

OLYMPUS ENDOACT

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

1.1 Product identifier

Product name : OLYMPUS ENDOACT
Product code : 107643E
Use of the Substance/Mixture : Booster
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 : 09.11.2016
version : 1.0

Section: 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin corrosion, Category 1A H314
Serious eye damage, Category 1 H318

The classification of this product is based only on its extreme pH value (in accordance with current European legislation).

2.2 Label elements

OLYMPUS ENDOACT

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal Word :

Danger

Hazard Statements :

H314

Causes severe skin burns and eye damage.

Precautionary Statements :

Prevention:

P280

Wear protective gloves/ eye protection/ face protection.

Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310

Immediately call a POISON CENTER/doctor.

Hazardous components which must be listed on the label:
sodium hydroxide

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: [%]
sodium hydroxide	1310-73-2 215-185-5 01-2119457892-27	Skin corrosion Category 1A; H314 Corrosive to metals Category 1; H290	>= 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 immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.

In case of skin contact :

Wash off immediately with plenty of water for at least 15 minutes. Use a mild soap if available. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention immediately.

OLYMPUS ENDOACT

- If swallowed : Rinse mouth with water. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention immediately.
- If inhaled : Remove to fresh air. Treat symptomatically. 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 : Treat symptomatically.

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 : Not flammable or combustible.
- Hazardous combustion products : Decomposition products may include the following materials:
Carbon oxides
nitrogen oxides (NOx)
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. In the event of fire and/or explosion do not breathe fumes.

Section: 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

- Advice for non-emergency personnel : Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid inhalation, ingestion and contact with skin and eyes. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Ensure clean-up is conducted by trained personnel only. Refer to protective measures listed in sections 7 and 8.
- Advice for emergency : If specialised clothing is required to deal with the spillage, take

OLYMPUS ENDOACT

responders : note of any information in Section 8 on suitable and unsuitable materials.

6.2 Environmental precautions

Environmental precautions : Do not allow contact with soil, surface or ground water.

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 : Do not ingest. Do not get in eyes, on skin, or on clothing. Do not breathe dust/fume/gas/mist/vapours/spray. Use only with adequate ventilation. Wash hands thoroughly after handling.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Do not store near acids. 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

Contains no substances with occupational exposure limit values.

DNEL

sodium hydroxide	:	End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term local effects
------------------	---	--

OLYMPUS ENDOACT

	Value: 1 mg/m ³
	End Use: Consumers Exposure routes: Inhalation Potential health effects: Long-term local effects Value: 1 mg/m ³

8.2 Exposure controls

Appropriate engineering controls

Engineering measures : Effective exhaust ventilation system. Maintain air concentrations below occupational exposure standards.

Individual protection measures

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Remove and wash contaminated clothing before re-use. Wash face, hands and any exposed skin thoroughly after handling. Provide suitable facilities for quick drenching or flushing of the eyes and body in case of contact or splash hazard.

Eye/face protection (EN 166) : Safety goggles
Face-shield

Hand protection (EN 374) : Recommended preventive skin protection
Gloves
Nitrile rubber
butyl-rubber
Breakthrough time: 1 – 4 hours
Minimum thickness for butyl-rubber 0.7 mm for nitrile rubber 0.4 mm or equivalent (please refer to the gloves manufacturer/distributor for advise).
Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough.

Skin and body protection (EN 14605) : Personal protective equipment comprising: suitable protective gloves, safety goggles and protective clothing

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.

Section: 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance : liquid

OLYMPUS ENDOACT

Colour	: light yellow
Odour	: slight
pH	: 13.5, 100 %
Flash point	: Not applicable.
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.

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

OLYMPUS ENDOACT

Acids

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.

Potential Health Effects

Eyes : Causes serious eye damage.

Skin : Causes severe skin burns.

Ingestion : Causes digestive tract burns.

Inhalation : May cause nose, throat, and lung irritation.

OLYMPUS ENDOACT

Chronic Exposure : Health injuries are not known or expected under normal use.

Experience with human exposure

Eye contact : Redness, Pain, Corrosion

Skin contact : Redness, Pain, Corrosion

Ingestion : Corrosion, Abdominal pain

Inhalation : Respiratory irritation, Cough

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 daphnia and other aquatic invertebrates : sodium hydroxide
48 h EC50: 40 mg/l

12.2 Persistence and degradability

Product

no data available

Components

Biodegradability : sodium hydroxide
Result: Not applicable - inorganic

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.

OLYMPUS ENDOACT

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 : Where possible recycling is preferred to disposal or incineration. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.
- Contaminated packaging : Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local, state, and federal regulations.
- Guidance for Waste Code selection : Inorganic 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 : 1824
- 14.2 UN proper shipping name : SODIUM HYDROXIDE SOLUTION
- 14.3 Transport hazard class(es) : 8
- 14.4 Packing group : III
- 14.5 Environmental hazards : No
- 14.6 Special precautions for user : None

Air transport (IATA)

- 14.1 UN number : 1824
- 14.2 UN proper shipping name : Sodium hydroxide solution
- 14.3 Transport hazard class(es) : 8
- 14.4 Packing group : III
- 14.5 Environmental hazards : No
- 14.6 Special precautions for user : None

OLYMPUS ENDOACT

Sea transport (IMDG/IMO)

14.1 UN number : 1824
 14.2 UN proper shipping name : SODIUM HYDROXIDE SOLUTION
 14.3 Transport hazard class(es) : 8
 14.4 Packing group : III
 14.5 Environmental hazards : No
 14.6 Special precautions for user : None
 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not applicable.

Section: 15. REGULATORY INFORMATION

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

National Regulations

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

Hazard class for water : WGK 1
 Classification according VwVwS, Annex 4.

German storage class : 8B

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
Skin corrosion 1A, H314	On basis of test data.
Serious eye damage 1, H318	Calculation method

Full text of H-Statements

H290 : May be corrosive to metals.
 H314 : Causes severe skin burns and eye damage.

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

OLYMPUS ENDOACT

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.

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	sodium hydroxide	1310-73-2	215-185-5
Inhalation	sodium hydroxide	1310-73-2	215-185-5
Dermal	sodium hydroxide	1310-73-2	215-185-5
Eyes	sodium hydroxide	1310-73-2	215-185-5
aquatic environment	No lead substance		

OLYMPUS ENDOACT

Physical properties DPD+ Substances:

Substance	Vapour pressure	Water solubility	Pow	Molar Mass
sodium hydroxide		1 g/ml		40 g/mol

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