

Safety data sheet
complying with Regulation 1907/2006/EC (REACH
Regulation), EU 2020/878 and Regulation No 1272/2008/EC
(CLP)

Printing date 03.02.2023

Version number 2 (replaces version 1)

Revision: 03.02.2023

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

1.1 Product identifier

Trade name: **MEDAPROTECT**

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

No further relevant information available.

Application of the substance / the mixture:

High efficiency disinfectant for medical and surgical instruments.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

MEDALKAN

Michalakopoulou 102, P.C. 11528, Athens, Greece

Tel.. 2107484847, Fax. 210 7772009

e-mail: contact@medalkan.gr

website: www.medalkan.com

1.4 Emergency telephone number:



European Emergency Tel.: 112

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation EC No 1272/2008 CLP:



GHS05 corrosion

Skin Corr. 1C H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.



GHS09 environment

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

2.2 Label elements

Labelling according to Regulation EC No 1272/2008 CLP:

The product is classified and labelled according to the CLP regulation.

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Hazard pictograms:



GHS05 GHS07 GHS09

Signal word: Danger

Hazard-determining components of labelling:

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine
didecyldimethylammonium chloride
Isotridecanol, ethoxylated

Hazard statements:

H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P264 Wash thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or 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.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Additional information:

EUH208 Contains Eucalyptus globulus oil. May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture: consisting of the following components.

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Ingredients according Regulation (EU) 2020/878:

CAS: 2372-82-9 EINECS: 219-145-8	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine ☠ Acute Tox. 3, H301; ☠ STOT RE 2, H373; ☠ Skin Corr. 1C, H314; ☠ Eye Dam. 1, H318; ☠ Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1)	≥5-<10%
CAS: 7173-51-5 EINECS: 230-525-2 Index number: 612-131-00-6	didecyldimethylammonium chloride ☠ Skin Corr. 1B, H314; ☠ Acute Tox. 4, H302	≥3-<5%
CAS: 69011-36-5 NLP: 500-241-6	Isotridecanol, ethoxylated ☠ Eye Dam. 1, H318; ☠ Acute Tox. 4, H302; Acute Tox. 4, H312	≥3-<5%
CAS: 67-63-0 EINECS: 200-661-7 Index number: 603-117-00-0 Reg.nr.: 01-2119457558-25-XXXX	propan-2-ol ☠ Flam. Liq. 2, H225; ☠ Eye Irrit. 2, H319; STOT SE 3, H336	≥1-<2.5%
CAS: 84625-32-1 EINECS: 283-406-2 Reg.nr.: 01-2119978250-37-XXXX	Eucalyptus globulus oil ☠ Flam. Liq. 3, H226; ☠ Asp. Tox. 1, H304; ☠ Aquatic Chronic 2, H411; ☠ Skin Irrit. 2, H315; Skin Sens. 1, H317	≥0.1-<0.25%

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

Immediately remove any clothing soiled by the product.

Take affected persons out into the fresh air.

After inhalation:

If breathing is difficult, remove to fresh air. Restore breathing. Keep warm and quiet.

In case of unconsciousness place patient stably in side position for transportation.

Seek medical treatment in case of complaints.

After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Wash contaminated clothing before use.

Remove contaminated clothing.

If skin irritation continues, consult a doctor.

After eye contact:

Rinse opened eye for at least 15 minutes under running water.

Remove contact lenses and continue rinsing for several minutes

Call a doctor immediately.

Avoid strong water jet-risk of cornea damage, consult a doctor.

After swallowing:

Drink plenty of water and provide fresh air. Call for a doctor immediately.

Do not induce vomiting; call for medical help immediately.

Never give anything by mouth to an unconscious person.

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4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents: CO₂, powder or water spray. Fight larger fires with water spray.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment:

Self contained breathing apparatus and full protective clothing must be worn in case of fire.

Additional information

Collect contaminated fire fighting water separately. It must not enter the sewage system.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Goggles and/ or face shield, if contact with eyes or splashes are anticipated.

Avoid contact with skin and eyes.

Wear protective clothing.

Ensure adequate ventilation.

6.1.1 For non-emergency personnel

Use personal protective equipment.

Avoid contact with dripping or leaking material

6.1.2 For emergency responders

First-aid responders must wear protective clothing, gloves, goggles and respiratory device with filter type A.

6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust, silica gel).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

6.4 Reference to other sections:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Open and handle receptacle with care.

Keep receptacles tightly sealed.

Avoid splashes or spray in enclosed areas.

Avoid contact with skin, eyes and clothing.

Do not eat, drink or smoke during the usage of the product.

Avoid inhaling vapors.

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Wash contaminated clothing before reuse.

Wash your hands and face in the break.

Information about fire - and explosion protection:

Keep away from heat, sparks, open flames and hot surfaces.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Store in cool, dry conditions in well sealed receptacles.

Requirements to be met by storerooms and receptacles:

Store in a cool location.

Prevent any seepage into the ground.

Information about storage in one common storage facility: Store away from oxidising agents.

Further information about storage conditions:

Store under lock and key and out of the reach of children.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

CAS: 57-55-6 Propane-1,2-diol

WEL (Great Britain)	Long-term value: 474* 10** mg/m ³ , 150* ppm *total vapour and particulates **particulates
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CAS: 67-63-0 propan-2-ol

WEL (Great Britain)	Short-term value: 1250 mg/m ³ , 500 ppm Long-term value: 999 mg/m ³ , 400 ppm
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DNELs

(CAS: 67-63-0) Propan-2-ol, Isopropanol

Workers

Long-term systemic effects, dermal: 888 mg/kg

Long-term systemic effects, inhalation: 500 mg/m³

Consumers

Long-term systemic effects, dermal: 319 mg/kg

Long-term systemic effects, inhalation: 89 mg/m³

Long-term systemic effects, oral: 26 mg/kg

8.2 Exposure controls

8.2.1. Appropriate engineering controls Provide adequate ventilation.

Individual protection measures, such as personal protective equipment

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Avoid contact with skin and eyes.

Remove contaminated clothes and wash before reusing them.

Do not breathe vapours or mists.

Do not eat, drink or smoke while using the product.

Wash hands before breaks and at the end of work.

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Respiratory protection:



In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Hand protection



Protective gloves resistant to chemicals (standard EN 374-1)

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

The determined penetration times according to EN 16523-1:2015 are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

Eye/face protection



Tightly sealed goggles (EN 166).

Body protection:



Chemically resistant, protective work clothing (EN 14605) and boots.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Physical state	Liquid
Colour:	Blue
Odour:	Aromatic
Odour threshold:	Not determined
Melting point/freezing point:	Not determined
Boiling point or initial boiling point and boiling range	Not determined

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Flammability	Not applicable
Lower and upper explosion limit	
Lower:	Not determined
Upper:	Not determined
Flash point:	Not determined
Auto-ignition temperature:	Not determined
Decomposition temperature:	Not determined
pH	10.8-11.2
Viscosity:	
Kinematic viscosity	Not determined
Dynamic:	Not determined
Solubility	
water:	Fully miscible
Partition coefficient n-octanol/water (log value)	Not determined
Vapour pressure:	Not determined
Density and/or relative density	
Density:	Not determined
Relative density	Not determined
Vapour density	Not determined

9.2 Other information

Appearance:

Form: Liquid

Important information on protection of health and environment, and on safety.

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

Cloud point / clarification point:

Oxidising properties Not classified as an oxidant according to CLP Regulation 1272/2008/EC.

Evaporation rate Not determined

Information with regard to physical hazard classes

Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
Flammable liquids	Void
Flammable solids	Void
Self-reactive substances and mixtures	Void
Pyrophoric liquids	Void
Pyrophoric solids	Void
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable gases in contact with water	Void

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Oxidising liquids	Void
Oxidising solids	Void
Organic peroxides	Void
Corrosive to metals	Void
Desensitised explosives	Void

SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.

10.2 Chemical stability

Thermal decomposition / conditions to be avoided Stable at environment temperature.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid Avoid heat, flames, sparks, other sources of ignition.

10.5 Incompatible materials Oxidizing agents

10.6 Hazardous decomposition products No dangerous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity Harmful if swallowed.

LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral	LD50	1,030 mg/kg (rat)
Dermal	LD50	50,000 mg/kg (rabbit)

CAS: 2372-82-9 N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine

Oral	LD50	261 mg/kg (rat)
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CAS: 7173-51-5 didecyldimethylammonium chloride

Oral	LD50	84 mg/kg (rat)
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CAS: 69011-36-5 Isotridecanol, ethoxylated

Oral	LD50	2,000 mg/kg (rat)
Dermal	LD50	2,000 mg/kg (rabbit)
Inhalative	LC50/4 h (vapour)	1,600 mg/l (rat)

CAS: 67-63-0 propan-2-ol

Oral	LD50	5,840 mg/kg (rat)
Dermal	LD50	13,900 mg/kg (rabbit)
Inhalative	LC50(6h)	10,000 ppm (rat)

Skin corrosion/irritation Causes severe skin burns and eye damage.

Serious eye damage/irritation Causes serious eye damage.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Based on available data, the classification criteria are not met.

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

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Aspiration hazard Based on available data, the classification criteria are not met.

Additional toxicological information:

Repeated dose toxicity Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

CAS: 67-63-0 propan-2-ol

EC50 (72h) 1,800 mg/l (algae)

LC50 (96h) 9,640-10,000 mg/l (Pimephales promelas) (Fish, Acute Toxicity Test)

EC50(24h) 9,714 mg/l (Daphnia magna) (Daphnia sp. Acute Immobilisation Test)

12.2 Persistence and degradability

(CAS: 67-63-0) propan-2-ol

BOD 5: 53 %

ThOD: 72 %

12.3 Bioaccumulative potential

(CAS: 67-63-0) Propan-2-ol

Partition coefficient n-octanol/water: 0,05

No bioaccumulation expected (log Pow < 1).

12.4 Mobility in soil No further relevant information available.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects

Remark:

Very toxic for fish

Toxic for fish

Additional ecological information:

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Also poisonous for fish and plankton in water bodies.

The product contains materials that are harmful to the environment.

Very toxic for aquatic organisms

Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values.

A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is

considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is

only low water-dangerous.

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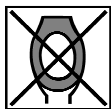
SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation



Dispose according to National Regulations.



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

European waste catalogue

HP6	Acute Toxicity
HP8	Corrosive
HP14	Ecotoxic

Uncleaned packaging:

Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN number or ID number

ADR, IMDG, IATA

UN1903

14.2 UN proper shipping name

ADR

1903 DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride, N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine), ENVIRONMENTALLY HAZARDOUS

IMDG

DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride, N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine), MARINE POLLUTANT

IATA

DISINFECTANT, LIQUID, CORROSIVE, N.O.S. (didecyldimethylammonium chloride, N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine)

14.3 Transport hazard class(es)

ADR, IMDG



Class

8 Corrosive substances.

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Label

8

IATA



Class

8 Corrosive substances.

Label

8

14.4 Packing group

ADR, IMDG, IATA

III

14.5 Environmental hazards:

Environmental Hazardous

Marine pollutant:

Yes

Symbol (fish and tree)

Special marking (ADR):

Symbol (fish and tree)

14.6 Special precautions for user

Warning: Corrosive substances.

Hazard identification number (Kemler code):

80

EMS Number:

F-A,S-B

Stowage Category

B

14.7 Maritime transport in bulk according to

IMO instruments

Not applicable.

Transport/Additional information:

ADR

Limited quantities (LQ)

5L

Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

Transport category

3

Tunnel restriction code

E

IMDG

Limited quantities (LQ)

5L

Excepted quantities (EQ)

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

UN "Model Regulation":

UN 1903 DISINFECTANT, LIQUID, CORROSIVE,

N.O.S. (DIDECYLDIMETHYLAMMONIUM

CHLORIDE, N-(3-AMINOPROPYL)-N-

DODECYLPROPANE-1,3-DIAMINE), 8, III,

ENVIRONMENTALLY HAZARDOUS

SECTION 15: Regulatory information

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

REACH Regulation 1907/2006/EC

Regulation (EU) 2020/878

CLP Regulation 1272/2008/EC

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Directive 98/24/EC on the protection of health and safety of workers from the risks related to chemicals agents at work.
 Council Directive 94/33/EC on the protection of young people at work, as ammended.
 Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding, as ammended

Directive 2012/18/EU

Named dangerous substances - ANNEX I Substance is not listed.

Seveso category E1 Hazardous to the Aquatic Environment

Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t

Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

REGULATION (EU) 2019/1148

Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

National regulations:

Other regulations, limitations and prohibitive regulations

Substances of very high concern (SVHC) according to REACH, Article 57

It doesn't contain substances of very high concern (SVHC).

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H301 Toxic if swallowed.

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H312 Harmful in contact with skin.

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H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H373 May cause damage to organs through prolonged or repeated exposure.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.

Classification according to Regulation (EC) No 1272/2008

Acute toxicity - oral
Skin corrosion/irritation
Serious eye damage/irritation
Hazardous to the aquatic environment - short-term (acute) aquatic hazard
Hazardous to the aquatic environment - long-term (chronic) aquatic hazard

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

Department issuing SDS:

SUST  SUSTCHEM S.A.
CHEM REACH & Chemical Services Department
CONSULTING
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T: +30 210 8252510 | F: +30 210 8252575
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Version number of previous version: 1

Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 3: Flammable liquids – Category 3
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Corr. 1C: Skin corrosion/irritation – Category 1C
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Asp. Tox. 1: Aspiration hazard – Category 1

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Safety data sheet
complying with Regulation 1907/2006/EC (REACH
Regulation), EU 2020/878 and Regulation No 1272/2008/EC
(CLP)

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Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

*** Data compared to the previous version altered.**

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