

**SAFETY DATA SHEET****Product Name** Isosulfan Blue Injection 1% (10 mg/mL)**1. Identification****Product Name:** Isosulfan Blue Injection 1% (10 mg/mL)**Chemical Family:** Mixture**Intended use:** Contrast agent for the delineation of lymphatic vessels**Details of the manufacturer:**

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

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Ranga Reddy Dist

Telangana State, India.

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2. Hazard(s) Identification

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients Moderate to severe irritant to the skin and eyes.

3. Composition/Information on Ingredients**Common Name** : Isosulfan Blue**C.A.S. No:** : 68238-36-8**Molecular Formula** : $C_{27}H_{31}N_2NaO_6S_2$ **Molecular Weight** : 566.67**Chemical Name** : N-[4-[[4-(diethylamino)phenyl](2,5-disulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-N-ethylethanaminium hydroxide, inner salt, sodium salt**4. First Aid Measures****Description Of First Aid Measures****General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).**Inhalation:** The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.**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) and seek medical advice.

Eye 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.**Ingestion:** Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

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Most Important Symptoms and Effects Both Acute and Delayed

Inhalation: May cause irritation to the respiratory tract.

Skin Contact: May cause mild skin irritation.

Eye Contact: May cause eye irritation.

Ingestion: May cause a light irritation of the linings of the mouth, throat, and gastrointestinal tract.

Injection: Isosulfan blue injection 1% has no known pharmacologic action. Following subcutaneous injection, isosulfan blue is selectively picked up by the lymphatic vessels. In studies with human volunteers administered up to 15 mg, baseline blood chemistry was not altered and no adverse reactions were observed.

Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention

Description of first aid measures:

Inhalation. No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention if cough or other symptoms develop.

Skin: No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye: If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional. For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention.

Ingestion: If swallowed, get medical help or contact a Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed: No data available

Indication of any immediate medical attention and special treatment needed Other information:

Additional details are provided on the product packaging and/or the product insert.

5. Fire Fighting Measures

Extinguishing media:

Suitable extinguishing media: Not flammable. Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media: None

Special hazards arising from the substance or mixture:

Fire hazard: Not flammable

Explosion hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions

Advice for Firefighters

Firefighting instructions: Use water spray/fog for cooling exposed containers. Exercise caution when fighting a chemical fire.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Sulfur oxides.

Firefighting Procedures: As in any fire, wear self-contained breathing apparatus and full protective gear.

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6. Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

General measures: Avoid all eye and skin contact and do not breathe vapor and mist. For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).

Emergency procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective equipment: Equipment cleanup crew with proper protection.

Environmental Precautions: Prevent entry to sewers and public waters.

Methods and Material for Containment and Cleaning Up

For containment: Absorb and/or contain spill with inert material, then place in suitable container. Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference to Other Sections: See heading 8, Exposure Controls and Personal Protection

7. Handling and Storage

Precautions for Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling

Conditions for Safe Storage, Including Any Incompatibilities

Storage conditions: Keep container closed when not in use. Store in a dry, cool place. Keep away from heat and direct sunlight.

Storage temperature: 20°C to 25°C (68°F to 77°F) Avoid excessive heat

Special rules on packaging: Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

Incompatible Materials or Ignition Sources: None specified.

Specific end use(s): Refer to product insert for usage instructions and product information

8. Exposure Controls/Personal Protection

Control Parameters: No Occupational Exposure Limits have been established for the product or its components.

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended

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exposure limits.

Personal protective equipment: Gloves

Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

Eye protection: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

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

9. Physical and Chemical Properties

Appearance	: Clear Blue color solution
pH	: Between 6.8 to 7.4
Solubility	: soluble in water, Insoluble in cyclohexane
Relative evaporation rate (butyl acetate=1)	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition Temperature	: Not available
Flammability (solid, gas)	: Not available
Vapor pressure	: Not available

10. Stability and Reactivity

Reactivity	: Hazardous reactions will not occur under normal conditions.
Chemical Stability	: Stable under normal conditions.
Possibility Of Hazardous Reactions	: Hazardous polymerization will not occur.
Conditions To Avoid	: Direct sunlight. Extremely high or low temperatures. UV light sources.
Incompatible Materials	: Oxidizers.
Hazardous Decomposition Products	: Carbon oxides (CO, CO ₂). Sulfur oxides.

11. Toxicological Information

Information on toxicological effects - Product

Acute Toxicity: Not Classified

LD50 and LC50 Data: Not available

Skin corrosion/irritation: Not classified. May cause mild skin irritation.

Serious eye damage/irritation: Not classified. May cause mild eye irritation.

Respiratory or skin sensitization: Not classified

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Germ cell mutagenicity: Not classified
Teratogenicity: Not available
Carcinogenicity: Not classified
Specific target organ toxicity (repeated exposure): Not classified
Reproductive toxicity: Not classified
Specific target organ toxicity (single exposure): Not classified
Aspiration hazard: Not classified
Information On Toxicological Effects - Ingredient(s)
LD50 and LC50 Data: Not available

12. Ecological Information

The following information is for the active ingredient Isosulfan Blue unless otherwise noted:

Toxicity: No data available.
Persistence and degradability: No data available.
Bioaccumulative potential: No data available.

13. Disposal Considerations

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.
Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. Transport Information

DOT (US): Not dangerous goods.
IMDG: Not dangerous goods.
IATA: Not dangerous goods.

15. Regulatory Information

US Federal regulations : Not applicable
US State regulations : Not applicable
Canadian regulations

Isosulfan Blue Injection, 1%

WHMIS Classification	Class D Division 2 Subdivision B - Toxic material causing other toxic effects
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This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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