

Safety data sheet

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

1.1. Product identifier

Code: C800061
Product name: ZETA 5 UNIT

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

Intended use: For professional use only. Disinfectant, detergent and deodorant for surgical aspirators.

1.3. Details of the supplier of the safety data sheet

Name: Zhermack S.p.a
Full address: Via Bovazecchino
District and Country: 45021 Badia Polesine (RO)
Italy
Tel. +39 0425-597611
Fax +39 0425-53596

e-mail address of the competent person responsible for the Safety Data Sheet: msds@zhermack.com

1.4. Emergency telephone number

For urgent inquiries refer to: UK Emergency number: 844 892 0111 (24 hours)

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments.

Hazard classification and indication:
Eye Dam. 1 H318
Skin Irrit. 2 H315

2.2. Label elements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

**C800061
ZETA 5 UNIT**

Signal words: Danger

Hazard statements:

H318 Causes serious eye damage.
H315 Causes skin irritation.

Precautionary statements:

P280 Wear protective gloves / protective clothing / eye protection / face protection.
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 or doctor/physician.

Contains: SODIUM 2-BIPHENYLATE

2.3. Other hazards.

Information not available.

SECTION 3. Composition/information on ingredients.**3.1. Substances.**

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 1272/2008 (CLP).
SODIUM 2-BIPHENYLATE		
CAS. 132-27-4	1 – 2,5	Acute Tox. 4 H302, Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Aquatic Acute 1 H400 M=1
EC. 205-055-6		
INDEX. 604-021-00-1		
SODIUM HYDROXIDE		
CAS. 1310-73-2	0,5 - 1	Met. Corr. 1 H290, Skin Corr. 1A H314
EC. 215-185-5		
INDEX. 011-002-00-6		
Reg. no. 01-2119457892-27-XXXX		

Note: Upper limit is not included into the range.

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures.**4.1. Description of first aid measures.**

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

4.2. Most important symptoms and effects, both acute and delayed.

For symptoms and effects caused by the contained substances, see chap. 11.

4.3. Indication of any immediate medical attention and special treatment needed.

Information not available.

SECTION 5. Firefighting measures.**5.1. Extinguishing media.**

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

5.3. Advice for firefighters.

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures.**6.1. Personal precautions, protective equipment and emergency procedures.**

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up.

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage.**7.1. Precautions for safe handling.**

Ensure that there is an adequate earthing system for the equipment and personnel. Avoid contact with eyes and skin. Do not breathe powders, vapours or mists. Do not eat, drink or smoke during use. Wash hands after use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container (0 - 25°C). Store in a ventilated and dry place, far away from sources of ignition. Keep containers well sealed. Keep the product in clearly labelled containers. Avoid overheating. Avoid violent blows. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

Medical device.

SECTION 8. Exposure controls/personal protection.**8.1. Control parameters.**

Regulatory References:

United Kingdom	EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended).
Éire	Code of Practice Chemical Agent Regulations 2011.
OEL EU	Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC.
TLV-ACGIH	ACGIH 2012

SODIUM HYDROXIDE**Threshold Limit Value.**

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV-ACGIH				2 (C)	

C800061
ZETA 5 UNIT

OEL	IRL	2
WEL	UK	2

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers.			Effects on workers			Chronic local	Chronic systemic
	Acute local	Acute systemic	Chronic local	Acute local	Acute systemic	Chronic local		
Inhalation.			1 mg/m3			VND	1 mg/m3	VND

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear a hood visor or protective visor combined with airtight goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	liquid
Colour	brown
Odour	characteristic
Odour threshold.	Not available.
pH.	12-14, 100%
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.

**C800061
ZETA 5 UNIT**

Flash point.	Not applicable.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	1-1,004
Solubility	soluble
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not classified.

9.2. Other information.

Information not available.

SECTION 10. Stability and reactivity.**10.1. Reactivity.**

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid.

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials.

SODIUM HYDROXIDE: strong acids, ammonia, zinc, lead, aluminium, water and flammable liquids.

10.6. Hazardous decomposition products.

Possible development of:

Carbon oxides

Nitrogen oxides (NO_x)

Sulfur oxides

Phosphorus oxides

SECTION 11. Toxicological information.**11.1. Information on toxicological effects.**

Acute toxicity:
Oral: > 2,000 mg/kg (SDS supplier).
Inhalation: No data available.

Irritation/Corrosion
Skin irritation: No data available.
Eye irritation: No data available.

Respiratory or skin Sensitization: No data available.

STOT – Repeated exposure: No data available.

Genotoxicity: No data available.

Carcinogenicity: No data available.

Toxicity to reproduction: No data available.

Developmental toxicity: No data available.

Aspiration toxicity: No data available.

Potential health effects**Inhalation**

Health injuries are not known or expected under normal use.

Ingestion

Health injuries are not known or expected under normal use.

Skin

Cause skin irritation.

Eye

Cause serious eye damage.

Chronic exposure

Health injuries are not known or expected under normal use.

Human experience**Eye contact**

Redness, pain, corrosion.

Skin contact

Redness, irritation.

Inhalation

Health injuries are not known or expected under normal use.

Ingestion

Health injuries are not known or expected under normal use.

SECTION 12. Ecological information.**12.1. Toxicity.**

IDROSSIDO DI SODIO
EC50 - Crostacei. 40 mg/l (Daphnia magna, MSDS supplier).

12.2. Persistence and degradability.

Information not available.

12.3. Bioaccumulative potential.

Information not available.

12.4. Mobility in soil.

Information not available.

12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.

SECTION 13. Disposal considerations.

13.1. Waste treatment methods.

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Avoid littering. Do not contaminate soil, sewers and waterways.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information.

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

SECTION 15. Regulatory information.

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

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product.

Point. 3

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Healthcare controls.

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

Composition according to Annex VII.a of Reg. (EC) 648/2004:

< 5%: disinfectant, perfume.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Met. Corr. 1	Substance or mixture corrosive to metals, category 1
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1A	Skin corrosion, category 1A
Eye Dam. 1	Serious eye damage, category 1
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
H290	May be corrosive to metals.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

R22	HARMFUL IF SWALLOWED.
R35	CAUSES SEVERE BURNS.
R36/38	IRRITATING TO EYES AND SKIN.
R37/38	IRRITATING TO RESPIRATORY SYSTEM AND SKIN.
R41	RISK OF SERIOUS DAMAGE TO EYES.
R50	VERY TOXIC TO AQUATIC ORGANISMS.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road

**C800061
ZETA 5 UNIT**

- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
8. Regulation (EC) 618/2012 (III Atp. CLP) of the European Parliament
9. The Merck Index. - 10th Edition
10. Handling Chemical Safety
11. Niosh - Registry of Toxic Effects of Chemical Substances
12. INRS - Fiche Toxicologique (toxicological sheet)
13. Patty - Industrial Hygiene and Toxicology
14. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
15. ECHA website

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

01/ 15.