



SAFETY DATA SHEET

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Definity® / Luminity®

Version 3.1 10/4/2015

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

COMPANY IDENTIFICATION: **Lantheus Medical Imaging**
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

EMERGENCY OVERVIEW:

Appearance	Clear, translucent liquid
Signal Word	Caution!
Hazard Statements	Target Organs: lungs, central nervous system.
Precautionary Measures	Avoid ingestion, inhalation, skin and eye contact. Wash hands after handling to minimize exposure.
Potential Health Effects	
Eyes	Not irritating to eyes
Skin	Possible mild skin irritation
Ingestion	Not Available
Inhalation	Not Available
Target Organs	Lungs, central nervous system

Signs and Symptoms Acute: headache, chest pain, cardiac irregularities, Back pain, skin flushing, injection site reactions, dizziness, breathing difficulties, pain, tingling, itching, nausea, vomiting, abdominal pain, diarrhea, changes in white blood cell parameters.

Environmental Effects Not Available

SECTION 3: COMPOSITION INFORMATION ON INGREDIENTS

Substance Definity® / Luminity®

Chemical Identity Aqueous Mixture

Common Name/Synonym: DMP 115; MRX 115; Perflutren Protein-Type A Microspheres Injectable Suspension

Hazardous Components

Component	Concentration	CAS
Glycerin	>10	56-81-5
Lipid Blend SG896	<1%	Not Available

Nonhazardous Components

Water	>50%	7732-18-5
Perfluoropropane	<1%	76-19-7
Propylene Glycol	>1%	57-55-6
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.
Skin contact	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation occurs, get medical advice/attention.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Obtain medical attention.
Ingestion	Obtain medical attention. Do NOT induce vomiting. Never give anything by mouth to an unconscious person.
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, changes in white blood cell parameters. Organs effected may include: lungs, central nervous system. Material not fully tested. Refer to Section 11. Pregnant or nursing women should avoid exposure.
Medical Surveillance	Employees, who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring worker's health.

SECTION 5: FIRE-FIGHTING MEASURES

Flammable Properties	Not Available
Extinguishing Media	Suitable extinguishing media: Dry chemical, Water spray, Foam Unsuitable extinguishing media: Do NOT use water jet.
Protection of Firefighters	Specific hazards: Not available. Protective equipment: Use personal protective equipment. In the event of fire, wear self-contained breathing apparatus.
Hazardous Combustion Products	Carbon oxides, nitrogen oxides (NOx)
Other Information	Decontaminate protective clothing and equipment before reuse.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precaution	Refer to protective measures listed in sections 7 and 8. Use personal protective equipment. Examples include tightly fitting safety goggles, lab coat and impervious gloves. Depending on the nature of the spill (quantity and extent of spill) additional protective clothing and equipment such as a self-contained breathing apparatus may be needed.
Environmental Precautions	Prevent release to drains and waterways. Prevent release to the environment.
Containment Methods	Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see section 13).
Cleanup Methods	Contain and collect spillage and place in container for disposal according to local regulations (see Section 13). Handle waste materials, including gloves, protective clothing, contaminated spill cleanup material, etc., as appropriate for chemically and pharmacologically similar materials.

SECTION 7: HANDLING AND STORAGE

Handling Precautions	Avoid exposure. Avoid inhalation of vapor or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways. <i>For a complete discussion of Handling and Storage information, please consult the full prescribing information.</i>
Storage Conditions	Keep refrigerated. (2 - 8 °C)
Container Requirements	Store in original container. Store in glass vials. Keep away from heat, sparks and flames.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Definity®	---	---	---	---
Glycerin	---	---	10mg/m ³ total 5mg/m ³ Respirable	---
Propylene Glycol	---	---	---	---



Exposure Control Banding Not Available

Lantheus Medical Imaging Exposure Guidelines Summary Not Available

Recommended Industrial Hygiene Monitoring Methods

Refer to any applicable NIOSH, OSHA or ASTM methods.

Engineering Controls and Ventilation

When handling small quantities in a clinical setting, good room ventilation is desirable. Specific engineering controls should not be needed. When handling larger quantities, such as in a manufacturing setting, ensure worker exposure is below the recommended exposure limit. If significant aerosol (mist) is generated, use process enclosures, containment technology, or other engineering controls to keep airborne levels below recommended exposure limit.

Respiratory Protection

Respiratory protection is not required for normal use of this material. If the occupational exposure control limit (ECL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the ECL.

Eye Protection

Follow good chemical hygiene practices when using clinical or consumer presentations. Safety glasses or goggles are recommended if eye contact is possible.

Hand Protection

Follow good chemical hygiene practices when using clinical or consumer presentations. Wear protective gloves when working with large quantities.

Skin and Body Protection

Follow good chemical hygiene practices when using clinical or consumer presentations. It is recommended that a laboratory coat or other chemical protective Garment is worn when this handling product.

Hygiene

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical State	Liquid
Color	Clear, translucent
Odor	Odorless

Physical and Chemical Properties

Molecular Weight	Not Available
Solubility	Soluble
Flashpoint	>200F
Density	Not Available
pH	6.2-8
Boiling Point	Not Available
Freezing Point	Not Available
Melting Point	Not Available
Vapor Density	Not Available
Vapor Pressure	Not Available

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability	Stable under normal conditions.
Conditions to Avoid	Not Available
Incompatible Products	Not available
Hazardous Decomposition Products	Hazardous decomposition products formed under fire conditions: Carbon oxides, nitrogen oxides (NOx).
Hazardous Reactions	None known. Stable under normal conditions. Hazardous polymerization does not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

Routes of Entry	Ingestion, Inhalation, Eye Contact, Skin Contact
Eye Irritation	Definity® Not Irritating to Eyes.
Skin Irritation	Definity® Possible mild skin irritant
Respiratory Irritation	Not Available
Sensitization	Not Available
Acute Toxicity	Acute toxicity (other routes of administration) <i>Definity®</i> 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

	ACGIH	OSHA	NTP	IARC
Definity®	---	---	---	---

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.

Clinical Trials

Definity®
 Symptoms: headache, chest pain, cardiac irregularities, Back pain, skin flushing, injection site reactions, dizziness, breathing difficulties, taste disturbance, pain, tingling, itching, nausea, vomiting, abdominal pain, diarrhea. Other effects include: changes in white blood cell parameters.
 Post-marketing experience in patients: serious immediate hypersensitivity reactions, which could be life threatening, have been rarely (<1:10,000 Definity® procedures) reported following the administration of Definity®, therefore, patients should be closely monitored.

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:

Ecotoxicological Information (Aquatic) Not available
 Ecotoxicological Information (Terrestrial) 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

US DOT Transportation Classification for All Modes

Proper shipping name	N/A
This material is not a dangerous good for the purpose of transportation.	
Hazard Class	N/A
UN No.	N/A
Packing Group	N/A
Label Codes	N/A
Marine Pollutant:	No
Special Precautions	NA

SECTION 15: REGULATORY INFORMATION

United States of America

OSHA Hazard Classification	Hazardous, Target Organs
313 Toxic Release Inventory.	No components listed on the SARA 313 inventory.
Listed Chemicals/Compounds	
TSCA Inventory	Yes

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

MSDS preparation information

Prepared by

Environment, Health and Safety 1-978-671-8673

Prepared on

11/4/2015

The information contained in this MSDS 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.