

SAFETY DATA SHEET

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

M0022770-GLYCOPYRROLATE



Version 1 Date of compilation: 26/11/2019

Version 5 (replaces version 4)

Revision date: 15/12/2023

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

1.1 Product identifier.

Product Name: GLYCOPYRROLATE
Product Code: M0022770
Chemical Name: Glycopyrronium bromide
CAS No: 596-51-0
EC No: 209-887-0

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

Raw material for master formulation

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **ACOFARMA DISTRIBUCIÓN S.A.**
Address: C/ Llobregat, 20, Pol. Ind. Santa Margarita
City: Terrassa
Province: Barcelona
Telephone: 902362203
Fax: 937360090
E-mail: atencioncliente@acofarma.com
Web: www.acofarma.es

1.4 Emergency telephone number: 902362203 (Only available during office hours; Monday-Friday; 09:00-18:00)

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.

Acute Tox. 4 : Harmful in contact with skin.

2.2 Label elements.

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

Pictograms:



Signal Word:

Warning

Hazard statements:

H302+H312 Harmful if swallowed or in contact with skin.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell
P302+P352 IF ON SKIN: Wash with plenty of water/...
P312 Call a POISON CENTER/doctor/... if you feel unwell.
P501 Dispose of contents/container in accordance with local/ national/ international regulations.

2.3 Other hazards.

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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: 596-51-0 EC No: 209-887-0	Glycopyrronium bromide	20 - 100 %	Acute Tox. 4, H312 - 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.

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

Ingestion.

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

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

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

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. Do not induce vomiting. If the person vomits, clear the respiratory tract.

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:

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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.

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

7.3 Specific end use(s).

No additional information is 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.

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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:	Raw material for master formulation				
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 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:					
PPE:	Protective goggles against particle impacts.				
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.				
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:	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 or almost white
Odour: No data available
Odour threshold: Not available
Melting point: Not available
Freezing point: Not available
Boiling point or initial boiling point and boiling range: Not available
Flammability: Not available
Lower explosion limit: Not available
Upper explosion limit: Not available
Flash point: Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available
pH: No data available
Kinematic viscosity: Not applicable

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Solubility: Soluble in ethanol (96%)
Hydrosolubility: Readily soluble in water
Liposolubility: Not available
Partition coefficient n-octanol/water (log value): -0.99
Vapour pressure: Not available
Absolute density: Not available
Relative density: Not available
Relative vapour density: Not applicable
Particle characteristics: Not available

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) N° 1272/2008.

There are no tested data available on the product.

a) acute toxicity;

Product classified:

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

Acute toxicity (Dermal), Category 4: Harmful in contact with skin.

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;

Not conclusive data for classification.

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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.

No information is available regarding the ecotoxicity.

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
Glycopyrrolate CAS No: 596-51-0 EC No: 209-887-0	-0.99	-	-	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. 4 : Acute toxicity (Dermal), Category 4

Acute Tox. 4 : Acute toxicity (Oral), Category 4

Changes regarding to the previous version:

- Change of the uses of the product (SECTION 7.3).
- Addition of personal protective equipment (SECTION 8.2).
- Modifications of the personal protective equipment (SECTION 8.2).

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.

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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.

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.