MATERIAL SAFETY DATA SHEET

DIPHENHYDRAMINE HYDROCHLORIDE INJECTION USP, 50MG/ML

1. IDENTIFICATION					
Material Identification	:	Diphenhydramine Hydrochloride Injection USP, 50mg/ml			
Active ingredient	:	(2-(diphenylmethoxy)-N,N-dimethyl-ethanamine, monohydrochloride			
Molecular Formula	:	$C_{17}H_{21}NO.HCL$	**Molecular Weight**	:	291.82 g/mol
CAS Number	:	147-24-0			
Product Use	:	Antihistamine			
Manufactured by	:	**Micro Labs Limited** Plot no. 113-116, KIADB, Bommasandra Industrial Area, Bommasandra-Jigani Link Road, Anekal taluk, Bangalore-560099, Karnataka, India	**Manufactured for**	:	**Armas Pharmaceuticals Inc.** 303 West Main Street Suite 300 Freehold, NJ 07728
Emergency Contact	:	+91-80-27839033			

2. HAZARDS IDENTIFICATION		
Label Elements		
Signal	:	Warning 
Physical hazards	:	Not classified
Classification of the substance	:	Acute toxicity, Oral (Category 4)
Hazard statements	:	H302: Harmful if swallowed
Precautionary statements	:	P260: Do not breathe dust/fume/gas/mist/vapors/spray P264: Wash {hands} thoroughly after handling. P301+312: IF SWALLOWED: Call a POISON CENTER or doctor / physician if you feel unwell. P314: Get medical attention/advice if you feel unwell P330: Rinse mouth. P501: Dispose of contents/container in accordance with all local and national regulations
Hazard(s) not otherwise classified (HNOC)	:	None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS #	EINECS #	% w/w	Label Elements EU classification (67/548/EEC) GHS & EU classification (1272/2008 EC) Risk phrases/Hazard statements
Active Pharmaceutical Ingredient				
Diphenhydramine Hydrochloride (2-(diphenylmethoxy)-N,N-dimethyl-ethanamine, monohydrochloride	147-24-0	205-687-2	Proprietary	EU 67/548/EEC: Classification: Acute oral toxicity Category 4 Risk Phrase Codes: R22 Hazard Symbols: Xn GHS & EU 1272/2008: Classification: Acute oral toxicity Category 4 Hazard codes: H302 Hazard symbol/Pictogram: GHS07
Excipients				
Sodium Hydroxide	1310-73-2	215-185-5	Proprietary	EU 67/548/EEC: Classification: Corrosive Risk phrase code: R35 Hazard symbol: C GHS & EU 1272/2008: Classification: Category 1/1A Hazard codes: H290, H314 Hazard symbol/Pictogram: GHS05
Hydrochloric Acid USPNF	7647-01-0	231-595-7	Proprietary	EU 67/548/EEC: Classification: Corrosive Risk phrase code: R34, R37 Hazard symbol: C, Xi GHS & EU 1272/2008: Classification: Category 1/1B Hazard codes: H290, H314, H335 Hazard symbol/Pictogram: GHS05, GHS07

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eyes Contact	:	The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.
Skin Contact	:	Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required). Get medical attention immediately.
Ingestion	:	Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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.

Inhalation	:	The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed, remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
General information	:	Remove from exposure. Remove contaminated clothing. For treatment advice, get the guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. FIRE FIGHTING MEASURES

Extinguishing media	:	In case of fire, use water, dry chemical spray, chemical foam, or alcohol-resistant foam.

General Information

As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH approved or equivalent), and full protective gear. During a fire, carbon oxides, Nitrogen oxides, Hydrogen chloride gas may be generated.

6. ACCIDENTAL RELEASE MEASURES

Remove any ignition source. Wear protective clothing, gloves and goggles. Pick up without raising dust. Keep contaminated material tightly closed containers. Wash with water. Don't throw this substance in sewer or ground water.

Personal precautions, protective equipment and emergency procedures	:	**For non-emergency personnel:** No action shall be taken involving any personal risk or without suitable training. 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 nonemergency personnel".
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 material for containment and cleaning up	:	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. Dispose of via a licensed waste disposal contractor.

7. HANDLING AND STORAGE		
Precautions for safe handling	:	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Conditions for safe storage, including any incompatibilities		
Storage conditions	:	Store at Controlled Room Temperature 15°C – 30°C (59°F - 86°F). Protect From Light.
Specific end use(s)	:	Pharmaceutical drug product for patients

8. EXPOSURE CONTROLS / PERSONAL PROTECTION		
Engineering Controls	:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment	:	Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Respiratory Protection	:	When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.
Hands	:	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.
Eye 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	:	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. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES		
Physical State	:	Injection
Color	:	Clear, colorless solution
Appearance	:	**Diphenhydramine Hydrochloride Injection USP 50mg/ml:** Clear, colorless solution, free from visible particles.
Molecular Formula	:	C17H21NO. HCL
Molecular Weight	:	291.82 g/mol
10. STABILITY AND REACTIVITY		
Reactivity	:	Stable under recommended storage conditions.
Conditions to Avoid	:	Direct sunlight. Extremely high or low temperatures.
Incompatible Materials	:	Strong oxidizers, Heat sources. Direct sunlight.

11. TOXICOLOGICAL INFORMATION		
Acute Toxicity	:	**Diphenhydramine Hydrochloride** Rat Oral LD 50 500 mg/kg Mouse Oral LD 50 114 mg/kg Guinea Pig Oral LD 50 284 mg/kg Human Oral LD min. 10.1 mg/kg **Hydrochloric Acid** Rat Oral LD 50 238-277 mg/kg
Skin Irritation/Sensitization	:	**Diphenhydramine Hydrochloride** Guinea Pig: Negative Mouse: Negative Skin irritation reported in clinical use
Eye irritation	:	Non-irritating
Germ cell mutagenicity	:	**Diphenhydramine Hydrochloride** Bacterial Mutagenicity (Ames) Salmonella: Negative *In Vitro* Mammalian Cell Mutagenicity Mouse Lymphoma: Negative *In Vitro* Chromosome Aberration Chinese Hamster Ovary cells: Positive without activation, Negative with activation *In Vitro* Sister Chromatid Exchange Chinese Hamster Ovary cells: Negative *In Vitro* Unscheduled DNA Synthesis Rat Hepatocyte: Negative **Hydrochloric Acid** Bacterial Mutagenicity (Ames) Salmonella: Negative *In Vivo* Micronucleus Rat: Negative

Carcinogenicity	:	**Diphenhydramine Hydrochloride** Not Carcinogenic **Hydrochloric Acid** IARC: Group 3 (Not Classifiable)
IARC:	:	No data available
NTP:	:	No data available

11. TOXICOLOGICAL INFORMATION

Reproductive toxicity:	:	Subcutaneous-Mouse TDLo: 1900 mg/kg (Reproductive-effects on embryo or fetus-fetal death) Subcutaneous-Mouse TDLo: 1900 mg/kg Reproductive-specific developmental abnormalities-musculoskeletal system) Subcutaneous-Mouse TDLo: 2500 mg/kg (Reproductive-effects on embryo or fetus-fetal death/fetotoxicty, i.e., stunted fetus) Subcutaneous-Mouse TDLo: 13440 mg/kg (Reproductive-fertility-abortion) Intraperitoneal-Rat TDLo: 1710 mg/kg (Reproductive-effects on embryo or fetus-fetal death/fetotoxicty, i.e., stunted fetus/ specific developmental abnormalities-musculoskeletal system) Intraperitoneal-Rat TDLo: 10 g/kg (Reproductive-effects on newborn-behavioral)

12. ECOLOGICAL INFORMATION

General Notes	:	The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.
Toxicity:	:	No data available
Persistence and degradability	:	No data available
Bioaccumulative potential	:	No data available
Mobility in soil	:	No data available
Results of PBT and vPvB	:	data not available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods	:	The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus or 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 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.

14. TRANSPORTATION INFORMATION

Environmental hazards	:	No data available
Special precautions for user	:	No data available
Transport hazard class(es)	:	No data available
Packing group	:	No data available
IATA UN number	:	No data available
Environmental hazards	:	No data available
Special precautions for user	:	No data available

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY / STATUTORY INFORMATION

Seveso regulation (Directive 96/82/EC)	:	Not Available
Candidate list (art. 59-REACH):	:	Not Available
Ozone depletion substance (2000/2037/EC)	:	Not Available
Import/export dangerous chemical (2008/689/EC)	:	Not Available

16. OTHER INFORMATION

Date of preparation: 20/03/23

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End of Safety Data Sheet