


PPE-Additive

Version number: GHS 6.1
Replaces version of: 2024-06-20 (GHS 5)

Revision: 2024-06-20

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

1.1 Product identifier

Trade name	PPE-Additive
Registration number (REACH)	not relevant (mixture)
Global Trade Item Number (GTIN)	



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

Relevant identified uses	professional use laboratory and analytical use
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1.3 Details of the supplier of the safety data sheet

Cube Dx GmbH
Westbahnstraße 55
A-4300 St. Valentin
Austria

Telephone: +43 (0)7435 58193 0
e-mail: support@cubedx.com
Website: https://www.cubedx.com

e-mail (competent person)	support@cubedx.com
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1.4 Emergency telephone number

Emergency information service	+43 (0)7435 58193 0 This number is only available during the following office hours: Mon - Thu 08:00 - 16:00, Fri 08:00 - 13:00
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SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Section	Hazard class	Category	Hazard class and category	Hazard statement
3.10	acute toxicity (oral)	3	Acute Tox. 3	H301
3.2	skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	serious eye damage/eye irritation	1	Eye Dam. 1	H318
3.8	specific target organ toxicity - single exposure	2	STOT SE 2	H371
4.1C	hazardous to the aquatic environment - chronic hazard	3	Aquatic Chronic 3	H412

For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects

Immediate effects can be expected after short-term exposure. Spillage and fire water can cause pollution of water-courses.

2.2 Label elements

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

- Signal word danger

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- Pictograms

GHS05, GHS06, GHS08



- Hazard statements

- H301 Toxic if swallowed.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H371 May cause damage to organs.
- H412 Harmful to aquatic life with long lasting effects.

- Precautionary statements

- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- Hazardous ingredients for labelling TMAC, IGEPAL

2.3 Other hazards

Results of PBT and vPvB assessment

Does not contain a PBT-/vPvB-substance at a concentration of $\geq 0,1\%$.

Endocrine disrupting properties

Contains an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture)

3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
IGEPAL	CAS No 9002-93-1	5 - < 10	Acute Tox. 4 / H302 Eye Dam. 1 / H318 Aquatic Chronic 2 / H411	
TMAC	CAS No 75-57-0 EC No 200-880-8 REACH Reg. No 01-2119970924-26- xxxx	5 - < 10	Acute Tox. 2 / H300 Acute Tox. 3 / H311 Skin Irrit. 2 / H315 STOT SE 1 / H370 Aquatic Chronic 2 / H411	

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Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
IGEPAL	-	-	1,800 mg/kg	oral
TMAC	-	-	>5 mg/kg >200 mg/kg	oral dermal

Remarks

For full text of abbreviations: see SECTION 16

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician. Provide fresh air.

Following skin contact

Wash with plenty of soap and water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO₂)

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

Nitrogen oxides (NO_x), Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Use only in well-ventilated areas.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Control of effects

Protect against external exposure, such as

frost

- Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

7.3 Specific end use(s)

See section 16 for a general overview.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)
this information is not available

Relevant DNELs of components						
Name of substance	CAS No	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
TMAC	75-57-0	DNEL	2.9 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
TMAC	75-57-0	DNEL	0.4 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

Relevant PNECs of components						
Name of substance	CAS No	Endpoint	Threshold level	Organism	Environmental compartment	Exposure time
TMAC	75-57-0	PNEC	0.6 µg/l	aquatic organisms	freshwater	short-term (single instance)
TMAC	75-57-0	PNEC	0.06 µg/l	aquatic organisms	marine water	short-term (single instance)
TMAC	75-57-0	PNEC	6 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
TMAC	75-57-0	PNEC	35 µg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
TMAC	75-57-0	PNEC	3.5 µg/kg	aquatic organisms	marine sediment	short-term (single instance)
TMAC	75-57-0	PNEC	6.6 µg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

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Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	not determined
Odour	characteristic
Melting point/freezing point	0 °C at 1,013 hPa
Boiling point or initial boiling point and boiling range	100 °C at 1,013 hPa
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	8.2 – 8.5
Kinematic viscosity	not determined
Solubility(ies)	not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure	32 hPa at 25 °C
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Density and/or relative density

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Density	not determined
Relative vapour density	information on this property is not available

Particle characteristics	not relevant (liquid)
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9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics	there is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

Oxidisers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Toxic if swallowed.

GHS of the United Nations, annex 4: May be harmful in contact with skin.

- Acute toxicity estimate (ATE)

Oral >61.4 mg/kg

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Acute toxicity estimate (ATE) of components			
Name of substance	CAS No	Exposure route	ATE
IGEPAL	9002-93-1	oral	1,800 mg/kg
TMAC	75-57-0	oral	>5 mg/kg
TMAC	75-57-0	dermal	>200 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye damage.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

May cause damage to organs.

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Harmful to aquatic life with long lasting effects.

Aquatic toxicity (chronic) of components					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
TMAC	75-57-0	LC50	130 µg/l	aquatic invertebrates	11 d
TMAC	75-57-0	EC50	80 µg/l	aquatic invertebrates	11 d

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12.2 Persistence and degradability

Degradability of components						
Name of sub-stance	CAS No	Process	Degradation rate	Time	Method	Source
TMAC	75-57-0	carbon dioxide generation	100 %	28 d		ECHA

12.3 Bioaccumulative potential

Data are not available.

Bioaccumulative potential of components				
Name of substance	CAS No	BCF	Log KOW	BOD5/COD
TMAC	75-57-0		<-1.6 (pH value: 7, 20 °C)	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB. Does not contain a PBT-/vPvB-substance at a concentration of $\geq 0,1\%$.

12.6 Endocrine disrupting properties

Contains an endocrine disruptor (ED) at a concentration of $\geq 0,1\%$.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN	UN 2810
IMDG-Code	UN 2810
ICAO-TI	UN 2810

14.2 UN proper shipping name

ADR/RID/ADN	TOXIC LIQUID, ORGANIC, N.O.S.
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IMDG-Code	TOXIC LIQUID, ORGANIC, N.O.S.
ICAO-TI	Toxic liquid, organic, n.o.s.
14.3 Transport hazard class(es)	
ADR/RID/ADN	6.1
IMDG-Code	6.1
ICAO-TI	6.1
14.4 Packing group	
ADR/RID/ADN	III
IMDG-Code	III
ICAO-TI	III
14.5 Environmental hazards	non-environmentally hazardous acc. to the dangerous goods regulations
14.6 Special precautions for user	
	Provisions for dangerous goods (ADR) should be complied within the premises.
14.7 Maritime transport in bulk according to IMO instruments	
	The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Classification code	T1
Danger label(s)	6.1
	
Special provisions (SP)	274, 614, 802(ADN)
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
Transport category (TC)	2
Tunnel restriction code (TRC)	E
Hazard identification No	60


International Maritime Dangerous Goods Code (IMDG) - Additional information

Marine pollutant	-
Danger label(s)	6.1
	
Special provisions (SP)	223, 274
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 L
EmS	F-A, S-A

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Stowage category	A
International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information	
Danger label(s)	6.1
	
Special provisions (SP)	A3, A4, A137
Excepted quantities (EQ)	E1
Limited quantities (LQ)	2 L

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)		
Name of substance	Name acc. to inventory	No
PPE-Additive	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC	3
IGEPAL	substances in tattoo inks and permanent make-up	75

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

Substance of Very High Concern (SVHC)			
Name acc. to inventory	CAS No	Listed in	Remarks
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated		Annex XIV	EDP (57f-env) rem-42 date1 date2

Legend

Annex XIV	List of substances subject to authorisation
date1	(a) 4 July 2019; (b) by way of derogation from point (a), 22 June 2022 for uses as follows: - for the research, development and production of medicinal products falling within the scope of Directive 2001/83/EC or medical devices or accessories to medical devices falling within the scope of Directive 93/42/EEC, Regulation (EU) 2017/745, Directive 98/79/EC or Regulation (EU) 2017/746 of the European Parliament and of the Council, in view of their use for the diagnosis, treatment or prevention of the coronavirus disease (COVID-19), - in medical devices or accessories to medical devices falling within the scope of Directive 93/42/EEC, Regulation (EU) 2017/745, Directive 98/79/EC or Regulation (EU) 2017/746, for the diagnosis, treatment or prevention of COVID-19.
date2	(a) 4 January 2021; (b) by way of derogation from point (a), 22 December 2023 for uses as follows: - for the research, development and production of medicinal products falling within the scope of Directive 2001/83/EC or medical devices or accessories to medical devices falling within the scope of Directive 93/42/EEC, Regulation (EU) 2017/745, Directive 98/79/EC or Regulation (EU) 2017/746, in view of their use for the diagnosis, treatment or prevention of COVID-19, - in medical devices or accessories to medical devices falling within the scope of Directive 93/42/EEC, Regulation (EU) 2017/745, Directive 98/79/EC or Regulation (EU) 2017/746, for the diagnosis, treatment or prevention of COVID-19.
EDP (57f-env)	Endocrine disrupting potential (article 57(f) - environment)
rem-42	Covering well-defined substances and UVCB substances, polymers and homologues

Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

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Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

Water Framework Directive (WFD)

none of the ingredients are listed

Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

15.2 Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
1.1	Global Trade Item Number (GTIN): 9120127730350	Global Trade Item Number (GTIN): 09120127730350	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor

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Abbr.	Descriptions of used abbreviations
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
log KOW	n-Octanol/water
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H300	Fatal if swallowed.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H370	Causes damage to organs.
H371	May cause damage to organs.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.