

Safety data sheet

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

1.1. Product identifier

Code: C810000, C810001
Product name: ZETA 1 ULTRA

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

Intended use: For professional use only. Disinfectant and detergent for surgical and rotating instruments.

1.3. Details of the supplier of the safety data sheet

Name: Zhermack S.p.a
Full address: Via Bovazecchino 100
District and Country: 45021 Badia Polesine (RO)
Italy
Tel. +39 0425-597611
Fax +39 0425-597689

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.

Hazard classification and indication:

Flammable liquid, category 3	H226	Flammable liquid and vapour.
Acute toxicity, category 4	H302	Harmful if swallowed.
Specific target organ toxicity - repeated exposure, category 2	H373	May cause damage to organs through prolonged or repeated exposure.
Serious eye damage, category 1	H318	Causes serious eye damage.
Skin irritation, category 2	H315	Causes skin irritation.
Hazardous to the aquatic environment, acute toxicity, category 1	H400	Very toxic to aquatic life.
Hazardous to the aquatic environment, chronic toxicity, category 1	H410	Very toxic to aquatic life with long lasting effects.

2.2. Label elements.

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



Signal words: Danger

Hazard statements:

H226 Flammable liquid and vapour.
 H302 Harmful if swallowed.
 H373 May cause damage to organs through prolonged or repeated exposure.
 H318 Causes serious eye damage.
 H315 Causes skin irritation.
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P233 Keep container tightly closed.
 P264 Wash hands thoroughly after handling.
 P280 Wear protective gloves / clothing and eye / face protection.
 P301+P312 IF SWALLOWED: call a POISON CENTER / doctor if you feel unwell.
 P304+P340 IF INHALED: remove person to fresh air and keep comfortable for breathing.

Contains: N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE
 QUATERNARY AMMONIUM COMPOUNDS, BENZYL-C12-16-ALKYLDIMETHYL, CHLORIDES
 ALCOHOLS, C9-11 ETHOXYLATED
 TETRASODIUM ETHYLENE DIAMINE TETRAACETATE

2.3. Other hazards.

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

Classification of the mixture, characterised by an extreme pH value, is based on the results of an in vivo assay conducted in accordance with the guidelines provided by OCSE (OECD Test Guideline 404 - Acute Dermal Irritation/Corrosion) and GLP certified - Good Laboratory Practices. For more information refer to section 11.

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

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 1272/2008 (CLP).
N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE		
CAS. 2372-82-9	10 - 20	Acute Tox. 3 H301, STOT RE 2 H373, Skin Corr. 1A H314, Aquatic Acute 1 H400 M=10, Aquatic Chronic 1 H410
EC. 219-145-8		

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**QUATERNARY AMMONIUM COMPOUNDS,
BENZYL-C12-16-ALKYLDIMETHYL, CHLORIDES**

CAS. 68424-85-1

9 - 19

Acute Tox. 4 H302, Skin Corr. 1B H314, Aquatic Acute 1 H400
M=10, Aquatic Chronic 1 H410

EC. 270-325-2

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**TETRASODIUM ETHYLENE DIAMINE
TETRAACETATE**

CAS. 64-02-8

5 - 10

Acute Tox. 4 H302, Acute Tox. 4 H332, STOT RE 2 H373, Eye
Dam. 1 H318

EC. 200-573-9

INDEX. 607-428-00-2

Reg. no. 01-2119486762-27-XXXX

PROPAN-2-OL

CAS. 67-63-0

5 - 10

Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336

EC. 200-661-7

INDEX. 603-117-00-0

Reg. no. 01-2119457558-25-XXXX

ALCOHOLS, C9-11 ETHOXYLATED

CAS. 68439-46-3

3 - 5

Acute Tox. 4 H302, Eye Dam. 1 H318

EC. -

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**ALCOHOLS, C12-14, ETHOXYLATED
PROPOXYLATED**

CAS. 68439-51-0

1 - 3

Aquatic Chronic 3 H412

EC. -

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**D-GLUCOPYRANOSE, OLIGOMERIC, C10-
16(EVEN NUMBERED) ALKYL GLYCOSIDES**

CAS. 110615-47-9

1 - 3

Eye Dam. 1 H318, Skin Irrit. 2 H315

EC. -

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Reg. no. 01-2119489418-23-XXXX

L-(+)-LACTIC ACID

CAS. 79-33-4

1 - 3

Eye Dam. 1 H318, Skin Irrit. 2 H315

EC. 201-196-2

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Reg. no. 01-2119474164-39-XXXX

**D-GLUCOPYRANOSE, OLIGOMERS, DECYL
OCTYL GLYCOSIDES**

CAS. 68515-73-1

1 - 3

Eye Dam. 1 H318

EC. 500-220-1

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Reg. no. 01-2119488530-36-XXXX

TRISODIUM NITRILOTRIACETATE

CAS. 5064-31-3

0,2 - 0,4

Carc. 2 H351, Acute Tox. 4 H302, Eye Irrit. 2 H319

EC. 225-768-6

INDEX. 607-620-00-6

Note: Upper limit is not included into the range.

The full wording of 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

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Excess pressure may form in containers exposed to fire at a risk of explosion. 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.

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

Disinfectant for medical devices.

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

Regulatory References:

AUS	Österreich	Grenzwerteverordnung 2011 - GKV 2011
BEL	Belgique	AR du 11/3/2002. La liste est mise à jour pour 2010
DEU	Deutschland	MAK-und BAT-Werte-Liste 2012
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2015
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GRB	United Kingdom	EH40/2005 Workplace exposure limits
IRL	Éire	Code of Practice Chemical Agent Regulations 2011
NLD	Nederland	Databank of the social and Economic Concil of Netherlands (SER) Values, AF 2011:18
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
POL	Polska	ROZPORZĄDZENIE MINISTRA PRACY I POLITYKI SPOŁECZNEJ z dnia 16 grudnia 2011r
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
	TLV-ACGIH	ACGIH 2014

TETRASODIUM ETHYLENE DIAMINE TETRAACETATE

Predicted no-effect concentration - PNEC.

Normal value in fresh water	2,2	mg/l
Normal value in marine water	0,22	mg/l
Normal value for water, intermittent release	1,2	mg/l
Normal value of STP microorganisms	43	mg/l
Normal value for the terrestrial compartment	0,72	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers.				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral.			VND	2,5 mg/kg				
Inhalation.	1,5 mg/m3	1,5 mg/m3	1,5 mg/m3	1,5 mg/m3	2,5 mg/m3	2,5 mg/m3	2,5 mg/m3	2,5 mg/m3

PROPAN-2-OL

Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
MAK	AUS	500	200	2000	800
VLEP	BEL	500	200	1000	400
AGW	DEU	500	200	1000	400
MAK	DEU	500	200	1000	400
TLV	DNK	490	200		
VLA	ESP	500	200	1000	400
VLEP	FRA			980	400
WEL	GRB	999	400	1250	500

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OEL	IRL		200		400	SKIN.
OEL	NLD	650				
TLV	NOR	245	100			
NDS	POL	900		1200		
MAK	SWE	350	150	600	250	
TLV-ACGIH		492	200	983	400	

Predicted no-effect concentration - PNEC.

Normal value in fresh water	140,9	mg/l
Normal value in marine water	140,9	mg/l
Normal value for fresh water sediment	552	mg/kg
Normal value for the terrestrial compartment	28	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers.			Effects on workers				
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral.			VND	26 mg/kg				
Inhalation.			VND	89 mg/m3			VND	500 mg/m3
Skin.			VND	319 mg/kg			VND	888 mg/kg

L-(+)-LACTIC ACID
Predicted no-effect concentration - PNEC.

Normal value in fresh water	1,3	mg/l
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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. Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

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 III 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.

Consider the appropriateness of providing antistatic clothing in the case of working environments in which there is a risk of explosion.

EYE PROTECTION

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

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental

absorption.

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 A 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.

ENVIRONMENTAL EXPOSURE CONTROLS.

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	liquid
Colour	green
Odour	characteristic
Odour threshold.	Not available.
pH.	10-12
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	46,2 °C.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower flammability limit.	Not available.
Upper flammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	1,030 g/ml
Solubility	soluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not explosive
Oxidising properties	Not available.

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.

The vapours may also form explosive mixtures with the air.

10.4. Conditions to avoid.

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

10.5. Incompatible materials.

Information not available.

10.6. Hazardous decomposition products.

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

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

INTERNAL TEST CARRIED OUT ON ZETA 1 ULTRA

Skin Irritation/Corrosion: Strong irritant (OECD 404, GLP, in vivo, rabbit, study report 2007).

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification. It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

Acute effects: ingestion of this product is harmful. Even small amounts of product may cause serious health problems (stomach pain, nausea, sickness, diarrhoea).

LD50 (Oral). 824 mg/kg (calculated).

This product may cause functional disorders or morphological mutations after repeated or prolonged exposure and/or may accumulate inside the human body and is thus graded as dangerous.

This product may cause serious ocular lesions, cornea opacity, iris lesions, irreversible eye coloration.

Acute effects: contact with skin may cause: irritation, erythema, edema, dryness and chapped skin. Ingestion may cause health disorders, including stomach pain and sting, nausea and sickness.

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LD50 (Oral). 4710 mg/kg Rat

LD50 (Dermal). 12800 mg/kg Rat

LC50 (Inhalation). 72,6 mg/l/4h Rat

Irritation/Corrosion

Skin irritation: Not irritating (publication, in vivo, rabbit, ECHA dossier).

Eye irritation: Irritating (comparable to OECD 405, in vivo, rabbit, ECHA dossier).

Respiratory or skin Sensitization: Not sensitising (OECD 406, GLP, Guinea pig, ECHA dossier).

STOT – Repeated exposure: Clinical signs of toxicity on the central nervous system (including ataxia, narcosis, lack of a startle reflex, and/or hypoactivity) are acute effects and not relevant for limit value determination for repeated dose systemic effects. (OECD 413, inhalation, rat-mouse, ECHA dossier).

Genotoxicity in vitro: Negative (Ames test, ECHA dossier).

Genotoxicity in vivo: Negative (OECD 474, mouse, ECHA dossier).

Carcinogenicity: Negative (OECD 451, inhalation, rat, ECHA dossier)

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Toxicity to reproduction: Possible adverse effects on fetal development (OECD 421, rat, ECHA dossier).
Aspiration toxicity: No data available.

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE
LD50 (Oral).261 mg/kg (OECD TG 401, rat, MSDS supplier).
LD50 (Dermal).> 600 mg/kg (OECD TG 402, rat, MSDS supplier).

Acute toxicity:

Inhalation: No data available.

Irritation/Corrosion

Skin irritation: Corrosive (OECD 404, in vivo, rabbit, SDS supplier).

Eye irritation: Corrosive (OECD 404, in vivo, rabbit, SDS supplier).

Respiratory or skin Sensitization: Not sensitising (OECD 406, GLP, in vivo, Guinea pig, SDS supplier).

STOT – Repeated exposure: NOAEL = 9 mg/kg (OECD 408, rat, oral, SDS supplier).

Genotoxicity in vitro: Negative (OECD 471, 473, 476, SDS supplier).

Genotoxicity in vivo: No data available.

Carcinogenicity: Negative (OECD 453, rat, SDS supplier).

Toxicity to reproduction: No data available.

Aspiration toxicity: No data available.

QUATERNARY AMMONIUM COMPOUNDS, BENZYL-C12-16-ALKYLDIMETHYL, CHLORIDES

LD50 (Oral).344 mg/kg (rat, MSDS supplier).

LD50 (Dermal).3340 mg/kg (rabbit, 24 h, MSDS supplier).

Irritation/Corrosion

Skin irritation: Corrosive (rabbit, SDS supplier).

Eye irritation: Corrosive (rabbit, SDS supplier).

Respiratory or skin Sensitization: Not sensitising (OECD 406, guinea pig, SDS supplier).

Genotoxicity in vitro: Negative (OECD 471, 473, SDS supplier).

Genotoxicity in vivo: Information not available.

Carcinogenicity: Information not available.

Toxicity to reproduction: Information not available.

Aspiration toxicity: Information not available.

ALCOHOLS, C12-14, ETHOXYLATED PROPOXYLATED

LD50 (Oral).> 2000 mg/kg (SDS supplier).

LD50 (Dermal).> 5000 mg/kg (rat, SDS supplier).

Acute toxicity:

Inhalation: No data available.

Irritation/Corrosion

Skin irritation: Not irritating (OECD 404, rabbit, SDS supplier).

Eye irritation: Not irritating (Draize test, rabbit, SDS supplier).

Respiratory or skin Sensitization: Not sensitising (Guinea pig maximization test, SDS supplier).

STOT – Repeated exposure: Repeated oral uptake of the substance did not cause substance-related effects (SDS supplier).

Genotoxicity in vitro: Negative (OECD 471, Ames test, SDS supplier).

Carcinogenicity: No data available.

Toxicity to reproduction: No data available.

Aspiration toxicity: No aspiration hazard expected (SDS supplier).

D-GLUCOPYRANOSE, OLIGOMERS, DECYL OCTYL GLYCOSIDES

LD50 (Oral).> 2000 mg/kg (OECD 423, GLP, rat, ECHA dossier).

LD50 (Dermal).> 2000 mg/kg (OECD 402, GLP, rat, ECHA dossier).

Acute toxicity:

Inhalation: No data available.

Irritation/Corrosion

Skin irritation: Not irritating (OECD 404, GLP, in vivo, rabbit, ECHA dossier).

Eye irritation: Highly irritating (read-across based on grouping of substances (category approach), OECD 405, in vivo, rabbit, ECHA dossier).

Respiratory or skin Sensitization: Not sensitising (read-across based on grouping of substances (category approach), EU Method B.6, GLP, in vivo, ECHA dossier).

STOT – Repeated exposure: No data available.

Genotoxicity in vitro: Negative (similar to OECD 476, GLP, mammalian cell gene mutation assay, ECHA dossier).

Genotoxicity in vivo: Insufficient data.

Carcinogenicity: No data available.

Toxicity to reproduction: Insufficient data.

Aspiration toxicity: No data available.

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ZETA 1 ULTRA****D-GLUCOPYRANOSE, OLIGOMERIC, C10-16(EVEN NUMBERED) ALKYL GLYCOSIDES**

LD50 (Oral).> 5000 mg/kg (OECD 401, GLP, rat, ECHA dossier).

LD50 (Dermal).> 2000 mg/kg (OECD 402, GLP, rabbit, ECHA dossier).

Acute toxicity:

Inhalation: No data available.

Irritation/Corrosion

Skin irritation: Irritating (OECD 404, GLP, in vivo, rabbit, ECHA dossier).

Eye irritation: Corrosive (OECD 405, GLP, in vivo, rabbit, ECHA dossier).

Respiratory or skin Sensitization: Not sensitising (OECD 406, GLP, in vivo, Guinea pig, ECHA dossier).

STOT – Repeated exposure: Negative (EU Method B.26, oral, rat, ECHA dossier).

Genotoxicity in vitro: Negative (OECD Guideline 473, GLP, ECHA dossier).

Genotoxicity in vivo: Negative (OECD 474, GLP, mouse, ECHA dossier).

Carcinogenicity: No data available.

Toxicity to reproduction: Negative (OECD 421, rat, oral, ECHA dossier).

Developmental toxicity: Negative (OECD 414, rat, oral, ECHA dossier).

Aspiration toxicity: No data available.

ALCOHOLS, C9-11 ETHOXYLATED

LD50 (Oral).> 300 mg/kg (MSDS supplier).

Acute toxicity:

Inhalation: No data available.

Dermal: No data available.

Irritation/Corrosion

Skin irritation: Not irritating (MSDS supplier).

Eye irritation: Corrosive (MSDS supplier).

Respiratory or skin Sensitization: No data available.

STOT – Repeated exposure: No data available.

Mutagenicity: Negative (MSDS supplier).

Carcinogenicity: No data available.

Toxicity to reproduction: No data available.

Aspiration toxicity: No data available.

TETRASODIUM ETHYLENE DIAMINE TETRAACETATE

LD50 (Oral).1780 mg/kg (MSDS supplier).

LC50 (Inhalation).1000 mg/m3 (rat, MSDS supplier).

Acute toxicity:

Dermal: Not applicable.

Irritation/Corrosion

Skin irritation: Not irritating (in vivo, rabbit, SDS supplier).

Eye irritation: Corrosive (in vivo, rabbit, SDS supplier).

Skin Sensitization: Not sensitising (OECD 406, Guinea Pig Maximation Test, SDS supplier).

STOT – Repeated exposure: Repeated exposure may cause damage to specific organs (inhalation, respiratory system, SDS supplier).

Genotoxicity in vitro: Negative (SDS supplier).

Genotoxicity in vivo: Negative (SDS supplier).

Carcinogenicity: Negative (SDS supplier).

Toxicity to reproduction: Negative (SDS supplier).

Aspiration toxicity: Not applicable.

TRISODIUM NITRILOTRIACETATE

LD50 (Oral).1750 mg/kg (similar OECD 401, rat, ECHA dossier).

LD50 (Dermal).> 2000 mg/kg (standard acute method, rabbit, ECHA dossier).

Acute toxicity:

Inhalation: Not toxic (maximum value tested 5 mg/l).

Irritation/Corrosion

Skin irritation: Not irritating (comparable to OECD 404, in vivo, rabbit, ECHA dossier).

Eye irritation: Slightly irritating (comparable to OECD 405, in vivo, rabbit, ECHA dossier).

Respiratory or skin Sensitization: Not sensitising (OECD 406, in vivo, Guinea pig, ECHA dossier).

STOT – Repeated exposure: Negative (subacute, inhalation, monkey, ECHA dossier).

Genotoxicity in vitro: Negative (OECD 471, Ames test, ECHA dossier).

Genotoxicity in vivo: No data available.

Carcinogenicity: Inconclusive (OECD 451, rat, oral, ECHA dossier).

Toxicity to reproduction: Negative (similar to OECD 416, rat, oral, ECHA dossier).

Aspiration toxicity: No data available.

L-(+)-LACTIC ACID

LD50 (Oral).> 3730 mg/kg (rat, MSDS supplier).

LD50 (Dermal).> 2000 mg/kg (rabbit, MSDS supplier).

Acute toxicity

Inhalation: No data available.

Irritation/Corrosion

Skin irritation: Mild skin irritating (rabbit, MSDS supplier).

Eye irritation: Irritating (rabbit, MSDS supplier).

Respiratory or skin Sensitization: No data available.

STOT – Repeated exposure: No data available.

Germ cell mutagenicity: Tests on bacterial or mammalian cell cultures did not show mutagenic effects (MSDS supplier).

Carcinogenicity: Animal testing did not show any carcinogenic effects (MSDS supplier).

Aspiration toxicity: No data available.

SECTION 12. Ecological information.

This product is dangerous for the environment and highly toxic for aquatic organisms. In the long term, it have negative effects on aquatic environment.

12.1. Toxicity.

PROPAN-2-OL

LC50 - for Fish.

9640 mg/l/96h (similar to OECD 203, Pimephales promelas, freshwater, ECHA dossier).

EC50 - for Crustacea.

> 10000 mg/l/48h (similar to OECD 202, Daphnia magna, 24h, ECHA dossier).

N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE

LC50 - for Fish.

0,68 mg/l/96h (OECD TG 203, Oncorhynchus mykiss, MSDS supplier).

EC50 - for Crustacea.

0,073 mg/l/48h (US_EPA, Daphnia magna, MSDS supplier).

EC50 - for Algae / Aquatic Plants.

0,054 mg/l/72h (US-EPA, Pseudokirchneriella subcapitata, MSDS supplier).

EC10 for Algae / Aquatic Plants.

0,012 mg/l/72h (OECD 201, Desmodesmus subspicatus, SDS supplier).

Chronic NOEC for Crustacea.

0,024 mg/l (OECD TG 211, Daphnia magna, MSDS supplier).

Chronic NOEC for Algae / Aquatic Plants.

0,0069 mg/l (OECD 201, Desmodesmus subspicatus, SDS supplier).

QUATERNARY AMMONIUM COMPOUNDS, BENZYL-C12-16-ALKYLDIMETHYL, CHLORIDES

LC50 - for Fish.

0,29 mg/l/96h (method US-EPA, Pimephales promelas, MSDS supplier).

EC50 - for Crustacea.

0,016 mg/l/48h (OECD TG 202, Daphnia magna, 48 h, MSDS supplier).

EC50 - for Algae / Aquatic Plants.

0,049 mg/l/72h (OECD TG 201, Pseudokirchneriella subcapitata, 72 h, MSDS supplier).

Chronic NOEC for Fish.

0,032 mg/l (method EPA-FIFRA, Pimephales promelas, 34 d, MSDS supplier).

Chronic NOEC for Crustacea.

0,0042 mg/l (method EPA-FIFRA, Daphnia magna, 21 d, MSDS supplier).

ALCOHOLS, C12-14, ETHOXYLATED PROPOXYLATED

LC50 - for Fish.

> 1 mg/l/96h (DIN 38412 Part 15, Leuciscus idus, SDS supplier).

EC50 - for Crustacea.

> 1 mg/l/48h (OECD 202 Part 1, Daphnia magna, SDS supplier).

EC50 - for Algae / Aquatic Plants.

> 1 mg/l/72h (OECD 201, SDS supplier).

D-GLUCOPYRANOSE,

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OLIGOMERS, DECYL
 OCTYL GLYCOSIDES

LC50 - for Fish.	180 mg/l/96h (similar to OECD 203, Danio rerio, freshwater, ECHA dossier).
EC50 - for Crustacea.	> 100 mg/l/48h (similar to OECD 202, Daphnia magna, freshwater, ECHA dossier).
Chronic NOEC for Crustacea.	> 100 mg/l (similar to OECD 202, Daphnia magna, freshwater, ECHA dossier).

D-GLUCOPYRANOSE,
 OLIGOMERIC, C10-16(EVEN
 NUMBERED) ALKYL
 GLYCOSIDES

LC50 - for Fish.	5,9 mg/l/96h (Annex of 92/69/EWG, GLP, Danio rerio, freshwater, ECHA dossier).
EC50 - for Crustacea.	14 mg/l/48h (Annex of 92/69/EWG, GLP, Daphnia magna, freshwater, ECHA dossier).

ALCOHOLS, C9-11
 ETHOXYLATED

LC50 - for Fish.	< 10 mg/l/96h (DIN EN ISO 7346-2, MSDS supplier).
EC50 - for Crustacea.	< 100 mg/l/48h (Daphnia, MSDS supplier).
Chronic NOEC for Algae / Aquatic Plants.	> 1 mg/l (MSDS supplier).

TETRASODIUM ETHYLENE
 DIAMINE TETRAACETATE

LC50 - for Fish.	> 100 mg/l/96h (MSDS supplier).
EC50 - for Crustacea.	> 100 mg/l/48h (MSDS supplier).
EC50 - for Algae / Aquatic Plants.	> 100 mg/l/72h (MSDS supplier).
Chronic NOEC for Fish.	36,9 mg/l (OECD 210, 35 d, Brachydanio rerio, MSDS supplier).
Chronic NOEC for Crustacea.	25 mg/l (OECD 211, 21 d, Daphnia magna, MSDS supplier).

TRISODIUM
 NITRILOTRIACETATE

LC50 - for Fish.	> 10 mg/l/96h (APHA (1971)-13th ed, Pimephales promelas, freshwater, ECHA dossier).
EC50 - for Crustacea.	> 10 mg/l/48h (APHA (1971) 13th ed, Gammarus pseudolimnaeus, freshwater, ECHA dossier).
EC50 - for Algae / Aquatic Plants.	> 91,5 mg/l/72h (OECD 201, Desmodesmus subspicatus, freshwater, ECHA dossier).
Chronic NOEC for Fish.	> 10 mg/l (EPA OPP 72-5, Pimephales promelas, freshwater, ECHA dossier).

L-(+)-LACTIC ACID

LC50 - for Fish.	320 mg/l/96h (Fish, MSDS supplier).
EC50 - for Crustacea.	240 mg/l/48h (Daphnia pulex, MSDS supplier).
EC50 - for Algae / Aquatic Plants.	3500 mg/l/72h (Scenedesmus capricornutum, fresh water, MSDS supplier).

12.2. Persistence and degradability.

ALCOHOLS, C12-14, ETHOXYLATED PROPOXYLATED

Elimination information: > 60 % (28 d) (OECD 301F; ISO 9408; 92/69/EEC, C.4-D)

PROPAN-2-OL

Rapidly biodegradable.

N-(3-AMINOPROPYL)-N-
DODECYLPROPANE-1,3-
DIAMINE

Rapidly biodegradable.

QUATERNARY AMMONIUM
COMPOUNDS, BENZYL-
C12-16-ALKYLDIMETHYL,
CHLORIDES

Rapidly biodegradable.

ALCOHOLS, C12-14,
ETHOXYLATED
PROPOXYLATED

Rapidly biodegradable.

D-GLUCOPYRANOSE,
OLIGOMERS, DECYL
OCTYL GLYCOSIDES

Rapidly biodegradable.

D-GLUCOPYRANOSE,
OLIGOMERIC, C10-16(EVEN
NUMBERED) ALKYL
GLYCOSIDES

Rapidly biodegradable.

ALCOHOLS, C9-11
ETHOXYLATED

Rapidly biodegradable.

TETRASODIUM ETHYLENE
DIAMINE TETRAACETATE
NOT rapidly biodegradable.

TRISODIUM
NITRILOTRIACETATE

Rapidly biodegradable.

L-(+)-LACTIC ACID

Rapidly biodegradable.

12.3. Bioaccumulative potential.

ALCOHOLS, C12-14, ETHOXYLATED PROPOXYLATED
Accumulation in organisms is not to be expected.

PROPAN-2-OL

Partition coefficient: n-
octanol/water. 0,05**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.

Waste transportation may be subject to ADR restrictions.

CONTAMINATED PACKAGING

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

SECTION 14. Transport information.**14.1. UN number.**

ADR / RID, IMDG, IATA: 1993

14.2. UN proper shipping name.

ADR / RID: FLAMMABLE LIQUID, N.O.S. (2-PROPANOL, N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE)

IMDG: FLAMMABLE LIQUID, N.O.S. (2-PROPANOL, N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE)

IATA: FLAMMABLE LIQUID, N.O.S. (2-PROPANOL, N-(3-AMINOPROPYL)-N-DODECYLPROPANE-1,3-DIAMINE)

14.3. Transport hazard class(es).

ADR / RID: Class: 3 Label: 3

IMDG: Class: 3 Label: 3

IATA: Class: 3 Label: 3



14.4. Packing group.

ADR / RID, IMDG, III
IATA:

14.5. Environmental hazards.

ADR / RID: Environmentally
Hazardous.



IMDG: Marine Pollutant.



IATA: NO

For Air transport, environmentally hazardous mark is only mandatory for UN 3077 and UN 3082.

14.6. Special precautions for user.

ADR / RID:	HIN - Kemler: 30	Limited Quantities 5 L	Tunnel restriction code (D/E)
	Special Provision: -		
IMDG:	EMS: F-E, S-E,	Limited Quantities 5 L	
IATA:	Cargo:	Maximum quantity: 220 L	Packaging instructions: 366
	Pass.:	Maximum quantity: 60 L	Packaging instructions: 355
	Special Instructions:	A3	

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

Information not relevant.

SECTION 15. Regulatory information.**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.**

Seveso category. 9i, 6

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

Product Point. 3 - 40

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:

15% ≤ x < 30%: disinfectant;

5% ≤ x < 15%: non-ionic surfactants;

> 5%: sodium salt of EDTA, phosphonates, non-ionic surfactants

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:

Flam. Liq. 2	Flammable liquid, category 2
Flam. Liq. 3	Flammable liquid, category 3
Carc. 2	Carcinogenicity, category 2
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Skin Corr. 1A	Skin corrosion, category 1A
Skin Corr. 1B	Skin corrosion, category 1B
Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
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
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H351	Suspected of causing cancer.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H332	Harmful if inhaled.

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H373	May cause damage to organs through prolonged or repeated exposure.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- 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. Regulation (EU) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
 4. Regulation (EU) 2015/830 of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - 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.

Zhermack S.p.a

Revision nr. 4

Dated 18/01/2018

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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.