

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 6/23/2022 Revision date: 2/14/2023 Supersedes version of: 2/14/2023 Version: 3.0

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

1.1. Product identifier

Product form : Mixture

Product name : SANI-CLOTH® AF UNIVERSAL

Product code : XP00363, XP00365, XP00390, XP00391, EAF1100, EAF1110, EAF1120,

EAF1150, EAF1130, EAF1140

Other means of identification : 5386 solution

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : Disinfection of Medical Devices

1.2.2. Uses advised against
No additional information available

1.3. Details of the supplier of the safety data sheet

PDI PDI

PDI, Pywell Road, Willowbrook East Industrial Estate

NN17 5XJ Corby - Northants

United Kingdom T +44 (0)1536 408085

contact@PDI-EMEA.com - https://wearepdi.com/en-uk/

1.4. Emergency telephone number

Emergency number : +44 (0)1536 408085

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful to aquatic life with long lasting effects.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Signal word (CLP) : -

Hazard statements (CLP) : H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) : P273 - Avoid release to the environment.

P501 - Dispose of contents/container to hazardous or special waste collection point, in

accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
2-AMINOETHANOL substance with national workplace exposure limit(s) (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GI, GR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, IS, NO, MK, RS, CH, TR); substance with a Community workplace exposure limit	CAS-No.: 141-43-5 EC-No.: 205-483-3 EC Index-No.: 603-030-00-8	≥ 0.25 - < 5	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Acute Tox. 4 (Dermal), H312 (ATE=1100 mg/kg bodyweight) Acute Tox. 4 (Inhalation), H332 (ATE=1.5 mg/l/4h) Skin Corr. 1B, H314 Eye Dam. 1, H318
DIDECYL DIMETHYL AMMONIUM CHLORIDE	CAS-No.: 7173-51-5 EC-No.: 230-525-2 EC Index-No.: 612-131-00-6	≥ 0.25 - < 5	Not classified
POTASSIUM CARBONATE substance with national workplace exposure limit(s) (LT, LV)	CAS-No.: 584-08-7 EC-No.: 209-529-3	≥ 0.25 – < 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Chronic 3, H412
Phosphoric acid substance with national workplace exposure limit(s) (AT, BE, BG, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GI, GR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, IS, NO, MK, RS, CH, TR); substance with a Community workplace exposure limit	CAS-No.: 7664-38-2 EC-No.: 231-633-2 EC Index-No.: 015-011-00-6	< 0.25	Skin Corr. 1B, H314

Specific concentration limits:		
Name	Product identifier	Specific concentration limits
2-AMINOETHANOL	CAS-No.: 141-43-5 EC-No.: 205-483-3 EC Index-No.: 603-030-00-8	(5 ≤C ≤ 100) STOT SE 3, H335
Phosphoric acid	CAS-No.: 7664-38-2 EC-No.: 231-633-2 EC Index-No.: 015-011-00-6	(10 ≤C < 25) Skin Irrit. 2, H315 (10 ≤C < 25) Eye Irrit. 2, H319 (25 ≤C ≤ 100) Skin Corr. 1B, H314

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the

product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

2-AMINOETHANOL (141-43-5)	
EU - Indicative Occupational Exposure Limit	(IOEL)
Local name	2-Aminoethanol
IOEL TWA	2.5 mg/m³
IOEL TWA [ppm]	1 ppm
IOEL STEL	7.6 mg/m³
IOEL STEL [ppm]	3 ppm
Remark	Skin
Regulatory reference	COMMISSION DIRECTIVE 2006/15/EC
United Kingdom - Occupational Exposure Lir	nits
Local name	2-Aminoethanol
WEL TWA (OEL TWA) [1]	2.5 mg/m³
WEL TWA (OEL TWA) [2]	1 ppm
WEL STEL (OEL STEL)	7.6 mg/m³
WEL STEL (OEL STEL) [ppm]	3 ppm
Remark	Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE
Phosphoric acid (7664-38-2)	
EU - Indicative Occupational Exposure Limit	(IOEL)
Local name	Orthophosphoric acid
IOEL TWA	1 mg/m³
IOEL STEL	2 mg/m³
Regulatory reference	COMMISSION DIRECTIVE 2000/39/EC
United Kingdom - Occupational Exposure Lir	nits
Local name	Orthophosphoric acid
WEL TWA (OEL TWA) [1]	1 mg/m³
WEL STEL (OEL STEL)	2 mg/m³
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):







8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Colour : Colourless.

Appearance : Non Woven Wipe impregnated with aqueous based solution.

Odour characteristic. Odour threshold Not available Melting point Not applicable. Freezing point Not available Boiling point Not available Flammability Non flammable. Explosive limits Not available Lower explosion limit Not available Upper explosion limit Not available Flash point Not available Auto-ignition temperature Not applicable. Decomposition temperature Not available рΗ Approx 11 Viscosity, kinematic Not available Solubility : Not available Partition coefficient n-octanol/water (Log Kow) : Not available Vapour pressure Not available Vapour pressure at 50°C : Not available Density : Not available

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Relative density : Not applicable.
Relative vapour density at 20°C : Not applicable.
Particle characteristics : Not applicable

2-AMINOETHANOL (141-43-5)	
Boiling point	170.8 °C Atm. press.: 1013 hPa
Flash point	86 °C Atm. press.: 1013 hPa
Vapour pressure	0.488 hPa Temp.: 25 °C

POTASSIUM CARBONATE (584-08-7)	
Boiling point	> 35 °C
Flash point	> 93 °C

Phosphoric acid (7664-38-2)	
Boiling point	296.5 °C Atm. press.: 983 hPa

DIDECYL DIMETHYL AMMONIUM CHLORIDE (7173-51-5)	
Flash point	> 26.4 °C Atm. press.: 103,6 kPa Remarks on result: 'other:'

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified

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Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Acute toxicity (inhalation)	: Not classified
2-AMINOETHANOL (141-43-5)	
ATE CLP (oral)	500 mg/kg bodyweight
ATE CLP (dermal)	1100 mg/kg bodyweight
ATE CLP (gases)	4500 ppmv/4h
ATE CLP (vapours)	11 mg/l/4h
ATE CLP (dust,mist)	1.5 mg/l/4h
POTASSIUM CARBONATE (584-08-7	7)
LD50 oral rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity), Remarks on results: other:
LD50 dermal rabbit	> 2000 mg/kg bodyweight Animal: rabbit, Guideline: other:, Remarks on results: other:
DIDECYL DIMETHYL AMMONIUM CI	HLORIDE (7173-51-5)
LD50 dermal rat	> 1000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity), Guideline: EU Method B.3 (Acute Toxicity (Dermal))
LD50 dermal rabbit	≈ 3342 mg/kg bodyweight Animal: rabbit, Guideline: other:, Remarks on results: other:, 95% CL: 0 - 4292
Skin corrosion/irritation	: Not classified pH: Approx 11
2-AMINOETHANOL (141-43-5)	
рН	≈ 12
POTASSIUM CARBONATE (584-08-7	7)
рН	11.6
Serious eye damage/irritation	: Not classified
2-AMINOETHANOL (141-43-5)	pH: Approx 11
	≈ 12
pH	
POTASSIUM CARBONATE (584-08-7	
рН	11.6
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
POTASSIUM CARBONATE (584-08-7	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
DIDECYL DIMETHYL AMMONIUM C	HLORIDE (7173-51-5)
Viscosity, kinematic	≈ 24.5 mm²/s Temp.: '20°C' Parameter: 'kinematic viscosity (in mm²/s)'
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11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects.

Hazardous to the aquatic environment, short-term : Not classified

(acute)

Hazardous to the aquatic environment, long-term

(chronic)

Not rapidly degradable

: Harmful to aquatic life with long lasting effects.

not rapidly dogradable	
POTASSIUM CARBONATE (584-0	08-7)
LC50 - Fish [1]	68 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
EC50 - Crustacea [1]	200 mg/l Test organisms (species): Daphnia pulex
Phosphoric acid (7664-38-2)	
EC50 - Crustacea [1]	> 100 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	> 100 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus)
DIDECYL DIMETHYL AMMONIUM	CHLORIDE (7173-51-5)
LC50 - Fish [1]	≈ 0.97 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
LC50 - Fish [2]	≈ 0.49 mg/l Test organisms (species): Danio rerio (previous name: Brachydanio rerio)
EC50 - Crustacea [1]	≈ 0.057 mg/l Test organisms (species): Daphnia magna
EC50 - Crustacea [2]	≈ 0.029 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	≈ 0.062 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)
LOEC (chronic)	≈ 0.047 mg/l Test organisms (species): Daphnia magna Duration: '21 d'
NOEC (chronic)	≈ 0.021 mg/l Test organisms (species): Daphnia magna Duration: '21 d'

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

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SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

UN-No. (ADR) : UN -

UN-No. (IMDG) : Not applicable UN-No. (IATA) : Not applicable UN-No. (ADN) : Not applicable UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

No data available

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

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Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals):

Didecyldimethylammonium chloride (7173-51-5)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of cha	Indication of changes		
Section	Changed item	Change	Comments
	Supersedes version of	Added	
	Revision date	Added	
	Flammability	Added	
1.1	Other means of identification	Added	
1.1	Product code	Added	
1.2	Industrial/Professional use spec	Added	
1.2	Use of the substance/mixture	Added	

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Indication of changes			
Section	Changed item	Change	Comments
2.1	Adverse physicochemical, human health and environmental effects	Added	
2.2	Precautionary statements (CLP)	Added	
3	Composition/information on ingredients	Modified	
4.1	First-aid measures after skin contact	Added	
4.1	First-aid measures after inhalation	Added	
4.1	First-aid measures after ingestion	Added	
4.1	First-aid measures after eye contact	Added	
4.3	Other medical advice or treatment	Added	
5.1	Suitable extinguishing media	Added	
5.2	Hazardous decomposition products in case of fire	Added	
5.3	Protection during firefighting	Added	
6.1	Protective equipment	Added	
6.1	Emergency procedures	Added	
6.2	Environmental precautions	Added	
6.3	Methods for cleaning up	Added	
6.3	Other information	Added	
6.4	Reference to other sections (8, 13)	Added	
7.1	Precautions for safe handling	Added	
7.1	Hygiene measures	Added	
7.2	Storage conditions	Added	
8.2	Environmental exposure controls	Added	
8.2	Respiratory protection	Added	
8.2	Hand protection	Added	
8.2	Eye protection	Added	
8.2	Appropriate engineering controls	Added	
8.2	Skin and body protection	Added	
9.1	Physical state	Added	
10.1	Reactivity	Added	
10.2	Chemical stability	Added	
10.3	Possibility of hazardous reactions	Added	
10.4	Conditions to avoid	Added	
10.6	Hazardous decomposition products	Added	
12.1	Ecology - general	Added	
13.1	Waste treatment methods	Added	
15.2	Chemical safety assessment	Added	
16	Abbreviations and acronyms	Added	

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	nyms:
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
ATE /	Acute Toxicity Estimate
BCF [Bioconcentration factor
BLV [Biological limit value
BOD E	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL [Derived Minimal Effect level
DNEL [Derived-No Effect Level
EC-No.	European Community number
EC50 !	Median effective concentration
EN E	European Standard
IARC I	International Agency for Research on Cancer
IATA I	International Air Transport Association
IMDG I	International Maritime Dangerous Goods
LC50 1	Median lethal concentration
LD50 1	Median lethal dose
LOAEL I	Lowest Observed Adverse Effect Level
NOAEC 1	No-Observed Adverse Effect Concentration
NOAEL 1	No-Observed Adverse Effect Level
NOEC 1	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT [Persistent Bioaccumulative Toxic
PNEC I	Predicted No-Effect Concentration
RID I	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP :	Sewage treatment plant
ThOD -	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S. 1	Not Otherwise Specified
vPvB \	Very Persistent and Very Bioaccumulative
ED [Endocrine disrupting properties

Full text of H- and EUH-statements:	
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4

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Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

The classification complies with

: ATP 12

Safety Data Sheet (SDS), EU - PDI