

SAFETY DATA SHEET

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

91151-DILTIAZEM HCL



Version 1 Date of compilation: 19/04/2016
Version 6 (replaces version 5)

Revision date: 20/01/2023

Page 1 of 10
Print date: 20/01/2023

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

1.1 Product identifier.

Product Name: DILTIAZEM HCL
Product Code: 91151
Chemical Name: (2S-cis)-3-acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride
CAS No: 33286-22-5
EC No: 251-443-3

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

Active pharmaceutical ingredient

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **GUINAMA**
Address: C/ Praga, s/n. P.I. Gutenberg
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:

Acute Tox. 4 : Harmful if swallowed.
Eye Dam. 1 : Causes serious eye damage.
Repr. 2 : Suspected of damaging fertility or the unborn child.

2.2 Label elements.

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

Pictograms:



Signal Word:

Danger

Hazard statements:

H302 Harmful if swallowed.
H318 Causes serious eye damage.
H361d Suspected of damaging the unborn child.

Precautionary statements:

P264 Wash ... thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell

-Continued on next page.-

SAFETY DATA SHEET

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

91151-DILTIAZEM HCL



Version 1 Date of compilation: 19/04/2016

Version 6 (replaces version 5)

Revision date: 20/01/2023

Page 2 of 10

Print date: 20/01/2023

P330 Rinse mouth.
P501 Dispose of contents/container to ...
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P310 Immediately call a POISON CENTER/doctor/...

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: 33286-22-5 EC No: 251-443-3	(2S-cis)-3-acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride	100	Acute Tox. 4, H302	-

3.2 Mixtures.

Not Applicable.

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.

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.

Harmful Product, prolonged exposure due to inhalation may cause anaesthetic effects and the need for immediate medical assistance.

Long-term chronic exposure may result in injury to certain organs or tissues.

Contact with eyes may cause irreversible damage.

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

-Continued on next page.-

SAFETY DATA SHEET

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

91151-DILTIAZEM HCL

Version 1 Date of compilation: 19/04/2016

Version 6 (replaces version 5)

Revision date: 20/01/2023

Page 3 of 10

Print date: 20/01/2023



In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

SECTION 5: FIREFIGHTING MEASURES.

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

5.1 Extinguishing media.

Suitable extinguishing media:

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

Unsuitable extinguishing media:

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

5.2 Special hazards arising from the substance or mixture.

Special risks.

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

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

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.

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 5 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.

-Continued on next page.-

SAFETY DATA SHEET

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

91151-DILTIAZEM HCL

Version 1 Date of compilation: 19/04/2016

Version 6 (replaces version 5)

Revision date: 20/01/2023



Page 4 of 10

Print date: 20/01/2023

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.

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:	Active pharmaceutical ingredient				
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:	Protective gloves against chemicals.				
Characteristics:	«CE» marking, category III.				
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420				
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.				
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.				
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480	Material thickness (mm):	0,35
Eye protection:		If the product is handled correctly, no individual protection equipment is necessary.			
Skin protection:					
PPE:	Work footwear.				
Characteristics:	«CE» marking, category II.				
CEN standards:	EN ISO 13287, EN 20347				
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.				
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident				

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Solid - Dust

Colour: white

Odour: odorless

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

Melting point: 210-215 °C

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

-Continued on next page.-

SAFETY DATA SHEET

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

91151-DILTIAZEM HCL



Version 1 Date of compilation: 19/04/2016

Version 6 (replaces version 5)

Revision date: 20/01/2023

Page 5 of 10

Print date: 20/01/2023

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

Flammability: nonflammable

Lower explosion limit: Lower Flammability Limit (micronized material): 35 g / m³

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

Flash point: > 60 °C

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

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

pH: 4,3-5,3 (water) (1%)

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

Solubility: soluble in methanol, chloroform, slightly soluble in absolute ethanol, practically insoluble in benzene

Hydrosolubility: soluble in water

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

Partition coefficient n-octanol/water (log value): log P:2,7

Vapour pressure: 1,54*10⁻¹¹

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

Explosive properties:

- DE (minimum ignition energy): 1 mJ (micronized material)

-MIT (ignicion- minimum temperature of dust suspended in the air: 4.8 bar (micronized material)

- Maximum explosion pressure (Pmax):> 348 bar / sec (micronized material)

-increased Maximum pressure (dP / dt max): 1 (micronised material)

- Class dust (ST): 12% (micronized material)

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 normal handling and storage conditions

10.3 Possibility of hazardous reactions.

As a precautionary measure, keep away from heat and electrostatic discharge

10.4 Conditions to avoid.

As a precautionary measure, keep away from heat and electrostatic discharge

10.5 Incompatible materials.

As a precautionary measure, keep away from strong oxidizing agents.

10.6 Hazardous decomposition products.

La descomposición térmica puede producir vapores tóxicos de dióxido de carbono en caso de combustión parcial y otros productos tóxicos de la combustión de materias orgánicas

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.

Splatters in the eyes can cause irritation and reversible damage.

a) acute toxicity;

Product classified:

Acute toxicity (Oral), Category 4: Harmful if swallowed.

The product is classified: Acute Tox. 4 H302

Test: DL50 - Route: Oral - Species: Rat 764 mg/kg

Test: DL50 - Route: Skin - Species: Rat > 2000 mg/kg

Test: DL50 - Route: Intravenous - Species: Rat 38 mg/kg

Test: DL50 - Route: Subcutaneous - Species: Rat 520 mg/kg

Test: DL50 - Route: intraperitoneal - Species: Mouse 177 mg/kg

-Continued on next page.-

SAFETY DATA SHEET

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

91151-DILTIAZEM HCL

Version 1 Date of compilation: 19/04/2016

Version 6 (replaces version 5)

Revision date: 20/01/2023



Page 6 of 10

Print date: 20/01/2023

Test: DL50 - Route: Intravenous - Species: Mouse 58 mg/kg
Test: DL50 - Route: Oral - Species: Mouse 508 mg/kg
Test: DL50 - Route: Subcutaneous - Species: Mouse 260 mg/kg

b) skin corrosion/irritation;
Not conclusive data for classification.

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 classified
Not listed in IARC, NTP, OSHA
Route: Oral - Species: Rat =< 100 mg/kg/day - Duration: 24 months - No evidence of carcinogenic potential

g) reproductive toxicity;
Product classified:
Reproductive toxicant, Category 2: Suspected of damaging fertility or the unborn child.
The product is classified: Repr. 2 H361d
Test: Embryo-fetal development - Species: Different species - Notes: diltiazem and other calcium blockers can cause abnormal embryo developmental
Test: Developmental toxicity - Notes: listed in California Proposition 65

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.

Inhalation: possible in the workplace without the use of personal protective equipment or in case of accidental release
Cutaneous exposure: possible in the workplace without the use of personal protective equipment or in case of accidental release
Contact with eyes: possible in the workplace without the use of personal protective equipment or in case of accidental release.
Symptoms related to exposure: not available; see section 4.2
Immediate, delayed and chronic effects: As in all cases of uncontrolled exposure to drugs, intoxication effects may occur.
Other information: not available

11.2 Information on other hazards.

Endocrine disrupting properties

Endocrine disrupting properties:

Unknown

Other information

There is no information available on other adverse health effects.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

Adopt good working practices, so that the product is not released into the environment.
DILTIAZEM CLORIDRATO_DILTIAZEM HYDROCHLORIDE - CAS: 33286-22-5
Not classified for environmental hazards

-Continued on next page.-

SAFETY DATA SHEET

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

91151-DILTIAZEM HCL

Version 1 Date of compilation: 19/04/2016

Version 6 (replaces version 5)

Revision date: 20/01/2023



Page 7 of 10

Print date: 20/01/2023

Aquatic acute toxicity:

Endpoint: CE50 - Species: Daphnia magna (water flea) 103.5 mg/l - Duration h: 48

Aquatic chronic toxicity:

No data available for the product

Effects in sewage plants:

No data available for the product

12.2 Persistence and degradability.

No information is available regarding the biodegradability

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
(2S-cis)-3-acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride CAS No: 33286-22-5 EC No: 251-443-3	log P:27	-	-	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.

No information is available.

12.7 Other adverse effects.

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.

-Continued on next page.-

SAFETY DATA SHEET

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

91151-DILTIAZEM HCL

Version 1 Date of compilation: 19/04/2016

Version 6 (replaces version 5)

Revision date: 20/01/2023



Page 8 of 10

Print date: 20/01/2023

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.

Transportation is not dangerous.

SECTION 15: REGULATORY INFORMATION.

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

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.

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

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. 4 : Acute toxicity (Oral), Category 4

Eye Dam. 1 : Serious eye damage, Category 1

Repr. 2 : Reproductive toxicant, Category 2

Changes regarding to the previous version:

- Change in the hazard classification (SECTION 2.1).
- Removal of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Addition of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Modification of specific hazards (SECTION 2.3).
- Changes in the composition of the product (SECTION 3.2).
- Modifications in the first aid measures (SECTION 4.1).
- Modification of the symptoms (SECTION 4.2).
- Modification of the medical attention measures (SECTION 4.3).
- Modification in the firefighting measures (SECTION 5.2).
- Modifications in the accidental release measures (SECTION 6.1).

-Continued on next page.-

SAFETY DATA SHEET

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

91151-DILTIAZEM HCL



Version 1 Date of compilation: 19/04/2016

Version 6 (replaces version 5)

Revision date: 20/01/2023

Page 9 of 10

Print date: 20/01/2023

- Modifications in the accidental release measures (SECTION 6.3).
- Modifications in the handling and storage precautions (SECTION 7.1).
- Modifications in the handling and storage precautions (SECTION 7.2).
- Modification in the values of the physical and chemical properties (SECTION 9).
- 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).
- Change in the hazard classification (SECTION 11.1).
- Addition of ecological information values (SECTION 12.3).
- Modification of the classification ADR/IMDG/ICAO/IATA/RID (SECTION 14).
- Addition of abbreviations and acronyms (SECTION 16).

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

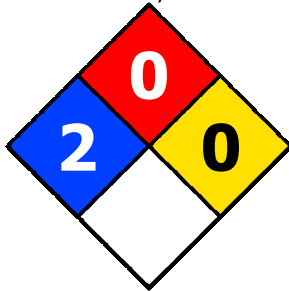
Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

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
33286-22-5	(2S-cis)-3-acetoxy-5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-1,5-benzothiazepin-4(5H)-one monohydrochloride	

Risk classification system NFPA 704:



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

Abbreviations and acronyms used:

BCF:	Bioconcentration factor.
CEN:	European Committee for Standardization.
EC50:	Half maximal effective concentration.
PPE:	Personal protection equipment.
LC50:	Lethal concentration, 50%.
LD50:	Lethal dose, 50%.
NOEC:	No observed effect concentration.

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.

-Continued on next page.-

SAFETY DATA SHEET

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

91151-DILTIAZEM HCL



Version 1 **Date of compilation: 19/04/2016**

Version 6 (replaces version 5)

Revision date: 20/01/2023

Page 10 of 10

Print date: 20/01/2023

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.