

## SAFETY DATA SHEET

Section 1: Identification	
<b>Material</b>	Diatrizoate meglumine and Diatrizoate sodium solution USP
<b>Recommended use</b>	Pharmaceutical product
<b>Manufacturer</b>	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)
<b>Distributor</b>	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
<b>Classification of the substance or mixture</b>	The product is not classified, according to the Globally Harmonized System (GHS).
<b>Label elements</b>	
<b>GHS label elements</b>	Not applicable
<b>Signal word</b>	Not applicable
<b>Hazard pictograms</b>	Not applicable
<b>Hazard statements</b>	Not applicable
<b>Results of PBT and vPvB assessment</b>	PBT: Not applicable vPvB: Not applicable
Section 3: Composition/Information on Ingredients	
<b>Ingredient</b>	<b>CAS</b>
Diatrizoate Meglumine	131-49-7
Diatrizoate Sodium	737-31-5
Edetate disodium dihydrate	6381-92-6
Simethicone emulsion	8050-81-5
Polysorbate 80	9005-65-6
Tri-sodium citrate dihydrate powder	6132-04-3
Saccharin sodium	6155-57-3
Strawberry Flavor	NA
Sodium Hydroxide	1310-73-2
Section 4: First-Aid Measures	
<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

<b>Skin Contact</b>	Immediately wash with water and soap and rinse thoroughly. If symptoms persist, consult a doctor.
<b>Inhalation</b>	Move patient to fresh air, if symptom arise consult a doctor. Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.
<b>Ingestion</b>	Immediately call a doctor. Vomiting may be induced if person is conscious and not experiencing convulsions. Never give anything by mouth to an unconscious person.
<b>Section 5: Fire-Fighting Measures</b>	
<b>Extinguishing Media</b>	CO <sub>2</sub> , Extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
<b>Special hazards arising from the substance or mixture</b>	In case of fire, the following can be released: Hydrogen Iodide, Iodine (red-brown gas) Carbon Dioxide (CO <sub>2</sub> ) In the absence of Oxygen: Carbon Monoxide (CO) Nitrogen Oxides (NxOy) Iodine Compounds
<b>Protective equipment</b>	Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus) (SCBA). In addition, firefighters should wear flame and chemicals resistant clothing, boots and gloves
<b>Advice for firefighters</b>	Evacuate personnel to an upwind direction, remove unneeded material and cool container(s) with water from a maximum distance. Move container from fire area if you can do it without risk.
<b>Section 6: Accidental Release Measures</b>	
<b>Personal precautions, protective equipment and emergency procedures</b>	Keep away from ignition sources. Wear protective equipment. Keep unprotected persons away.
<b>Environmental precautions</b>	Do not allow to enter sewers/ surface or ground- water. Dilute with plenty of water.
<b>Methods and material for containment and cleaning up</b>	Absorb with liquid-binding material. Absorb spill with inert material (e.g. sand, vermiculite or other non-combustible absorbent materials) and place into a closed container for reclamation or disposal. Flush residual spill area with water to process sewer if allowable under national, state, or local permits and regulations.
<b>Section 7: Handling and Storage</b>	
<b>Precautions for safe handling</b>	Avoid splashes or spray in enclosed areas. Avoid contact with the eyes and skin.

<b>Information about protection against explosions and fires</b>	No special measures required.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in a cool, dry place in well-sealed receptacles. Store only in the original receptacle.
<b>Storage Conditions</b>	Store in cool, dry conditions in well-sealed receptacles. Protect from heat and direct sunlight. Store at room temperature (20-25 degrees C).
<b>8. Exposure controls / personal protection</b>	
<b>Components with limit values that require monitoring at the workplace</b>	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
<b>Additional information</b>	The lists that were valid during the creation were used as basis.
<b>Personal Protective Equipment</b>	The usual precautionary measures for handling chemicals should be followed. Wash hands before breaks and at the end of work. Ensure good ventilation/exhaustion at the workplace.
<b>Protection of hands</b>	Protective gloves. The glove material must be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.  Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
<b>Eyes</b>	Safety glasses
<b>Body protection</b>	Protective work clothing
<b>Section 9: Physical and Chemical Properties</b>	
<b>Physical State</b>	Solution
<b>Description</b>	Diatrizoate Meglumine and Diatrizoate Sodium Solution USP is available as clear, aqueous, pale yellow color solution, with strawberry flavor in packages of:  Twenty-four 30 mL single dose bottles (NDC 31722-019-30). Twelve 120 mL single dose bottles (NDC 31722-019-12).

Section 10: Stability and Reactivity	
<b>Stability</b>	Stable at normal conditions
<b>Conditions to Avoid</b>	No further relevant information available.
<b>Hazardous decomposition products</b>	No dangerous decomposition products known.
<b>Incompatible Materials</b>	No further relevant information available.
Section 11: Toxicological Information	
<b>General Information</b>	The information included in this section describes the potential hazards of the individual ingredients
<b><u>Acute Toxicity: (Species, Route, End Point, Dose)</u></b>	
<b>Diatrizoate Meglumine</b> LD50 iv - 21,200 mg/kg (Mouse); 14,565 mg/kg (Rat) LD50 ip - 44,504 mg/Kg (Rat)	
<b>Diatrizoate Sodium</b> LD50 iv - 11,300 mg/kg (Cat) 13,200 mg/kg (Dog) 14,000 mg/kg (Mouse) 11,400 mg/kg (Rat) 12,200 mg/kg (Rabbit) LD50 im - 20,349 mg/Kg (Mouse)	
Section 12: Ecological Information	
<b>Toxicity</b>	
<b>Persistence and degradability:</b> No further relevant information available.	
<b>Bio accumulative potential:</b> No further relevant information available.	
<b>Mobility in soil:</b> No further relevant information available.	
<b>Additional ecological information</b>	
<b>General notes:</b> Water hazard class 1 (Self-assessment): slightly hazardous for water Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.	
<b>Results of PBT and vPvB assessment</b>	
<b>PBT:</b> Not applicable.	
<b>vPvB:</b> Not applicable.	
<b>Other adverse effects:</b> No further relevant information available.	

Section 13: Disposal Considerations	
<b>Waste treatment methods Recommendation:</b>	Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Reutilize if possible or contact a waste processor for recycling or safe disposal.
<b>Uncleaned packaging:</b>	Disposal must be made according to official regulations. Packaging that cannot be cleansed are to be disposed of in the same manner as the product.  Water, if necessary, with cleansing agents.
Section 14: Transport Information	
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.	
Section 15: Regulatory Information	
<p><b>GHS label elements:</b> Not applicable</p> <p><b>Hazard pictograms:</b> Not applicable</p> <p><b>Signal word:</b> Not applicable</p> <p><b>Hazard statements:</b> Not applicable</p> <p><b>Proposition 65</b></p> <p><b>Chemicals known to cause cancer:</b> None of the ingredients are listed.</p> <p><b>Chemicals known to cause reproductive toxicity for females:</b> None of the ingredients are listed.</p> <p><b>Chemicals known to cause reproductive toxicity for males:</b> None of the ingredients are listed.</p> <p><b>Chemicals known to cause developmental toxicity:</b> None of the ingredients are listed</p> <p><b>Carcinogenic categories</b></p> <p><b>EPA (Environmental Protection Agency) -</b> None of the ingredients are listed.</p> <p><b>TLV (Threshold Limit Value established by ACGIH) -</b> None of the ingredients are listed.</p> <p><b>NIOSH-Ca (National Institute for Occupational Safety and Health) -</b> None of the ingredients are listed.</p>	

## Section 16: Other Information, including date of preparation or last revision

**Issue Date: 14-12-2023**

**Version: 00**

**Further information**

**Revision date: NA**

**Revision note: NA**

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