

# SAFETY DATA SHEET

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

## 10223-Guinoxome liposomal solution



Version 1 Date of compilation: 28/03/2018

Version 5 (replaces version 4)

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

#### 1.1 Product identifier.

Product Name: Guinoxome liposomal solution  
Product Code: 10223

#### 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 Irrit. 2 : Causes serious eye irritation.

Flam. Liq. 2 : Highly flammable liquid and vapour.

#### 2.2 Label elements.

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

Pictograms:



Signal Word:

**Danger**

Hazard statements:

H225 Highly flammable liquid and vapour.  
H319 Causes serious eye irritation.

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.  
P264 Wash ... thoroughly after handling.  
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

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P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].  
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.  
P370+P378 In case of fire: Use... to extinguish.  
P403+P235 Store in a well-ventilated place. Keep cool.  
P501 Dispose of contents/container to ...

### 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: 603-002-00-5 CAS No: 64-17-5 EC No: 200-578-6 Registration No: 01-2119457610-43-XXXX	ethanol, ethyl alcohol	10 - 75 %	Eye Irrit. 2, H319 - Flam. Liq. 2, H225	-

(\*) 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.

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.

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### 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 Highly inflammable, it can cause or considerably worsen a fire, the necessary prevention measures should be taken and risks avoided. In case of fire, the following measures are recommended:

### 5.1 Extinguishing media.

#### Suitable extinguishing media:

Extinguisher powder or CO<sub>2</sub>. 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.

#### 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.

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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.

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
ethanol, ethyl alcohol CAS No: 64-17-5 EC No: 200-578-6	DNEL (Workers)	Inhalation, Chronic, Systemic effects	950 (mg/m <sup>3</sup> )
	DNEL (Consumers)	Inhalation, Chronic, Systemic effects	114 (mg/m <sup>3</sup> )
	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 <sup>3</sup> )
	DMEL (Consumers)	Inhalation, Short term, Local effects	950 (mg/m <sup>3</sup> )
	DMEL (Consumers)	Oral, Chronic, Systemic effects	87 (mg/kg)
	DMEL (Consumers)	Inhalation, Chronic, Systemic effects	114 (mg/m <sup>3</sup> )
	DMEL (Consumers)	Dermal, Chronic, Systemic effects	206 (mg/kg)
	DMEL (Consumers)	Dermal, Chronic, Systemic effects	206 (mg/kg)

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)

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	STP	580 (mg/L)
	sediment (marine water)	2,9 (mg/kg sediment dw)
	oral	0,38 (g/kg food)

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.

<b>Concentration:</b>	<b>100 %</b>		
<b>Uses:</b>	<b>Use, base for industrial pharmaceutical compounding.</b>		
<b>Breathing protection:</b>			
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		
<b>Hand protection:</b>			
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
		Material thickness (mm):	0,35
<b>Eye protection:</b>			
PPE:	Face shield.		
Characteristics:	«CE» marking, category II. Face and eye protector against splashing liquid.		
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. Make sure that mobile parts move smoothly.		
Observations:	Face shields should offer a field of vision with a dimension in the central line of, at least, 150 mm vertically once attached to the frame.		
<b>Skin protection:</b>			
PPE:	Anti-static 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, EN 1149-1, EN 1149-2, EN 1149-3, EN 1149-5		
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.		
PPE:	Anti-static safety footwear.		
Characteristics:	«CE» marking, category II.		
CEN standards:	EN ISO 13287, EN ISO 20344, EN ISO 20346		
Maintenance:	The footwear should be checked regularly		

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Observations:	The level of comfort during use and acceptability are factors that are assessed very differently depending on the user. Therefore, it is advisable to try on different footwear models and, if possible, different widths.
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### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

#### 9.1 Information on basic physical and chemical properties.

Physical state: Liquid

Colour: yellow

Odour: characteristic

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: 17 °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

##### 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.

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.

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

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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
ethanol, ethyl alcohol	Oral	LD50	Rat	7060 mg/kg bw [1]	
		LD50	mouse	3 450 mg/kg bw [2]	
		[1] Toxicology and Applied Pharmacology. Vol. 16, Pg. 718, 1970			
		[2] Publication 1967, Gig. Sanit. 32, 31. cited in RTECS (1992) loc. cit.			
	Dermal	DL50	Rabit	20000 mg/Kg (-) [1]	
		[1] -			
CAS No: 64-17-5	EC No: 200-578-6	Inhalation	CL50	Rat	124.7 mg/L (4h) [1]
			[1] -		

a) acute toxicity;

Not conclusive data for classification.

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.

Name	Ecotoxicity			
	Type	Test	Kind	Value

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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 Crustacean 9280 mg/l (48 h) [1] EC50 Crustacean 9950 mg/l (48 h) [2] LC50 Ceriodaphnia dubia 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
	Aquatic plants	

CAS No: 64-17-5 EC No: 200-578-6

### 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

### 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.

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### 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: UN1170

### 14.2 UN proper shipping name.

Description:

ADR/RID: UN 1170, ETHANOL (ETHYL ALCOHOL), 3, PG II, (D/E)

IMDG: UN 1170, ETHANOL (ETHYL ALCOHOL), 3, PG II

ICAO/IATA: UN 1170, ETHANOL (ETHYL ALCOHOL), 3, PG II

### 14.3 Transport hazard class(es).

Class(es): 3

### 14.4 Packing group.

Packing group: II

### 14.5 Environmental hazards.

Marine pollutant: No

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

### 14.6 Special precautions for user.

Labels: 3



Hazard number: 33

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

Proceed in accordance with point 6.

ADR LQ: 1 L

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### 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.  
H319 Causes serious eye irritation.

Classification codes:

Eye Irrit. 2 : Eye irritation, Category 2

Flam. Liq. 2 : Flammable liquid, 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 10.2).
- 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).

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

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# SAFETY DATA SHEET

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

## 10223-Guinoxome liposomal solution



Version 1 Date of compilation: 28/03/2018

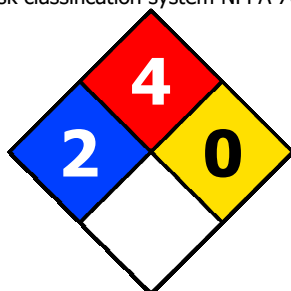
Version 5 (replaces version 4)

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Risk classification system NFPA 704:



Health hazard: 2 (Hazardous)

Flammability: 4 (Below 73°F)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:

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.