

## SAFETY DATA SHEET

Version 3.2 9/23/2025

<b>SECTION 1: PRODUCT AND COMPANY IDENTIFICATION</b>	
<b>PRODUCT NAME:</b>	DEFINITY®
<b>Synonyms</b>	Luminy®; DMP 115; MRX 115; Perflutren Protein-Type A Microspheres
<b>Product Uses</b>	This material is used as a medical imaging agent.
<b>COMPANY IDENTIFICATION:</b>	<b>Lantheus</b> 201 Burlington Road, South Building Bedford, MA 01730 United States of America 1-800-299-3431
<b>EMERGENCY PHONE:</b>	<b>CHEMTREC 1-800-424-9300</b> For International Transportation Emergencies Call CHEMTREC@ 1-703-527-3887 Collect calls are accepted

<b>SECTION 2: HAZARDS IDENTIFICATION</b>	
<b>Classification</b>	This material is not considered hazardous under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)
<b>Label Elements</b>	None Required
<b>Hazards not otherwise classified (HNOC)</b>	None identified

<b>SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS</b>		
<b>Component</b>	<b>Concentration</b>	<b>CAS</b>
Water	>50%	7732-18-5
Glycerin	>10	56-81-5
Propylene Glycol	>1%	57-55-6
Lipid Blend SG896	<1%	Not Available
Perfluoropropane	<1%	76-19-7
Sodium Chloride	<1%	7647-14-5

Disodium orthophosphate-heptahydrate	<1%	7782-85-6
Sodium phosphate monobasic	<1%	10049-21-5

**SECTION 4: FIRST AID MEASURES**

<p><b>Eye Contact</b> Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention if symptoms occur.</p>
<p><b>Skin Contact</b> Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention if symptoms occur.</p>
<p><b>Inhalation</b> Move to fresh air. If breathing is difficult, give oxygen. Obtain medical attention if symptoms occur.</p>
<p><b>Ingestion</b> Do not induce vomiting. Obtain medical attention if symptoms occur.</p>
<p><b>Note to Physicians</b> This material is used as a medical imaging agent. This product may cause: headache, chest pain, cardiac irregularities, back pain, skin flushing, injection site reactions, dizziness, breathing difficulties, pain, tingling, itching, nausea, vomiting, abdominal pain, diarrhea, and changes in white blood cell parameters. Organs effected may include: lungs, central nervous system.</p>

**SECTION 5: FIRE-FIGHTING MEASURES**

<p><b>Flammable Properties</b> Material is an aqueous solution. Not expected to be flammable.</p>
<p><b>Suitable Extinguishing Media</b> Use agent most appropriate to extinguish surrounding fire.</p>
<p><b>Protection of Firefighters</b> In the event of fire, wear self-contained breathing apparatus.</p>

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

<p><b>Personal Precaution</b> Use personal protective equipment as required. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing.</p>
<p><b>Environmental Precautions</b> Avoid release to the environment.</p>
<p><b>Methods for Containment and Clean Up</b> Soak up with inert absorbent material. Keep in suitable, closed container for disposal.</p>

**SECTION 7: HANDLING AND STORAGE**
**Handling Precautions**

Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid ingestion and inhalation.

**Storage Conditions**

Keep refrigerated. (2 - 8 °C)

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**
**Exposure Limit(s)**

Component	ACGIH	OSHA	NIOSH
Glycerin	---	---	Total: 10 mg/m <sup>3</sup> Respirable: 5 mg/m <sup>3</sup>

**Engineering Controls and Ventilation**

Ensure adequate ventilation, especially in confined areas. Ensure that eye wash stations and safety showers are close to the workstation location.

**Respiratory Protection**

Follow the OSHA respirator regulations found in 29 CFR 1910.134. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

**Eye/Face Protection**

Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133.

**Skin and Body Protection**

Wear appropriate protective gloves and clothing to prevent skin exposure.

**Hygiene Measures**

Wash hands and face before breaks and immediately after handling the product.

<b>SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES</b>	
<b>Physical State</b>	Liquid
<b>Appearance</b>	Clear, translucent
<b>Odor</b>	Odorless
<b>pH</b>	6.2-8
<b>Molecular Weight</b>	Not Available
<b>Solubility</b>	Soluble
<b>Flashpoint</b>	>200F
<b>Density</b>	Not Available
<b>Boiling Point</b>	Not Available
<b>Melting Point</b>	Not Available
<b>Vapor Density</b>	Not Available
<b>Vapor Pressure</b>	Not Available

<b>SECTION 10: STABILITY AND REACTIVITY</b>	
<b>Stability</b>	Stable under normal conditions.
<b>Conditions to Avoid</b>	Not Available
<b>Incompatible Products</b>	Not Available
<b>Hazardous Decomposition Products</b>	None under normal use conditions
<b>Hazardous Reactions</b>	None under normal processing

<b>SECTION 11: TOXICOLOGY INFORMATION</b>	
<b>Routes of Entry</b>	Ingestion, Inhalation, Eye Contact, Skin Contact
<b>Eye Irritation</b>	Not irritating to eyes
<b>Skin Irritation</b>	Possible mild skin irritation
<b>Respiratory Irritation</b>	Not Available
<b>Sensitization</b>	Not Available
<b>Acute Toxicology</b> DEFINITY® LD <sub>50</sub> (rat, intravenous): 10 mL/kg Maximum nonlethal dose (dog, intravenous): 5 mL/kg LD <sub>50</sub> (Monkey, intravenous): 5 mL/kg	
<b>Repeated Dose Toxicity</b> DEFINITY® 1 months intravenous (daily) rat study: LOAEL = 0.1 mL/kg Effects include: breathing difficulties, convulsions, behavioral changes, unconsciousness, death. Microscopic changes were observed in the following organs: lungs, lymph nodes.  1 months intravenous (daily) rat study with recovery period (1 months ): NOAEL = 0.03 mL/kg microscopic changes were observed in the following organs: lungs. After recovery, all parameters returned to normal.  1 Weeks intravenous (daily) dog study : LOAEL = 0.01 mL/kg Effects include: redness and swelling of skin, salivation, increased urine volume, hypoactivity, labored respiration, rapid respiration, ataxia, weakness, collapse, tremors.  1 months intravenous (daily) Monkey study with recovery period (1 months ): NOAEL = 0.3 mL/kg (males and females). Effects include: salivation, dilated pupils, hypoactivity, uncoordination, decrease in heart rate, labored respiration, death. After recovery, all parameters returned to normal.  1 months intravenous (daily) Monkey study: NOAEL = 1 mL/kg/day (males and females). Effects include: weakness, collapse, death.	

**Genetic Toxicity**

DEFINITY®

**in vitro**

Ames reverse-mutation assay -- negative  
 Forward gene mutation assay -- negative  
 Chromosome aberrations assay -- negative

**in vivo**

intravenous, Mutagenicity (micronucleus test) (mouse) -- negative  
 intravenous, Mutagenicity (micronucleus test) (rat) -- negative

**Mutagenicity Assessment**

This material was negative in a battery of in vivo and in vitro genotoxicity assays.

**Carcinogenicity**

Not Available

**Reproductive/Developmental Toxicity**

DEFINITY®

Intravenous (daily) Study of Fertility and Early Embryonic Development (rat): NOAEL = 1 ml/kg (parent, males and females). Effects include: death.

No effects were found on mating or fertility.

Intravenous (daily) Study of Embryo-Fetal Development (rat): NOAEL = 2 ml/kg (embryo/fetus).

No significant adverse effects were observed. intravenous (daily) Study of Embryo-Fetal Development (rabbit): NOAEL = 2.5 ml/kg (parent, females).

Maternal effects include: breathing difficulties, muscle rigidity, convulsions, collapse, death. No effects were observed in the fetus/embryo.

**Target Organs**

DEFINITY®: lungs, central nervous system

**Symptoms**

DEFINITY®: See "Human Experience"

**Other Toxicity Information**

Not Available

**SECTION 12: ECOLOGICAL INFORMATION**
**Environmental Fate**

Not Available

**Environmental Toxicity**

Not Available

**SECTION 13: DISPOSAL CONSIDERATIONS**
**Advice on Disposal and Packaging**

Disposal should be in accordance with applicable regional, national, and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

**SECTION 14: TRANSPORT INFORMATION**
**DOT**

Not Regulated

**IATA**

Not Regulated

**SECTION 15: REGULATORY INFORMATION**
**United States of America**

OSHA Hazard  
Classification

Not Applicable

313 Toxic Release Inventory

No components listed on the SARA 313 inventory.

Listed  
Chemicals/Compounds  
TSCA Inventory

Not listed. Food, drug and cosmetic products are exempt from TSCA.

**International**
**Canada**

WHMIS

Product is not according to Control Products Regulations.

DSL/NDSL

Yes

**Mexico**

Mexico Classification Health classification - Minimal hazard - 0 - Substances that do not pose a hazard under emergency conditions other than that of ordinary combustible materials.

**Europe**

EINECS/ELINCS Number

Perfluoropropane: 200-941-9  
Water: 231-791-2  
Glycerin: 200-289-5  
Propylene Glycol: 200-338-0  
Sodium Chloride: 231-598-3

R-phrase(s)

Product is not classified as dangerous according to Directives 1999/45/EC and 67/548/EEC

**SECTION 16: OTHER INFORMATION****SDS Preparation Information**

<b>Prepared by</b>	Environment, Health and Safety 1-978-671-8673
<b>Prepared on</b>	9/23/2025

The information contained in this SDS is believed to be accurate and represents the best information reasonably available at the time of preparation. However, we make no warranty, express or implied, with respect to such information and we assume no liability from its use.