

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Solution for injection

Product Name: PROVAYBLUE® (Methylene Blue) Injection

Product Codes: 0517-0374-05; 0517-0125-05; 0517-0381-05; 0517-0371-05

1.2. Intended Use of the Product

PROVAYBLUE® (Methylene Blue) is an oxidation-reduction agent indicated for the treatment of pediatric and adult patients with acquired methemoglobinemia.

1.3. Name, Address, and Telephone of the Responsible Party

Company	Supplier	Distributor
Provepharm SAS 22 rue Marc Donadille 13013 Marseille, France t: +33 (0)491 086 942 f: +33 (0)491 086 901 www.provepharm.com contact: hse@provepharm.com	<i>Ampules manufactured by:</i> CENEXI, 52 rue Marcel et Jacques Gaucher 94120 Fontenay sous-bois, France <i>Vials manufactured by:</i> CENEXI HSC 2 rue Louis Pasteur 14200 Hérouville-Saint-Clair, France	American Regent, Inc. 5 Ramsey Road P.O. Box 9001 Shirley, NY 11967 T: 1-800-645-1706 www.americanregent.com

1.4. Emergency Telephone Number

Emergency Number : CHEMTREC 1-800-424-9300

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

May cause irritation of the eyes, skin, gastrointestinal and respiratory tract.

2.4. Unknown Acute Toxicity (GHS-US): No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance Not applicable

3.2. Mixture

Name	Product identifier	Quantity/mL	Classification (GHS-US)
Methylene Blue	32680-41-4	5.0 mg	Not listed
Water for Injection	7732-18-5	q.s. 1.0 mL	Not listed

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: In case of doubt or if symptoms persist, always call a doctor

First-aid Measures After Inhalation: May cause irritation of the respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.

First-aid Measures After Skin Contact: May cause slight skin irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.

First-aid Measures After Eye Contact: Causes eye irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.

First-aid Measures After Ingestion: Ingestion causes abdominal pain and nausea. Flush mouth out with water. Seek medical attention

4.1. Most important symptoms and effects, both acute and delayed

Exposure to product may result in headache, confusion, dizziness and nausea. May cause precordial and abdominal pain and the formation of methemoglobin. See prescribing information.

4.2. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

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SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, foam, dry chemical or Carbon Dioxide (CO₂). Caution: CO₂ will displace air in confined spaces and may cause an Oxygen deficient atmosphere.

Unsuitable Extinguishing Media: None.

5.2. Special Hazards Arising From the Substance or Mixture

Reactivity: When heated, PROVAYBLUE™ thermally decomposes to form toxic vapors. (i.e. Carbon Monoxide, Carbon Dioxide, Halogenated Compounds and oxides of Sulfur and Nitrogen).

5.3. Advice for Firefighters

Firefighting Instructions: Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers.

Protection During Firefighting: PROVAYBLUE™ thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE) as identified in section 8.

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection. Refer to section 8: Exposure controls/personal protection

Emergency Procedures: Isolate the hazard area. Ventilate area.

6.2. Environmental Precautions

This material is not considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.

6.3. Methods and Material for Containment and Cleaning Up

Methods for containment: Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.

Methods for Cleaning Up: Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes and clothing. Do not mix with other drugs.

Use in a well ventilated area. Wash thoroughly after handling.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Store in a well ventilated area. Keep containers closed when not in use. Product residue may remain in empty containers. Observe all label precautions until container is cleaned, discarded or destroyed.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature]. Do not refrigerate or freeze.

Keep the ampule/vial in the original package to protect from light.

7.3. Specific End Use(s) Pharmaceutical.

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

Exposure Guidelines	OSHA PEL	ACGIH TLV	OTHER
Methylene Blue Water for Injection	Not listed Not listed	Not listed Not listed	

8.2. Exposure Controls

Appropriate Engineering Controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves. Safety glasses.



Hand Protection : Wear chemically resistant protective gloves.

Eye Protection : Chemical goggles or safety glasses.

Skin and Body Protection : Wear suitable protective clothing. Wash contaminated clothing before reuse.

Respiratory Protection : In case of inadequate ventilation wear respiratory protection.

Consumer Exposure Controls : Do not eat or drink

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, dark blue solution
Odor	: solution Odorless
Odor Threshold	: solution Odorless
pH	: 3.0 to 4.5
Relative Evaporation Rate	: Not applicable
Melting Point	: 100-110 °C (with decomposition)
Freezing Point	: Approximately 32 degrees Fahrenheit
Boiling Point	: 180°C (Decomposes)
Flash Point	: Not applicable
Auto-ignition Temperature	: Not applicable
Decomposition Temperature	: No data
Flammability (solid, gas)	: Nonflammable, noncombustible
Vapor Pressure	: applicable Not
Relative Vapor Density at 20 °C	: No data
Relative Density	: Applicable
Specific Gravity	: Approximately 1.0
Solubility	: Soluble in ethanol, chloroform; slightly soluble in pyridine; insoluble in ethyl ether Soluble in glacial acetic acid and glycerol; insoluble in xylene and oleic acid, in ethanol 2%, and in acetone 0.5%. In water, 43,600 mg/L at 25 deg C.
Partition coefficient: n-octanol/water	: No data
Viscosity	: No data

9.1. Other Information No additional information available

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SECTION 10: STABILITY AND REACTIVITY

- 10.1 Reactivity:** Reactive with alkalis, oxidizing agents, reducing agent
- 10.2 Chemical Stability:** Stable under recommended storage conditions
- 10.3 Possibility of Hazardous Reactions:**
- 10.4 Conditions to Avoid:** Avoid heat, light. Keep away from flames, thermally decomposes to form toxic vapors.
- 10.5 Incompatible Materials:** Reactive with strong Oxidizers, Reducing agents and Alkalis.
- 10.6 Hazardous Decomposition Products:** Carbon Monoxide, Carbon Dioxide, Halogenated Compounds, oxides of Sulfur and Nitrogen may be released by thermal decomposition.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Potential Acute Toxicity: Hemolytic anemia, anaphylaxis

Skin Corrosion/Irritation: Skin irritation is possible.

Serious Eye Damage/Irritation: eye irritation.

Respiratory or Skin Sensitization: No available data concerning sensitivity of this product.

Potential Chronic Toxicity

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Methylene Blue is not considered carcinogenic. No adequate and well controlled studies in humans concerning the carcinogenic effects of Methylene Blue.

Reproductive Toxicity: Animal studies concerning Methylene Blue illustrated adverse effects; decreased sperm motility. No adequate and well controlled studies in humans concerning the reproductive effects of Methylene Blue.

Developmental: Methylene Blue is not considered a teratogen; however, it may be teratogenic if used during amniocentesis. Intra-amniotic injection of pregnant women with a methylene blue class product during the second trimester was associated with neonatal intestinal atresia and fetal death.

Specific Target Organ Toxicity (Single Exposure): No data

Specific Target Organ Toxicity (Repeated Exposure): May be toxic to lungs, eyes, hematopoietic & central nervous system.

Aspiration Hazard: No data

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: No data available

12.2. Persistence and Degradability

Short term products of biodegradation are not likely. No data available on the long term degradation of the product.

12.3. Bioaccumulative Potential

No applicable bioaccumulation is expected in the environment.

12.4. Mobility in Soil

Appreciable volatilization is not expected into the air or aquatic environment.

12.5. Other Adverse Effects

No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal.

SECTION 14: TRANSPORT INFORMATION

14.1 In Accordance with DOT Not considered a DOT regulated material - Non-hazardous for shipment.

14.2 In Accordance with IMDG Not regulated for transport

14.3 In Accordance with IATA Not considered a DOT regulated material - Non-hazardous for shipment.

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

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15.2 US State Regulations

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 01/27/2022

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

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