

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

1.1. Product identifier

Product form : Mixture
Product name : Crystal violet oxalate
Product code : 361490

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

1.2.1. Relevant identified uses

Main use category : For professional use only
Use of the substance/mixture : In vitro diagnostic medical device.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

RAL DIAGNOSTICS
Site Montesquieu
33650 MARTILLAC - FRANCE
T 33 05 57 96 04 04 - F 33 05 57 96 04 05
commercial@ral-diagnostics.fr - www.ral-diagnostics.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids, Category 3 H226
Serious eye damage/eye irritation, Category 2 H319
Carcinogenicity, Category 2 H351
Hazardous to the aquatic environment — Chronic Hazard, Category 3 H412

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Flammable liquid and vapour. Suspected of causing cancer. Causes serious eye irritation. Harmful to aquatic life with long lasting effects.

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS02

GHS07

GHS08

Signal word (CLP) :

Warning

Contains :

C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride

Hazard statements (CLP) :

H226 - Flammable liquid and vapour.
H319 - Causes serious eye irritation.
H351 - Suspected of causing cancer.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP) :

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 - Wear protective gloves, protective clothing, eye protection, face protection.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

No additional information available

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]
Ethyl alcohol substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43	10 -20	Flam. Liq. 2, H225
C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride substance listed as REACH Candidate ([4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)])	(CAS-No.) 548-62-9 (EC-No.) 208-953-6 (EC Index-No.) 612-204-00-2 (REACH-no) 02-2119824931-38	≤ 5	Carc. 2, H351 Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general :

IF exposed or concerned: Get medical advice/attention.

First-aid measures after inhalation :

Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact :

Rinse skin with water/shower. Take off immediately all contaminated clothing.

First-aid measures after eye contact :

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion :

Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after eye contact : Eye irritation.

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

Fire hazard : Flammable liquid and vapour.

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. No open flames, no sparks, and no smoking. Avoid contact with skin and eyes.

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. Notify authorities if product enters sewers or public waters.

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. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Wear personal protective equipment. Do not handle until all safety precautions have been read and understood. Avoid contact with skin and eyes.

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 container tightly closed. Store locked up.

Storage temperature : 15 – 25 °C

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

Ethyl alcohol (64-17-5)	
Ireland - Occupational Exposure Limits	
Local name	Ethanol [Ethyl alcohol]
OEL STEL [ppm]	1000 ppm
Regulatory reference	Chemical Agents Code of Practice 2020
United Kingdom - Occupational Exposure Limits	
Local name	Ethanol
WEL TWA (OEL TWA) [1]	1920 mg/m ³
WEL TWA (OEL TWA) [2]	1000 ppm
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

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

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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
Appearance	: clear.
Colour	: Violet. Dark.
Odour	: No data available
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: 39.57 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 0.98
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Flammable liquid and vapour.

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

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

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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 toxicological effects

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

C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)

LD50 oral	711 mg/kg
LD50 dermal rat	> 6869 mg/kg

Ethyl alcohol (64-17-5)

LD50 oral rat	15010 mg/kg bodyweight Animal: rat, Animal sex: female, Guideline: OECD Guideline 401 (Acute Oral Toxicity), 95% CL: 14450 - 15560
LD50 oral	8300 mg/kg bodyweight Animal: mouse
LD50 dermal rat	> 2000 mg/kg
LC50 Inhalation - Rat	> 20 mg/l

Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Causes serious eye irritation.
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Suspected of causing cancer.

Ethyl alcohol (64-17-5)

IARC group	1 - Carcinogenic to humans
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C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)

NOAEL (chronic, oral, animal/male, 2 years)	250 mg/kg bodyweight mouse
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Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified

Ethyl alcohol (64-17-5)

NOAEL (subchronic, oral, animal/male, 90 days)	< 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)
NOAEL (subchronic, oral, animal/female, 90 days)	> 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents)

Aspiration hazard : Not classified

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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 (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Harmful to aquatic life with long lasting effects.

C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)

LC50 - Fish [1]	82 µg/l
EC50 - Crustacea [1]	350 µg/l
EC50 72h - Algae [1]	0.21 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

Ethyl alcohol (64-17-5)

LC50 - Fish [1]	14.2 g/l Test organisms (species): Pimephales promelas
EC50 72h - Algae [1]	1900 – 1970 mg/l (marine water)
EC50 96h - Algae [1]	275 mg/l (freshwater)
ErC50 algae	275 mg/l Source: ECHA
NOEC (chronic)	9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d'
NOEC chronic fish	250 mg/l

12.2. Persistence and degradability

C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)

Persistence and degradability	Not readily biodegradable.
BOD (% of ThOD)	0.12 % ThOD
Biodegradation	10 %

Ethyl alcohol (64-17-5)

Persistence and degradability	Readily biodegradable.
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12.3. Bioaccumulative potential

Ethyl alcohol (64-17-5)

Partition coefficient n-octanol/water (Log Pow)	-0.32 Source: ICSC
Bioaccumulative potential	No bioaccumulation.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Component

C.I. Basic Violet 3; 4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (548-62-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
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12.6. Other adverse effects

Other adverse effects : Avoid discarding in the environment. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

SECTION 13: Disposal considerations






13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions. Dispose in a safe manner in accordance with local/national regulations.

Additional information : Flammable vapours may accumulate in the container.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
UN 1170	UN 1170	UN 1170	UN 1170	UN 1170
14.2. UN proper shipping name				
ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	Ethanol solution	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Transport document description				
UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III, (D/E)	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III, MARINE POLLUTANT	UN 1170 Ethanol solution, 3, III	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III
14.3. Transport hazard class(es)				
3	3	3	3	3
				
14.4. Packing group				
III	III	III	III	III
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : Yes	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available				

14.6. Special precautions for user

Overland transport

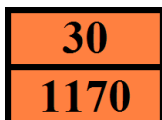
Classification code (ADR) : F1
Special provisions (ADR) : 144, 601
Limited quantities (ADR) : 5I
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P001, IBC03, LP01, R001
Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions (ADR) : T2

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Portable tank and bulk container special provisions (ADR) : TP1
Tank code (ADR) : LGBF
Vehicle for tank carriage : FL
Transport category (ADR) : 3
Special provisions for carriage - Packages (ADR) : V12
Special provisions for carriage - Operation (ADR) : S2
Hazard identification number (Kemler No.) : 30
Orange plates :



Tunnel restriction code (ADR) : D/E
EAC code : •2YE

Transport by sea

Special provisions (IMDG) : 144, 223
Limited quantities (IMDG) : 5 L
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : P001, LP01
IBC packing instructions (IMDG) : IBC03
Tank instructions (IMDG) : T2
Tank special provisions (IMDG) : TP1
EmS-No. (Fire) : F-E
EmS-No. (Spillage) : S-D
Stowage category (IMDG) : A
Properties and observations (IMDG) : Colourless, volatile liquids. Pure ETHANOL: flashpoint 13°C c.c. Explosive limits: 3.3% to 19% Miscible with water.
MFAG-No : 128

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y344
PCA limited quantity max net quantity (IATA) : 10L
PCA packing instructions (IATA) : 355
PCA max net quantity (IATA) : 60L
CAO packing instructions (IATA) : 366
CAO max net quantity (IATA) : 220L
Special provisions (IATA) : A3, A58, A180
ERG code (IATA) : 3L

Inland waterway transport

Classification code (ADN) : F1
Special provisions (ADN) : 144, 601
Limited quantities (ADN) : 5 L
Excepted quantities (ADN) : E1
Equipment required (ADN) : PP, EX, A
Ventilation (ADN) : VE01
Number of blue cones/lights (ADN) : 0

Rail transport

Classification code (RID) : F1
Special provisions (RID) : 144, 601
Limited quantities (RID) : 5L

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Excepted quantities (RID)	: E1
Packing instructions (RID)	: P001, IBC03, LP01, R001
Mixed packing provisions (RID)	: MP19
Portable tank and bulk container instructions (RID)	: T2
Portable tank and bulk container special provisions (RID)	: TP1
Tank codes for RID tanks (RID)	: LGBF
Transport category (RID)	: 3
Special provisions for carriage – Packages (RID)	: W12
Colis express (express parcels) (RID)	: CE4
Hazard identification number (RID)	: 30

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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

Contains no REACH substances with Annex XVII restrictions

Contains a substance on the REACH candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: [4-[4,4'-bis(dimethylamino)benzhydrylidene]cyclohexa-2,5-dien-1-ylidene]dimethylammonium chloride (C.I. Basic Violet 3) [with $\geq 0.1\%$ of Michler's ketone (EC No. 202-027-5) or Michler's base (EC No. 202-959-2)] (EC 208-953-6, CAS 548-62-9)

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

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 changes:			
Section	Changed item	Change	Comments
	Properties and observations (IMDG)	Added	
	UN-No. (RID)	Modified	
	Issue date	Added	
	Supersedes	Modified	
	Revision date	Modified	
	Proper Shipping Name (RID)	Modified	
	Portable tank and bulk container special provisions (RID)	Modified	
	Portable tank and bulk container instructions (RID)	Modified	
	Special provisions (RID)	Modified	

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	Special provisions (IATA)	Modified	
	Proper Shipping Name (IATA)	Modified	
	Proper Shipping Name (IMDG)	Modified	
	EmS-No. (Spillage)	Modified	
	Tank special provisions (IMDG)	Modified	
	Tank instructions (IMDG)	Modified	
	Special provisions (IMDG)	Modified	
	Portable tank and bulk container special provisions (ADR)	Modified	
	Portable tank and bulk container instructions (ADR)	Modified	
5.3	EAC code	Modified	
14.1	UN-No. (IMDG)	Modified	
14.1	UN-No. (IATA)	Modified	
14.1	UN-No. (ADR)	Modified	
14.1	UN-No. (ADN)	Modified	
14.2	Proper Shipping Name (ADN)	Modified	
14.2	Proper Shipping Name (ADR)	Modified	
14.6	Special provisions (ADN)	Modified	
14.6	Packing instructions (IMDG)	Modified	
14.6	Special provisions (ADR)	Modified	

Abbreviations and acronyms:

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
BLV	Biological limit value
CAS-No.	Chemical Abstract Service number
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
EC-No.	European Community number
EN	European Standard
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration

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NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
vPvB	Very Persistent and Very Bioaccumulative
WGK	Water Hazard Class

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Carc. 2	Carcinogenicity, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H351	Suspected of causing cancer.
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.

The classification complies : ATP 12
with

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.