

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

#### 1.1. Product identifier

Product form	: Substance
Substance name	: Sulfamethoxazole
Chemical name	: Sulfamethoxazole
EC-No.	: 211-963-3
CAS-No.	: 723-46-6
Product code	: 201600854

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

##### Relevant identified uses

Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

##### Uses advised against

Restrictions on use	: Not for food, drug or home use
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#### 1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe  
7, Allée Kastner, CS30026  
F 67081 Strasbourg  
France  
T +33(0)388412035, F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu), [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Emergency telephone number

Emergency number	: +33(0)390215608
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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]

Reproductive toxicity, Category 2	H361
Specific target organ toxicity – Repeated exposure, Category 1	H372
Hazardous to the aquatic environment – Chronic Hazard, Category 2	H411

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

##### Adverse physicochemical, human health and environmental effects

Toxic to aquatic life with long lasting effects. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

#### 2.2. Label elements

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

Hazard pictograms (CLP)	:		
		GHS08	GHS09
Signal word (CLP)	:	Danger	

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- Hazard statements (CLP) : H361 - Suspected of damaging fertility or the unborn child.  
H372 - Causes damage to organs (skin) through prolonged or repeated exposure.  
H411 - Toxic to aquatic life with long lasting effects.
- Precautionary statements (CLP) : P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P273 - Avoid release to the environment.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P314 - Get medical advice/attention if you feel unwell.  
P391 - Collect spillage.  
P405 - Store locked up.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP) :



GHS08

### 2.3. Other hazards

- Other information : Active substance (in pharmaceutical products).  
Warning - substance not yet tested completely.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Sulfamethoxazole	CAS-No.: 723-46-6 EC-No.: 211-963-3	≤ 100	Repr. 2, H361 STOT RE 1, H372 Aquatic Chronic 2, H411

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 general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- 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 with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

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

No additional information available

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

No additional information available

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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
- Unsuitable extinguishing media : Do not use a heavy water stream.

#### 5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

#### 5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- 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

- General measures : Avoid contact with skin, eyes and clothing.

##### For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

##### 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. Prevent entry to sewers and public waters.

#### 6.3. Methods and material for containment and cleaning up

- For containment : Absorb with an inert material and place in an appropriate waste disposal container.
- Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

#### 6.4. Reference to other sections

See Section 13 for disposal information.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Additional hazards when processed : Do not expose pregnant or breastfeeding women.
- Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
- Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

#### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
- Packaging materials : Keep in original containers.

#### 7.3. Specific end use(s)

No additional information available

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### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

##### Appropriate engineering controls

###### Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

##### Personal protection equipment

###### Eye and face protection

###### Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

###### Skin protection

###### Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

###### Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

###### Respiratory protection

###### Respiratory protection:

In case of dust formation use respirator with filter: P3

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white, almost white.
Appearance	: Crystalline powder.
Molecular mass	: 253.28 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 167 – 172 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: < 0.1 g/l
Partition coefficient n-octanol/water (Log Kow)	: Not available
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

#### 9.2. Other information

No additional information available

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### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No additional information available

#### 10.2. Chemical stability

No additional information available

#### 10.3. Possibility of hazardous reactions

No additional information available

#### 10.4. Conditions to avoid

No additional information available

#### 10.5. Incompatible materials

No additional information available

#### 10.6. Hazardous decomposition products

No additional information available

### SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (dermal) : Not classified (Lack of data)  
Acute toxicity (inhalation) : Not classified (Lack of data)

#### Sulfamethoxazole (723-46-6)

LD50 oral rat	> 2000 mg/kg
Skin corrosion/irritation	: Not classified (Lack of data)
Serious eye damage/irritation	: Not classified (Lack of data)
Respiratory or skin sensitisation	: Not classified (Inconclusive data)
Germ cell mutagenicity	: Not classified (Inconclusive data)
Carcinogenicity	: Not classified (Inconclusive data)
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Causes damage to organs (skin) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Lack of data)

#### 11.2. Information on other hazards

No additional information available

### SECTION 12: Ecological information

#### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)  
Hazardous to the aquatic environment, long-term (chronic) : Toxic to aquatic life with long lasting effects.

#### Sulfamethoxazole (723-46-6)

LC50 - Fish [1]	562.2 mg/l (96 Hours, <i>Oryzias latipes</i> (Ricefish))
EC50 - Crustacea [1]	75 mg/l (48 Hours, <i>Daphnia magna</i> (Water flea)) (OECD 202 method)

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### Sulfamethoxazole (723-46-6)

ErC50 algae	3.4 mg/l (72 Hours, Raphidocelis subcapitata) (OECD 201 method)
NOEC chronic fish	0.533 mg/l (21 days, Danio rerio(zebra fish))
NOEC chronic crustacea	< 0.625 mg/l (21 days, Daphnia magna (Water flea)) (OECD Guideline 211)

### 12.2. Persistence and degradability

#### Sulfamethoxazole (723-46-6)

Persistence and degradability	Not rapidly degradable
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### 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

No additional information available

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
UN 3077	UN 3077	UN 3077
<b>14.2. UN proper shipping name</b>		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
<b>Transport document description</b>		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
<b>14.3. Transport hazard class(es)</b>		
9	9	9

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ADR	IMDG	IATA
		
<b>14.4. Packing group</b>		
III	III	III
<b>14.5. Environmental hazards</b>		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes EmS-No. (Fire): F-A EmS-No. (Spillage): S-F	Dangerous for the environment: Yes
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	: TP33
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 and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	:



Tunnel restriction code (ADR) : -

#### Transport by sea

Special provisions (IMDG)	: 274, 335, 375, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP02, P002
Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: BK1, BK2, BK3, T1
Tank special provisions (IMDG)	: TP33
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

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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, A215
ERG code (IATA)	: 9L

### 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

#### 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

##### Ozone Regulation (1005/2009)

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

##### Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

##### Explosives Precursors Regulation (EU 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 (EC 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)

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

### Indication of changes

Section	Changed item	Comments
	UN-No. (RID)	<b>Added</b>
	Number of blue cones/lights (ADN)	<b>Added</b>
	Equipment required (ADN)	<b>Added</b>
	Carriage permitted (ADN)	<b>Added</b>
	Excepted quantities (ADN)	<b>Added</b>
	Limited quantities (ADN)	<b>Added</b>
	Danger labels (ADN)	<b>Added</b>
	Classification code (ADN)	<b>Added</b>
	Proper Shipping Name (RID)	<b>Added</b>
	Hazard identification number (RID)	<b>Added</b>

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Indication of changes		
Section	Changed item	Comments
	Colis express (express parcels) (RID)	<b>Added</b>
	Special provisions for carriage - Loading, unloading and handling (RID)	<b>Added</b>
	Special provisions for carriage – Bulk (RID)	<b>Added</b>
	Special provisions for carriage – Packages (RID)	<b>Added</b>
	Transport category (RID)	<b>Added</b>
	Tank codes for RID tanks (RID)	<b>Added</b>
	Portable tank and bulk container special provisions (RID)	<b>Added</b>
	Portable tank and bulk container instructions (RID)	<b>Added</b>
	Mixed packing provisions (RID)	<b>Added</b>
	Special packing provisions (RID)	<b>Added</b>
	Packing instructions (RID)	<b>Added</b>
	Excepted quantities (RID)	<b>Added</b>
	Limited quantities (RID)	<b>Added</b>
	Special provisions (RID)	<b>Added</b>
	Packing group (RID)	<b>Added</b>
	Classification code (RID)	<b>Added</b>
	ERG code (IATA)	<b>Added</b>
	Special provisions (IATA)	<b>Added</b>
	CAO max net quantity (IATA)	<b>Added</b>
	CAO packing instructions (IATA)	<b>Added</b>
	PCA max net quantity (IATA)	<b>Added</b>
	PCA packing instructions (IATA)	<b>Added</b>
	PCA limited quantity max net quantity (IATA)	<b>Added</b>
	PCA Limited quantities (IATA)	<b>Added</b>
	PCA Excepted quantities (IATA)	<b>Added</b>
	Danger labels (IATA)	<b>Added</b>
	Proper Shipping Name (IATA)	<b>Added</b>
	Proper Shipping Name (IMDG)	<b>Added</b>
	Danger labels (IMDG)	<b>Added</b>
	EmS-No. (Spillage)	<b>Added</b>
	EmS-No. (Fire)	<b>Added</b>
	Limited quantities (IMDG)	<b>Added</b>
	Stowage and handling (IMDG)	<b>Added</b>
	Stowage category (IMDG)	<b>Added</b>
	Tank special provisions (IMDG)	<b>Added</b>

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Indication of changes		
Section	Changed item	Comments
	Tank instructions (IMDG)	<b>Added</b>
	IBC special provisions (IMDG)	<b>Added</b>
	IBC packing instructions (IMDG)	<b>Added</b>
	Excepted quantities (IMDG)	<b>Added</b>
	Special provisions (IMDG)	<b>Added</b>
	Special provisions for carriage - Loading, unloading and handling (ADR)	<b>Added</b>
	Special provisions for carriage - Bulk (ADR)	<b>Added</b>
	Special provisions for carriage - Packages (ADR)	<b>Added</b>
	Tank code (ADR)	<b>Added</b>
	Portable tank and bulk container special provisions (ADR)	<b>Added</b>
	Portable tank and bulk container instructions (ADR)	<b>Added</b>
	Mixed packing provisions (ADR)	<b>Added</b>
	Special packing provisions (ADR)	<b>Added</b>
	Packing instructions (ADR)	<b>Added</b>
	Vehicle for tank carriage	<b>Added</b>
	Supersedes version of	<b>Added</b>
	Revision date	<b>Added</b>
1.1	EC-No.	<b>Added</b>
1.1	CAS-No.	<b>Added</b>
1.1	Synonyms	<b>Removed</b>
1.2	Restrictions on use	<b>Added</b>
1.2	Use of the substance/mixture	<b>Added</b>
1.2	Function or use category	<b>Added</b>
2.1	Adverse physicochemical, human health and environmental effects	<b>Added</b>
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<b>Added</b>
2.2	Hazard statements (CLP)	<b>Added</b>
2.2	Precautionary statements (CLP)	<b>Added</b>
2.2	Signal word (CLP)	<b>Added</b>
2.2	Hazard pictograms (CLP)	<b>Added</b>
2.3	Other information	<b>Added</b>
4.1	First-aid measures general	<b>Added</b>
4.1	First-aid measures after skin contact	<b>Added</b>
4.1	First-aid measures after inhalation	<b>Added</b>
4.1	First-aid measures after ingestion	<b>Added</b>

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Indication of changes		
Section	Changed item	Comments
4.1	First-aid measures after eye contact	<b>Added</b>
5.1	Unsuitable extinguishing media	<b>Added</b>
5.1	Suitable extinguishing media	<b>Added</b>
5.2	Hazardous decomposition products in case of fire	<b>Added</b>
5.3	Protection during firefighting	<b>Added</b>
5.3	Firefighting instructions	<b>Added</b>
6.1	Protective equipment	<b>Added</b>
6.1	Emergency procedures	<b>Added</b>
6.1	General measures	<b>Added</b>
6.2	Environmental precautions	<b>Added</b>
6.3	For containment	<b>Added</b>
6.3	Methods for cleaning up	<b>Added</b>
6.4	Reference to other sections (8, 13)	<b>Added</b>
7.1	Additional hazards when processed	<b>Added</b>
7.1	Precautions for safe handling	<b>Added</b>
7.1	Hygiene measures	<b>Added</b>
7.2	Storage conditions	<b>Added</b>
7.2	Packaging materials	<b>Added</b>
8.2	Respiratory protection	<b>Added</b>
8.2	Hand protection	<b>Added</b>
8.2	Eye protection	<b>Added</b>
8.2	Appropriate engineering controls	<b>Added</b>
8.2	Skin and body protection	<b>Added</b>
9	Molecular mass	<b>Added</b>
9	Melting point	<b>Added</b>
9	Colour	<b>Added</b>
9	Appearance	<b>Modified</b>
11.1	IARC group	<b>Removed</b>
12.1	NOEC chronic fish	<b>Added</b>
12.1	NOEC chronic crustacea	<b>Added</b>
12.1	ErC50 algae	<b>Added</b>
12.1	LC50 - Fish [1]	<b>Added</b>
12.1	EC50 - Crustacea [1]	<b>Added</b>
14.1	UN-No. (ADN)	<b>Added</b>
14.1	UN-No. (IMDG)	<b>Added</b>
14.1	UN-No. (IATA)	<b>Added</b>
14.1	UN-No. (ADR)	<b>Added</b>

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Indication of changes		
Section	Changed item	Comments
14.2	Proper Shipping Name (ADN)	<b>Added</b>
14.2	Proper Shipping Name (ADR)	<b>Added</b>
14.3	Danger labels (RID)	<b>Added</b>
14.3	Danger labels (ADR)	<b>Added</b>
14.3	Class (ADR)	<b>Added</b>
14.4	Packing group (ADN)	<b>Added</b>
14.4	Packing group (IATA)	<b>Added</b>
14.4	Packing group (IMDG)	<b>Added</b>
14.4	Packing group (ADR)	<b>Added</b>
14.6	Additional requirements/Remarks (ADN)	<b>Added</b>
14.6	Special provisions (ADN)	<b>Added</b>
14.6	Special packing provisions (IMDG)	<b>Added</b>
14.6	Packing instructions (IMDG)	<b>Added</b>
14.6	Transport category (ADR)	<b>Added</b>
14.6	Special provisions (ADR)	<b>Added</b>
14.6	Excepted quantities (ADR)	<b>Added</b>
14.6	Limited quantities (ADR)	<b>Added</b>
14.6	Tunnel restriction code (ADR)	<b>Added</b>
14.6	Hazard identification number (Kemler No.)	<b>Added</b>
14.6	Classification code (ADR)	<b>Added</b>

Full text of H- and EUH-statements:	
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
H361	Suspected of damaging fertility or the unborn child.
H372	Causes damage to organs (skin) through prolonged or repeated exposure.
H411	Toxic to aquatic life with long lasting effects.
Repr. 2	Reproductive toxicity, Category 2
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Safety Data Sheet (SDS), EU

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