

Material Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

Product identifier: Ephedrine sulfate injection, 50mg/mL **CAS No.:** 134-72-5

Substance name: Ephedrine Sulfate **EC No.:** NA

Route of administration: Intravenous

REACH Registration No.: NA

Use: The following SDS applies only to formulated product in vials and standard shipments of these vials. If handling Ephedrine Sulfate Injection in manufacturing situations, consult the MSDS for the active ingredient and take appropriate precautions.

Pharmaceutical. Ephedrine Sulfate Injection is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

Manufacturer Name and Address: GLAND PHARMA LTD. DUNDIGAL(R&D)
Sy.No.143 to 148,150 & 151, D.P. Pally
Near Gandimaisamma X Roads, Dundigal (M)
Medchal-Malkajgiri, District Hyderabad - 500043
TELANGANA, INDIA

Telephone No.: 040-30510999

Fax No.: 040-30510800

e-Mail address: purchase@glandpharma.com

Supplier Name: Gland Pharma Limited

Telephone No.: 040-30510999

Fax No.: 040-30510800

e-Mail address: purchase@glandpharma.com

Effective Date: 04 August 2023

Revision No.: 00

SECTION 2: Hazards identification

Classification according to Regulation (EC) No 1272/2008 (CLP): Not classified

Classification According to EU-directive 67/548/EEC or 1999/45/EC: Not classified

Classification of the Substance or Mixture

Physical Hazards: Not classifiable.

Health Hazards:

Skin irritation Category 3

Eye irritation Category 2B

Specific target organ toxicity –
single exposure (respiratory tract irritation) Category 3

Symbol(s):



Hazard Statement(s):

H316 Causes mild skin irritation.

H320 Causes eye irritation.

H335 May cause respiratory irritation.

Precautionary Statement(s):

P233 Keep container tightly closed.

P261 Avoid breathing dust/fume/gas/mist/vapor/spray.

P271 Use only in a well-ventilated area.

P264 Wash potentially exposed skin after handling.
 P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 P304 + P312 IF INHALED: Call a POISON CENTER/doctor/physician if you feel unwell.
 P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P337 + P313 If eye irritation persists: Get medical advice/attention.
 P332 + P313 If skin irritation occurs: Get medical advice/attention.
 P308 + P313 IF exposed or concerned: Get medical advice/attention.
 P403 Store in a well-ventilated place.
 P405 Store locked up.
 P501 Dispose of contents/container in accordance with local/provincial/federal regulations.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: 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 No.	Ingredient %	Manufacture
Ephedrine Sulfate	134-72-5	50mg/ml	Gland
Sodium Hydroxide	1310-73-2	**	Gland
Glacial acetic acid	64-19-7	**	Gland
Water for Injection	7732-18-5	**	Gland

**The exact percentage (concentration) of composition has been withheld as a trade secret

SECTION 4: First aid measures

Description of necessary first aid measures

General: Take a copy of the Safety Data Sheet when going for medical treatment.

Inhalation: In case of inhalation, remove to fresh air. If not breathing, call 911 and provide artificial respiration. Do not use mouth-to-mouth method; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device if breathing is difficult. Seek emergency medical attention immediately.

Skin Contact: In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Eye Contact: In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Ingestion: In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-Protection of the First Aider Do not use mouth-to-mouth methods if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or another proper respiratory medical device.

Most Important Symptoms and Effects Both Acute and Delayed

Symptoms

For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Dizziness; rapid or pounding heartbeat; high blood pressure; headache; sweating; dry mouth, nose, or throat; muscle cramps; nausea; vomiting; anxiety, restlessness, or nervousness; trembling; vertigo; trouble sleeping; possible allergic reaction to material if inhaled, ingested or in contact with skin; chills; fever; seizures; spasms; rapid, pounding, or irregular heartbeat; changes in blood pressure; mood or mental changes; troubled breathing; pulmonary edema; enlarged pupils; blurred vision; nausea; vomiting; respiratory distress; hallucinations; delusions; coma.

Indication of Any Immediate Medical Attention and Special Treatment Needed

Notes to Physician: Treat symptomatically.

Hypersensitivity to any of the components of the product; pre-existing cardiovascular, kidney, nervous system or ocular diseases; enlarged prostate, psychoneurotic disorders, hypertension, diabetes mellitus history of seizures; hyperthyroidism.

SECTION 5: Firefighting measures

Extinguishing media Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific hazards arising from the substance or mixture

Hazardous Combustion Products: These products include carbon oxides, nitrogen oxides, sulfur oxides, and other hazardous products of combustion. No information identified. May emit carbon monoxide, carbon dioxide, and oxides of sulfur and nitrogen.

Flammability/Explosivity

No explosivity or flammability data identified. High airborne concentrations of finely divided organic particles can potentially explode if ignited.

Advice for firefighters In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

Special Protective Equipment/Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe dust.

Environmental precautions

Do not empty into drains. Avoid release to the environment.

For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

Methods and material for containment and cleaning up

DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter into solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container for disposal in accordance with applicable waste disposal regulations (see section 13). Decontaminate the area twice.

Measures for Cleaning /Collecting:

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

SECTION 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 (see Section 8). 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 as directed by product packaging. Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] Protect from moisture. Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Specific End Use: Pharmaceuticals, indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

SECTION 8: Exposure controls/personal protection**Control Parameters:**

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Glacial Acetic acid

USA ACGIH ACGIH TWA (ppm) 10 ppm

USA ACGIH ACGIH STEL (ppm) 15 ppm

USA OSHA OSHA PEL (TWA) (mg/m³) 25 mg/m³

USA OSHA OSHA PEL (TWA) (ppm) 10 ppm

USA NIOSH NIOSH REL (TWA) (mg/m³) 25 mg/m³

USA NIOSH NIOSH REL TWA [ppm] 10 ppm

USA NIOSH NIOSH REL (STEL) (mg/m³) 37 mg/m³

USA NIOSH NIOSH REL STEL [ppm] 15 ppm

USA IDLH US IDLH (ppm) 50 ppm

Alberta OEL STEL (mg/m³) 37 mg/m³

Alberta OEL STEL (ppm) 15 ppm

Alberta OEL TWA (mg/m³) 25 mg/m³

Alberta OEL TWA (ppm) 10 ppm
British Columbia OEL STEL (ppm) 15 ppm
British Columbia OEL TWA (ppm) 10 ppm
Manitoba OEL STEL (ppm) 15 ppm
Manitoba OEL TWA (ppm) 10 ppm
New Brunswick OEL STEL (mg/m³) 37 mg/m³
New Brunswick OEL STEL (ppm) 15 ppm
New Brunswick OEL TWA (mg/m³) 25 mg/m³
New Brunswick OEL TWA (ppm) 10 ppm
Newfoundland & Labrador OEL STEL (ppm) 15 ppm
Newfoundland & Labrador OEL TWA (ppm) 10 ppm
Nova Scotia OEL STEL (ppm) 15 ppm
Nova Scotia OEL TWA (ppm) 10 ppm
Nunavut OEL STEL (ppm) 15 ppm
Nunavut OEL TWA (ppm) 10 ppm
Northwest Territories OEL STEL (ppm) 15 ppm
Northwest Territories OEL TWA (ppm) 10 ppm
Ontario OEL STEL (ppm) 15 ppm
Ontario OEL TWA (ppm) 10 ppm
Prince Edward Island OEL STEL (ppm) 15 ppm
Prince Edward Island OEL TWA (ppm) 10 ppm
Québec VECD (mg/m³) 37 mg/m³
Québec VECD (ppm) 15 ppm
Québec VEMP (mg/m³) 25 mg/m³
Québec VEMP (ppm) 10 ppm
Saskatchewan OEL STEL (ppm) 15 ppm
Saskatchewan OEL TWA (ppm) 10 ppm
Yukon OEL STEL (mg/m³) 43 mg/m³
Yukon OEL STEL (ppm) 25 ppm
Yukon OEL TWA (mg/m³) 25 mg/m³
Yukon OEL TWA (ppm) 10 ppm

Sodium hydroxide

USA ACGIH ACGIH Ceiling (mg/m³) 2 mg/m³
USA OSHA OSHA PEL (TWA) (mg/m³) 2 mg/m³
USA NIOSH NIOSH REL (ceiling) (mg/m³) 2 mg/m³
USA IDLH US IDLH (mg/m³) 10 mg/m³
Alberta OEL Ceiling (mg/m³) 2 mg/m³
British Columbia OEL Ceiling (mg/m³) 2 mg/m³
Manitoba OEL Ceiling (mg/m³) 2 mg/m³
New Brunswick OEL Ceiling (mg/m³) 2 mg/m³
Newfoundland & Labrador OEL Ceiling (mg/m³) 2 mg/m³
Nova Scotia OEL Ceiling (mg/m³) 2 mg/m³
Nunavut OEL Ceiling (mg/m³) 2 mg/m³
Northwest Territories OEL Ceiling (mg/m³) 2 mg/m³
Ontario OEL Ceiling (mg/m³) 2 mg/m³
Prince Edward Island OEL Ceiling (mg/m³) 2 mg/m³
Québec PLAFOND (mg/m³) 2 mg/m³
Saskatchewan OEL Ceiling (mg/m³) 2 mg/m³
Yukon OEL Ceiling (mg/m³) 2 mg/m³

Exposure Controls

Appropriate Engineering Controls: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves. Protective clothing. Protective goggles

Materials for Protective Clothing: Chemically resistant materials and fabrics.

Hand Protection: Wear protective gloves.

Eye and Face Protection: Chemical safety goggles.

Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information: When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

Physical State/Color: Liquid

Appearance: Clear, Colorless with a pungent odor

Odor: No data available.

Odor Threshold: No data available.

pH: 4.5 – 7.0

Melting Point: 38.1 °C

Freezing Point: No data available.

Boiling Point: 260 °C

Flash Point: No data available.

Evaporation Rate: No data available.

Flammability (solid, gas): No data available.

Flammability Limit - Lower: No data available.

Flammability Limit - Upper: No data available.

Vapor Pressure: No data available.

Vapor Density: No data available.

Relative Density: No data available.

Solubility(ies): No data available.

Auto-Ignition Temperature: No data available.

Decomposition Temperature: No data available.

Viscosity: No data available.

SECTION 10: Stability and Reactivity**Reactivity**

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

Incompatible products

Incompatible materials

Acids. Bases. Oxidizing agents.

Hazardous decomposition products

Nitrogen oxides (NOx). Sulfur oxides.

SECTION 11: Toxicological information

Information on Toxicological Effects

General Information: The following information is available for the individual ingredients.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including chest pain, chills or fever, increased sweating, convulsions, dizziness, rapid, pounding, or irregular heart rhythm, hallucinations, headache, high or low blood pressure, nausea, or vomiting, troubled breathing, trembling, restlessness, or anxiety, blurred vision, difficult or painful urination, troubled sleeping, and weakness. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Acute Toxicity: (Species, Route, End Point, Dose)**Ephedrine sulfate**

Mouse Oral LD50 812 mg/kg

Rat Oral LD50 404mg/kg

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Ephedrine sulfate

13 Week(s)	Rat Oral,	in feed	2000 ppm	NOAEL	None identified
------------	-----------	---------	----------	-------	-----------------

13 Week(s)	Mouse Oral,	in feed	5000 ppm	NOAEL	None identified
------------	-------------	---------	----------	-------	-----------------

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**Ephedrine sulfate**

Bacterial Mutagenicity (Ames) Negative

Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Negative

Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))**Ephedrine sulfate**

2 Year(s)	Rat Oral,	in feed	250 ppm	NOAEL	Not carcinogenic
-----------	-----------	---------	---------	-------	------------------

2 Year(s)	Mouse Oral,	in feed	250 ppm	NOAEL	Not carcinogenic
-----------	-------------	---------	---------	-------	------------------

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA

Toxicokinetic/Metabolism: Prolong/enhance neural transmission; block channel gating; modulate G-protein coupled signal transduction.

Target Organ Effects: Possible target organs include the heart, lungs, cardiovascular system and central nervous system.

Reproductive Effects: No data available.

Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.

Aspiration Hazard: No data available

SECTION 12: Ecological information

Toxicity

Ecology - General: Not classified.

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be Avoided.

Sodium Hydroxide

LC50 Fish 1 5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow through])

EC50 Daphnia 1 1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)

LC50 Fish 2 12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

EC50 Daphnia 2 340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

NOEC Chronic Fish 252 mg/l (Species: Pimephales promelas)

Persistence and degradability

Ephedrine sulfate USP is reported to decompose gradually on exposure to light. The half-life for vapor-phase Ephedrine sulfate USP will be degraded in the atmosphere by reaction in air is estimated to be 4 hours.

Bioaccumulation

An estimated BCF of 1.4 suggests the potential for bioconcentration in aquatic organisms is low (Ephedrine sulfate USP). An estimated BCF of 3 suggests the potential for bioconcentration in aquatic organisms is low.

Mobility

Ephedrine sulfate USP is expected to have high mobility in soil upon an estimated Koc of 72. The Koc value of 1, suggests that Glacial Acetic acid is expected to have very high mobility in soil.

Other Adverse Effects

Other Information: Avoid release to the environment

SECTION 13: Disposal considerations

Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and

environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, territorial, provincial, and international regulations.

Disposal of Wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging Disposal should be in accordance with applicable regional, national and local laws and regulations. Do not reuse container.

US EPA Waste Number Not applicable.

California Hazardous Waste Codes Not available.

SECTION 14: Transport Information

Transport Based on the available data, this substance is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

UN number None assigned.

UN proper shipping name None assigned.

Transport hazard classes and packing group None assigned.

Environmental hazards Based on the available data, this substance is not regulated as an environmental hazard or a marine pollutant.

Special precautions for users Avoid release to the environment.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: Not applicable

SECTION 15: Regulatory information

US Federal Regulations

Ephedrine Sulfate Injection

SARA Section 311/312 Hazard Classes Health hazard - Respiratory or skin sensitization

Water for injection

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium Hydroxide

Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State Regulations

Sodium Hydroxide

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

Canadian Regulations

Sodium Hydroxide

Listed on the Canadian DSL (Domestic Substances List)

Ephedrine sulfate

CERCLA/SARA 313 Emission reporting: Not Listed

California Proposition: 65 Not Listed

Inventory - United States TSCA - Sect. 8(b): Present

Australia (AICS): Present

EU EINECS/ELINCS List: 205-154-4

Water for Injection

CERCLA/SARA 313 Emission reporting: Not Listed

California Proposition 65: Not Listed

Inventory - United States TSCA - Sect. 8(b): Present

Australia (AICS): Present

REACH - Annex IV - Exemptions from the obligations of Register: Present

EU EINECS/ELINCS List: 231-791-2

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Abbreviations and acronyms:

ACGIH - American Conference of Governmental Industrial Hygienists;

ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail;

AIHA - American Industrial Hygiene Association;

CAS# - Chemical Abstract Services Number;

CLP - Classification, Labelling, and Packaging of Substances and Mixtures;

DNEL - Derived No Effect Level;

DOT - Department of Transportation;

EINECS - European Inventory of New and Existing Chemical Substances;

ELINCS - European List of Notified Chemical Substances;

EU -European Union;

GHS - Globally Harmonized System of Classification and Labeling of Chemicals;

IARC - International Agency for Research on Cancer;

IDLH - Immediately Dangerous to Life or Health;

IATA - International Air Transport Association;

IMDG - International Maritime Dangerous Goods;

LOEL -Lowest Observed Effect Level;

LOAEL - Lowest Observed Adverse Effect Level;

NIOSH - The National Institute for Occupational Safety and Health;

NOEL – No Observed Effect Level

NOAEL - No Observed Adverse Effect Level;

NTP -National Toxicology Program;

OEL - Occupational Exposure Limit;

OSHA -Occupational Safety and Health Administration;

PNEC - Predicted No Effect Concentration;

SARA - Superfund Amendments and Reauthorization Act;

STOT -Specific Target Organ Toxicity;
STEL - Short Term Exposure Limit;
TDG -Transportation of Dangerous Goods;
TSCA - Toxic Substances Control Act;
TWA- Time Weighted Average;
WHMIS - Workplace Hazardous Materials Information System

Issue date 04-08-2023

Revision date Initial submission

Version # 00

Further information Not available

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

Disclaimer: The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a potent pharmaceutical product.