



<b>SDS Title:</b> Glycopyrrolate Injection Safety Data Sheet (Meitheal)	<b>SDS Number:</b> SDS-000048	<b>Page Number:</b> Page 1 of 14
<b>Function:</b> Regulatory Affairs	<b>Effective Date:</b> September 02, 2021	<b>Version number:</b> 1.0

## Section 1. Identification

- GHS product identifier** : Glycopyrrolate Injection
- Other means of identification** : NDCs 71288-414-03, 71288-414-04, 71288-415-06, and 71288-415-21
- Product type** : Liquid.

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

- Product use** : Pharmaceuticals. (For intended use only.)  
Observe technical data sheet/instructions for use.  
Specific Treatments: Anticholinergic agents.
- Area of application** : Professional applications.
- Supplier's details** : Meitheal Pharmaceuticals, Inc.  
8700 W. Bryn Mawr, Suite 600S  
Chicago, IL 60631  
  
Telephone: 224-443-4617  
www.meithealpharma.com
- e-mail address of person responsible for this SDS** : info@meithealpharma.com
- Emergency telephone number (with hours of operation)** : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

## Section 2. Hazards identification

- OSHA/HCS status** : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.
- Classification of the substance or mixture** : Not classified.
- GHS label elements**
- Signal word** : No signal word.
- Hazard statements** : No known significant effects or critical hazards.
- Precautionary statements**
- Prevention** : Not applicable.
- Response** : Not applicable.
- Storage** : Not applicable.

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## Section 2. Hazards identification

- Disposal** : Not applicable.  
**Hazards not otherwise classified** : None known.

## Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture  
**Other means of identification** : NDCs 71288-414-03, 71288-414-04, 71288-415-06, and 71288-415-21

Ingredient name	Other names	%	CAS number
water	-	≥90	7732-18-5
benzyl alcohol	-	<1	100-51-6
Hydrochloric acid	-	≤0.3	7647-01-0
sodium hydroxide	-	≤0.3	1310-73-2
glycopyrronium bromide	-	≤0.1	596-51-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

**There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health and hence require reporting in this section.**

## Section 4. First aid measures

### Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.  
**Inhalation** : No known significant effects or critical hazards.  
**Skin contact** : No known significant effects or critical hazards.  
**Ingestion** : No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

- Eye contact** : No specific data.

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## Section 4. First aid measures

- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

### Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

## Section 5. Fire-fighting measures

### Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : Do not use water jet.

**Specific hazards arising from the chemical** : In a fire or if heated, a pressure increase will occur and the container may burst.

**Hazardous thermal decomposition products** : No specific data.

**Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

**Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

## Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

**For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

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## Section 6. Accidental release measures

**Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### Methods and materials for containment and cleaning up

**Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

**Large spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

## Section 7. Handling and storage

### Precautions for safe handling

**Protective measures** : Put on appropriate personal protective equipment (see Section 8).

**Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

**Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

## Section 8. Exposure controls/personal protection

### Control parameters

#### Occupational exposure limits

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## Section 8. Exposure controls/personal protection

Ingredient name	Exposure limits
water benzyl alcohol  Hydrochloric acid     sodium hydroxide     glycopyrronium bromide	None. <b>OARS WEEL (United States, 1/2021).</b> TWA: 10 ppm 8 hours. <b>ACGIH TLV (United States, 1/2021).</b> C: 2 ppm <b>NIOSH REL (United States, 10/2020).</b> CEIL: 5 ppm CEIL: 7 mg/m <sup>3</sup> <b>OSHA PEL (United States, 5/2018).</b> CEIL: 5 ppm CEIL: 7 mg/m <sup>3</sup> <b>ACGIH TLV (United States, 1/2021).</b> C: 2 mg/m <sup>3</sup> <b>NIOSH REL (United States, 10/2020).</b> CEIL: 2 mg/m <sup>3</sup> <b>OSHA PEL (United States, 5/2018).</b> TWA: 2 mg/m <sup>3</sup> 8 hours. None.

**Appropriate engineering controls**

: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

**Environmental exposure controls**

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

**Individual protection measures**

**Hygiene measures**

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

**Eye/face protection**

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

**Skin protection**

**Hand protection**

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

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## Section 8. Exposure controls/personal protection

- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

## Section 9. Physical and chemical properties

- Appearance**
- Physical state** : Liquid. [Clear.]
  - Color** : Colorless.
  - Odor** : Not available.
  - Odor threshold** : Not available.
  - pH** : 2 to 3
  - Melting point** : Not available.
  - Boiling point** : Not available.
  - Flash point** : Not available.
  - Evaporation rate** : Not available.
  - Flammability (solid, gas)** : Not applicable.
  - Lower and upper explosive (flammable) limits** : Not available.
  - Vapor pressure** : Not available.
  - Vapor density** : Not available.
  - Relative density** : 0.9973 to 0.9983 [at 25°C]
  - Density** : Not available.
  - Solubility** : Easily soluble in the following materials: cold water and hot water.
  - Solubility in water** : Not available.
  - Partition coefficient: n-octanol/water** : Not applicable.
  - Auto-ignition temperature** : Not available.
  - Decomposition temperature** : Not available.
  - SADT** : Not available.
  - Viscosity** : Not available.
  - Flow time (ISO 2431)** : Not available.

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## Section 10. Stability and reactivity

- Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.  
Under normal conditions of storage and use, hazardous polymerization will not occur.
- Conditions to avoid** : No specific data.
- Incompatible materials** : No specific data.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
benzyl alcohol	LC50 Inhalation Dusts and mists	Rat - Male, Female	>4178 mg/m <sup>3</sup>	4 hours
	LD50 Dermal	Rabbit	2000 mg/kg	-
	LD50 Oral	Rat	1230 mg/kg	-
glycopyrronium bromide	LD50 Oral	Rat	709 mg/kg	-

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
benzyl alcohol	Skin - Moderate irritant	Rabbit	-	24 hours 100 milligrams	-
Hydrochloric acid	Eyes - Mild irritant	Rabbit	-	0.5 minutes 5 mg	-
sodium hydroxide	Eyes - Mild irritant	Rabbit	-	400 ug	-
	Eyes - Severe irritant	Rabbit	-	24 hours 50 ug	-
	Eyes - Severe irritant	Rabbit	-	1 %	-
	Eyes - Severe irritant	Rabbit	-	0.5 minutes 1 mg	-
	Skin - Severe irritant	Rabbit	-	24 hours 500 mg	-

#### Sensitization

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## Section 11. Toxicological information

Not available.

### Mutagenicity

**Conclusion/Summary** : Not available.

### Carcinogenicity

**Conclusion/Summary** : Not available.

### Classification

Product/ingredient name	OSHA	IARC	NTP
Hydrochloric acid	-	3	-

### Reproductive toxicity

**Conclusion/Summary** : Not available.

### Teratogenicity

**Conclusion/Summary** : Not available.

### Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
benzyl alcohol	Category 3	-	Respiratory tract irritation
Hydrochloric acid	Category 3	-	Respiratory tract irritation
sodium hydroxide	Category 3	-	Respiratory tract irritation
glycopyrronium bromide	Category 3	-	Respiratory tract irritation

### Specific target organ toxicity (repeated exposure)

Not available.

### Aspiration hazard

Not available.

**Information on the likely routes of exposure** : Not available.

### Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

### Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : No specific data.





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## Section 11. Toxicological information

- Inhalation** : No specific data.  
**Skin contact** : No specific data.  
**Ingestion** : No specific data.

### Delayed and immediate effects and also chronic effects from short and long term exposure

#### Short term exposure

- Potential immediate effects** : Not available.  
**Potential delayed effects** : Not available.

#### Long term exposure

- Potential immediate effects** : Not available.  
**Potential delayed effects** : Not available.

#### Potential chronic health effects

Not available.

- General** : No known significant effects or critical hazards.  
**Carcinogenicity** : No known significant effects or critical hazards.  
**Mutagenicity** : No known significant effects or critical hazards.  
**Teratogenicity** : No known significant effects or critical hazards.  
**Developmental effects** : No known significant effects or critical hazards.  
**Fertility effects** : No known significant effects or critical hazards.

### Numerical measures of toxicity

#### Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
benzyl alcohol	1230	2000	N/A	N/A	1.5
glycopyrronium bromide	709	N/A	N/A	N/A	N/A

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## Section 12. Ecological information

### Toxicity

Product/ingredient name	Result	Species	Exposure
benzyl alcohol	Acute LC50 10000 µg/l Fresh water	Fish - Lepomis macrochirus	96 hours
Hydrochloric acid	Acute LC50 240000 µg/l Marine water	Crustaceans - Carcinus maenas - Adult	48 hours
sodium hydroxide	Acute LC50 282 ppm Fresh water	Fish - Gambusia affinis - Adult	96 hours
	Acute EC50 40.38 mg/l Fresh water	Crustaceans - Ceriodaphnia dubia - Neonate	48 hours
	Acute LC50 125 ppm Fresh water	Fish - Gambusia affinis - Adult	96 hours

**Conclusion/Summary** : Not available.

### Persistence and degradability

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
benzyl alcohol	-	-	Readily

### Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
water	-1.38	-	low
benzyl alcohol	0.87	-	low

### Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : Not available.

**Other adverse effects** : No known significant effects or critical hazards.

## Section 13. Disposal considerations

**Disposal methods** : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

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## Section 14. Transport information

	DOT Classification	IMDG	IATA
<b>UN number</b>	Not regulated.	Not regulated.	Not regulated.
<b>UN proper shipping name</b>	-	-	-
<b>Transport hazard class(es)</b>	-	-	-
<b>Packing group</b>	-	-	-
<b>Environmental hazards</b>	No.	No.	No.

### Additional information

**Special precautions for user** : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

**Transport in bulk according to IMO instruments** : Not available.

## Section 15. Regulatory information

**U.S. Federal regulations** : TSCA 8(a) CDR Exempt/Partial exemption: Not determined  
 United States inventory (TSCA 8b): Not determined.  
 Clean Water Act (CWA) 311: Hydrochloric acid; sodium hydroxide

**Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs)** : Listed

**Clean Air Act Section 602 Class I Substances** : Not listed

**Clean Air Act Section 602 Class II Substances** : Not listed

**DEA List I Chemicals (Precursor Chemicals)** : Not listed

**DEA List II Chemicals (Essential Chemicals)** : Not listed

### SARA 302/304

### Composition/information on ingredients



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## Section 15. Regulatory information

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Hydrochloric acid	≤0.3	Yes.	500	50.6	5000	506.5

**SARA 304 RQ** : 5000000 lbs / 2270000 kg [600992.7 gal / 2275005 L]

**SARA 311/312**

**Classification** : Not applicable.

**Composition/information on ingredients**

Name	%	Classification
benzyl alcohol	<1	FLAMMABLE LIQUIDS - Category 4 ACUTE TOXICITY (oral) - Category 4 ACUTE TOXICITY (dermal) - Category 4 ACUTE TOXICITY (inhalation) - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
Hydrochloric acid	≤0.3	SKIN CORROSION - Category 1B SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
sodium hydroxide	≤0.3	HNOC - Corrosive to digestive tract CORROSIVE TO METALS - Category 1 SKIN CORROSION - Category 1A SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
glycopyrrolonium bromide	≤0.1	HNOC - Corrosive to digestive tract [severe] ACUTE TOXICITY (oral) - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

**SARA 313**

Not applicable.

**State regulations**

**Massachusetts** : None of the components are listed.

**New York** : None of the components are listed.

**New Jersey** : None of the components are listed.

**Pennsylvania** : None of the components are listed.

**California Prop. 65**

This product does not require a Safe Harbor warning under California Prop. 65.

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## Section 15. Regulatory information

### International regulations

#### Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

#### Montreal Protocol

Not listed.

#### Stockholm Convention on Persistent Organic Pollutants

Not listed.

#### Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

#### UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

## Section 16. Other information

### Hazardous Material Information System (U.S.A.)

Health	0
Flammability	0
Physical hazards	0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

### National Fire Protection Association (U.S.A.)



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## Section 16. Other information

Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

### Procedure used to derive the classification

Classification	Justification
Not classified.	

### History

<b>Date of issue/Date of revision</b>	: 09/02/2021
<b>Date of previous issue</b>	: No previous validation
<b>Version</b>	: 1.0
<b>Prepared by</b>	: Sphera Solutions
<b>Key to abbreviations</b>	: ATE = Acute Toxicity Estimate AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution) N/A = Not available UN = United Nations
<b>References</b>	: HCS (U.S.A.)- Hazard Communication Standard International transport regulations

### Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

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## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Glycopyrrolate Injection USP 0.2 mg/mL (NDC 71288-407-03, 712888-407-04, 71288-408-06 and 71288-408-21)

### 1.2. Intended Use of the Product

**Use of the Substance/Mixture:** For professional use only. Used as a preoperative antimuscarinic to reduce salivary, tracheobronchial, and pharyngeal secretions; to reduce the volume and free acidity of gastric secretions; and to block cardiac vagal inhibitory reflexes during induction of anesthesia and intubation.

### 1.3. Name, Address, and Telephone of the Responsible Party

#### Company

Meitheal Pharmaceuticals Inc.  
8700 W. Bryn Mawr, Suite 600S  
Chicago, IL 60631  
Tel: 224-443-4617  
[www.meithealpharma.com](http://www.meithealpharma.com)

### 1.4. Emergency Telephone Number

Emergency Number : 844-824-8426

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

Not classified

### 2.2. Label Elements

#### GHS-US Labeling

No labeling applicable

### 2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
Water	AQUA / Aqua	(CAS-No.) 7732-18-5	98.9 4	Not classified



Meitheal Pharmaceuticals, Inc.

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Glycopyrronium bromide	Pyrrrolidinium, 1,1-dimethyl-3-hydroxy-, bromide, .alpha.-cyclopentylmandelate / Glycopyrrolate / Glycopyrronium / Pyrrrolidinium, 3-[(2-cyclopentyl-2-hydroxy-2-phenylacetyl)oxy]-1,1-dimethyl-, bromide (1:1) / Pyrrrolidinium, 3-[[cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethyl-, bromide / Asecryl / Gastrodyn / Nodapton / Robinul	(CAS-No.) 596-51-0	0.9	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2B, H320 STOT SE 3, H335
Hydrochloric acid	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous	(CAS-No.) 7647-01-0	0.1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
Sodium hydroxide	Caustic soda / Sodium hydroxide (Na(OH)) / SODIUM HYDROXIDE / LYE	(CAS-No.) 1310-73-2	0.04	Met. Corr. 1, H290 Acute Tox. 3 (Oral), H301 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402 Aquatic Chronic 3, H412
Benzyl alcohol	Benzenecarbinol / Benzenemethanol / Methanol, phenyl- / Phenylmethanol / Phenylmethyl alcohol / BENZYL ALCOHOL / .alpha.-Hydroxytoluene	(CAS-No.) 100-51-6	0.02	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401

Full text of H-phrases: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First-aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

### 4.2. Most Important Symptoms and Effects Both Acute and Delayed

**Symptoms/Injuries:** Not expected to present a significant hazard under anticipated conditions of normal use.

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.





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**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Water spray, fog, carbon dioxide (CO<sub>2</sub>), alcohol-resistant foam, or dry chemical.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Product is not flammable.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Carbon oxides (CO, CO<sub>2</sub>). Bromine compounds.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

#### 6.1.1. For Non-Emergency Personnel

**Protective Equipment:** Use appropriate personal protective equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Personnel

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Materials for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Precautions for Safe Handling:** Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

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**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

## 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Store in a dry, cool place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Materials:** Strong oxidizers.

## 7.3. Specific End Use(s)

For professional use only. Used as a preoperative antimuscarinic to reduce salivary, tracheobronchial, and pharyngeal secretions; to reduce the volume and free acidity of gastric secretions; and to block cardiac vagal inhibitory reflexes during induction of anesthesia and intubation.

# SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

## 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Glycopyrronium bromide (596-51-0)		
Internal	TWA (mg/m <sup>3</sup> )	0.1 µg/mL
Benzyl alcohol (100-51-6)		
USA AIHA	WEEL TWA (ppm)	10 ppm
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
USA IDLH	US IDLH (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	2 mg/m <sup>3</sup>
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m <sup>3</sup> )	7 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm

## 8.2. Exposure Controls

Appropriate Engineering Controls : Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing : Chemically resistant materials and fabrics.

Hand Protection : Wear protective gloves.



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Eye and Face Protection	: Chemical safety goggles.
Skin and Body Protection	: Wear suitable protective clothing.
Respiratory Protection	: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
Other Information	: When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear colorless solution
Odor	: Odorless
Odor Threshold	: No data available
pH	: 2 - 3
Evaporation Rate	: No data available
Melting Point	: 193 °C (379.4 °F)
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
<b>Flammability (solid, gas)</b>	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
<b>Solubility</b>	: Soluble in water
<b>Partition Coefficient: N-Octanol/Water</b>	: No data available
<b>Viscosity</b>	: No data available

### 9.2. Other Information

 No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong oxidizers.
- 10.6. Hazardous Decomposition Products:** None expected under normal conditions of use.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on Toxicological Effects

**Acute Toxicity:** Not classified

<b>Glycopyrronium bromide (596-51-0)</b>	
LD50 Oral Rat	709 mg/kg



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<b>Benzyl alcohol (100-51-6)</b>	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
<b>Sodium hydroxide (1310-73-2)</b>	
LD50 Oral Rat	140 - 340 mg/kg
<b>Hydrochloric acid (7647-01-0)</b>	
LD50 Dermal Rabbit	> 5010 mg/kg

**Skin Corrosion/Irritation:** Not classified. (pH: 2 - 3)

**Serious Eye Damage/Irritation:** Not classified. (pH: 2 - 3)

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

<b>Hydrochloric acid (7647-01-0)</b>	
IARC group	3

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** Prolonged exposure may cause irritation.

**Symptoms/Injuries After Skin Contact:** Prolonged exposure may cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause slight irritation to eyes.

**Symptoms/Injuries After Ingestion:** Ingestion may cause adverse effects.

**Chronic Symptoms:** None expected under normal conditions of use.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

Ecology - General : Not classified.

<b>Benzyl alcohol (100-51-6)</b>	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
LC50 Fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
ErC50 (Algae)	770 mg/l
<b>Sodium hydroxide (1310-73-2)</b>	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l
<b>Hydrochloric acid (7647-01-0)</b>	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)

### 12.2. Persistence and Degradability

<b>Glycopyrrolate Injection USP 0.2 mg/mL</b>	
Persistence and Degradability	Not established.



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**12.3. Bioaccumulative Potential**

<b>Glycopyrrolate Injection USP 0.2 mg/mL</b>	
<b>Bioaccumulative Potential</b>	Not established.
<b>Benzyl alcohol (100-51-6)</b>	
<b>Log Pow</b>	1.1

**12.4. Mobility in Soil** No additional information available

**12.5. Other Adverse Effects**

**Other Information** : Avoid release to the environment.

**SECTION 13: DISPOSAL CONSIDERATIONS**

**13.1. Waste Treatment Methods**

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Ecology - Waste Materials:** Avoid release to the environment.

**SECTION 14: TRANSPORT INFORMATION**

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

**14.1. In Accordance with DOT** Not regulated for transport

**14.2. In Accordance with IMDG** Not regulated for transport

**14.3. In Accordance with IATA** Not regulated for transport

**SECTION 15: REGULATORY INFORMATION**

**15.1. US Federal Regulations**

<b>Benzyl alcohol (100-51-6)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Sodium hydroxide (1310-73-2)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>CERCLA RQ</b>	1000 lb
<b>Hydrochloric acid (7647-01-0)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
<b>CERCLA RQ</b>	5000 lb
<b>SARA Section 302 Threshold Planning Quantity (TPQ)</b>	500 lb (gas only)
<b>SARA Section 313 - Emission Reporting</b>	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

**15.2. US State Regulations**

<b>Benzyl alcohol (100-51-6)</b>
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U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List
<b>Sodium hydroxide (1310-73-2)</b> U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List
<b>Hydrochloric acid (7647-01-0)</b> U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List

**SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION**

**Date of Preparation or Latest Revision** : 09/02/2021  
**Other Information** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

**GHS Full Text Phrases:**

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Eye Irrit. 2B	Serious eye damage/eye irritation Category 2B
Flam. Liq. 4	Flammable liquids Category 4
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H227	Combustible liquid
H290	May be corrosive to metals
H301	Toxic if swallowed
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage



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H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H320	Causes eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

*This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.*