

SAFETY DATA SHEET

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

PLURAZYME EXTRA

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	04.05.2026	199999900022	Date of first issue: 04.05.2026
			Country / Language : DE / EN

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

1.1 Product identifier

Product name : PLURAZYME EXTRA

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

Use of the Sub-
stance/Mixture : Cleaning agent for instruments and medical 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
responsible for the SDS : sds.sap-ehs@schumacher-online.com

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)

Serious eye damage, Category 1	H318: Causes serious eye damage.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms :



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/ doctor.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

Alcohols, C9-11-branched, ethoxylated

Additional Labelling

EUH208 Contains (R)-p-mentha-1,8-diene, subtilisin. May produce an allergic reaction.

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.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Alcohols, C9-11-branched, ethoxylated	169107-21-5	Acute Tox. 4; H302 Eye Dam. 1; H318	$\geq 3 - < 10$
Poly(oxy-1,2-ethanediyl), α -[2-(didecylmethylammonio)ethyl]- ω -hydroxy-, propanoate	94667-33-1 619-057-3 01-2119950327-36	Acute Tox. 4; H302 Skin Corr. 1B; H314 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	$\geq 0,25 - < 1$
(R)-p-mentha-1,8-diene	5989-27-5 227-813-5 601-096-00-2 01-2119529223-47	Flam. Liq. 3; H226 Skin Irrit. 2; H315 Skin Sens. 1B; H317 Asp. Tox. 1; H304 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 Acute toxicity estimate Acute oral toxicity: 2.000 mg/kg	$\geq 0,25 - < 1$
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 esti-	$\geq 0,1 - < 0,25$

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		mate	
		Acute oral toxicity: 1.800 mg/kg	

For explanation of abbreviations see section 16.

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 off immediately with plenty of water for at least 15 minutes.
Call a physician if irritation persists. |
| In case of eye contact | : Remove contact lenses.
Protect unharmed eye.
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

- | | |
|-------|------------------------------|
| Risks | : Causes serious eye damage. |
|-------|------------------------------|

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. |
|------------------------------|--|

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Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : No hazardous combustion products are known

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.
Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : If the product contaminates rivers and lakes or drains inform respective authorities.

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.

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 : Normal measures for preventive fire protection.

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fire and explosion

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

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
(R)-p-mentha-1,8-diene	5989-27-5	AGW	5 ppm 28 mg/m ³	DE TRGS 900
	Peak-limit: excursion factor (category): 4;(II)			
	Further information: Skin absorption, When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child, Substance sensitizing through the skin			
		MAK	5 ppm 28 mg/m ³	DE DFG MAK
	Further information: Danger of sensitization of the skin, Danger of absorption through the skin, Damage to the embryo or foetus is unlikely when the MAK value or the BAT value is observed			

8.2 Exposure controls

Individual protection measures, such as personal protective equipment (PPE)

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

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compatibility and the test according to EN 374-1
Type A/B under laboratory conditions.

Skin and body protection	:	Long sleeved clothing
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
Form	:	liquid
Colour	:	blue
Odour	:	citrus
Melting point/ range	:	not determined
Boiling point/boiling range	:	not determined
Upper explosion limit / Upper flammability limit	:	not determined
Lower explosion limit / Lower flammability limit	:	not determined
Flash point	:	not determined
Decomposition temperature	:	No data available
pH	:	ca. 6,8
Viscosity	:	
Viscosity, kinematic	:	not determined
Solubility(ies)	:	
Water solubility	:	(20 °C) completely miscible
Partition coefficient: n-octanol/water	:	No data available

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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 : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Strong acids and oxidizing agents

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.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

(R)-p-mentha-1,8-diene:

Acute oral toxicity : LD50 (Rat): 2.000 mg/kg

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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

Causes eye burns.

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 hazard

Not classified based on available information.

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:

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Remarks : No data available

SECTION 12: Ecological information

12.1 Toxicity

Components:

(R)-p-mentha-1,8-diene:

Toxicity to fish : LC50 (Fish): 0,46 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants : ErC50 (algae): 0,32 mg/l
Exposure time: 72 h

M-Factor (Acute aquatic toxicity) : 1

subtilisin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 8,2 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants : (Pseudokirchneriella subcapitata (green algae)): 0,83 mg/l
Exposure time: 72 h

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Poly(oxy-1,2-ethanediyl), α -[2-(didecylmethylammonio)ethyl]- ω -hydroxy-, propanoate:

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

(R)-p-mentha-1,8-diene:

Partition coefficient: n-octanol/water : log Pow: 4,38 (37,00 °C)
pH: 7,2

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 : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: The product should not be allowed to enter drains, water courses or the soil.
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

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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

14.2 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.

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SECTION 15: Regulatory information

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

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).	Number on list 3
Regulation (EU) No 2024/590 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 2 obviously hazardous to water
Classification according to AwSV, Annex 1 (5.2)

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial and livestock rearing emissions (integrated pollution prevention and control)
Volatile organic compounds (VOC) content: 0,06 %

Other regulations:

Take note of Law on the protection of mothers at work, in education and in studies (Maternity Protection Act - MuSchG).

15.2 Chemical safety assessment

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

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SECTION 16: Other information

Full text of H-Statements

H226	:	Flammable liquid and vapour.
H302	:	Harmful if swallowed.
H304	:	May be fatal if swallowed and enters airways.
H314	:	Causes severe skin burns and eye damage.
H315	:	Causes skin irritation.
H317	:	May cause an allergic skin reaction.
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.
H410	:	Very toxic to aquatic life with long lasting effects.
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
Asp. Tox.	:	Aspiration hazard
Eye Dam.	:	Serious eye damage
Flam. Liq.	:	Flammable liquids
Resp. Sens.	:	Respiratory sensitisation
Skin Corr.	:	Skin corrosion
Skin Irrit.	:	Skin irritation
Skin Sens.	:	Skin sensitisation
STOT SE	:	Specific target organ toxicity - single exposure
DE DFG MAK	:	Germany. MAK BAT Annex IIa
DE TRGS 900	:	Germany. TRGS 900 - Occupational exposure limit values.
DE DFG MAK / MAK	:	MAK value
DE TRGS 900 / AGW	:	Time Weighted Average

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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 Harmonised System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air

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Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organisation; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardisation; 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 - Organisation 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

Classification of the mixture:

Eye Dam. 1	H318
Aquatic Chronic 3	H412

Classification procedure:

Calculation method
Calculation method

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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