

SAFETY DATA SHEET

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

9456-Foam base guinama



Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 1 of 13

Print date: 30/10/2023

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

1.1 Product identifier.

Product Name: Foam base guinama
Product Code: 9456

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:

Eye Dam. 1 : Causes serious eye damage.
Flam. Liq. 3 : Flammable liquid and vapour.
Skin Corr. 1C : Causes severe skin burns and eye damage.

2.2 Label elements.

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

Pictograms:



Signal Word:

Danger

Hazard statements:

H226 Flammable liquid and vapour.
H314 Causes severe skin burns and eye damage.

Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P240 Ground and bond container and receiving equipment.
P241 Use explosion-proof [electrical/ventilating/lighting/...] equipment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P264 Wash ... thoroughly after handling.

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama



Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 2 of 13

Print date: 30/10/2023

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor/...
P321 Specific treatment (see ... on this label).
P363 Wash contaminated clothing before reuse.
P370+P378 In case of fire: Use... to extinguish.
P403+P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.
P501 Dispose of contents/container to ...

Contains:

Lactic acid

N-[3-(methylamino)propyl]-N-alkyl(cocoalkyl)oxide

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.

2,6-di-tert-butyl-p-cresol CAS 128370

Propylene glycol CAS 57556

Sorbitan monolaurate, ethoxylated (EO 1-6.5) CAS 9005645

N- [3- (methylamino) PROPYL] -N-ALKY (COCOALKY) OXIDE CAS 68155099

Water CAS 7732185

Lactic acid CAS 50215

diethyl phthalate CAS 84662

Ethyl alcohol ETHANOL CAS 64175

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: 603-002-00-5 CAS No: 64-17-5 EC No: 200-578-6 Registration No: 01-2119457610-43-XXXX	ethanol, ethyl alcohol	15%	Eye Irrit. 2, H319 - Flam. Liq. 2, H225	-
CAS No: 50-21-5 EC No: 200-018-0 Registration No: 01-2119548400-48-XXXX	Lactic acid	7.2%	Eye Dam. 1, H318 - Skin Corr. 1C, H314	-
CAS No: 68155-09-9 EC No: 268-938-5	N-[3-(methylamino)propyl]-N-alkyl(cocoalkyl)oxide	1.2%	Aquatic Acute 1, H400 - Eye Dam. 1, H318 - Skin Irrit. 2, H315	-

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama



Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 3 of 13

Print date: 30/10/2023

CAS No: 128-37-0 EC No: 204-881-4 Registration No: 01-2119565113-46-XXXX	2,6-di-tert-butyl-p-cresol	0.1%	Aquatic Acute 1, H400 (M=1) - Aquatic Chronic 1, H410 (M=1)	-
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(*) 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.

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. The use of personal protective equipment is recommended for people providing first aid (see section 8).

Ingestion.

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

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

Corrosive Product, contact with eyes or skin can cause burns; ingestion or inhalation can cause internal damage, if this occurs immediate medical assistance is required.

Contact with eyes may cause irreversible damage.

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

Request immediate medical attention. Never administer anything orally to persons who are unconscious. Do not induce vomiting. If the person vomits, clear the respiratory tract. Cover the affected area with a dry sterile bandage. Protect the affected area from pressure or friction.

SECTION 5: FIREFIGHTING MEASURES.

Flammable product, the necessary prevention measures should be taken in order to avoid risks, In case of fire, the following measures are recommended:

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.

During a fire and depending on its magnitude the following may occur:

- Flammable vapors or gases.

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. Follow the instructions given in the emergency or fire evacuation plan or plans if available.

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama

Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023



Page 4 of 13

Print date: 30/10/2023

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. During extinction and depending on the magnitude and proximity to the fire, additional protective equipment such as chemical protection gloves, heat-reflecting suits or gas-tight suits may be required.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

Eliminate possible ignition points and ventilate the area. No smoking. Avoid breathing fumes. For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

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.

The fumes are heavier than air and can spread across the ground. They can form explosive mixtures with air. Prevent the creation of flammable or explosive fume concentrations in the air; prevent fume concentrations above work exposure limits. The product must only be used in areas where all unprotected flames and other ignition points have been eliminated. Electrical equipment has to be protected according to applicable standards.

The product can be electrostatically charged: always use earth grounds when transferring the product. Operators must use anti-static footwear and clothing, and floors must be conductors.

Keep the container tightly closed and isolated from heat sources, sparks, and fire. Do not use tools that can cause sparks. 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.

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.

Classification and threshold amount of storage in accordance with Annex I to Directive 2012/18/EU (SEVESO III):

Code	Description	Qualifying quantity (tonnes) for the application of	
		Lower-tier requirements	Upper-tier requirements
P5c	FLAMMABLE LIQUIDS	5.000	50.000

7.3 Specific end use(s).

Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama



Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 5 of 13

Print date: 30/10/2023

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
ethanol, ethyl alcohol CAS No: 64-17-5 EC No: 200-578-6	DNEL (Workers)	Inhalation, Chronic, Systemic effects	950 (mg/m ³)
	DNEL (Consumers)	Inhalation, Chronic, Systemic effects	114 (mg/m ³)
	DNEL (Workers)	Dermal, Chronic, Systemic effects	343 (mg/kg bw/day)
	DNEL (Consumers)	Dermal, Chronic, Systemic effects	206 (mg/kg bw/day)
	DNEL (Workers)	Inhalation, Chronic, Local effects	1900 (mg/m ³)
	DMEL (Consumers)	Inhalation, Short term, Local effects	950 (mg/m ³)
	DMEL (Consumers)	Oral, Chronic, Systemic effects	87 (mg/kg)
	DMEL (Consumers)	Inhalation, Chronic, Systemic effects	114 (mg/m ³)
	DMEL (Consumers)	Dermal, Chronic, Systemic effects	206 (mg/kg)
	DMEL (Consumers)	Dermal, Chronic, Systemic effects	206 (mg/kg)
N-[3-(methylamino)propyl]-N-alkyl(cocoalkyl)oxide CAS No: 68155-09-9 EC No: 268-938-5	DNEL (Workers)	Inhalation, Chronic, Systemic effects	3,52 (mg/m ³)
	DNEL (Consumers)	Inhalation, Chronic, Systemic effects	0,87 (mg/m ³)
	DNEL (Workers)	Dermal, Chronic, Systemic effects	5 (mg/kg/bw /día)
	DNEL (Consumers)	Dermal, Chronic, Systemic effects	2,5 (mg/kg/bw /día)
	DNEL (Consumers)	Oral, Chronic, Systemic effects	0,05 (kg bw/día)
2,6-di-tert-butyl-p-cresol CAS No: 128-37-0 EC No: 204-881-4	DNEL (Workers)	Inhalation, Chronic, Systemic effects	3,5 (mg/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
ethanol, ethyl alcohol CAS No: 64-17-5 EC No: 200-578-6	Fresh water	0,96 (mg/L)
	Marine water	0,79 (mg/L)
	aqua (intermittent releases)	2,75 (mg/L)
	Soil	0,63 (mg/kg soil dw)
	sediment (freshwater)	3,6 (mg/kg sediment dw)
	STP	580 (mg/L)
	sediment (marine water)	2,9 (mg/kg sediment dw)
	oral	0,38 (g/kg food)
N-[3-(methylamino)propyl]-N-alkyl(cocoalkyl)oxide CAS No: 68155-09-9 EC No: 268-938-5	Agua fresca	30,3 (ug/l)
	Marine water	3,03 (ug/l)
	STD	9,7 (ug/l)

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama



Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 6 of 13

Print date: 30/10/2023

	Sedimento de agua dulce	0,214 (mg/kg dwt)
	Sedimento de agua marina	0,201 (mg/kg dwt)
	Soil	0,025 (ppb)
	Intoxicación secundaria	0,5 (mg/kg)

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:	Non-disposable protective gloves against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals for which the glove has been tested.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	A schedule for the periodical replacement of gloves should be established in order to guarantee their replacement before pollutants permeate them. The use of contaminated gloves could be more dangerous than not using gloves, since the pollutant can gradually accumulate in the glove's material.		
Observations:	They are to be replaced whenever tears, cracks or deformations are observed or when exterior dirt could reduce their strength.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
Eye protection:			
PPE:	Protective goggles with built-in frame.		
Characteristics:	«CE» marking, category II. Eye protector with built-in frame for protection against dust, smoke, fog and vapour.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
Skin protection:			
PPE:	Chemical protective clothing		
Characteristics:	«CE» marking, category III. Clothing should fit properly. The level of protection must be set according to a test parameter called BT (Breakthrough Time), which indicates how long it takes for the chemical to pass through the material.		
CEN standards:	EN 464,EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing's design should facilitate correct positioning, staying in place without moving for the period of use expected, bearing in mind environmental factors as well as any movement or position the user might adopt while carrying out the activity.		
PPE:	Anti-static safety footwear against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals against which the footwear is resistant.		
CEN standards:	EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345		

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama



Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 7 of 13

Print date: 30/10/2023

Maintenance:	For correct maintenance of this kind of safety footwear, it is necessary to observe the instructions specified by the manufacturer. The footwear should be replaced as soon as any sign of damage is observed.
Observations:	The footwear should be cleaned regularly and dried when damp, although it should not be placed too close to a source of heat in order to avoid any sharp changes in temperature.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Liquid

Colour: Clear

Odour: Odorless

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: 34 °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: 2.5-2.7

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: 0.95-1.05 gr/ml

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

Foaming liquid.

9.2 Other information

Information with regard to physical hazard classes

Flammable liquids:

Sustained combustibility: Yes.

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.

Flammable liquid and vapour.

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.

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama

Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023



Page 8 of 13

Print date: 30/10/2023

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

Splatters in the eyes can cause irritation and reversible damage.

Toxicological information about the substances present in the composition.

Name	Acute toxicity			
	Type	Test	Kind	Value
ethanol, ethyl alcohol CAS No: 64-17-5 EC No: 200-578-6	Oral	LD50	Rat	7060 mg/kg bw [1]
		LD50	mouse	3 450 mg/kg bw [2]
	Dermal	[1] Toxicology and Applied Pharmacology. Vol. 16, Pg. 718, 1970		
		[2] Publication 1967, Gig. Sanit. 32, 31. cited in RTECS (1992) loc. cit.		
2,6-di-tert-butyl-p-cresol CAS No: 128-37-0 EC No: 204-881-4	Inhalation	DL50	Rabbit	20000 mg/Kg (-) [1]
	Inhalation	[1] -		
		CL50	Rat	124.7 mg/L (4h) [1]
2,6-di-tert-butyl-p-cresol CAS No: 128-37-0 EC No: 204-881-4	Oral	[1] -		
		LD50	Rat	890 mg/kg [1]
	Dermal	[1] Neoplasma. Vol. 24, Pg. 253, 1977.		
	Inhalation			

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Product classified:

Skin Corrosive, Category 1C: Causes severe skin burns and eye damage.

c) serious eye damage/irritation;

Product classified:

Serious eye damage, Category 1: Causes serious eye damage.

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.

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama

Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 9 of 13

Print date: 30/10/2023



SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

Name	Ecotoxicity			
	Type	Test	Kind	Value
ethanol, ethyl alcohol	Fish	LC50	Fish	11000 mg/l (96 h) [1]
		[1] Bengtsson, B.E., L. Renberg, and M. Tarkpea 1984. Molecular Structure and Aquatic Toxicity - an Example with C1-C13 Aliphatic Alcohols. Chemosphere 13(5/6):613-622		
	Aquatic invertebrates	LC50 EC50 LC50	Crustacean Crustacean Ceriodaphnia dubia	9280 mg/l (48 h) [1] 9950 mg/l (48 h) [2] 5012 mg/l (48 h) [3]
		[1] Takahashi, I.T., U.M. Cowgill, and P.G. Murphy 1987. Comparison of Ethanol Toxicity to Daphnia magna and Ceriodaphnia dubia Tested at Two Different Temperatures: Static Acute Toxicity Test Results. Bull.Environ.Contam.Toxicol. 39(2):229-236. Ziegenfuss, P.S., W.J. Renaudette, and W.J. Adams 1986. Methodology for Assessing the Acute Toxicity of Chemicals Sorbed to Sediments: Testing the Equilibrium Partitioning Theory. In: T.M.Poston and R.Purdy (Eds.), Aquatic Toxicology and Environmental Fate, 9th Volume, ASTM STP 921, Philadelphia, PA :479-493 [2] Barera, Y., and W.J. Adams 1983. Resolving Some Practical Questions About Daphnia Acute Toxicity Tests. In: W.E.Bishop (Ed.), Aquatic Toxicology and Hazard Assessment, 6th Symposium, ASTM STP 802, Philadelphia, PA :509-518. Rossini, G.D.B., and A.E. Ronco 1996. Acute Toxicity Bioassay Using Daphnia obtusa as a Test Organism. Environ.Toxicol.Water Qual. 11(3):255-258 [3] Takahashi, I.T., U.M. Cowgill, and P.G. Murphy 1987. Comparison of Ethanol Toxicity to Daphnia magna and Ceriodaphnia dubia Tested at Two Different Temperatures: Static Acute Toxicity Test Results. Bull.Environ.Contam.Toxicol. 39(2):229-236. Ziegenfuss, P.S., W.J. Renaudette, and W.J. Adams 1986. Methodology for Assessing the Acute Toxicity of Chemicals Sorbed to Sediments: Testing the Equilibrium Partitioning Theory. In: T.M.Poston and R.Purdy (Eds.), Aquatic Toxicology and Environmental Fate, 9th Volume, ASTM STP 921, Philadelphia, PA :479-493		
CAS No: 64-17-5 EC No: 200-578-6	Aquatic plants			
N-[3-(methylamino)propyl]-N-alkyl(cocoalkyl)oxide	Fish	CL50 Agudo NOEC crónico	Fish Fish	0.68 mg/l (96h) [1] 0.42 mg/l (302 días) [2]
		[1] OECD 203 Fish, acute Toxicity test [2] Fish Life Cycle Toxicity EPA OPPTS 850.1500		
	Aquatic invertebrates	EC50 Agudo NOEC crónico	Daphnia Daphnia	19.9 mg/l (48h) [1] 0.7 mg/l (21días) [2]
		[1] OECD 202 Daphnia sp. Acute immobilization Test [2] OECD 211 Daphnia Magna Reproduction Test		
	Aquatic plants	EC50 Agudo	Algae	0.705 mg/l (72h) [1]

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama



Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 10 of 13

Print date: 30/10/2023

CAS No: 68155-09-9

EC No: 268-938-5

[1] OECD 201 Alga, Growth inhibition test

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.

Information about the bioaccumulation of the substances present.

Name	Bioaccumulation			
	Log Pow	BCF	NOECs	Level
ethanol, ethyl alcohol CAS No: 64-17-5 EC No: 200-578-6	-0,31	3	-	Very low
Lactic acid CAS No: 50-21-5 EC No: 200-018-0	-0,72	-	-	Very low

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.

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama



Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 11 of 13

Print date: 30/10/2023

14.1 UN number or ID number.

UN No: UN1993

14.2 UN proper shipping name.

Description:

ADR/RID: UN 1993, FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHANOL ETHYL ALCOHOL), 3, PG III, (D/E)

IMDG: UN 1993, FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHANOL ETHYL ALCOHOL), 3, PG III

ICAO/IATA: UN 1993, FLAMMABLE LIQUID, N.O.S. (CONTAINS ETHANOL ETHYL ALCOHOL), 3, PG III

14.3 Transport hazard class(es).

Class(es): 3

14.4 Packing group.

Packing group: III

14.5 Environmental hazards.

Marine pollutant: No

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): F-E,S-E

14.6 Special precautions for user.

Labels: 3



Hazard number: 30

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: 10 L

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:

H225	Highly flammable liquid and vapour.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama



Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 12 of 13

Print date: 30/10/2023

H319 Causes serious eye irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Classification codes:

Aquatic Acute 1 : Acute toxicity to the aquatic environment, Category 1
Aquatic Chronic 1 : Chronic effect to the aquatic environment, Category 1
Eye Dam. 1 : Serious eye damage, Category 1
Eye Irrit. 2 : Eye irritation, Category 2
Flam. Liq. 2 : Flammable liquid, Category 2
Flam. Liq. 3 : Flammable liquid, Category 3
Skin Corr. 1C : Skin Corrosive, Category 1C
Skin Irrit. 2 : Skin irritant, 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).
- Modification of the information of the stability and reactivity conditions (SECTION 10.1).
- Modification of the information of the stability and reactivity conditions (SECTION 10.2).
- Modification of the information of the stability and reactivity conditions (SECTION 10.3).
- Modification of the information of the stability and reactivity conditions (SECTION 10.4).
- Modification of the information of the stability and reactivity conditions (SECTION 10.5).
- Modification of the information of the stability and reactivity conditions (SECTION 10.6).
- Addition of ecological information values (SECTION 12.1).

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

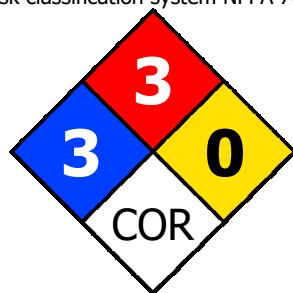
Physical hazards On basis of test data
Health hazards Calculation method
Environmental hazards Calculation method

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
64-17-5	ethanol, ethyl alcohol	Registered
50-21-5	Lactic acid	Registered
68155-09-9	N-[3-(methylamino)propyl]-N-alkyl(cocoalkyl)oxide	Registered
128-37-0	2,6-di-tert-butyl-p-cresol	Registered

Risk classification system NFPA 704:



Health hazard: 3 (Extreme Danger)

Flammability: 3 (Below 100°F)

Reactivity: 0 (Stable)

Specific hazard: COR (Corrosive)

Abbreviations and acronyms used:

-Continued on next page.-

SAFETY DATA SHEET

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

9456-Foam base guinama



Version 1 Date of compilation: 7/07/2016

Version 5 (replaces version 4)

Revision date: 23/10/2023

Page 13 of 13

Print date: 30/10/2023

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

BCF: Bioconcentration factor.

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.

EC50: Half maximal effective concentration.

PPE: Personal protection equipment.

IATA: International Air Transport Association.

ICAO: International Civil Aviation Organization.

IMDG: International Maritime Code for Dangerous Goods.

LC50: Lethal concentration, 50%.

LD50: Lethal dose, 50%.

NOEC: No observed effect concentration.

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.

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.