

Section 1: Identification

1.1 Product identifier

Product Form: Mixture

Product Name: REZIPRES® (Ephedrine Hydrochloride Injection)

Synonym: Ephedrine Hydrochloride Injection

Trade Name: REZIPRES®

1.2 Intended Use of the Product

Pharmaceutical.

1.3 Name, Address, Email and Telephone Number of the Responsible Party

Company

XGen Pharmaceuticals DJB, Inc.
300 Daniel Zenker Drive
Horseheads, NY 14845

Telephone: 1-607-562-2700

Fax: 1-607-562-2760

Email: customer-service@xgenpharmadjb.com

1.4 Emergency phone number

Phone Number: National Poison Control 1-800-222-1222

Section 2: Hazard(s) Identification

2.1 Hazard Classification: Not classified.

2.2 Signal Word(s): Warning

2.3 Health Hazards: Acute toxicity, oral
Specific target organ toxicity, single exposure

Category 4
Category 2 (cardiovascular system, nervous system)

2.4 Pictograms



2.5 Hazard Statements: H316 Causes mild skin irritation.

H320 Causes eye irritation.

H335 May cause respiratory irritation.

H303 May be harmful if swallowed.

- 2.6 Precautionary Statements:**
- P233 Keep container tightly closed.
 - P261 Avoid breathing dust/fume/gas/mist/vapor/spray.
 - P264 Wash potentially exposed skin after handling.
 - P301 IF SWALLOWED: Get medical help
+
P317
 - P304 IF INHALED: Remove person to fresh air and
+
keep comfortable for breathing.
P340
 - P305 IF IN EYES: Rinse cautiously with water for
+
several minutes. Remove contact lenses, if
P351 present and easy to do. Continue rinsing.
+
P338
 - P337 If eye irritation persists: Get medical
+
advice/attention.
P317
 - P332 If skin irritation occurs: Get medical
+
help.
P317
 - P308 If exposed or concerned: Get medical
+
help immediately.
P316
 - P403 Store in a well-ventilated place.
 - P501 Dispose of contents/container in accordance
with local/provincial/federal regulations.

2.7 Description of other hazards: None

NOTE. This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: Composition/ Information on Ingredients

Ingredient	CAS#	Conc. (%)
Ephedrine Hydrochloride	50-98-6	0.5
Sodium Chloride	7647-14-5	0.8
Hydrochloric Acid	7647-01-0	*Used to adjust pH
Sodium Hydroxide	1310-73-2	*Used to adjust pH
Water for Injection	7732-18-5	q.s.

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

Occupational exposure limits, if available, are listed in Section 8.

Section 4: First-Aid Measures

4.1 After skin contact: Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

4.2 After eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.

4.3 After inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately.

4.4 After swallowing: Wash out mouth with water. Remove dentures if any. 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. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

4.5 Indication of Any Immediate Medical Attention and Special Treatment Needed
If you feel unwell, seek medical advice (show the label where possible).

4.6 Specific treatments: No specific treatment.

4.7 Protection of first-aiders: No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

Section 5: Fire-Fighting Measures

5.1 Suitable extinguishing agents: Use an extinguishing agent suitable for the surrounding fire.

5.2 Special Hazards Arising from the Substance or Mixture: No specific fire or explosion hazard.

5.3 Special protective equipment for firefighters: 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

6.1 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. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment

6.2 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".

6.3 Measures for environmental protection: 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).

6.4 Measures for cleaning/collecting: Stop leak if without risk. Move containers from spill area. Approach release from upwind. 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. Contaminated absorbent material may pose the same hazard as the spilled product.

6.5 Reference to Other Sections: Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7: Handling and Storage

7.1 Handling: Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing

vapor or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

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. See also Section 8 for additional information on hygiene measures. Remove contaminated clothing and protective equipment before entering eating areas.

- 7.2 Storage:** 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. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8: Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits: None

8.2 Appropriate Engineering Controls: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

8.3 Environmental Exposure Controls: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

8.4 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. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

8.5 Skin 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. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated. 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

8.6 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

8.7 Respiratory Protection: Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator

selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

8.8 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

Section 9: Physical and Chemical Properties

- 9.1 **Form:** Liquid.
- 9.2 **Color:** Colorless.
- 9.3 **Odor:** Not available.
- 9.4 **Odor threshold:** Not available.
- 9.5 **pH:** 5.0 to 6.5
- 9.6 **Melting point/melting range:** Not available.
- 9.7 **Boiling point/boiling range:** Not available.
- 9.8 **Flash point:** Not available.
- 9.9 **Evaporation rate:** Not available.
- 9.10 **Flammability:** Not available.
- 9.11 **Upper/lower flammability or explosive limits:** Not available.
- 9.12 **Auto ignition temperature:** Not available.
- 9.13 **Danger of explosion:** Not available.
- 9.14 **Vapor pressure:** Not available.
- 9.15 **Vapor density:** Not available.
- 9.16 **Relative density:** Not available.
- 9.17 **Solubility in/Miscibility with water:** Soluble in water.

Section 10: Stability and Reactivity

- 10.1 **Reactivity:** Stable and non-reactive under normal conditions of use, storage and transport.
- 10.2 **Chemical stability:** Stable.
- 10.3 **Conditions to avoid:** No specific data available.
- 10.4 **Incompatible materials:** As a precautionary measure keep away from strong oxidizers.
- 10.5 **Hazardous decomposition products:** No data available.

Section 11: Toxicological Information

11.1 Acute toxicity:

Ingredient	Species	Route	Type	Dosage
Ephedrine hydrochloride	Rat	Dermal	LD50	>2000 mg/kg
	Rat	Inhalation	LC50	>5.2 mg/l, 4 hrs
	Mouse Rat	Oral	LD50	400 mg/kg 710 mg/kg
Sodium Chloride	Rat	Oral	LD50	3000 mg/kg
	Rabbit	Dermal	LD50	10,000 mg/kg
	Rat	Inhalation	LC50	42 g/m ³ , 1 hr

11.2 Potential routes of exposure/potential health effects

Skin: Knowledge about health hazard is incomplete.

Eye: No known significant effects or critical hazards.

Inhalation: Knowledge about health hazard is incomplete.

Ingestion: Harmful if swallowed. .

Carcinogenic effects: Based on available data, the classification criteria are not met. A related material has not caused cancer in animal studies

Mutagenic effects: Knowledge about mutagenicity is incomplete.

Reproductive toxicity: Based on available data, the classification criteria are not met. A review of limited human pregnancy data has not demonstrated an increase in adverse developmental effects.

Sensitization: Knowledge about health hazard is incomplete.

Target organs: May cause damage to organs (cardiovascular system, nervous system).

Section 12: Ecological Information

12.1 Ecotoxicity: There is no data available.

12.2 Mobility in soil: Not available.

12.3 Biodegradation: There is no data available.

12.4 Bioaccumulative potential (Ephedrine Hydrochloride):
Octanol/water partition coefficient log Kow -2.07, at 25 °C

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

Section 13: Disposal Considerations

Disposal information: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should 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. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14: Transport Information

14.1 DOT regulations:

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
-	Not regulated.	-	-

14.2 Air transport ICAO-TI and IATA-DGR:

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
-	Not regulated.	-	-

Environmental Hazards: None.

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.

Section 15: Regulatory Information

15.1 US Federal Regulations

DEA List I Chemicals: Listed.

California Proposition 65: Not listed.

Section 16: Other Information

Date of Issue: 12/17/2021

Version: 0

Revised Sections: Not Applicable.

The information within this document is believed to be accurate and represents the best information currently available to XGen Pharmaceuticals DJB. . The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall XGen Pharmaceuticals DJB., its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if XGen Pharmaceuticals DJB., has been advised of the possibility of such damages.

End of Safety Data Sheet