

Olympus EndoDet Plus

Section: 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name : Olympus EndoDet Plus
Product code : 116044E
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 . Semi-automatic process
Recommended restrictions on use : Reserved for industrial and professional use.

1.3 Details of the supplier of the safety data sheet

Company : OLYMPUS Deutschland GmbH
Wendenstraße 14-18
Hamburg, Germany 20097
040-23773-0

1.4 Emergency telephone number

Emergency telephone number : 0049-2173-5991700 (24/7)
Poison Information Centre telephone number : +49 (0)551 19240
Date of Compilation/Revision version : 24.10.2016 : 1.5

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)

Not a hazardous substance or mixture.

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Additional Labelling:

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

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: [%]
Fattyalcohol ethoxylates > 5EO	147993-63-3	Acute aquatic toxicity Category 1; H400 Skin corrosion/irritation Category 2; H315	>= 5 - < 10
Sodiumcumenesulphonate	28348-53-0 248-983-7	Eye irritation Category 2; H319	>= 3 - < 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

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : Not flammable or combustible.

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 : 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 : 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 : Wash hands after handling. For personal protection see section 8.

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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 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 . Semi-automatic 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
formic acid	64-18-6	AGW	5 ppm 9.5 mg/m3	TRGS 900
Further information	DFG	Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission).		
	EU	European Union (The EU has established a limit value: deviations in value and peak limit are possible)		
	Y	When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child		

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

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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	: light yellow
Odour	: slight
pH	: 6.0 - 7.0, 100 %
Flash point	: 100 °C closed cup
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	: 1.058 - 1.066
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

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Stable under normal conditions.

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

None known.

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.

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Aspiration toxicity : There is no data available for this product.

Components

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

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

Acute dermal toxicity : Sodiumcumenesulphonate
LD50 rabbit: > 2,000 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

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

12.2 Persistence and degradability

Product

no data available

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Components

Biodegradability : Sodiumcumenesulphonate
Result: 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.
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 : Not dangerous goods

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class(es)
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

according to Detergents Regulation EC 648/2004 : 5 % or over but less than 15 %: Non-ionic surfactants
Other constituents: Enzymes

National Regulations

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

Hazard class for water : WGK 2
Classification according VwVwS, Annex 4.

German storage class : 12

15.2 Chemical Safety Assessment

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

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

Classification	Justification
Not Classified	

Full text of H-Statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.

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

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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

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.
Ingestion	No lead substance		
Inhalation	No lead substance		
Dermal	Fattyalcohol ethoxylates > 5EO	147993-63-3	
Eyes	Sodiumcumenesulphonate	28348-53-0	248-983-7
aquatic environment	Fattyalcohol ethoxylates > 5EO	147993-63-3	

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 . Semi-automatic 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 : **PROC1:** Use in closed process, no likelihood of exposure
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