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CIN U46909GJ2025PTC164345

MATERIAL SAFETY DATA SHEET

16-section GHS format

Darifenacin Hydrobromide

CAS 133099-04-4 · ≥99% Pharma Grade

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE SUPPLIER

Product Name	Darifenacin Hydrobromide
C.A.S. Number	133099-04-4
Product Category	Active Pharmaceutical Ingredients (APIs)
Product Group	Urology
Grade / Standard	≥99% Pharma Grade
Identified Uses	Overactive bladder treatment API. Industrial and professional use.
Supplier	Scapex Exports Pvt. Ltd., 830, 8th Floor, Sun Gravitas, Times of India Road, Shyamal, Ahmedabad 380015, Gujarat, India
Emergency Telephone	+91 9925522674 (Mon–Sat, 09:30–18:30 IST)

2. HAZARDS IDENTIFICATION

GHS Classification	Not classified as dangerous for transport
Signal Word	**WARNING**
Pictograms	Exclamation mark

◇ Exclamation mark

Hazard statements

- H302 — Harmful if swallowed.
- H315 — Causes skin irritation.
- H319 — Causes serious eye irritation.
- H335 — May cause respiratory irritation.

Precautionary statements

- P101 If medical advice is needed, have product container or label at hand.
- P102 Keep out of reach of children.

- P262 Do not get in eyes, on skin, or on clothing.
- P264 Wash hands thoroughly after handling.
- P280 Wear protective gloves and eye protection.
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes.
- P337+P313 If eye irritation persists: Get medical advice / attention.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Identity	Darifenacin Hydrobromide
C.A.S. Number	133099-04-4
Concentration / Grade	≥99% Pharma Grade
Impurities	No impurities present at concentrations that alter the classification.

4. FIRST-AID MEASURES

Inhalation	Remove to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult give oxygen. Obtain medical attention.
Skin contact	Remove contaminated clothing. Wash the affected area with plenty of soap and water for at least 15 minutes. Obtain medical attention if irritation persists.
Eye contact	Rinse immediately with plenty of water for at least 15 minutes holding the eyelids open. Remove contact lenses if present and easy to do. Obtain immediate medical attention.
Ingestion	Do NOT induce vomiting. Rinse the mouth with water. Never give anything by mouth to an unconscious person. Obtain immediate medical attention and show this Material Safety Data Sheet.
Note to physician	Treat symptomatically. No specific antidote is known.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	Water spray, dry chemical powder, carbon dioxide or alcohol-resistant foam.
Unsuitable extinguishing media	High-pressure water jet.
Specific hazards	Thermal decomposition may generate irritating and toxic gases.
Advice for fire-fighters	Wear self-contained breathing apparatus and full protective clothing. Prevent fire-fighting water entering drains or watercourses.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions	Evacuate unnecessary personnel. Ensure adequate ventilation. Wear the protective equipment described in Section 8. Eliminate ignition sources where the product is flammable.

Environmental precautions	Prevent entry into drains, sewers, surface water and groundwater. Notify the authorities if release to the environment occurs.
Containment and cleaning	Contain with an inert absorbent (dry sand, earth or vermiculite) and collect into a labelled closed container for disposal. Do not use combustible absorbents where the product is an oxidiser. Ventilate the area and wash the spill site after pick-up.

7. HANDLING AND STORAGE

Handling	Use only in well-ventilated areas. Avoid contact with skin, eyes and clothing. Avoid formation and inhalation of dust, mist or vapour. Do not eat, drink or smoke in the work area.
Storage	Store in the original tightly closed container in a cool, dry, well-ventilated place away from direct sunlight and heat, and away from the incompatible materials listed in Section 10.
Packaging	Use only the original packaging or an equivalent material approved for this product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational exposure limits	Refer to the national occupational exposure limits applicable in the country of use. Where no limit is established, keep airborne concentrations as low as reasonably practicable.
Engineering controls	Local exhaust ventilation at points of dust, mist or vapour generation. Eyewash stations and safety showers close to the work station.
Eye / face protection	Chemical safety goggles to EN 166 / IS 5983. Face shield where splashing is possible.
Skin protection	Chemical-resistant gloves to EN 374 (nitrile or butyl rubber). Chemical-resistant apron, suit and boots as required by the task.
Respiratory protection	Where ventilation is insufficient use an approved respirator with a P2/P3 particulate filter for dusts or an appropriate vapour cartridge for solvents.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White to off-white powder
Odour	Characteristic
Physical state	Solid
Flash point	Not applicable
Purity / assay	≥99% Pharma Grade
pH, melting point, boiling point, density, solubility	See the Darifenacin Hydrobromide specification sheet

10. STABILITY AND REACTIVITY

Reactivity	Stable under the recommended handling and storage conditions.
Conditions to avoid	Heat, direct sunlight, moisture, ignition sources and mechanical damage to packaging.
Incompatible materials	Strong oxidising agents, strong acids and strong bases.
Hazardous decomposition products	Oxides of carbon and other toxic fumes on thermal decomposition.

11. TOXICOLOGICAL INFORMATION

Likely routes of exposure	Inhalation, skin contact, eye contact and ingestion.
Acute toxicity	Product-specific LD50/LC50 data available from the manufacturer on request.
Carcinogenicity	Not classified as carcinogenic.
Reproductive toxicity	Not classified.

12. ECOLOGICAL INFORMATION

Aquatic toxicity	No significant ecotoxicity expected at normal use concentrations.
Persistence and degradability	Assess against local discharge consent limits before release.
Other adverse effects	Do not allow the product to enter drains, sewers or watercourses.

13. DISPOSAL CONSIDERATIONS

Waste treatment	Dispose of product and container through an authorised waste treatment or disposal facility in accordance with local, state and national regulations.
Contaminated packaging	Empty containers retain product residue. Triple-rinse where appropriate and offer for approved reconditioning or disposal.

14. TRANSPORT INFORMATION

UN number	Not regulated
UN proper shipping name	Not applicable
Transport hazard class	—
Packing group	—
Marine pollutant	No
IMDG / IATA / ADR	Not classified as dangerous goods for transport by sea, air or road.

15. REGULATORY INFORMATION

Classification system	GHS Rev. 9; CLP Regulation (EC) No. 1272/2008.
EU REACH	Registration status held by the manufacturer. A REACH statement is available on request.
India	Manufacture, Storage and Import of Hazardous Chemicals Rules, as applicable.

16. OTHER INFORMATION

Basis of classification	Assigned on the basis of the chemical class of the product and the standard commercial grade supplied. Where the manufacturer of a particular batch publishes a different classification, that classification governs.
Revision	Revision 1 — first issue
Prepared by	Quality Assurance, Scapex Exports Pvt. Ltd.

Disclaimer. This Material Safety Data Sheet is provided in good faith and is believed correct at the date of issue. It relates only to the material identified and is not a specification. It does not constitute a warranty of merchantability or fitness for a particular purpose. Users must satisfy themselves as to its suitability and completeness for their own use.