

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878 Issue date: 10/7/2011 Revision date: 12/5/2022 Supersedes version of: 11/27/2020 Version: 11.0

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

1.1. Product identifier

Product form : Substance
Trade name : CARVEDILOL

Chemical name : 1-(9H-Carbazol-4-yloxy)-3-[[2-(2-methoxyphenoxy)ethyl]amino]-2-propanol IUPAC name : 1-(9H-Carbazol-4-yloxy)-3-[[2-(2-methoxyphenoxy)ethyl]amino]-2-propanol

CAS-No. : 72956-09-3 Product code : 71650

Type of product : Active Ingredient for Medicinal / Pharmaceutical Use

Formula : C24H26N2O4

Synonyms : 2RS)-1-(9H-Carbazol-4-yloxy)-3[[2-(2-methoxy phenoxy) ethyl] amino]-2-propanol; / (±)-[3-

(9H-carbazol-4-yloxy)-2-hydroxypropyl][2-(2-methoxyphenoxy)ethyl]amine

Product group : Active Ingredient for Medicinal/Pharmaceutical Use

Other means of identification : SMILES: COC1=CC=CC=C1OCCNCC(0)COC1=CC=CC2=C1C1=CC=CC1N2

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

1.2.1. Relevant identified uses

Main use category : Industrial use,API

Industrial/Professional use spec : Active Ingredient for Medicinal / Pharmaceutical Use

For professional use only

Industrial

Use of the substance/mixture : b-adrenocetor antagonist, nonselective beta-adrenergic blocking agent

Use of the substance/mixture : Pharmaceuticals Function or use category : Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

MOEHS IBÉRICA, S.L. Roma, 8 - P.I. Cova Solera

08191 Rubi Spain

T +34 93 586 05 20 - F +34 93 699 8350 hse@moehs.es - www.moehs.com

Manufacturer

COPRIMA S.L. Pablo Picasso, 15 08213 Polinya SPAIN

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Manufacturer

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Cesar Martinell i Brunet, 12 A P.I. Rubi Sud

08191 Rubi Spain

T +34 93 586 05 20 - F +34 93 699 8350 hse@moehs.es - www.moehs.com

1.4. Emergency telephone number

Emergency number : +34 93 586 05 20 (9:00 - 17:00)

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 1 H410

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

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Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP)



GHS09

Signal word (CLP) : Warning

Hazard statements (CLP) : H410 - Very toxic to aquatic life with long lasting effects.

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

P391 - Collect spillage.

P501 - Dispose of contents and container to an approved waste disposal plant.

2.3. Other hazards

Other hazards which do not result in classification

: Dust may form explosive mixture in air.

vPvB: not relevant - no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
CARVEDILOL	CAS-No.: 72956-09-3	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : If you feel unwell, seek medical advice. Never give anything by mouth to an unconscious

person. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor. Specific treatment. People with over sensibility problems are not allowed to work or be exposed to the product. If you feel unwell, seek medical advice

(show the label where possible).

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

breathe fresh air. Allow the victim to rest.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water,

followed by warm water rinse.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness

persists.

First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Immediately call a POISON CENTER/doctor. Obtain

emergency medical attention. Do NOT induce vomiting.

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

Symptoms/effects : If you feel unwell, seek medical advice. Not expected to present a significant hazard under

anticipated conditions of normal use.

Symptoms/effects after inhalation : May cause drowsiness or dizziness.

Symptoms/effects after eye contact : mild eye irritation.

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

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Dust may form explosive mixture in air.

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

5.3. Advice for firefighters

Precautionary measures fire : Stop leak if safe to do so. Keep away from combustible materials. Minimize generation of

dust which may be combustible.

Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire fighting water from

entering the environment. Exercise caution when fighting any chemical fire.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No open flames. No smoking. No flames, no sparks. Eliminate all sources of ignition.

6.1.1. For non-emergency personnel

Protective equipment : Breathing equipment.

Emergency procedures : Evacuate unnecessary personnel.

Measures in case of dust release : Dust formation: dust mask.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Stop leak without risks if possible. Collect spillage.

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away

from other materials.

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or

smoking and when leaving work. Provide good ventilation in process area to prevent

formation of vapour.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Heat sources.

Keep container closed when not in use. Store at room temperature.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

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

Control banding : MOEHS occupational exposure band: 3 (0.01 - 0.1 mg/m3)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Dust extraction (suction). Local exhaust or breathing protection.

8.2.2. Personal protection equipment

Personal protective equipment:

Avoid all unnecessary exposure. Dust/aerosol mask with filter type P3. Safety glasses. Gloves.

Personal protective equipment symbol(s):









8.2.2.1. Eye and face protection

Eye protection:

Chemical goggles or safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Protective clothing

Hand protection:

Wear protective gloves.

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Hand protection		
Туре	Material	Standard
Disposable gloves	Nitrile rubber (NBR), Butyl rubber, Natural rubber, Polyvinylchloride (PVC), Fluoroelastomer (FKM), Neoprene rubber (HNBR), Latex	EN ISO 374-1

8.2.2.3. Respiratory protection

Respiratory protection:

Wear appropriate mask

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	P3	Dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Particle shape

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Colour : white to slightly yellow.

Appearance : Dust.

Molecular mass : 406.48 g/mol
Odour : characteristic.

Odour threshold : Not available Melting point : $114 - 118 \,^{\circ}\text{C}$ Freezing point : Not available Boiling point : $\approx 655 \,^{\circ}\text{C}$

Flammability : Dust could form explosive mixtures with air Explosive properties : May form combustible dust concentrations in air.

Explosive limits : Not applicable Lower explosion limit : Not applicable Upper explosion limit : Not applicable : ≈ 350 °C Flash point Auto-ignition temperature : Not applicable : Not available Decomposition temperature рΗ : Not available pH solution : Not available

pH solution : Not available
Viscosity, kinematic : Not applicable
Solubility : insoluble in water.

Water: 14.7 mg/l (22°C, HPLC, 24 h) Organic solvent:8.5 g/100ml DMSO

Partition coefficient n-octanol/water (Log Kow) : Not available

Partition coefficient n-octanol/water (Log Pow) : 4.19 (Expow database)

Vapour pressure : Not available
Vapour pressure at 50°C : Not available
Density : Not available
Relative density : Not available
Relative vapour density at 20°C : Not applicable
Particle size : Not available
Particle size distribution : Not available

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: Not available

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Particle aspect ratio : Not available
Particle aggregation state : Not available
Particle agglomeration state : Not available
Particle specific surface area : Not available
Particle dustiness : Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Minimum ignition energy : 8 mJ

Additional information : Minimum Explosive Concentration : 30 g/m3.

Dust Cloud minimum Flammability Temperature : 460°C. Layer Minimum flammability Temperature : Melt. Explosion Severity Factor Kmax (bar.m/s) : 214.

Explosivity Pmax: 7.9 bar. Explosion Class: St2

SECTION 10: Stability and reactivity

10.1. Reactivity

Dust may form explosive mixture in air.

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides.

SECTION 11: Toxicological information

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

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

CARVEDILOL (72956-09-3)	
LD50 oral rat	> 8000 ml/kg
LD50, oral, mouse	> 8000 mg/kg

Skin corrosion/irritation : Not classified

Additional information : Based on available data, the classification criteria are not met

Serious eye damage/irritation : Not classified

Additional information : Based on available data, the classification criteria are not met

Respiratory or skin sensitisation : Not classified

Additional information : Based on available data, the classification criteria are not met

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Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	· Not classified

CARVEDILOL (72956-09-3)	
NOAEL (oral, rat, 90 days)	100 mg/kg bodyweight/day
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

: The substance is not 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

11.2.2. Other information

Potential adverse human health effects and symptoms

: Based on available data, the classification criteria are not met

: Based on available data, the classification criteria are not met

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Toxic to aquatic life.

Ecology - water : Very toxic to aquatic life with long lasting effects.

Hazardous to the aquatic environment, short-term

(acute)

: Not classified

Hazardous to the aquatic environment, long-term

: Very toxic to aquatic life with long lasting effects.

(chronic)

CARVEDILOL (72956-09-3)	
LC50 - Fish [1]	> 1.34 mg/l
LC50 - Fish [2]	0.99 mg/l Bluegill Sunfish
EC50 - Crustacea [1]	7.38 mg/l (average measured concentration)
ErC50 algae	1.72 mg/l (72 h)

12.2. Persistence and degradability

CARVEDILOL (72956-09-3)	
Persistence and degradability	Minimally biodegradable. May cause long-term adverse effects in the environment.
Biodegradation	0 % (28 days, Manometric respiratory test)

12.3. Bioaccumulative potential

CARVEDILOL (72956-09-3)	
Bioconcentration factor (BCF REACH)	75.21 (Estimated by BCFWIN v2.17)
Partition coefficient n-octanol/water (Log Pow)	4.19 (Expow database)

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CARVEDILOL (72956-09-3)	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

CARVEDILOL (72956-09-3)	
Mobility in soil	Strong
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	5.41 (Estimated by PCKOWIN v. 1.66)

12.5. Results of PBT and vPvB assessment

CARVEDILOL (72956-09-3)

vPvB: not relevant - no registration required

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties

: The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of

contents/container to an approved waste disposal plant.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number or ID number

 UN-No. (ADR)
 : UN 3077

 UN-No. (IMDG)
 : UN 3077

 UN-No. (IATA)
 : UN 3077

 UN-No. (ADN)
 : UN 3077

 UN-No. (RID)
 : UN 3077

14.2. UN proper shipping name

Proper Shipping Name (ADR) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Proper Shipping Name (IMDG) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Proper Shipping Name (IATA) : Environmentally hazardous substance, solid, n.o.s.

Proper Shipping Name (ADN) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Proper Shipping Name (RID) : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

Transport document description (ADR) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (E)
Transport document description (IMDG) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III,

MARINE POLLUTANT

Transport document description (IATA) : UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III

Transport document description (ADN) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III
Transport document description (RID) : UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III

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14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : 9
Danger labels (ADR) : 9



IMDG

Transport hazard class(es) (IMDG) : 9
Danger labels (IMDG) : 9



IATA

Transport hazard class(es) (IATA)

Danger labels (IATA)



ADN

Transport hazard class(es) (ADN) : 9
Danger labels (ADN) : 9



RID

Transport hazard class(es) (RID) : 9
Danger labels (RID) : 9



14.4. Packing group

Packing group (ADR) : III
Packing group (IMDG) : III
Packing group (IATA) : III
Packing group (ADN) : III
Packing group (RID) : III

14.5. Environmental hazards

Dangerous for the environment : Yes
Marine pollutant : Yes

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Classification code (ADR) : M7

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Special provisions (ADR) : 274, 335, 601, 375

Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1

Packing instructions (ADR) : P002, IBC08, LP02, R001

Mixed packing provisions (ADR) : MP10
Portable tank and bulk container instructions (ADR) : T1, BK1, BK2

Portable tank and bulk container special provisions

(ADR)

Tank code (ADR) : SGAV, LGBV

Vehicle for tank carriage : AT
Transport category (ADR) : 3
Special provisions for carriage - Packages (ADR) : V13
Special provisions for carriage - Bulk (ADR) : VC1, VC2
Special provisions for carriage - Loading, unloading : CV13

and handling (ADR)

Hazard identification number (Kemler No.) : 90

Orange plates :

90 3077

Tunnel restriction code (ADR) : E EAC code : 2Z

Transport by sea

Special provisions (IMDG) : 274, 335, 966, 967, 969

Limited quantities (IMDG) : 5 kg
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : P002, LP02
Special packing provisions (IMDG) : PP12
IBC packing instructions (IMDG) : IBC08
IBC special provisions (IMDG) : B3

Tank instructions (IMDG) : T1, BK1, BK2, BK3

Tank special provisions (IMDG) : TP33
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-F
Stowage category (IMDG) : A
Stowage and handling (IMDG) : SW23

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y956
PCA limited quantity max net quantity (IATA) : 30kgG
PCA packing instructions (IATA) : 956
PCA max net quantity (IATA) : 400kg
CAO packing instructions (IATA) : 956
CAO max net quantity (IATA) : 400kg

Special provisions (IATA) : A97, A158, A179, A197

ERG code (IATA) : 9L

Inland waterway transport

Classification code (ADN) : M7

Special provisions (ADN) : 274, 335, 375, 601

Limited quantities (ADN) : 5 kg
Excepted quantities (ADN) : E1
Carriage permitted (ADN) : T* B**
Equipment required (ADN) : PP, A
Number of blue cones/lights (ADN) : 0

Rail transport

Classification code (RID) : M7

Special provisions (RID) : 274, 335, 375, 601

Limited quantities (RID) : 5kg

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Excepted quantities (RID) : E1

Packing instructions (RID) : P002, IBC08, LP02, R001

Special packing provisions (RID) : PP12, B3

Mixed packing provisions (RID) : MP10

Portable tank and bulk container instructions (RID) : T1, BK1, BK2

Portable tank and bulk container special provisions : TP33

(RID)

Tank codes for RID tanks (RID) : SGAV, LGBV

Transport category (RID) : 3

Special provisions for carriage – Packages (RID) : W13

Special provisions for carriage – Bulk (RID) : VC1, VC2

Special provisions for carriage - Loading, unloading : CW13, CW31

and handling (RID)

Colis express (express parcels) (RID) : CE11 Hazard identification number (RID) : 90

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)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

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

Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances

Hazardous to Waters (AwSV).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed SZW-lijst van mutagene stoffen : The substance is not listed SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed SZW-lijst van reprotoxische stoffen – : The substance is not listed

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

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Denmark

Classification remarks : Emergency management guidelines for the storage of flammable liquids must be followed

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Switzerland

Storage class (LK) : LK 11/13 - Solids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE

COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and

amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:	
Aquatic Chronic 1 Hazardous to the aquatic environment – Chronic Hazard, Category 1	
H410	Very toxic to aquatic life with long lasting effects.

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.

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