Components:

subtilisin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 8,200000 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants : (Pseudokirchneriella subcapitata (green algae)): 0,8300000 mg/l
Exposure time: 72 h

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

subtilisin:

Partition coefficient: n-octanol/water : Remarks: No data available

12.4 Mobility in soil

No data available

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12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

Product:

Additional ecological information : No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

Waste Code : used product
070699
WASTES FROM ORGANIC CHEMICAL PROCESSES;
wastes from MFSU of greases, lubricants, soaps, detergents,
disinfectants and personal care products; wastes not otherwise specified.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good

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IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 75
If you intend to use this product as tattoo ink, please contact your vendor.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances. : Not applicable

Water hazard class (Germany) : WGK 1 slightly hazardous to water
Classification according to AwSV, Annex 1 (5.2)

TA Luft List (Germany) : 5.2.1: Total dust:
Not applicable
5.2.2: Inorganic substances in powdered form:
Not applicable
5.2.4: Inorganic substances in gaseous form:
Not applicable
5.2.5: Organic Substances:
Not applicable
5.2.7.1.1: Carcinogenic substance:
Not applicable
5.2.7.1.1: Quartz fine dust PM4:
Not applicable
5.2.7.1.1: Formaldehyde:
Not applicable
5.2.7.1.1: fibres:
Not applicable
5.2.7.1.2: Germ cell mutagens:
Not applicable
5.2.7.1.3: Substances toxic to reproduction:
Not applicable
5.2.7.2: Poorly degradable, easily enrichable and highly toxic

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organic substances:
Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Not applicable

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this mixture.

SECTION 16: Other information

Full text of H-Statements

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.

Full text of other abbreviations

Acute Tox.	: Acute toxicity
Aquatic Acute	: Short-term (acute) aquatic hazard
Aquatic Chronic	: Long-term (chronic) aquatic hazard
Eye Dam.	: Serious eye damage
Resp. Sens.	: Respiratory sensitisation
Skin Irrit.	: Skin irritation
STOT SE	: Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - Interna-

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tional Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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