



CUVPOSA SAFETY DATA SHEET (SDS)

I. IDENTIFICATION:

Chemical Name: Glycopyrrolate Oral Solution

Distributor: Merz North America, Inc.
6501 Six Forks Road
Raleigh, NC 27615
Emergency: (800) 373-7542 or International +1-484-951-2432
Information: 844-469-6379

Intended Use: CUVPOSA is a prescription medication to help reduce chronic severe drooling in children aged 3 to 16 years with neurologic conditions that cause too much (abnormal) drooling.

II. HAZARDS IDENTIFICATION:

This product is not considered to be hazardous per the Occupational Safety & Health Administration's (OSHA's) Hazard Communication Standard 29CFR1910.1200.

III. COMPOSITION / INFORMATION ON INGREDIENTS:

This product has no hazardous components above reporting thresholds.

IV. FIRST AID MEASURES:

General: In case of accident involving illness, seek medical advice immediately.

Eye Contact: Remove contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Obtain medical attention if irritation persists.

Skin Contact: Remove contaminated clothing. Flush skin with plenty of water.

Inhalation: Not expected under normal conditions. Remove to fresh air if necessary.

Ingestion: Seek medical advice if necessary. Provide container labeling or SDS if possible.

V. FIRE FIGHTING MEASURES:

Extinguishing media: Use extinguishing media appropriate to the surrounding fire.

Special considerations: Toxic gases and vapors may be released if involved in a fire.

VI. ACCIDENTAL RELEASE MEASURES:

Small spill: Utilize appropriate personal protective equipment. Gather spilled material with absorbent material (e.g., cloth) and place in a glass or plastic container. Assess and document the amount of material collected.

Large spill: Contain spill to the extent possible using available absorbents. Prevent entry into water systems, surface waters, or groundwater. Notify the appropriate emergency response personnel. Do not attempt clean-up without appropriate protective equipment.

VII. HANDLING AND STORAGE:

Store at room temperature 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP controlled room temperature]. This product is best stored in the original container. Handle in accordance with good industrial hygiene and safety practices.



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VIII. EXPOSURE CONTROLS / PERSONAL PROTECTION:

Exposure Limits: Not established.

Personal Protection Recommendations:

Ventilation: A local and/or general exhaust system is recommended to minimize airborne contaminants.

Respirator: Use a powered or air-purifying respirator meeting an approved standard if indicated by environmental assessment. Selection should be based upon anticipated exposure and capacity of respirator.

Gloves: Impervious gloves should be worn.

Clothing: Wear clean, body-covering protective clothing that is suitable for the task being performed.

Eye Protection: Utilize safety eyewear that complies with an approved standard when protection from splash or spray is required.

IX. PHYSICAL AND CHEMICAL PROPERTIES:

Appearance: Clear liquid
Odor: Cherry
Specific Gravity: 1.1 – 1.2
pH: 3.1 – 4.1
Viscosity: LT 42.1 mm²/s

Vapor pressure, Odor threshold, Vapor density, Upper/lower flammability or explosive limits, Relative density, Melting point/Freezing point, Initial boiling point and Boiling range, Solubility, Flashpoint, Partition coefficient: n-octanol/water, Auto-ignition temperature, Evaporation rate, and Decomposition temperature: No information available

X. STABILITY AND REACTIVITY:

Stability: Stable under normal conditions of use.

Hazardous Decomposition Products: Toxic gases and vapors may be released if involved in a fire.

Incompatibilities: Not established. This product is a mixture that has not been tested as a whole.

XI. TOXICOLOGICAL INFORMATION:

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Toxicity data:	Glycopyrrolate: Oral LD50 (rat)=709 mg/kg Intraperitoneal LD50 (rat)=196 mg/kg Oral LD50 (mouse)=570 mg/kg
Carcinogenicity:	Long-term animal studies have not been performed to evaluate the carcinogenic potential of glycopyrrolate.
Reproductive Effects:	Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. It is not known whether glycopyrrolate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.

XII. ECOLOGICAL INFORMATION:

Not established. This product is a mixture that has not been tested as a whole.

XIII. DISPOSAL CONSIDERATIONS:

Ensure compliance with local, state and federal regulations.



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XIV. TRANSPORT INFORMATION:

Non-hazardous for transport

XV. REGULATORY INFORMATION:

TSCA: All components are listed on the TSCA Inventory or exempt.

SARA 311/312: Not Applicable

SARA 313: This product does not contain any chemicals above reporting thresholds.

XVI. OTHER INFORMATION:

Revision Date: June 3, 2016

The information contained in this SDS is to the best of Merz North America, Inc.'s knowledge and is believed to be accurate and reliable as of the revision date. However, no representation, warranty, or guarantee is implied or expressed regarding the accuracy, reliability, or completeness of this information. Information contained within this SDS is related to occupational exposure. See the instructions for use for more information regarding use.
