

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

93857-Calamine lotion

Version 1 Date of compilation: 31/07/2017

Version 4 (replaces version 3)

Revision date: 13/09/2023

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: Calamine lotion
Product Code: 93857

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

Use, base for industrial pharmaceutical compounding.

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **GUINAMA**
Address: C/ Oslo Nº3
City: 46185 La Pobla de Vallbona
Province: Valencia
Telephone: +34961869090 / 902119816
Fax: +34961850352
E-mail: ventas@guinama.com
Web: www.guinama.com

1.4 Emergency telephone number: +34961869090 / 902119816 (Only available during office hours; Monday-Friday; 08:00-18:00)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

In accordance with Regulation (EC) No 1272/2008:

Aquatic Chronic 2 : Toxic to aquatic life with long lasting effects.
Eye Irrit. 2 : Causes serious eye irritation.

2.2 Label elements.

Labelling in accordance with Regulation (EC) No 1272/2008:

Pictograms:



Signal Word:

Warning

Hazard statements:

H319 Causes serious eye irritation.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

P264 Wash ... thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.
P391 Collect spillage.
P501 Dispose of contents/container to ...

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2.3 Other hazards.

The mixture does not contain substances classified as PBT.
The mixture does not contain substances classified as vPvB.
The mixture does not contain any endocrine disrupting properties substances.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not applicable.

3.2 Mixtures.

Substances posing a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, assigned a Community exposure limit in the workplace, and classified as PBT/vPvB or included in the Candidate List:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
Index No: 030-013-00-7 CAS No: 1314-13-2 EC No: 215-222-5 Registration No: 01-2119463881-32-XXXX	zinc oxide	2.5 - 25 %	Aquatic Acute 1, H400 - Aquatic Chronic 1, H410	-
CAS No: 3486-35-9 EC No: 222-477-6 Registration No: 01-2120770499-38-XXXX	Zinc carbonate	2.5 - 25 %	Aquatic Acute 1, H400 (M=1) - Aquatic Chronic 1, H410 (M=1)	-
CAS No: 68439-49-6 EC No: 500-212-8	Alcohols, C16-18, ethoxylated	1 - 3 %	Acute Tox. 4, H302 - Aquatic Acute 1, H400 - Eye Dam. 1, H318	-

(*) The complete text of the H phrases is given in section 16 of this Safety Data Sheet.

[2] Substance with a national workplace exposure limit (see section 8.1).

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Don't let the person to rub the affected eye.

Skin contact.

Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

Ingestion.

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

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

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Irritant Product, repeated or prolonged contact with skin or mucous membranes can cause redness, blisters or dermatitis, inhalation of spray mist or particles in suspension may cause irritation of the respiratory tract, some symptoms may not be immediate.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Cover the affected area with a dry sterile bandage. Protect the affected area from pressure or friction.

SECTION 5: FIREFIGHTING MEASURES.

The product is NOT classified as flammable, in case of fire the following measures should be taken:

5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture.

Special risks.

Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways. Product residues and extinguishing media may contaminate the aquatic environment.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product dangerous for the environment, in case of large spills or if the product contaminates lakes, rivers, or sewers, inform the responsible authorities according to local legislation. Prevent the contamination of drains, surface or subterranean waters, and the ground.

6.3 Methods and material for containment and cleaning up.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

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7.2 Conditions for safe storage, including any incompatibilities.

Store according to local legislation. Observe indications on the label. Store the containers between 15 and 25 ° C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

Concentration levels DNEL/DMEL:

Name	DNEL/DMEL	Type	Value
zinc oxide CAS No: 1314-13-2 EC No: 215-222-5	DNEL (Workers)	Inhalation, Chronic, Systemic effects	5 (mg/m ³)
	DNEL (Workers)	Inhalation, Chronic, Systemic effects	1 (mg Zn/m ³)
	DNEL (Consumers)	Inhalation, Short term, Systemic effects	1,3 (mg Zn/m ³)
	DNEL (Consumers)	Inhalation, Chronic, Systemic effects	2,5 (mg Zn/m ³)

DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.

DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

Concentration levels PNEC:

Name	Details	Value
zinc oxide CAS No: 1314-13-2 EC No: 215-222-5	STP	100 (µg/L)
	Sedimento de agua dulce	117,8 (mg/Kg sedimento base seca. Se aplica por defecto un factor genérico del factor de biodisponibili dad de 0.5: PNEC= 325.6 mg/kg sedimento base seca)

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	Sedimento de agua marina	56,6 (mg/kg sedimento base seca. Se aplica por defecto un factor genérico del factor de biodisponibilidad de 0.5: PNEC=113 mg/kg sediment d.w.)
	Soil	35,6 (mg/kg suelo base seca. Se aplica por defecto un factor genérico del factor de biodisponibilidad/envejecimiento de 3)
	Oral	(No hay potencial de bioacumulación)

PNEC: Predicted No Effect Concentration, concentration of the substance below which adverse effects are not expected in the environmental compartment.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %
Uses:	Use, base for industrial pharmaceutical compounding.
Breathing protection:	
PPE:	Filter mask for protection against gases and particles.
Characteristics:	«CE» marking, category III. The mask must have a wide field of vision and an anatomically designed form in order to be sealed and watertight.
CEN standards:	EN 136, EN 140, EN 405
Maintenance:	Should not be stored in places exposed to high temperatures and damp environments before use. Special attention should be paid to the state of the inhalation and exhalation valves in the face adaptor.
Observations:	Read carefully the manufacturer's instructions regarding the equipment's use and maintenance. Attach the necessary filters to the equipment according to the specific nature of the risk (Particles and aerosols: P1-P2-P3, Gases and vapours: A-B-E-K-AX), changing them as advised by the manufacturer.
Filter Type needed:	A2
Hand protection:	
PPE:	Work gloves.
Characteristics:	«CE» marking, category I.
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.
Material:	PVC (polyvinyl chloride)
Breakthrough time (min.):	> 480
Material thickness (mm):	0,35
Eye protection:	
If the product is handled correctly, no individual protection equipment is necessary.	
Skin protection:	

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PPE:	Work footwear.
Characteristics:	«CE» marking, category II.
CEN standards:	EN ISO 13287, EN 20347
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Liquid

Colour: Not applicable/Not available due to the nature/properties of the product

Odour: Not applicable/Not available due to the nature/properties of the product

Odour threshold: Not applicable/Not available due to the nature/properties of the product

Melting point: Not applicable/Not available due to the nature/properties of the product

Freezing point: Not applicable/Not available due to the nature/properties of the product

Boiling point or initial boiling point and boiling range: Not applicable/Not available due to the nature/properties of the product

Flammability: Not applicable/Not available due to the nature/properties of the product

Lower explosion limit: Not applicable/Not available due to the nature/properties of the product

Upper explosion limit: Not applicable/Not available due to the nature/properties of the product

Flash point: > 60 °C

Auto-ignition temperature: Not applicable/Not available due to the nature/properties of the product

Decomposition temperature: Not applicable/Not available due to the nature/properties of the product

pH: Not applicable/Not available due to the nature/properties of the product

Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product

Solubility: Not applicable/Not available due to the nature/properties of the product

Hydrosolubility: Not applicable/Not available due to the nature/properties of the product

Liposolubility: Not applicable/Not available due to the nature/properties of the product

Partition coefficient n-octanol/water (log value): Not applicable/Not available due to the nature/properties of the product

Vapour pressure: Not applicable/Not available due to the nature/properties of the product

Absolute density: Not applicable/Not available due to the nature/properties of the product

Relative density: Not applicable/Not available due to the nature/properties of the product

Relative vapour density: Not applicable/Not available due to the nature/properties of the product

Particle characteristics: Not applicable/Not available due to the nature/properties of the product

9.2 Other information

Not applicable/Not available due to the nature/properties of the product

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

IRRITANT MIXTURE. Splashes in the eyes can cause irritation.

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11.1 Information on hazard classes as defined in Regulation (EC) N° 1272/2008.

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.

Toxicological information about the substances present in the composition.

Name	Acute toxicity			
	Type	Test	Kind	Value
zinc oxide	Oral	DL50	Rat	15000 mg/kg [1]
		DL50	Rat	>5000 mg/kg [2]
	Dermal	[1] Löser 1972 [2] Löser 1977		
CAS No: 1314-13-2 EC No: 215-222-5	Inhalation	CL50	Rat	>5.7 mg/l (4h) [1]
		[1] Klimisch et al. (1982)		

a) acute toxicity;

Not conclusive data for classification.

Acute Toxicity Estimate (ATE):

Mixtures:

ATE (Oral) = 33.333 mg/kg

b) skin corrosion/irritation;

Not conclusive data for classification.

c) serious eye damage/irritation;

Product classified:

Eye irritation, Category 2: Causes serious eye irritation.

d) respiratory or skin sensitisation;

Not conclusive data for classification.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) reproductive toxicity;

Not conclusive data for classification.

h) STOT-single exposure;

Not conclusive data for classification.

i) STOT-repeated exposure;

Not conclusive data for classification.

j) aspiration hazard;

Not conclusive data for classification.

11.2 Information on other hazards.

Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

No information is available regarding the ecotoxicity of the substances present.

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12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.
No information is available on the degradability of the substances present.
No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation of the substances present.

12.4 Mobility in soil.

No information is available about the mobility in soil.
The product must not be allowed to go into sewers or waterways.
Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.
No information is available about other adverse effects for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transport following ADR rules for road transport, RID rules for railway, ADN for inner waterways, IMDG for sea, and ICAO/IATA for air transport.

Land: Transport by road: ADR, Transport by rail: RID.

Transport documentation: Consignment note and written instructions

Sea: Transport by ship: IMDG.

Transport documentation: Bill of lading

Air: Transport by plane: ICAO/IATA.

Transport document: Airway bill.

14.1 UN number or ID number.

UN No: UN3082

14.2 UN proper shipping name.

Description:

ADR/RID: UN 3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (CONTAINS ZINC OXIDE), 9, PG III, (-)

IMDG: UN 3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (CONTAINS ZINC OXIDE / ZINC CARBONATE), 9, PG III, MARINE POLLUTANT

ICAO/IATA: UN 3082, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (CONTAINS ZINC OXIDE), 9, PG III

14.3 Transport hazard class(es).

Class(es): 9

14.4 Packing group.

Packing group: III

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14.5 Environmental hazards.

Marine pollutant: Yes



Dangerous for the environment

Transport by ship, FEM – Emergency sheets (F – Fire, S - Spills): F-A,S-F

14.6 Special precautions for user.

Labels: 9



Hazard number: 90

Provisions concerning carriage in bulk ADR: Not authorized carriage in bulk in accordance with ADR.

Proceed in accordance with point 6.

ADR LQ: 5 L

IMDG LQ: 5 L

ICAO LQ: 30 kg B

14.7 Maritime transport in bulk according to IMO instruments.

The product is not transported in bulk.

SECTION 15: REGULATORY INFORMATION.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Complete text of the H phrases that appear in section 3:

H302	Harmful if swallowed.
H318	Causes serious eye damage.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Classification codes:

Acute Tox. 4 : Acute toxicity (Oral), Category 4

Aquatic Acute 1 : Acute toxicity to the aquatic environment, Category 1

Aquatic Chronic 1 : Chronic effect to the aquatic environment, Category 1

Aquatic Chronic 2 : Chronic effect to the aquatic environment, Category 2

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Eye Dam. 1 : Serious eye damage, Category 1
Eye Irrit. 2 : Eye irritation, Category 2

Changes regarding to the previous version:

- Changes in the information of the supplier (SECTION 1.3).
- Changes in the composition of the product (SECTION 3.2).
- Elimination of ecological information values (SECTION 12.2).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

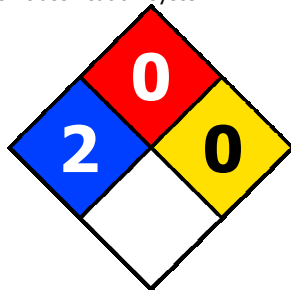
Physical hazards On basis of test data
Health hazards Calculation method
Environmental hazards Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
1314-13-2	zinc oxide	Registered
3486-35-9	Zinc carbonate	Registered
68439-49-6	Alcohols, C16-18, ethoxylated	Registered

Risk classification system NFPA 704:



Health hazard: 2 (Hazardous)
Flammability: 0 (Will not burn)
Reactivity: 0 (Stable)

Abbreviations and acronyms used:

ADR/RID: Agreement concerning the International Carriage of Dangerous Goods by Road.

CEN: European Committee for Standardization.

DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.

PPE: Personal protection equipment.

IATA: International Air Transport Association.

ICAO: International Civil Aviation Organization.

IMDG: International Maritime Code for Dangerous Goods.

PNEC: Predicted No Effect Concentration, concentration of the substance below which adverse effects are not expected in the environmental compartment.

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

Regulation (EU) 2020/878.

Regulation (EC) No 1907/2006.

Regulation (EC) No 1272/2008.

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The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.