

GE Healthcare



OPTISON™ (Perflutren Protein-Type A Microspheres Injectable Suspension, USP)

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: OPTISON™

Synonyms: None

Manufacturer: Manufactured for GE Healthcare Inc., Princeton, NJ 08540
by Mallinckrodt Inc., St. Louis, MO 63042

Technical Information No.: (800) 654-0118

CHEMTREC Emergency No.: (800) 424-9300 for US / (708) 527-3887 outside US

2. COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient :</u>	<u>CAS No.</u>	<u>% V</u>
Human Albumin, 1%	None	1
Octafluoropropane	76-19-7	<1
N-acetyltryptophan	87-32-1	<1
Caprylic acid	124-07-2	<1
Sodium chloride	7647-14-5	<1
Water	7732-18-5	98

3. HAZARD IDENTIFICATION

OPTISON™ is an ultrasound contrast agent used in humans during ultrasound imaging examinations of the heart. The contrast enhanced image facilitates improved visualization of the heart anatomy in patients with sub-optimal baseline images. Each vial contains 3 ml and is intended for intravenous injection.

Physical & Chemical Hazard Ratings (0 = no hazard)

NFPA:	Health 0	Flammability 0	Stability 0
HMIS:	Health 0	Flammability 0	Stability 0

Transportation Symbol: None

Emergency Overview: Read package insert prior to use. As part of good laboratory practice, personal hygiene and safety procedure, avoid unnecessary exposure to this substance. If exposure occurs, flush the affected area with soap and water.

Potential Health Effects: Not expected to be a health hazard via routes of entry into the body (inhalation, Ingestion, absorption or injection). No adverse effects expected upon skin or eye contact. No adverse effects expected as a result of chronic exposure. May provoke an allergic reaction in people with hypersensitivity to blood products.

4. FIRST AID MEASURES

Eyes: In case of eye contact, immediately flush eyes with water for at least 15 minutes. Call a physician if irritation develops.

Skin: Wash exposed area with soap and water. Call a physician if irritation develops.

Ingestion: No adverse effects expected. Call a physician if cramping or nausea develops.

Inhalation: No adverse effects expected, which would require first aid or other medical assistance.

Note to Physician: Treat symptomatically

5. FIRE FIGHTING MEASURES

Flammable Properties: Not flammable

Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Hazardous Combustion products: Carbon oxides

Explosion Data: None

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand. MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENT RELEASE MEASURES

SPILLS:

Since the quantity per vial is small (3 ml), spills can be absorbed with an inert material and discarded.

Wash the affected area with soap and water.

Ensure compliance with local, state and federal regulations.

7. HANDLING AND STORAGE

Handling: Always observe good laboratory and hygiene practices when handling. Avoid direct contact with the material. Wear appropriate protective clothing and impervious gloves.

Storage: Store in a refrigerator at 2-8° C in a tightly closed container. Do not freeze or expose to heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limits: This product is considered not to be hazardous and has no occupational exposure limits (e.g. PEL, TLV, IDLH, etc.) established for it.

Engineering Measures: Eyewash station and good general room ventilation

Eye/Face Protection: Avoid contact with eyes & face use eye protection

Skin & Body Protection: Avoid contact with skin cover exposed skin

Respiratory Protection: Not required

Hygiene Measures: When using, do not eat, drink or smoke. Remove and wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid solution

Autoignition Temperature: None

Appearance: Clear liquid with an upper white layer.

Flammable Limits: None

Odor: Odorless

Boiling Point: 100°C (212°F)

Solubility: Soluble in water

Melting Point: None

Specific Gravity: 0.972

Vapor Pressure (mm Hg): .760mm

Viscosity: -1.0

Evaporation Rate: <1 (water = 1)

pH: 6.4 – 7.4

Vapor Density: No data available

Flash Point: None

10. STABILITY AND REACTIVITY

Stability: Stable under specified conditions of use and storage.

Conditions to Avoid: None known

Incompatible Products: Strong oxidizing and reducing agents

Hazardous Decomposition Products: None known

Hazardous Polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity: Product does not present an acute toxicity hazard.

Carcinogenicity: No known carcinogenic effects.

Reproductive Toxicity: No known adverse reproductive effects.

Target Organ Effects: No known adverse effects to the eyes or skin.

Endocrine Disruptor Information: Does not contain known or suspected endocrine disruptors.

Other: As part of the product clinical studies, forty (40) normal subjects received injections of up to 40 ml of OPTISON™ with absence of clinically significant changes in safety parameters.

12. ECOLOGICAL INFORMATION

Ecotoxicity: Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

13. DISPOSAL CONSIDERATIONS

If medical waste is involved, such as blood, blood products and/or sharps (needle/syringes, glass, etc.), the waste must be handled as a biohazard and disposed of accordingly. If not a biohazard, waste OPTISON™ is considered non-hazardous. Consult local, state and federal regulations for proper disposal.

14. TRANSPORT INFORMATION

DOT: Not regulated

IATA: Not regulated

TDG: Not regulated

IMDG/IMO: Not regulated

MEX: Not regulated

RID: Not regulated

ICAO: Not regulated

ADR: Not regulated

15. REGULATORY INFORMATION

OSHA Hazard Communication: This product is not considered hazardous under the OSHA Hazard Communication Standard (29 CFR 1910.1200) guidelines.

CERCLA Reportable Quantities: Not regulated

SARA Title III: Not regulated

CWA: Not regulated

RCRA hazardous Waste Status: Non-hazardous (See Section 12 for details)

California Proposition 65: Not regulated

Mexico: Minimum risk, Grade = 0

Canada: WHMIS Hazard Class = Non-controlled

16. OTHER INFORMATION

Issue Date: 31-Aug-07

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