

SAFETY DATA SHEET

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

94130-Dimethyl sulphoxide pharma grade



Version 1 Date of compilation: 7/10/2016
Version 5 (replaces version 4)

Revision date: 10/09/2023

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

1.1 Product identifier.

Product Name: Dimethyl sulphoxide pharma grade
Product Code: 94130
Chemical Name: dimethyl sulfoxide
CAS No: 67-68-5
EC No: 200-664-3
Registration No: 01-2119431362-50-XXXX

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

Excipient pharmaceutical use

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **GUINAMA**
Address: C/ Oslo N°3
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.

The product is not classified as hazardous within the meaning of Regulation (EC) No 1272/2008.

2.2 Label elements.

Este producto no esta clasificado como peligroso según el Reglamento CE 1272/2008.

2.3 Other hazards.

The substance is not PBT
The substance is not vPvB
Substance does not have endocrine disrupting properties.

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.

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 67-68-5 EC No: 200-664-3	dimethyl sulfoxide	75 - 100 %	-	-

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3.2 Mixtures.
Not applicable.

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation.

If breathing stops, seek emergency medical attention. 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.

Skin contact.

Remove contaminated clothing.

Ingestion.

Keep calm. NEVER induce vomiting.

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

No known acute or delayed effects from exposure to the product.

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.

SECTION 5: FIREFIGHTING MEASURES.

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.

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

6.3 Methods and material for containment and cleaning up.

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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 product does not require special handling measures, the following general measures are recommended:

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.

The product does not require special storage measures. As general storage measures, sources of heat, radiation, electricity and contact with food should be avoided.

Keep away from oxidising agents and from highly acidic or alkaline materials.

Store the containers between 15 and 25 °C, in a dry and well-ventilated place.

Store according to local legislation. Observe indications on the label. 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
dimethyl sulfoxide CAS No: 67-68-5 EC No: 200-664-3	DNEL (Workers)	Inhalation, Chronic, Local effects	265 (mg/m ³)
	DNEL (Workers)	Inhalation, Chronic, Systemic effects	484 (mg/m ³)
	DNEL (Consumers)	Oral, Chronic, Systemic effects	60 (mg/kg)
	DNEL (Workers)	Dermal, Chronic, Systemic effects	200 (mg/kg)
	DNEL (Consumers)	Dermal, Chronic, Systemic effects	100 (mg/kg)
	DNEL (Consumers)	Inhalation, Chronic, Systemic effects	120 (mg/m ³)
	DNEL (Consumers)	Inhalation, Chronic, Local effects	47 (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
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dimethyl sulfoxide CAS No: 67-68-5 EC No: 200-664-3	Aquatic compartment-freshwater	17 (mg/L)
	Aquatic compartment-marine water	1,7 (mg/L)
	Aquatic compartment-sediment in freshwater	13,4 (mg/kg)
	Sewage treatment plant	11 (mg/L)
	Oral secondary poisoning	700 (mg/kg food)
	Ground	3,02 (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:

Concentration:	100 %		
Uses:	Excipient pharmaceutical use		
Breathing protection:			
PPE:	Particle filter mask		
Characteristics:	«CE» marking, category III. Made of filtering material, it covers nose, mouth and chin.		
CEN standards:	EN 149		
Maintenance:	Check for any tears, defects, etc. before use. Since it is disposable individual protection equipment, it should be replaced after use.		
Observations:	Does not protect worker unless properly adjusted. Follow the manufacturer's instructions regarding suitable use of the equipment.		
Filter Type needed:	P2		
Hand protection:			
PPE:	Protective gloves.		
Characteristics:	«CE» marking, category II.		
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	
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:	Protective clothing.		
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.		
CEN standards:	EN 340		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.		

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Liquid

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Colour: Colorless
Odour: sulphurous
Odour threshold: Not applicable/Not available due to the nature/properties of the product
Melting point: 18.5 °C
Freezing point: Not applicable/Not available due to the nature/properties of the product
Boiling point or initial boiling point and boiling range: 189 °C
Flammability: Not applicable/Not available due to the nature/properties of the product
Lower explosion limit: 2.6%
Upper explosion limit: 28.5%
Flash point: 87 °C
Auto-ignition temperature: Not applicable/Not available due to the nature/properties of the product
Decomposition temperature: >190 °C
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: >1000g/l
Liposolubility: Not applicable/Not available due to the nature/properties of the product
Partition coefficient n-octanol/water (log value): -1.34998
Vapour pressure: 55,6 Pa
Absolute density: 1104 kg/m³
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
Dynamic viscosity: 2 mPa.s (20 °C)

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.

Heating. An interval from approx. 15 Kelvin below point of inflammation

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.

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

There are no tested data available on the product.

Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values (lethal dose/lethal dose = 50%) relevant for classification:

We are not aware of quantitative data on the toxicity of this product.

Component type value species

Oral LD50 28,300 mg/kg (rat)

Dermal LD50 40,000 mg/kg (rat)

· Skin corrosion/irritation Slight irritations.

· Serious eye damage or eye irritation Slight irritation

· After inhalation No irritation.

Respiratory or skin sensitization

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Based on available data, the classification criteria are not met.
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.
· Specific target organ toxicity (STOT) - single exposure
Based on available data, the classification criteria are not met.
· Specific target organ toxicity (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.

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.

Aquatic toxicity: No further relevant information available.

· Type of test Effective concentration Method Evaluation

EC50/72 h 12,000-17,000 mg/l (Algae)

EC50/48 h 24,600 mg/l (daphnia magna)

LC50/96 h >25,000 mg/l (fish)

12.2 Persistence and degradability.

hardly biodegradable

No information is available on the degradability

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

Information about the bioaccumulation.

Name	Bioaccumulation			
	Log Pow	BCF	NOECs	Level
dimethyl sulfoxide CAS No: 67-68-5 EC No: 200-664-3	-1.34998	-	-	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.

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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.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR/RID: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

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.

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).

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- Modifications in the first aid measures (SECTION 4.1).

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

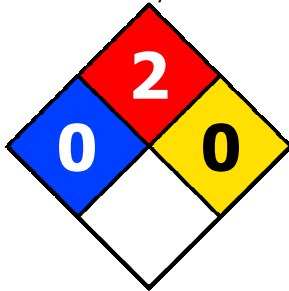
Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is recommended that the product only be employed for the purposes advised.

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

CAS No	Name	State
67-68-5	dimethyl sulfoxide	Registered

Risk classification system NFPA 704:



Health hazard: 0 (Normal Material)

Flammability: 2 (Below 200°F)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:

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.

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.

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

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preparation, and it must not be considered as a guarantee of its properties.