Printing date 11.06.2015 Version number 8 Revision: 11.06.2015

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

- · 1.1 Product identifier
- · Trade name: Calcimol base
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture self-curing radiopaque calcium hydroxide paste
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

VOCO GmbH

Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

- Further information obtainable from: Scientific department tel. +49 (0)4721-719-0
- · 1.4 Emergency telephone number: Poison Control Center Mainz +49 (0)6131-19240

## SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

As a medical device the product is not subject to labelling regulations under 1272/2008/EC.

- · Hazard pictograms GHS07, GHS09
- · Signal word Warning
- · Hazard statements

Causes skin irritation.

Causes serious eye irritation.

Toxic to aquatic life with long lasting effects.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- · 2.3 Other hazards Use only for intended scope of application
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

## SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:					
		salicylate	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	25-50%	
	1314-13-2 CS: 215-222-5		Aquatic Acute 1, H400; Aquatic Chronic 1, H410	5-10%	

Printing date 11.06.2015 Version number 8 Revision: 11.06.2015

Trade name: Calcimol base

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### SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation: Seek medical treatment in case of complaints.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: If symptoms persist consult doctor.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

#### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

#### SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

### **SECTION 7: Handling and storage**

- · 7.1 Precautions for safe handling For dental use only.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles: See storage instructions on package
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Keep container tightly sealed.
- $\cdot$  7.3 *Specific end use(s) No further relevant information available.*

#### SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· Additional information: The lists valid during the making were used as basis.

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Trade name: Calcimol base

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- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Avoid contact with the eyes and skin.

· Protection of hands:



Protective gloves

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Eye protection: Safety glasses

#### SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Pasty
Colour: Beige
Odour: Aromatic

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Self-igniting: Product is not selfigniting.

• Danger of explosion: Product does not present an explosion hazard.

· Density: Not determined.

· Solubility in / Miscibility with

water: Not miscible or difficult to mix.

· Viscosity:

Dynamic: Not determined. Kinematic: Not determined.

• 9.2 Other information No further relevant information available.

#### SECTION 10: Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

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Trade name: Calcimol base

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## **SECTION 11: Toxicological information**

- · 11.1 Information on toxicological effects
- · Acute toxicity
- · LD/LC50 values relevant for classification:

1314-13-2 zinc oxide

*Oral* | *LD50* | > 5000 mg/kg (rat)

- · Primary irritant effect:
- · Skin corrosion/irritation Irritant to skin and mucous membranes.
- · Serious eye damage/irritation Irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.
- · Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

Irritant

### SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Remark: Toxic for fish
- · Additional ecological information:
- · General notes:

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

### SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

#### **SECTION 14: Transport information**

· 14.1 UN-Number

· ADR UN3082

Attention: special provisions A197 IATA, 375 ADR and/or IMDG-Code paragraph 2.10.2.7 may be applied during

transport.

· IMDG, IATA UN3082

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Printing date 11.06.2015 Version number 8 Revision: 11.06.2015

Trade name: Calcimol base

	(Contd. of page
· 14.2 UN proper shipping name · ADR	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE
· IMDG	LIQUID, N.O.S. (zinc oxide) ENVIRONMENTALLY HAZARDOUS SUBSTANCE
·IATA	LIQUID, N.O.S. (zinc oxide), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (zinc oxide)
· 14.3 Transport hazard class(es)	
· ADR, IMDG, IATA	
dh. ¥₂>	
· Class · Label	<ul><li>9 Miscellaneous dangerous substances and articles.</li><li>9</li></ul>
· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	Product contains environmentally hazardous substances
· Marine pollutant:	zinc oxide Yes Symbol (fish and tree)
Special marking (ADR):	Symbol (fish and tree)
Special marking (IATA):	Symbol (fish and tree)
· 14.6 Special precautions for user	Warning: Miscellaneous dangerous substances and articles.
· Danger code (Kemler):	90
· EMS Number:	F- $A$ , $S$ - $F$
· 14.7 Transport in bulk according to Annex MARPOL73/78 and the IBC Code	x <b>II of</b> Not applicable.
Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5L
Transport category	3
· Tunnel restriction code	E
· UN ''Model Regulation'':	UN3082, ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, N.O.S. (zinc oxide), 9, III

### SECTION 15: Regulatory information

- $\cdot$  15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.

### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing MSDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0

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Trade name: Calcimol base

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#### · Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organisation

ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3 Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

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Printing date 10.06.2015 Version number 8 Revision: 10.06.2015

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

- · 1.1 Product identifier
- · Trade name: Calcimol catalyst
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture self-curing radiopaque calcium hydroxide paste
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

VOCO GmbH

Anton-Flettner-Str. 1-3 D-27472 Cuxhaven

- Further information obtainable from: Scientific department tel. +49 (0)4721-719-0
- · 1.4 Emergency telephone number: Poison Control Center Mainz +49 (0)6131-19240

## SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation. Eye Dam. 1 H318 Causes serious eye damage.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

As a medical device the product is not subject to labelling regulations under 1272/2008/EC.

- · Hazard pictograms GHS05, GHS09
- · Signal word Danger
- · Hazard statements

Causes skin irritation.

Causes serious eye damage.

Toxic to aquatic life with long lasting effects.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation occurs: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- · 2.3 Other hazards Use only for intended scope of application
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

## SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:				
	calcium dihydroxide	25-50%		
EINECS: 215-137-3	CS: 215-137-3 Eye Dam. 1, H318			
	Skin Irrit. 2, H315; STOT SE 3, H335			
	N-Ethyl-Toluolsulfonamid	25-50%		
	STOT SE 3, H336			

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Printing date 10.06.2015 Version number 8 Revision: 10.06.2015

Trade name: Calcimol catalyst

	(Cont	d. of page 1)
CAS: 1314-13-2	zinc oxide	5-10%
EINECS: 215-222-5	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	

#### SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation: Seek medical treatment in case of complaints.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing: If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

#### **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

#### SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

## SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling For dental use only.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: See storage instructions on package
- · 7.3 Specific end use(s) No further relevant information available.

#### SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· Additional information: The lists valid during the making were used as basis.

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Trade name: Calcimol catalyst

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- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Avoid contact with the eyes and skin.

· Protection of hands:



Protective gloves

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Eye protection: Safety glasses

#### SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Pasty
Colour: White
Odour: Light

· pH-value: Not determined.

· Change in condition

Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined.

· Flash point: Not applicable.

· Self-igniting: Product is not selfigniting.

• Danger of explosion: Product does not present an explosion hazard.

· Density: Not determined.

· Solubility in / Miscibility with

water: Not miscible or difficult to mix.

· Viscosity:

**Dynamic:** Not determined. **Kinematic:** Not determined.

• 9.2 Other information No further relevant information available.

#### SECTION 10: Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

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Trade name: Calcimol catalyst

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## **SECTION 11: Toxicological information**

- · 11.1 Information on toxicological effects
- · Acute toxicity
- · LD/LC50 values relevant for classification:

1314-13-2 zinc oxide

*Oral* | *LD50* | > 5000 mg/kg (rat)

- · Primary irritant effect:
- · Skin corrosion/irritation Irritant to skin and mucous membranes.
- · Serious eye damage/irritation Strong irritant with the danger of severe eye injury.
- · Respiratory or skin sensitisation No sensitising effects known.
- · Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

Irritant

### SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · Remark: Toxic for fish
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

### SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

#### **SECTION 14: Transport information**

· 14.1 UN-Number

· ADR UN3082

Attention: special provisions A197 IATA, 375 ADR and/or

IMDG-Code paragraph 2.10.2.7 may be applied during

transport.

· IMDG, IATA UN3082

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Trade name: Calcimol catalyst

	(Contd. of page
· 14.2 UN proper shipping name	
· ADR	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (zinc oxide)
· IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (zinc oxide), MARINE POLLUTANT
· IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE LIQUID, N.O.S. (zinc oxide)
14.3 Transport hazard class(es)	
ADR, IMDG, IATA	
<u>√</u> (¥2)	
· Class · Label	<ul><li>9 Miscellaneous dangerous substances and articles.</li><li>9</li></ul>
· 14.4 Packing group	
· ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	Product contains environmentally hazardous substances zinc oxide
· Marine pollutant:	Yes
· Special marking (ADR):	Symbol (fish and tree) Symbol (fish and tree)
· Special marking (ADK). · Special marking (IATA):	Symbol (fish and tree)
14.6 Special precautions for user	Warning: Miscellaneous dangerous substances an
	articles.
Danger code (Kemler):	90 E A C E
EMS Number:	F-A,S-F
14.7 Transport in bulk according to Anne. MARPOL73/78 and the IBC Code	x <b>II of</b> Not applicable.
Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5L
· Transport category	3
· Tunnel restriction code	E
· UN ''Model Regulation'':	UN3082, ENVIRONMENTALLY HAZARDOU SUBSTANCE, LIQUID, N.O.S. (zinc oxide), 9, III

### SECTION 15: Regulatory information

- $\cdot$  15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.

### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing MSDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0

(Contd. on page 6)

Printing date 10.06.2015 Version number 8 Revision: 10.06.2015

Trade name: Calcimol catalyst

(Contd. of page 5)

#### · Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3 Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1 Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1 Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

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