

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

Product name : SEKUSEPT MULTIENZYME P
Product code : 114549E
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
Medical devices . Manual 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-European
Poison Information Centre telephone number : Not Available

Date of Compilation/Revision : 10.08.2017
Version : 2.0

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

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Not a hazardous substance or mixture.

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.	ClassificationREGULATION (EC) No 1272/2008	Concentration: [%]
Sodiumcumenesulphonat e	28348-53-0 248-983-7	Eye irritation Category 2; H319	>= 3 - < 5
Substances with a workplace exposure limit :			
Propylene glycol	57-55-6 200-338-0 01-2119456809-23		>= 50 - <= 100
ethanol	64-17-5 200-578-6 01-2119457610-43	Flammable liquids Category 2; H225	>= 2.5 - < 5
glycerin	56-81-5 200-289-5		>= 2.5 - < 5

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.
- 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

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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 : Decomposition products may include the following materials:
Carbon oxides
nitrogen oxides (NO_x)
Sulphur oxides
Oxides of phosphorus

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.

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.

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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. Keep away from oxidizing agents. Keep out of reach of children. Keep container tightly closed. Store in suitable labeled containers.
- Storage temperature : 0 °C to 25 °C

7.3 Specific end uses

- Specific use(s) : Medical devices . Dipping process
Medical devices . Manual 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 (particles)	10 mg/m3	UKCOSSTD
Further information	2	Where no specific short-term exposure limit is listed, a figure three times the long-term exposure should be used		
		TWA (Total vapour and particles)	150 ppm 474 mg/m3	UKCOSSTD
Further information	2	Where no specific short-term exposure limit is listed, a figure three times the long-term exposure should be used		
ethanol	64-17-5	TWA	1,000 ppm 1,920 mg/m3	UKCOSSTD
Further information	2	Where no specific short-term exposure limit is listed, a figure three times the long-term exposure should be used		
glycerin	56-81-5	TWA (Mist)	10 mg/m3	UKCOSSTD
Further information	2	Where no specific short-term exposure limit is listed, a figure three times the long-term exposure should be used		
subtilisin	9014-01-1	TWA	0.00004 mg/m3	UKCOSSTD
Further information	39	One of the suitable measurement methods is the fluorescence polarisation technique developed by the Health and Safety Laboratory (HSL). The previous limit for subtilisin was based on high-volume static sampling to achieve sufficient sensitivity. However, improvements in the analytical methodology have improved the sensitivity and the WEL for subtilisin reflects this. The limit is based on standard personal sampling (MDHS14/3).6 Short-term reference period (15 minute) sampling is not appropriate.		
	53+5 4	Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological, irritant or other mechanism. Once the		

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		airways have become hyper-responsive, further exposure to the substance, sometimes even to tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance those who are likely to become hyper-responsive. 54 Substances that can cause occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing airway hyper-responsiveness, but which do not include the disease themselves. The latter substances are not classified asthmagens or respiratory sensitisers.
	55	Wherever it is reasonably practicable, exposure to substances that can cause occupational asthma should be prevented. Where this is not possible, the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive. For substances that can cause occupational asthma, COSHH requires that exposure be reduced as low as is reasonably practicable. Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance.
	38	Subtilisins are proteolytic enzymes derived from Bacillus subtilis. They are used in biological washing powders, animal feedstuffs etc. The enzyme preparation contains active enzyme, inactive enzyme and protein residues.
	Sen	Capable of causing occupational asthma. The identified substances are those which: - are assigned the risk phrase 'R42: May cause sensitisation by inhalation'; or 'R42/43: May cause sensitisation by inhalation and skin contact' or - are listed in section C of HSE publication 'Asthmagens? Critical assessments of the evidence for agents implicated in occupational asthma' as updated from time to time, or any other substance which the risk assessment has shown to be a potential cause of occupational asthma.
	2	Where no specific short-term exposure limit is listed, a figure three times the long-term exposure should be used
	56	The 'Sen' notation in the list of WELs has been assigned only to those substances which may cause 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 Value: 213 mg/cm2

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	End Use: Consumers Exposure routes: Ingestion Potential health effects: Long-term systemic effects Value: 85 ppm
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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

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, 89/686/EEC), 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.

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Section: 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	: liquid
Colour	: dark blue
Odour	: Perfumes, fragrances
pH	: 8.6, 100 %
Flash point	: 56 °C closed cup, 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
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.

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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

Decomposition products may include the following materials:

Carbon oxides
nitrogen oxides (NO_x)
Sulphur oxides
Oxides of phosphorus

Section: 11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

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

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

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Acute oral toxicity : Sodiumcumenesulphonate
LD50 rat: 7,000 mg/kg

Propylene glycol
LD50 rat: 22,000 mg/kg

ethanol
LD50 rat: 10,470 mg/kg

glycerin
LD50 rat: 18,300 mg/kg

Components

Acute inhalation toxicity : Sodiumcumenesulphonate
4 h LC50 rat: 770 mg/l

Propylene glycol
4 h LC50 rat: 158.5 mg/l

ethanol
4 h LC50 rat: 117 mg/l

Components

Acute dermal toxicity : Sodiumcumenesulphonate
LD50 rabbit: 2,000 mg/kg

ethanol
LD50 rabbit: > 15,800 mg/kg

glycerin
LD50 rabbit: 23,000 mg/kg

Potential Health Effects

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

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12.1 Ecotoxicity

Environmental Effects : This product has no known ecotoxicological effects.

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 : Sodiumcumenesulphonate
96 h LC50 Fish: 450 mg/l

Propylene glycol
96 h LC50: > 10,000 mg/l

ethanol
96 h LC50 Pimephales promelas (fathead minnow): > 100 mg/l

glycerin
96 h LC50 Fish: 855 mg/l

Components

Toxicity to daphnia and other aquatic invertebrates : Propylene glycol
48 h EC50: 18,340 mg/l

Components

Toxicity to algae : Propylene glycol
96 h EC50: 19,000 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 : Sodiumcumenesulphonate
Result: Readily biodegradable.

Propylene glycol
Result: Readily biodegradable.

ethanol
Result: Readily biodegradable.Result: Readily biodegradable.

glycerin
Result: Readily biodegradable.

12.3 Bioaccumulative potential

no data available

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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.

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

Guidance for Waste Code selection : Organic wastes containing dangerous substances. If this product is used in any further 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)

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- 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

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

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

This product contains substances for which Chemical Safety Assessments are still required.

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

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Full text of H-Statements

H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.

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; AICS – Australian Inventory of Chemical Substances; 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 – 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; TCSI – Taiwan Chemical Substance 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.

SEKUSEPT MULTIENZYME P**ANNEX: EXPOSURE SCENARIOS****DPD+ Substances:**

The following substances are the lead substances that contribute to the mixture Exposure Scenario according to the DPD+ Rule:

Route	Substance	CAS-No.	EINECS-No.
Respiratory sensitiser	subtilisin	9014-01-1	232-752-2
	No lead substance, not hazardous		

To calculate if your downstream Operating Conditions and Risk management Measures are safe, please calculate your risk factor at the website below:

www.ecetoc.org/tra

Short title of Exposure Scenario : **Medical devices . Dipping process**

Use descriptors

- Main User Groups : Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- Sectors of end-use : **SU22:** Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- Process categories : **PROC13:** Treatment of articles by dipping and pouring
PROC8a: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated facilities
- Product categories : **PC35:** Washing and cleaning products (including solvent based products)
- Environmental Release Categories : **ERC8a:** Wide dispersive indoor use of processing aids in open systems

Short title of Exposure Scenario : **Medical devices . Manual process**

Use descriptors

- Main User Groups : Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- Sectors of end-use : **SU22:** Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- Process categories : **PROC10:** Roller application or brushing
PROC8a: Transfer of substance or preparation (charging/ discharging) from/ to vessels/ large containers at non-dedicated

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facilities

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

Environmental Release Categories : **ERC8a:** Wide dispersive indoor use of processing aids in open systems