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

# 7723-ANHIDROUS LANOLIN



Version 1 Date of compilation: 7/06/2017

Version 5 (replaces version 4) Revision date: 23/10/2023 Print date: 23/10/2023

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

#### 1.1 Product identifier.

Product Name: ANHIDROUS LANOLIN

 Product Code:
 7723

 Chemical Name:
 Lanolin

 CAS No:
 8006-54-0

 EC No:
 232-348-6

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

Excipient pharmaceutical use cosmetic 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.

			(*)Classification No 127	Regulation (EC) 2/2008
Identifiers	Name	Concentrate	Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 8006-54-0 EC No: 232-348-6	Lanolin	99.98%	-	-

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Index No: 603-001- 00-X CAS No: 67-56-1 EC No: 200-659-6	methanol	1ppm%	Acute Tox. 3 *, H311 - Acute Tox. 3 *, H331 - Acute Tox. 3 *, H301 - Flam. Liq. 2, H225 - STOT SE 1, H370 **	STOT SE 1, H370: C ≥ 10 % STOT SE 2, H371: 3 % ≤ C < 10 %
CAS No: 128-37-0 EC No: 204-881-4	2,6-di-tert-butyl-p-cresol	0.02%	Aquatic Acute 1, H400 (M=1) - Aquatic Chronic 1, H410 (M=1)	1

<sup>\*,\*\*</sup> See Regulation (EC) No. 1272/2008, Annex VI, section 1.2.

### 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.

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#### 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.

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.

Work exposure limit for:

Name	CAS No.	Country	Limit value	ppm	mg/m³
methanol	67-56-1	European	Eight hours	200 (skin)	260 (skin)
methanoi	07-30-1	Union [1]	Short term		
mathanal	67-56-1	European	Eight hours	200 (skin)	260 (skin)
methanol	0/-50-1	Union [1]	Short term		

[1] According both Binding Occupational Esposure Limits (BOELVs) and Indicative Occupational Exposure Limits (IOELVs) adopted by Scientific Committee for Occupational Exposure Limits to Chemical Agents (SCOEL).

The product does NOT contain substances with Biological Limit Values.

Concentration levels DNEL/DMEL:

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Name	DNEL/DMEL	Туре	Value
	DNEL	Inhalation, Short term, Systemic effects	130
	(Workers)		(mg/m³)
	DNEL	Inhalation, Short term, Systemic effects	26
	(Consumers)		(mg/m³)
	DNEL (Consumers)	Oral, Chronic, Systemic effects	4 (mg/kg)
	DNEL	Oral, Short term, Systemic effects	4 (mg/kg )
	(Consumers)	Oral, Short term, Systemic effects	T (Hig/kg )
	DNEL	Dermal, Short term, Systemic effects	20 (mg/kg
	(Workers)		)
	DNEL	Dermal, Short term, Systemic effects	4 (mg/kg )
	(Consumers)	·	
methanol	DNEL	Inhalation, Chronic, Systemic effects	130
CAS No: 67-56-1	(Workers)	7.1.1.1.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.	(mg/m3)
EC No: 200-659-6	DNEL	Inhalation, Chronic, Systemic effects	26
	(Consumers) DNEL	Inhalation, Chronic, Local effects	(mg/m3) 130
	(Workers)	initialiation, Chronic, Local effects	(mg/m3)
	DNEL	Inhalation, Chronic, Local effects	26
	(Consumers)	Imalation, amone, Local effects	(mg/m3)
	DNEL	Dermal, Chronic, Systemic effects	20 (mg/kg)
	(Workers)	, ,	,
	DNEL	Dermal, Chronic, Systemic effects	4 (mg/kg )
	(Consumers)		
	DNEL	Inhalation, Short term, Local effects	130
	(Workers) DNEL	Inhalation, Short term, Local effects	(mg/kg)
	(Consumers)	Inidiation, Short term, Local effects	26 (mg/m3)
2,6-di-tert-butyl-p-cresol	DNEL	Inhalation, Chronic, Systemic effects	3,5
CAS No: 128-37-0	(Workers)	Inidiation, emonie, systemic eneces	(mg/m <sup>3</sup> )
EC No: 204-881-4	( 1 1 1)		( 3, )
	DNEL	Inhalation, Short term, Systemic effects	130
	(Workers)		(mg/m³)
	DNEL	Inhalation, Short term, Systemic effects	26
	(Consumers) DNEL	Oral Chronic Systemic effects	(mg/m³)
	(Consumers)	Oral, Chronic, Systemic effects	4 (mg/kg)
	DNEL	Oral, Short term, Systemic effects	4 (mg/kg )
	(Consumers)	Ordi, Short term, Systemic circus	i (ilig/kg /
	DNEL	Dermal, Short term, Systemic effects	20 (mg/kg
	(Workers)	, , ,	`)
	DNEL	Dermal, Short term, Systemic effects	4 (mg/kg )
	(Consumers)		120
methanol	DNEL (Morkora)	Inhalation, Chronic, Systemic effects	130 (mg/m <sup>2</sup> )
CAS No: 67-56-1	(Workers) DNEL	Inhalation, Chronic, Systemic effects	(mg/m3) 26
EC No: 200-659-6	(Consumers)	Inidiation, Chronic, Systemic enects	(mg/m3)
	DNEL	Inhalation, Chronic, Local effects	130
	(Workers)		(mg/m3)
	DNEL	Inhalation, Chronic, Local effects	26
	(Consumers)		(mg/m3)
	DNEL	Dermal, Chronic, Systemic effects	20 (mg/kg)
	(Workers)	Danieral Chinari C. 1	A /
	(Consumers)	Dermal, Chronic, Systemic effects	4 (mg/kg )
	(Consumers) DNEL	Inhalation, Short term, Local effects	130
	(Workers)	initialiation, Short term, Local effects	(mg/kg)
	DNEL	Inhalation, Short term, Local effects	26
	(Consumers)		(mg/m3)
2,6-di-tert-butyl-p-cresol	DNEL	Inhalation, Chronic, Systemic effects	3,5
CAS No: 128-37-0	(Workers)	·	(mg/m³)
EC No: 204-881-4	1		l

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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
	aqua (freshwater)	20,8 (mg/L)
	aqua (marine water)	2,08 (mg/L)
	aqua (intermittent releases)	1540 (mg/L)
methanol CAS No: 67-56-1 EC No: 200-659-6	STP	100 (mg/L)
	sediment (freshwater)	77 (mg/kg
		sediment dw)
	sediment (marine water)	7,7 (mg/kg
		sediment dw)
	soil	100 (mg/kg
		wt)
	aqua (freshwater)	20,8 (mg/L)
	aqua (marine water)	2,08 (mg/L)
	aqua (intermittent releases)	1540 (mg/L)
methanol	STP	100 (mg/L)
CAS No: 67-56-1	sediment (freshwater)	77 (mg/kg
EC No: 200-659-6		sediment dw)
LC NO. 200-035-0	sediment (marine water)	7,7 (mg/kg
		sediment dw)
	soil	100 (mg/kg
		wt)

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 cosmetic use
<b>Breathing protect</b>	ion:
If the recommended	technical measures are observed, no individual protection equipment is necessary.
Hand protection:	
If the product is han	dled correctly, no individual protection equipment is necessary.
Eye protection:	
If the product is han	dled correctly, no individual protection equipment is necessary.
Skin protection:	
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
Maintenance.	not be used by other people.
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any
Obsci vations.	injury resulting from an accident

### **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.**

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

Physical state: Solid

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

Odour: Characteristic

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

Melting point: 36-42 °C

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

Boiling point or initial boiling point and boiling range: 180 °C

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

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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: 285-295 °C

Auto-ignition temperature: 296 °C

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: Soluble in organic solvents such as hexane and petroleum ether

Hydrosolubility: Insoluble

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: 0.9

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.**

# 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008.

# Toxicological information.

Name		Acute toxicity				
Name	Тур	e Test	Kind	Value		
	Oral	DL50	-	100 mg/Kg (-) [1]		
months mal		[1] -				
methanol	Dermal	LD50	-	300 mg/Kg (-)		
CAS No: 67-56-1 EC No: 2	200-659-6 Inhalati	on CL50	Rat	3 mg/L (4 h)		
	Oral	LD50	Rat	890 mg/kg [1]		
2,6-di-tert-butyl-p-cresol		[1] Neo	plasma. Vol. 24,	Pg. 253, 1977.		
z,o-di-tert-butyr-p-cresor	Dermal					
CAS No: 128-37-0 EC No: 2	204-881-4 Inhalati	on				

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		01	DL50	-	100 mg/Kg (-) [1]
methanol		Oral	[1] -		
medianoi		Dermal	LD50	-	300 mg/Kg (-)
CAS No: 67-56-1	EC No: 200-659-6	Inhalation	CL50	Rat	3 mg/L (4 h)
		Oral	LD50	Rat	890 mg/kg [1]
2,6-di-tert-butyl-p-cresol		Ordi	[1] Neop	lasma. Vol. 24	, Pg. 253, 1977.
2,0 di tere butyi p cres	301	Dermal			
CAS No: 128-37-0	EC No: 204-881-4	Inhalation			

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Not conclusive data for classification.

- c) serious eye damage/irritation; Not conclusive data for classification.
- 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;
- 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.

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

# **SECTION 12: ECOLOGICAL INFORMATION.**

# 12.1 Toxicity.

Name		Ecotoxicity			
Name	Туре	Test	Kind	Value	
methanol	Fish	LC50 NOEC	Lepomis macrochirus Oryzias latipes	15400 mg/L (96 h) 15800 mg/L (-)	
	Aquatic invertebrates	EC50 NOEC	Nitrocra spinipes Daphnia magna	12000 mg/L (96 h) 122 mg/L (-)	

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CAS No: 67-56-1	EC No: 200-659-6	Aquatic plants	EC50	Microcystis aeruginosa	530 mg/L (168 h)
		Fish	LC50 NOEC	Lepomis macrochirus Oryzias latipes	15400 mg/L (96 h) 15800 mg/L (-)
methanol		Aquatic invertebrates	EC50 NOEC	Nitrocra spinipes Daphnia magna	12000 mg/L (96 h) 122 mg/L (-)
CAS No: 67-56-1	EC No: 200-659-6	Aquatic plants	EC50	Microcystis aeruginosa	530 mg/L (168 h)

# 12.2 Persistence and degradability.

Rapid biodegradability if finely dispersed.

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		
methanol		0.77	2		Manu Jawa		
CAS No: 67-56-1	EC No: 200-659-6	-0,77	3	-	Very low		
methanol		0.77	2		Van dan		
CAS No: 67-56-1	EC No: 200-659-6	-0,77	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.

# 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.**

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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.**

# Classification codes:

Acute Tox. 3: Acute toxicity (Dermal), Category 3 Acute Tox. 3: Acute toxicity (Inhalation), Category 3 Acute Tox. 3: Acute toxicity (Oral), Category 3

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

Flam. Liq. 2: Flammable liquid, Category 2

STOT SE 1 : Specific target organ toxicity following a single exposure, Category 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.

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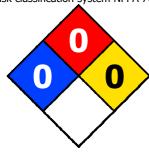
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#### Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
8006-54-0	Lanolin	Registered
67-56-1	methanol	Registered
128-37-0	2,6-di-tert-butyl-p-cresol	Registered

Risk classification system NFPA 704:



Health hazard: 0 (Normal Material)

Flammability: 0 (Will not burn)

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. Lethal concentration, 50%. LC50:

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