SAFETY DATA SHEET

Version 3.2 12/1/2022

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Definity®

Synonyms Luminity®; DMP 115; MRX 115; Perflutren Protein-Type A Microspheres

Product Uses This material is used as a medical imaging agent.

COMPANY IDENTIFICATION: **Lantheus**
331 Treble Cove Road
Billerica, MA 01862
United States of America
1-800-299-3431

EMERGENCY PHONE: **CHEMTREC 1-800-424-9300.**
For International Transportation Emergencies Call CHEMTREC @ 1-703-527-3887.
Collect Calls are accepted

SECTION 2: HAZARDS IDENTIFICATION

Classification
This material is not considered hazardous under 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Label Elements
None required

Hazards not otherwise classified (HNOC)
None identified

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Component	Concentration	CAS
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

Eye contact
Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Obtain medical attention if symptoms occur.

Skin contact
Wash off immediately with plenty of water for at least 15 minutes. Obtain medical attention if symptoms occur.

Inhalation
Move to fresh air. If breathing is difficult, give oxygen. Obtain medical attention if symptoms occur.

Ingestion
Do not induce vomiting. Obtain medical attention if symptoms occur.

Note to Physicians
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.

SECTION 5: FIRE-FIGHTING MEASURES

Flammable Properties
Material is an aqueous solution. Not expected to be flammable.

Suitable Extinguishing Media
Use agent most appropriate to extinguish surrounding fire.

Protection of Firefighters
In the event of fire, wear self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precaution
Use personal protective equipment as required. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing

Environmental Precautions
Avoid release to the environment

Methods for Containment and Clean Up
Soak up with inert absorbent material. Keep in suitable, closed container for disposal.

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^3 Respirable: 5 mg/m^3

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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Liquid
Appearance	Clear, translucent
Odor	Odorless
pH	6.2-8
Molecular Weight	Not Available
Solubility	Soluble
Flashpoint	>200F
Density	Not Available
Boiling Point	Not Available
Melting Point	Not Available
Melting Point	Not Available
Vapor Density	Not Available
Vapor Pressure	Not Available

SECTION 10: STABILITY AND REACTIVITY

Stability	Stable under normal conditions.
Conditions to Avoid	Not Available
Incompatible Products	Not Available
Hazardous Decomposition Products	None under normal use conditions
Hazardous Reactions	None under normal processing

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, Inhalation, Eye Contact, Skin Contact
Eye Irritation	Not irritating to eyes.
Skin Irritation	Possible mild skin irritant
Respiratory Irritation	Not Available
Sensitization	Not Available

Acute Toxicity
Definity®
LDlo (rat, intravenous): 10 mL/kg
Maximum nonlethal dose (dog, intravenous): 5 mL/kg
LDlo (Monkey, intravenous): 5 mL/kg

Repeated Dose Toxicity
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

Prepared by	Environment, Health and Safety 1-978-671-8673
Prepared on	12/1/2022

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.