

Safety Data Sheet

According to Regulation (EC) No 1907/2006

Suma Med Enzyme

Revision: 2021-08-01 **Version:** 08.1

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

1.1 Product identifier

Trade name: Suma Med Enzyme

UFI: 5SX4-80S1-5007-ET4A

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

Product use: Hard surface cleaner.

for cleaning of medical devices. For professional use only.

Uses advised against: Uses other than those identified are not recommended.

SWED - Sector-specific worker exposure description :

AISE_SWED_PW_1_1 AISE_SWED_PW_8a_2 AISE_SWED_PW_13_2 AISE_SWED_PW_19_1

1.3 Details of the supplier of the safety data sheet

Diversey Europe Operations BV, Maarssenbroeksedijk 2, 3542DN Utrecht, The Netherlands

Contact details

Diversey Ltd

Weston Favell Centre, Northampton NN3 8PD, United Kingdom

Tel: 01604 405311, Fax: 01604 406809

 $Regulatory\ Email:\ customerservice.uk@diversey.com$

1.4 Emergency telephone number

Seek medical advice (show the label or safety data sheet where possible)

For medical or environmental emergency only:

call 0800 052 0185

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not classified as hazardous

2.2 Label elements

Contains 2-phenoxyethanol (Phenoxyethanol)

Hazard statements:

EUH210 - Safety data sheet available on request.

Further indications on the label:

Contains: preservative.

2.3 Other hazards

No other hazards known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Ingredient(s)	EC number	CAS number	REACH number	Classification	Notes	Weight percent
propane-1,2-diol	200-338-0	57-55-6	01-2119456809-23	Not classified as hazardous		20-30

Workplace exposure limit(s), if available, are listed in subsection 8.1.

ATE, if available, are listed in section 11.

[1] Exempted: ionic mixture. See Regulation (EC) No 1907/2006, Annex V, paragraph 3 and 4. This salt is potentially present, based on calculation, and included for classification and labelling purposes only. Each starting material of the ionic mixture is registered, as required. [6] Exempted: biocidal active. See Article 15(2) of Regulation (EC) No 1907/2006.

For the full text of the H and EUH phrases mentioned in this Section, see Section 16...

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation: Get medical attention or advice if you feel unwell.

Skin contact: Wash skin with plenty of lukewarm, gently flowing water. If skin irritation occurs: Get medical advice

or attention

Rinse cautiously with water for several minutes. If irritation occurs and persists, get medical Eye contact:

attention

Rinse mouth. Immediately drink 1 glass of water. Never give anything by mouth to an unconscious Ingestion:

person. Get medical attention or advice if you feel unwell.

Self-protection of first aider: Consider personal protective equipment as indicated in subsection 8.2.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation: No known effects or symptoms in normal use. Skin contact: No known effects or symptoms in normal use. No known effects or symptoms in normal use. Eye contact: Ingestion: No known effects or symptoms in normal use.

4.3 Indication of any immediate medical attention and special treatment needed

No information available on clinical testing and medical monitoring. Specific toxicological information on substances, if available, can be found

SECTION 5: Firefighting measures

5.1 Extinguishing media

Carbon dioxide. Dry powder. Water spray jet. Fight larger fires with water spray jet or alcohol-resistant foam.

5.2 Special hazards arising from the substance or mixture

No special hazards known.

5.3 Advice for firefighters

As in any fire, wear self contained breathing apparatus and suitable protective clothing including gloves and eye/face protection.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

No special measures required.

6.2 Environmental precautions

Dilute with plenty of water. Do not allow to enter drainage system, surface or ground water.

6.3 Methods and material for containment and cleaning up

Dyke to collect large liquid spills. Absorb with liquid-binding material (sand, diatomite, universal binders, sawdust). Do not place spilled materials back into the original container. Collect in closed and suitable containers for disposal.

6.4 Reference to other sections

For personal protective equipment see subsection 8.2. For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Measures to prevent fire and explosions:

No special precautions required.

Measures required to protect the environment:

For environmental exposure controls see subsection 8.2.

Advices on general occupational hygiene:

Handle in accordance with good industrial hygiene and safety practice. Do not mix with other products unless adviced by Diversey.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local and national regulations. Keep only in original packaging.

For conditions to avoid see subsection 10.4. For incompatible materials see subsection 10.5.

7.3 Specific end use(s)

No specific advice for end use available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters Workplace exposure limits

Air limit values, if available:

Ingredient(s)	UK - Long term value(s)	UK - Short term value(s)
propane-1,2-diol	150 ppm total	450 ppm total
	particulates and vapour	particulate and vapour
	474 mg/m ³ total	1422 mg/m³ total
	particulates and vapour	particulate and vapour
	10 mg/m ³ particulates	30 mg/m ³ particulate

Biological limit values, if available:

Recommended monitoring procedures, if available:

Additional exposure limits under the conditions of use, if available:

DNEL/DMEL and **PNEC** values

Human exposure

DNEL oral exposure - Consumer (mg/kg bw)

 BITEE oral expectate Confound (mg/kg bit)				
Ingredient(s)	Short term - Local effects	Short term - Systemic effects	Long term - Local effects	Long term - Systemic effects
propane-1,2-diol	-	-	-	85
p. opao 1,2 a.o.				

DNEL dermal exposure - Worker

zitzz domiai expecuie iii	511.61				
Ing	gredient(s)	Short term - Local effects	Short term - Systemic effects (mg/kg bw)	Long term - Local effects	Long term - Systemic effects (mg/kg bw)
prop	pane-1,2-diol	=	-	=	=

DNEL dermal exposure - Consumer

Ingredient(s)	Short term - Local effects	Short term - Systemic effects (mg/kg bw)	Long term - Local effects	Long term - Systemic effects (mg/kg bw)
propane-1,2-diol	-	-	-	213

DNEL inhalatory exposure - Worker (mg/m³)

Ingredient(s)	Short term - Local effects	Short term - Systemic effects	Long term - Local effects	Long term - Systemic effects
propane-1,2-diol	-	-	10	168

DNEL inhalatory exposure - Consumer (mg/m³)

Ditte initiation of exposure Constitution (mg/m)								
Ingredient(s)	Short term - Local Short term - System		Long term - Local	Long term - Systemic				
	effects	effects	effects	effects				
propane-1,2-diol	-	-	10	50				

Environmental exposure

Environmental exposure - PNEC

Ingredient(s)	Surface water, fresh (mg/l)	Surface water, marine (mg/l)	Intermittent (mg/l)	Sewage treatment plant (mg/l)
propane-1,2-diol	260	26	183	20000

Environmental exposure - PNEC, continued

Ingredient(s)	Sediment, freshwater (mg/kg)	Sediment, marine (mg/kg)	Soil (mg/kg)	Air (mg/m³)
propane-1,2-diol	572	57.2	50	-

8.2 Exposure controls

The following information applies for the uses indicated in subsection 1.2 of the Safety Data Sheet. If available, please refer to the product information sheet for application and handling instructions. Normal use conditions are assumed for this section.

Recommended safety measures for handling the $\underline{\quad undiluted\quad}$ product:

Appropriate engineering controls: No special requirements under normal use conditions. Appropriate organisational controls: No special requirements under normal use conditions.

REACH use scenarios considered for the undiluted product:

	SWED - Sector-specific	LCS	PROC	Duration	ERC
	worker exposure			(min)	
	description				
Manual transfer and dilution	AISE_SWED_PW_8a_2	PW	PROC 8a	60	ERC8a
Automatic application in a dedicated closed system	AISE_SWED_PW_1_1	PW	PROC 1	60	ERC8a

Personal protective equipment

Hand protection: Body protection:

Respiratory protection:

Eye / face protection: Safety glasses are not normally required. However, their use is recommended in those cases where

splashes may occur when handling the product (EN 166). No special requirements under normal use conditions. No special requirements under normal use conditions. No special requirements under normal use conditions.

Environmental exposure controls: No special requirements under normal use conditions.

Recommended safety measures for handling the diluted product:

Recommended maximum concentration (% w/w): 0.6

Appropriate engineering controls: No special requirements under normal use conditions. Appropriate organisational controls: No special requirements under normal use conditions.

REACH use scenarios considered for the diluted product:

	SWED	LCS	PROC	Duration (min)	ERC
Manual application by dipping, soaking, pouring	AISE_SWED_PW_13_2	PW	PROC 13	60	ERC8a
Manual application	AISE SWED PW 19 1	PW	PROC 19	480	ERC8a

Personal protective equipment

Eye / face protection:
Hand protection:
Body protection:
No special requirements under normal use conditions.

Environmental exposure controls:
No special requirements under normal use conditions.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Information in this section refers to the product, unless it is specifically stated that substance data is listed

Method / remark

Physical State: Liquid

Colour: Clear , Light , Yellow

Odour: Product specific

Odour threshold: Not applicable

Melting point/freezing point (°C): Not determined Not relevant to classification of this product

Initial boiling point and boiling range (°C): Not determined See substance data

Substance data, boiling point

Ingredient(s)	Value	Method	Atmospheric pressure
	(°C)		(hPa)
propane-1,2-diol	185-190	Method not given	1013

Method / remark

Flammability (solid, gas): Not applicable to liquids

Flammability (liquid): Not flammable.
Flash point (°C): Not applicable.
Sustained combustion: Not applicable.
(UN Manual of Tests and Criteria, section 32, L.2)

Lower and upper explosion limit/flammability limit (%): Not determined See substance data

Substance data, flammability or explosive limits, if available:

Ingredient(s)	Lower limit (% vol)	Upper limit (% vol)
propane-1,2-diol	2.6	12.6

Method / remark

Autoignition temperature: Not determined

Decomposition temperature: Not applicable.

pH: ≈ 7 (neat) ISO 4316 **Dilution pH**: ≈ 7 (0.6 %) ISO 4316

Kinematic viscosity: Not determined

Solubility in / Miscibility with Water: Fully miscible

Substance data, solubility in water

Ingredient(s)	Value (g/l)	Method	Temperature (°C)
propane-1,2-diol	Soluble	Method not given	

Substance data, partition coefficient n-octanol/water (log Kow): see subsection 12.3

Method / remark

Vapour pressure: Not determined

Relative density: ≈ 1.13 (20 °C) Relative vapour density: No data available.

Particle characteristics: No data available.

See substance data

Substance data, vapour pressure

Ingredient(s)	Value (Pa)	Method	Temperature (°C)
propane-1,2-diol	18.6	Method not given	20

Method / remark

OECD 109 (EU A.3)

Not relevant to classification of this product

Not applicable to liquids.

9.2 Other information

9.2.1 Information with regard to physical hazard classes

Explosive properties: Not explosive.

Oxidising properties: Not oxidising.

Corrosion to metals: Not corrosive

UN Manual of Tests and Criteria, section 37

9.2.2 Other safety characteristics

No other relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity

No reactivity hazards known under normal storage and use conditions.

10.2 Chemical stability

Stable under normal storage and use conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known under normal storage and use conditions.

10.4 Conditions to avoid

None known under normal storage and use conditions.

10.5 Incompatible materials

None known under normal use conditions.

10.6 Hazardous decomposition products

None known under normal storage and use conditions.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Mixture data:.

Relevant calculated ATE(s):

ATE - Oral (mg/kg): >2000

Substance data, where relevant and available, are listed below:.

Acute toxicity

					•
Ac	:ui	te d	oral	toxi	city

Ingredient(s)	Endpoint	Value (mg/kg)	Species	Method	Exposure time (h)	ATE (mg/kg)
propane-1,2-diol	LD 50	> 10000	Rat	Method not given		Not established

Acute dermal toxicity

Ingredient(s)	Endpoint	Value (mg/kg)	Species	Method	Exposure time (h)	ATE (mg/kg)
propane-1,2-diol	LD 50	> 2000	Rabbit	Method not given		Not established

Acute inhalative toxicity

	Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (h)
Ī	propane-1,2-diol	LC 50	> 317 (mist) No mortality	Rabbit	Non guideline test	
			observed			

Acute inhalative toxicity, continued

Ingredient(s)	ATE - inhalation, dust (mg/l)	ATE - inhalation, mist (mg/l)	ATE - inhalation, vapour (mg/l)	ATE - inhalation, gas (mg/l)
propane-1,2-diol	Not established	Not established	Not established	Not established

Irritation and corrosivity Skin irritation and corrosivity

OKIT ITITATION AND CONOSIVITY					
Ingredient(s)	Result	Species	Method	Exposure time	
propane-1,2-diol	Not irritant	Rabbit	OECD 404 (EU B.4)		

Eye irritation and corrosivity

Ingredient(s)	Result	Species	Method	Exposure time
propane-1,2-diol	Not corrosive or	Rabbit	OECD 405 (EU B.5)	
	irritant			

Respiratory tract irritation and corrosivity

Ingredient(s)	Result	Species	Method	Exposure time
propane-1,2-diol	No data available			

Sensitisation

Sensitisation by skin contact						
Ingredient(s)	Result	Species	Method	Exposure time (h)		
propane-1,2-diol	Not sensitising	Guinea pig	OECD 406 (EU B.6) / GPMT			

Sensitisation by inhalation

 Conditionation by inhalation							
Ingredient(s)	Result	Species	Method	Exposure time			
propane-1,2-diol	No data available						

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction) Mutagenicity

Ingredient(s)	Result (in-vitro)	Method (in-vitro)	Result (in-vivo)	Method (in-vivo)
propane-1,2-diol	No evidence for mutagenicity, negative	Method not	No data available	
	test results	given	!	

Carcinogenicity

Ingredient(s)	Effect
propane-1,2-diol	No evidence for carcinogenicity, negative test results

Toxicity for reproduction

Ingredient(s)	Endpoint	Specific effect	Value (mg/kg bw/d)	Species	Method	Exposure time	Remarks and other effects reported
propane-1,2-diol			No data				No evidence for reproductive
			available				toxicity

Repeated dose toxicity Sub-acute or sub-chronic oral toxicity

Sub-acute of sub-critoriic oral toxicity						
Ingredient(s)	Endpoint	Value	Species	Method	Exposure	Specific effects and organs
		(mg/kg bw/d)			time (days)	affected
propane-1,2-diol		No data				
		available				

Sub-chronic dermal toxicity

Ingredient(s)	Endpoint	Value (mg/kg bw/d)	Species	Method	Exposure time (days)	Specific effects and organs affected
propane-1,2-diol		No data available				

Sub-chronic inhalation toxicity

Ingredient(s)	Endpoint	Value (mg/kg bw/d)	Species	Method	Exposure time (days)	Specific effects and organs affected
propane-1,2-diol		No data				
		available				

Childric toxicity								
Ingredient(s)	Exposure	Endpoint	Value	Species	Method	Exposure	Specific effects and	Remark
	route		(mg/kg bw/d)			time	organs affected	
propane-1,2-diol			No data					
			available					

STOT-single exposure

	Ingredient(s)	Affected organ(s)
ſ	propane-1,2-diol	No data available

STOT-repeated exposure

 o i o i i opeatea expectare				
Ingredient(s)	Affected organ(s)			
propane-1,2-diol	No data available			

Aspiration hazard

Substances with an aspiration hazard (H304), if any, are listed in section 3.

Potential adverse health effects and symptoms

Effects and symptoms related to the product, if any, are listed in subsection 4.2.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties
Endocrine disrupting properties - Human data, if available:

11.2.2 Other information

No other relevant information available.

SECTION 12: Ecological information

12.1 Toxicity

No data is available on the mixture.

Substance data, where relevant and available, are listed below:

Aquatic short-term toxicity

Aquatic short-term toxicity - fish

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (h)
propane-1,2-diol	LC 50	> 1000	Fish	Method not given	24

Aquatic short-term toxicity - crustacea

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (h)
propane-1,2-diol	EC 50	> 100	Daphnia	Method not given	48

Aquatic short-term toxicity - algae

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (h)
propane-1,2-diol	EC 50	24200	Desmodesmus subspicatus	OECD 201 (EU C.3)	72

Aquatic short-term toxicity - marine species

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time (days)
propane-1,2-diol		No data available			

Impact on sewage plants - toxicity to bacteria

Ingredient(s)	Endpoint	Value (mg/l)	Inoculum	Method	Exposure time
propane-1,2-diol	EC ₀	> 20000	Pseudomonas putida	Method not given	18 hour(s)

Aquatic long-term toxicity Aquatic long-term toxicity - fish

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time	Effects observed
propane-1,2-diol		No data available				

Aquatic long-term toxicity - crustacea

Ingredient(s)	Endpoint	Value (mg/l)	Species	Method	Exposure time	Effects observed
propane-1,2-diol	NOEC	13020	Ceriodaphnia dubia	Method not given	7 day(s)	

Aquatic toxicity to other aquatic benthic organisms, including sediment-dwelling organisms, if available:

Ingredient(s)	Endpoint	Value (mg/kg dw sediment)	Species	Method	Exposure time (days)	Effects observed
propane-1,2-diol		No data				
		available				

Terrestrial toxicityTerrestrial toxicity - soil invertebrates, including earthworms, if available:

Terrestrial toxicity - plants, if available:

Terrestrial toxicity - birds, if available:

Terrestrial toxicity - beneficial insects, if available:

Terrestrial toxicity - soil bacteria, if available:

12.2 Persistence and degradability

Abiotic degradation

Abiotic degradation - photodegradation in air, if available:

Abiotic degradation - hydrolysis, if available:

Abiotic degradation - other processes, if available:

BiodegradationReady biodegradability - aerobic conditions

Ingredient(s)	Inoculum	Analytical method	DT 50	Method	Evaluation
propane-1,2-diol			> 70 % in 28 day(s)	OECD 301A	Readily biodegradable

Ready biodegradability - anaerobic and marine conditions, if available:

Degradation in relevant environmental compartments, if available:

12.3 Bioaccumulative potential

attition coemician in-octanor, water (log Now)								
Ingredient(s)	Ingredient(s) Value		Evaluation	Remark				
propane-1,2-diol	-1.07	Method not given	No bioaccumulation expected					

Bioconcentration factor (BCF)

Ingredient(s)	Value	Species	Method	Evaluation	Remark
propane-1,2-diol	No data available				

12.4 Mobility in soil

Adsorption/Desorption to soil or sediment

Ingredient(s)	Adsorption coefficient Log Koc	Desorption coefficient Log Koc(des)	Method	Soil/sediment type	Evaluation
propane-1,2-diol	No data available				Potential for mobility in soil, soluble in water

12.5 Results of PBT and vPvB assessment

Substances that fulfill the criteria for PBT/vPvB, if any, are listed in section 3.

12.6 Endocrine disrupting properties

Endocrine disrupting properties - Environmental effects, if available:

12.7 Other adverse effects

No other adverse effects known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused

products:

The concentrated contents or contaminated packaging should be disposed of by a certified handler or according to the site permit. Release of waste to sewers is discouraged. The cleaned packaging material is suitable for energy recovery or recycling in line with local legislation.

20 01 30 - detergents other than those mentioned in 20 01 29.

European Waste Catalogue:

Empty packaging

Recommendation: Suitable cleaning agents: Dispose of observing national or local regulations.

Water, if necessary with cleaning agent.

SECTION 14: Transport information

Land transport (ADR/RID), Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)

14.1 UN number: Non-dangerous goods

14.2 UN proper shipping name: Non-dangerous goods **14.3 Transport hazard class(es):** Non-dangerous goods

14.4 Packing group: Non-dangerous goods

14.5 Environmental hazards: Non-dangerous goods **14.6 Special precautions for user:** Non-dangerous goods

14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code: Non-dangerous goods

SECTION 15: Regulatory information

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

EU regulations:

- Regulation (EC) No. 1907/2006 REACH
- Regulation (EC) No 1272/2008 CLP
- Regulation (EC) No. 648/2004 Detergents regulation
- Directive 93/42/EEC on medical devices
- substances identified as having endocrine disrupting properties in accordance with the criteria set out in Delegated Regulation (EU) 2017/2100 or Regulation (EU) 2018/605

Authorisations or restrictions (Regulation (EC) No 1907/2006, Title VII respectively Title VIII): Not applicable.

Ingredients according to EC Detergents Regulation 648/2004

Phenoxyethanol, enzymes

Seveso - Classification: Not classified

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out on the mixture

SECTION 16: Other information

The information in this document is based on our best present knowledge. However, it does not constitute a guarantee for any specific product features and does not establish a legally binding contract

SDS code: MSDS4537 Version: 08.1 Revision: 2021-08-01

Reason for revision:

Overall design adjusted in accordance with Amendment 2020/878, Annex II of Regulation (EC) No 1907/2006, This data sheet contains changes from the previous version in section(s):, 6, 7, 9, 11, 16

Classification procedure

The classification of the mixture is in general based on calculation methods using substance data, as required by Regulation (EC) No 1272/2008. If for certain classifications data on the mixture is available or for example bridging principles or weight of evidence can be used for classification, this will be indicated in the relevant sections of the Safety Data Sheet. See section 9 for physical chemical properties, section 11 for toxicological information and section 12 for ecological information.

Full text of the H and EUH phrases mentioned in section 3:

Abbreviations and acronyms:

- AISE The international Association for Soaps, Detergents and Maintenance Products
- ATE Acute Toxicity Estimate
- DNEL Derived No Effect Limit
- EC50 effective concentration, 50%
- ERC Environmental release categories EUH CLP Specific hazard statement
- LC50 Lethal Concentration, 50% / Median Lethal Concentration
 LCS Life cycle stage
 LD50 Lethal Dose, 50% / Median Lethal dose
 NOAEL No observed adverse effect level

- NOEL No observed effect level
- OECD Organization for Economic Cooperation and Development

- PBT Persistent, Bioaccumulative and Toxic
 PNEC Predicted No Effect Concentration
 PROC Process categories
 REACH number REACH registration number, without supplier specific part
- vPvB very Persistent and very Bioaccumulative

End of Safety Data Sheet