

Material Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION	
<i>Product Information</i>	
Product Name	Definity®
Version	2.1, 05/21/2008
Synonyms	DMP 115; MRX 115; Perflutren Protein-Type A Microspheres Injectable Suspension, Luminity® (in Europe)
Product Uses	This material is used as a medical imaging agent.
<i>Company Identification</i>	
Address	Lantheus Medical Imaging 331 Treble Cove Road Billerica, MA 01862 United States Of America 1-800-299-3431
Emergency Phone Number	CHEMTREC 1-800-424-9300. For all international transportation emergency call CHEMTREC at 1-703-527-3887. Collect calls accepted.

2. COMPOSITION INFORMATION ON INGREDIENTS		
Components	Concentration	CAS No.
<i>Hazardous Components</i>		
Glycerin	> 10 %	56-81-5
Lipid Blend SG896	< 1 %	Not available
<i>Other Ingredients</i>		
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

3. HAZARDS IDENTIFICATION	
<i>Emergency Overview</i>	
Appearance	Liquid: clear translucent
Signal Word	Warning!
Hazard Statements	Target Organs: lungs, central nervous system.
Precautionary Measures	Avoid ingestion, inhalation, skin and eye contact. Wash hands after handling to minimize exposure.
<i>Potential Health Effects</i>	
Eyes	Not irritating to eyes.
Skin	Possible mild skin irritant.
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, diarrhoea, changes in white blood cell parameters.
<i>Environmental Effects</i>	
	Not available

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.
Notes 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, diarrhoea, 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.

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 (NO _x).
Other Information	Decontaminate protective clothing and equipment before reuse.

6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	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.

7. HANDLING AND STORAGE	
Handling Precautions	Avoid exposure - obtain special instructions before use. Avoid inhalation of vapour or mist. Keep away from heat and sources of ignition. Prevent release to drains and waterways.
Storage Conditions	Keep refrigerated. (2 - 8 °C)
Container Requirements	Store in original container. Store in glass vials. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION				
Exposure Limit(s)	Company Guideline	ACGIH	OSHA	NIOSH
Definity®	---	---	---	---
Glycerin	---	10 mg/m ³ TWA	10 mg/m ³ TWA 5 mg/m ³ TWA	---
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 limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.			
Eye Protection	Follow good chemical hygiene practices when using clinical or consumer presentations. Glasses or goggles are recommended if eye contact is possible.			
Hand Protection	Follow good chemical hygiene practices when using clinical or consumer presentations. Wear 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 be worn when handling product.			
Hygiene	Wash hands and face before breaks and immediately after handling the product.			

9. PHYSICAL AND CHEMICAL PROPERTIES	
<i>Appearance</i>	
Physical State	Liquid
Color	Clear, translucent
Form	Not available
<i>Descriptive Properties</i>	
Molecular Weight	Not available
Odor	Odorless
pH	5.5 - 7.5

9. 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 (NO _x).
Hazardous Reactions	None known. Stable under normal conditions. Hazardous polymerization does not occur.

10. TOXICOLOGICAL INFORMATION	
Routes of Entry	Ingestion, Inhalation, Eye Contact, Skin Contact
Eye Irritation	<u>Definity®</u> Not Irritating to Eyes.
Skin Irritation	<u>Definity®</u> Possible mild skin irritant.
Respiratory Irritation	Not available
Sensitization	Not available
Acute Toxicity Study	Acute toxicity (other routes of administration) <u>Definity®</u> LD ₅₀ (rat, intravenous): 10 mL/kg Maximum nonlethal dose (dog, intravenous): 5 mL/kg LD ₅₀ (Monkey, intravenous): 5 mL/kg
Repeated Dose Toxicity	<u>Definity®</u> 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	<u>Definity®</u> 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		<u>Definity®</u> 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 <u>Definity®</u> 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, diarrhoea. 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		<u>Definity®</u> lungs, central nervous system		
Symptoms		<u>Definity®</u> See "Human Experience".		
Other Toxicity Information		<u>Not available</u>		

11. ECOLOGICAL INFORMATION	
Ecotoxicological Information (Aquatic)	Not available
Ecotoxicological Information (Terrestrial)	Not available
Chemical Fate	Not available.

12. 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.

13. TRANSPORT INFORMATION*Transportation Classification for All Modes:*

This material is not a dangerous good for the purpose of transportation.

14. 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 as it is 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.

EuropeEINECS/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.

15. OTHER INFORMATION

MSDS preparation information

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

Prepared on 5/21/08

Other information

HMIS	Health	1*	
	Flammability	1	
	Reactivity	1	
	Personal Protective Equipment	See Section 8.	
	Health	1	
	Fire	1	
	Reactivity	ND	
	Special	ND	

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.