

SEKUSEPT MULTIENZYME**Section: 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****1.1 Product identifier**

Product name : SEKUSEPT MULTIENZYME

Product code : 114550E

Use of the
Substance/Mixture : Instrument cleaner

Substance type: : Mixture

For professional users only.

Product dilution information : No dilution information provided.

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

Identified uses : Medical devices . Dipping process

Recommended restrictions
on use : Reserved for industrial and professional use.**1.3 Details of the supplier of the safety data sheet**Company : Ecolab Ltd.
PO Box 11; Winnington Avenue
Northwich, Cheshire, United Kingdom CW8 4DX
+ 44 (0)1606 74488
ccs@ecolab.com**1.4 Emergency telephone number**Emergency telephone
number : +441618841235
+32-(0)3-575-5555 Trans-EuropeanPoison Information Centre
telephone number : For medical professionals only: 0344 892 0111

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Section: 2. HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

2.2 Label elements

SEKUSEPT MULTIENZYME**Labelling (REGULATION (EC) No 1272/2008)**

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Additional Labelling:

Special labelling of certain mixtures : Safety data sheet available on request.

Contains: subtilisin, May produce an allergic reaction.

2.3 Other hazards

None known.

Section: 3. COMPOSITION/INFORMATION ON INGREDIENTS**3.2 Mixtures****Hazardous components**

Chemical Name	CAS-No. EC-No. REACH No.	Classification REGULATION (EC) No 1272/2008	Concentration : [%]
ethanol	64-17-5 200-578-6 01-2119457610-43	Flammable liquids Category 2; H225 Serious eye damage/eye irritation Category 2; H319 Serious eye damage/eye irritation Category 2 50 - 100 %	>= 1 - < 10
Sodium p-cumenesulphonate	15763-76-5 239-854-6 01-2119489411-37	Eye irritation Category 2; H319	>= 1 - < 10
subtilisin	9014-01-1 232-752-2 01-2119480434-38	Skin irritation Category 2; H315 Serious eye damage Category 1; H318 Respiratory sensitization Category 1; H334 Specific target organ toxicity - single exposure Category 3; H335 Acute toxicity Category 4; H302 Acute aquatic toxicity Category 1; H400 Chronic aquatic toxicity Category 2; H411 M = 1	>= 0.1 - < 0.25
Substances with a workplace exposure limit :			
Propylene glycol	57-55-6 200-338-0 01-2119456809-23	Not Classified;	>= 50 - < 70
glycerin	56-81-5 200-289-5 01-2119471987-18	Not Classified;	>= 1 - < 10

For the full text of the H-Statements mentioned in this Section, see Section 16.

Section: 4. FIRST AID MEASURES**4.1 Description of first aid measures**

In case of eye contact : Rinse with plenty of water.

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- In case of skin contact : Rinse with plenty of water.
- If swallowed : Rinse mouth. Get medical attention if symptoms occur.
- If inhaled : Get medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

4.3 Indication of immediate medical attention and special treatment needed

- Treatment : No specific measures identified.

Section: 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during firefighting : Fire Hazard
Keep away from heat and sources of ignition.
Flash back possible over considerable distance.
Beware of vapours accumulating to form explosive concentrations.
Vapours can accumulate in low areas.
- Hazardous combustion products : Depending on combustion properties, decomposition products may include following materials:
Carbon oxides
nitrogen oxides (NO_x)
Sulphur oxides
metal oxides

5.3 Advice for firefighters

- Special protective equipment for firefighters : Use personal protective equipment.
- Further information : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Section: 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

- Advice for non-emergency personnel : Remove all sources of ignition. Refer to protective measures listed in sections 7 and 8.
- Advice for emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials.

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6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up : Eliminate all ignition sources if safe to do so. Stop leak if safe to do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Flush away traces with water. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway.

6.4 Reference to other sections

See Section 1 for emergency contact information.
For personal protection see section 8.
See Section 13 for additional waste treatment information.

Section: 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling : Keep away from fire, sparks and heated surfaces. Take necessary action to avoid static electricity discharge (which might cause ignition of organic vapours).

Hygiene measures : Wash hands before breaks and immediately after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep away from heat and sources of ignition. Protect from frost, heat and sunlight. Store at room temperature in the original container. Keep away from oxidizing agents. Keep out of reach of children. Keep container tightly closed. Store in suitable labeled containers.

Storage temperature : 5 °C to 25 °C

7.3 Specific end uses

Specific use(s) : Medical devices . Dipping process

Section: 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propylene glycol	57-55-6	TWA (Total vapour and particles)	150 ppm 474 mg/m ³	UKCOSSTD
		TWA (particles)	10 mg/m ³	UKCOSSTD
ethanol	64-17-5	TWA	1,000 ppm 1,920 mg/m ³	UKCOSSTD
glycerin	56-81-5	TWA (Mist)	10 mg/m ³	UKCOSSTD

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subtilisin	9014-01-1	TWA	0.00004 mg/m3	UKCOSSTD
Further information	Sen	Capable of causing occupational asthma.		

DNEL

Propylene glycol	:	End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 168 mg/m3 End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 10 mg/m3 End Use: Consumers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 50 mg/m3 End Use: Consumers Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 10 mg/m3 End Use: Consumers Exposure routes: Dermal Potential health effects: Long-term systemic effects 213 mg/kg End Use: Consumers Exposure routes: Ingestion Potential health effects: Long-term systemic effects Value: 85 ppm
triethanolamine	:	End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 5 mg/m3 End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 5 mg/m3 End Use: Workers Exposure routes: Dermal Potential health effects: Long-term systemic effects Value: 6.3 mg/kg bw/day End Use: Workers Exposure routes: Dermal Potential health effects: Long-term local effects Value: 0.14 mg/cm2 End Use: Consumer use Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 1.25 mg/m3

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	End Use: Consumer use Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 1.25 mg/m³ End Use: Consumer use Exposure routes: Dermal Potential health effects: Long-term systemic effects Value: 2.66 mg/kg bw/day End Use: Consumer use Exposure routes: Dermal Potential health effects: Long-term local effects Value: 0.07 mg/cm² End Use: Consumer use Exposure routes: Ingestion Potential health effects: Long-term systemic effects Value: 3.3 mg/kg bw/day
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PNEC

Propylene glycol	: Fresh water Value: 260 mg/l Marine water Value: 26 mg/l Intermittent use/release Value: 183 mg/l Fresh water sediment Value: 572 mg/kg Marine sediment Value: 57.2 mg/kg Sewage treatment plant Value: 20000 mg/l Soil Value: 50 mg/kg
triethanolamine	: Fresh water Value: 0.32 mg/l Marine water Value: 0.032 mg/l Intermittent use/release Value: 5.12 mg/l Fresh water sediment Value: 1.7 mg/kg Marine sediment

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	Value: 0.17 mg/kg
	Sewage treatment plant Value: 10 mg/l
	Soil Value: 0.151 mg/kg

8.2 Exposure controls**Appropriate engineering controls**

Engineering measures : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures : Wash hands before breaks and immediately after handling the product.

Eye/face protection (EN 166) : No special protective equipment required.

Hand protection (EN 374) : No special protective equipment required.

Skin and body protection (EN 14605) : No special protective equipment required.

Respiratory protection (EN 143, 14387) : None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements(89/656/EEC, (EU) 2016/425), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization.

Environmental exposure controls

General advice : Consider the provision of containment around storage vessels.

Section: 9. PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties**

Appearance	: liquid
Colour	: blue
Odour	: slight
pH	: 8.5, 100 %
Flash point	: 56 °C, Does not sustain combustion.
Odour Threshold	: Not applicable and/or not determined for the mixture
Melting point/freezing point	: Not applicable and/or not determined for the mixture
Initial boiling point and boiling range	: Not applicable and/or not determined for the mixture
Evaporation rate	: Not applicable and/or not determined for the mixture

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Flammability (solid, gas)	: Not applicable and/or not determined for the mixture
Upper explosion limit	: Not applicable and/or not determined for the mixture
Lower explosion limit	: Not applicable and/or not determined for the mixture
Vapour pressure	: Not applicable and/or not determined for the mixture
Relative vapour density	: Not applicable and/or not determined for the mixture
Relative density	: 1.06
Water solubility	: soluble
Solubility in other solvents	: Not applicable and/or not determined for the mixture
Partition coefficient: n-octanol/water	: Not applicable and/or not determined for the mixture
Auto-ignition temperature	: Not applicable and/or not determined for the mixture
Thermal decomposition	: Not applicable and/or not determined for the mixture
Viscosity, kinematic	: Not applicable and/or not determined for the mixture
Explosive properties	: Not applicable and/or not determined for the mixture
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

9.2 Other information

Not applicable and/or not determined for the mixture

Section: 10. STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Heat, flames and sparks.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

In the event of fire, see Section 5

Section: 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Information on likely routes of : Inhalation, Eye contact, Skin contact

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exposure

Product

Acute oral toxicity	: There is no data available for this product.
Acute inhalation toxicity	: There is no data available for this product.
Acute dermal toxicity	: There is no data available for this product.
Skin corrosion/irritation	: There is no data available for this product.
Serious eye damage/eye irritation	: There is no data available for this product.
Respiratory or skin sensitization	: There is no data available for this product.
Carcinogenicity	: There is no data available for this product.
Reproductive effects	: There is no data available for this product.
Germ cell mutagenicity	: There is no data available for this product.
Teratogenicity	: There is no data available for this product.
STOT - single exposure	: There is no data available for this product.
STOT - repeated exposure	: There is no data available for this product.
Aspiration toxicity	: There is no data available for this product.

Components

Acute oral toxicity	: ethanol LD50 rat: 10,470 mg/kg Sodium p-cumenesulphonate LD50 rat: > 7,000 mg/kg subtilisin LD50 rat: 1,800 mg/kg Propylene glycol LD50 rat: 22,000 mg/kg glycerin LD50 rat: 18,300 mg/kg
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Components

Acute inhalation toxicity	: ethanol 4 h LC50 rat: 117 mg/l Test atmosphere: vapour Propylene glycol 4 h LC50 rabbit: 158.5 mg/l Test atmosphere: dust/mist
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Components

Acute dermal toxicity	: ethanol LD50 rabbit: 15,800 mg/kg glycerin LD50 rabbit: 23,000 mg/kg
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Potential Health Effects

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Eyes	: Health injuries are not known or expected under normal use.
Skin	: Health injuries are not known or expected under normal use.
Ingestion	: Health injuries are not known or expected under normal use.
Inhalation	: Health injuries are not known or expected under normal use.
Chronic Exposure	: Health injuries are not known or expected under normal use.

Experience with human exposure

Eye contact	: No symptoms known or expected.
Skin contact	: No symptoms known or expected.
Ingestion	: No symptoms known or expected.
Inhalation	: No symptoms known or expected.

Section: 12. ECOLOGICAL INFORMATION**12.1 Toxicity**

Environmental Effects	: This product has no known ecotoxicological effects.
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Product

Toxicity to fish	: no data available
Toxicity to daphnia and other aquatic invertebrates	: no data available
Toxicity to algae	: no data available

Components

Toxicity to fish	: ethanol 96 h LC50 Pimephales promelas (fathead minnow): > 100 mg/l
	Sodium p-cumenesulphonate 96 h LC50 Oncorhynchus mykiss (rainbow trout): > 1,000 mg/l
	subtilisin 96 h LC50 Oncorhynchus mykiss (rainbow trout): 8.2 mg/l
	Propylene glycol 96 h LC50 Fish: > 10,000 mg/l
	glycerin 96 h LC50 Fish: 855 mg/l

Components

Toxicity to daphnia and other aquatic invertebrates	: ethanol 48 h EC50 Aquatic Invertebrate: 857 mg/l
	subtilisin 48 h EC50 Daphnia magna (Water flea): 0.868 mg/l
	Propylene glycol 48 h EC50 Aquatic Invertebrate: 18,340 mg/l

Components

Toxicity to algae	: Sodium p-cumenesulphonate 96 h EC50 Pseudokirchneriella subcapitata (algae): > 230 mg/l
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subtilisin72 h EC50 *Pseudokirchneriella subcapitata* (green algae): 1.44 mg/l

12.2 Persistence and degradability

Product

Biodegradability : The surfactants contained in the product are biodegradable according to the requirements of the detergent regulation 648/2004/EC

Components

Biodegradability : ethanolResult: Readily biodegradable.

Sodium p-cumenesulphonateResult: Readily biodegradable.

subtilisinResult: Readily biodegradable.

Propylene glycolResult: Readily biodegradable.

glycerinResult: Readily biodegradable.

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

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 Other adverse effects

no data available

Section: 13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

13.1 Waste treatment methods

Product : Diluted product can be flushed to sanitary sewer if regulations permit.

Contaminated packaging : Dispose of in accordance with local, state, and federal regulations.

Guidance for Waste Code selection : Organic wastes containing not dangerous substances with concentration $\geq 0.1\%$. If this product is used in any further

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processes, the final user must redefine and assign the most appropriate European Waste Catalogue Code. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable European (EU Directive 2008/98/EC) and local regulations.

Section: 14. TRANSPORT INFORMATION

The shipper/consignor/sender is responsible to ensure that the packaging, labeling, and markings are in compliance with the selected mode of transport.

Land transport (ADR/ADN/RID)

- | | |
|-----------------------------------|-----------------------|
| 14.1 UN number | : Not dangerous goods |
| 14.2 UN proper shipping name | : Not dangerous goods |
| 14.3 Transport hazard class(es) | : Not dangerous goods |
| 14.4 Packing group | : Not dangerous goods |
| 14.5 Environmental hazards | : Not dangerous goods |
| 14.6 Special precautions for user | : Not dangerous goods |

Air transport (IATA)

- | | |
|-----------------------------------|-----------------------|
| 14.1 UN number | : Not dangerous goods |
| 14.2 UN proper shipping name | : Not dangerous goods |
| 14.3 Transport hazard class(es) | : Not dangerous goods |
| 14.4 Packing group | : Not dangerous goods |
| 14.5 Environmental hazards | : Not dangerous goods |
| 14.6 Special precautions for user | : Not dangerous goods |

Sea transport (IMDG/IMO)

- | | |
|---|-----------------------|
| 14.1 UN number | : Not dangerous goods |
| 14.2 UN proper shipping name | : Not dangerous goods |
| 14.3 Transport hazard class(es) | : Not dangerous goods |
| 14.4 Packing group | : Not dangerous goods |
| 14.5 Environmental hazards | : Not dangerous goods |
| 14.6 Special precautions for user | : Not dangerous goods |
| 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | : Not dangerous goods |

Section: 15. REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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according to Detergents : less than 5 %: Anionic surfactants, Non-ionic surfactants
 Regulation EC 648/2004 Other constituents: Enzymes
 Preservation agents:
 2-phenoxyethanol

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

Candidate List of Substances : Not applicable.
 of Very High Concern for
 Authorisation

National Regulations

Take note of Dir 94/33/EC on the protection of young people at work.

Other regulations : The Chemicals (Hazard Information and Packaging for Supply)
 Regulations.
 The Control of Substances Hazardous to Health Regulations.
 Health and Safety at Work Act.

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out on the product.

Section: 16. OTHER INFORMATION**Procedure used to derive the classification according to REGULATION (EC) No 1272/2008**

Classification	Justification
Not a hazardous substance or mixture.	Calculation method

Full text of H-Statements

H225 Highly flammable liquid and vapour.
 H302 Harmful if swallowed.
 H315 Causes skin irritation.
 H318 Causes serious eye damage.
 H319 Causes serious eye irritation.
 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

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European 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;

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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 - International 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; TECL - 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

Prepared by : Regulatory Affairs

Numbers quoted in the MSDS are given in the format: 1,000,000 = 1 million and 1,000 = 1 thousand. 0.1 = 1 tenth and 0.001 = 1 thousandth

REVISED INFORMATION: Significant changes to regulatory or health information for this revision is indicated by a bar in the left-hand margin of the SDS.

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.

Annex: Exposure Scenarios**Exposure Scenario: Medical devices . Dipping process**

Life Cycle Stage : Widespread use by professional workers

Product category : **PC35** Washing and cleaning products (including solvent based products)

Contributing scenario controlling environmental exposure for:

Environmental release category : **ERC8a** Wide dispersive indoor use of processing aids in open systems

Daily amount per site : 7.5 kg

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Type of Sewage Treatment Plant : Municipal sewage treatment plant

Contributing scenario controlling worker exposure for:

Process category : **PROC13** Treatment of articles by dipping and pouring

Exposure duration : 60 min

Operational conditions and risk management measures : Indoor

Local Exhaust Ventilation is not required

General ventilation Ventilation rate per hour 1

Skin Protection : see section 8

Respiratory Protection : see section 8