Printing date 03.05.2023 Version number 9 Revision: 03.05.2023

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

- · 2.2 Label elements
- · 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.

· 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

Avoid release to the environment.

Wear 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.

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

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · After inhalation: Seek medical treatment in case of complaints.

(Contd. on page 2)

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Trade name: Calcimol base

(Contd. of page 1)

- · 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: 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.

No special precautions are necessary if used correctly.

Follow the instructions for use.

- 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

- · 8.1 Control parameters
- · Additional information about design of technical facilities: No further data; see item 7.
- · 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.
- · 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.

(Contd. on page 3)

(Contd. of page 2)

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 03.05.2023 Version number 9 Revision: 03.05.2023

Trade name: Calcimol base

Protection of hands:



· 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.

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· 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/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

· Flash point: Not applicable.

• Auto-ignition temperature: Product is not selfigniting.

• Explosive properties: 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 No further relevant information available.
- · 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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Printing date 03.05.2023 Version number 9 Revision: 03.05.2023

Trade name: Calcimol base

(Contd. of page 3)

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- Primary irritant effect:
- · Skin corrosion/irritation

Causes skin irritation.

· Serious eye damage/irritation

Causes serious eye irritation.

- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met. · Aspiration hazard Based on available data, the classification criteria are not met.

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: Ti	ransport	inf	^c ormai	tion

· 14.1 UN-Number	Attention: special provisions A197 IATA, 375 ADR and/or IMDG-Code paragraph 2.10.2.7 may be applied during
	transport.
· ADR, IMDG, IATA	UN3082

(Contd. on page 5)

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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 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	
₩	
· Class · Label	9 Miscellaneous dangerous substances and articles.9
· 14.4 Packing group · ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	Product contains environmentally hazardous substances zinc oxide
· Marine pollutant:	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 an articles.
Hazard identification number (Kemler code):	90
· EMS Number:	F-A,S-F
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	of Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5L
· Transport category	3 E
· Tunnel restriction code	E
· UN ''Model Regulation'':	UN 3082 ENVIRONMENTALLY HAZARDOU, SUBSTANCE, LIQUID, N.O.S. (ZINC OXIDE), 9, III

SECTION 15: Regulatory information

- · 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.
- · Seveso category E2 Hazardous to the Aquatic Environment
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t

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 SDS: Scientific department

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(Contd. of page 5)

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 03.05.2023 Version number 9 Revision: 03.05.2023

Trade name: Calcimol base

· Contact: Tel.: +49 (0)4721-719-0

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)

Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2

Printing date 03.05.2023 Version number 10 Revision: 03.05.2023

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

- · 2.2 Label elements
- · 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.

· 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 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.

Immediately call a POISON CENTER/doctor.

Specific treatment (see on this label).

Take off contaminated clothing and wash it before reuse.

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 compone	Dangerous components:		
Ī		• • • • • • • • • • • • • • • • • • • •	25-50%	
	EINECS: 215-137-3	Eye Dam. 1, H318		
		Skin Irrit. 2, H315; STOT SE 3, H335		
		N-Ethyl-Toluolsulfonamid	25-50%	
		Aquatic Chronic 3, H412		
		(Contd	l. on page 2)	

Printing date 03.05.2023 Version number 10 Revision: 03.05.2023

Trade name: Calcimol catalyst

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.

No special precautions are necessary if used correctly.

Follow the instructions for use.

- · 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

- · 8.1 Control parameters
- · Additional information about design of technical facilities: No further data; see item 7.
- · 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.

(Contd. on page 3)

Printing date 03.05.2023 Version number 10 Revision: 03.05.2023

Trade name: Calcimol catalyst

(Contd. of page 2)

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

Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· 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 Light

· pH-value: Not determined.

· Change in condition Melting point/freezing point: Undetermined. **Initial boiling point and boiling range:** Undetermined. · Flash point: Not applicable. Product is not selfigniting. · Auto-ignition temperature: · Explosive properties: Product does not present an explosion hazard. Not determined. · Density: · Solubility in / Miscibility with Not miscible or difficult to mix. water: · Viscosity: Dynamic: Not determined. Kinematic: Not determined. 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 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.

(Contd. on page 4)

Printing date 03.05.2023 Version number 10 Revision: 03.05.2023

Trade name: Calcimol catalyst

(Contd. of page 3)

· 10.5 Incompatible materials: No further relevant information available.

· 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification:

CAS: 1305-62-0 calcium dihydroxide

Oral LD50 7,340 mg/kg (rat)

- · Primary irritant effect:
- · Skin corrosion/irritation

Causes skin irritation.

· Serious eye damage/irritation

Causes serious eye damage.

- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

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:

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

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

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.

(Contd. on page 5)

Printing date 03.05.2023 Version number 10 Revision: 03.05.2023

Trade name: Calcimol catalyst

(Contd. of page 4)

· Uncleaned packaging:

• Recommendation: Disposal must be made according to official regulations.

4/4 7737 37 4	
14.1 UN-Number	Attention: special provisions A197 IATA, 375 ADR and/o IMDG-Code paragraph 2.10.2.7 may be applied during
	transport.
ADR, IMDG, IATA	UN3082
14.2 UN proper shipping name	
ADR	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANC
	LIQUID, N.O.S. (zinc oxide)
IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANC
IATA	LIQUID, N.O.S. (zinc oxide), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANC
IAIA	LIQUID, N.O.S. (zinc oxide)
14.3 Transport hazard class(es)	2 / ()
ADR, IMDG, IATA	
<i>A</i> . ∧	
Alb, (1)	
\vee	
Class	9 Miscellaneous dangerous substances and articles.
Label	9
14.4 Packing group	
ADR, IMDG, IATA	III
14.5 Environmental hazards:	Product contains environmentally hazardous substance
Marin and Cont	zinc oxide
Marine pollutant:	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 as
	articles.
Hazard identification number (Kemler code):	90
EMS Number:	F-A,S-F
14.7 Transport in bulk according to Annex II o	
Marpol and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	<i>5L</i>
Transport category Tunnel restriction code	3 E
UN ''Model Regulation'':	UN 3082 ENVIRONMENTALLY HAZARDOU

Printing date 03.05.2023 Version number 10 Revision: 03.05.2023

Trade name: Calcimol catalyst

(Contd. of page 5)

SECTION 15: Regulatory information

- 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.
- · Seveso category E2 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t

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 SDS: Scientific department
- · Contact: Tel.: +49 (0)4721-719-0
- · Abbreviations and acronyms:

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

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