GE Healthcare

PRODUCT INFORMATION DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

1.1 **Product Identifier**: **OPTISON™**

Synonym: Perflutren Protein-Type A Microspheres, Injectable Suspension

1.2 **Relevant use**: OPTISON™ is an ultrasound contrast agent used in humans during ultrasound imaging examinations of the heart. Each vial contains 3 ml and is intended for intravenous injection.

1.3 **Supplier**: GE Healthcare AS, , P.O. Box 4220 Nydalen, 0401 Oslo, Norway

Contact: +47 2318 5050 Fax no: +47 23186060. http://www.gehealthcare.com

1.4 **Emergency Phone No**: Giftinformasjonssentralen: +47 22591300 (Norway)

2. HAZARDS IDENTIFICATION

2.1 **Classification of the substance:** OPTISON™ is not classified as hazardous according to Regulation (EC) No 1272/2008

Potential adverse health effects: Not expected to be a health hazard via routes of entry into the body (inhalation, ingestion, absorption or ingestion). 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.

2.2 **Label elements:** None required

2.3 **Other hazards:** None identified

3. COMPOSITION, INFORMATION ON INGREDIENTS

Composition:

	CAS no.
Human Albumin, 1%	none
Octafluoropropane	76-19-7
N-acetyltryptophan	87-32-1
Caprylic acid	124-07-2
Sodium chloride	7647-14-5
Water	7732-18-5

4. FIRST-AID MEASURES

Description of first aid measures:

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

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

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

Ingestion: No adverse effects expected

5. FIRE-FIGHTING MEASURES

Flammable properties: Not flammable, water based.

5.1 **Extinguishing Media**: Use extinguishing measures that are appropriate to the surrounding environment.

5.2 **Special hazards arising from the substance or mixture.** None.

5.3 **Advice for firefighters:** Use personal protective equipment and extinguishing media appropriate for surrounding fire.

6. ACCIDENTAL RELEASE MEASURES

6.1 **Personal precautions, protective equipment and emergency procedures**: Since the quantity per vial is small, spills can be absorbed with an inert material and discarded.

6.2 **Environmental precautions**: None

6.3 **Methods and material for containment and cleaning up**: Wash the affected area with soap and water.

7. HANDLING AND STORAGE

7.1 **Precautions for safe handling**: Always observe good laboratory and hygiene practices when handling. Avoid direct contact with the material. Wear appropriate protective clothing and gloves.

The product is sensitive to sudden blows and should be handled gently, avoiding vigorous shaking or a severe impact, such as dropping a vial on the floor.

7.2 **Conditions for safe storage**: Store in a refrigerator at 2-8°C in a tightly closed container. Do not freeze or expose to heat.

7.3 **Specific end use:** OPTISON™ is a suspension of microspheres. The product should be re-suspended by gently rotating the vial before use. The product should be used within 30 min of penetrating the stopper.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 **Control parameters.** The product is not considered hazardous and has no exposure limits.

8.2 **Exposure controls**

Eye protection: Wear safety glasses

Skin protection: Wear suitable clothing and gloves.

Ventilation: No specific requirements

9. PHYSICAL AND CHEMICAL PROPERTIES

a)	**Appearance**:	Clear liquid with an upper white layer. Homogenous white suspension after mixing.
b)	**Odour**:	Odourless
c)	**Odour threshold**:	Not relevant
d)	**pH**	6.4-7.4
e)	**Melting point**:	~0°C
f)	**Initial boiling point and boiling range**	~100°C
g)	**Flash point**	None
h)	**Evaporation rate**	<1 (water=1)

i)	**Flammability (solid, gas)**	Not flammable
j)	**Upper/lower flammability or explosive limits**	None
k)	**Vapour pressure**	
l)	**Vapour density**	No data available
m)	**Relative density**	0.97 g/ml
n)	**Solubility(ies)**	Soluble in water
o)	**Partition coefficient: n-octanol/water**	No data available
p)	**Auto-ignition temperature**	None
q)	**Decomposition temperature**	No data available
r)	**Viscosity**	-1.0
s)	**Explosive properties**	None
t)	**Oxidising properties**	None

10. STABILITY AND REACTIVITY

10.1 **Reactivity**: Stable under specified conditions of use and storage.

10.2 **Conditions to avoid**: None known

10.3 **Incompatible materials**: Strong oxidizing and reducing agents

10.4 **Hazardous decomposition products** None known

11. TOXICOLOGICAL INFORMATION

As part of clinical studies, injections in healthy volunteers of up to 40 ml of OPTISON™ have been performed with no clinically significant changes in safety parameters.

12. ECOLOGICAL INFORMATION

12.1 **Toxicity:** Product does not present an acute toxicity hazard. LD50 has not been determined.

12.2 **Persistence and degradability:** Contains no substances known to be hazardous to the environment or that are not biodegradable

13. DISPOSAL CONSIDERATION

Waste treatment methods: Waste of OPTISON™ is considered non-hazardous. If medical waste is involved (blood, blood products, needles/syringes) the waste should be handled as a biohazard and disposed of accordingly.

14. TRANSPORT INFORMATION

Not regulated (no UN No. in ADR)

An outer carton must always be used for transport. For product integrity: The product should be transported upright at 2-8°C but will tolerate room temperature (up to 25°C) for 24 hours. Product must not be frozen.The product is sensitive to sudden blows and the packaging contains glass and should be handled with care. Protect against light and heat sources.

15. REGULATORY INFORMATION

15.1 **Safety, health and environmental regulations/legislation specific for the substance or mixture**
None

15.2 **Chemical safety assessment**

A chemical safety assessment has not been carried out.

16. OTHER INFORMATION

According to Chapter 1.5.2 of the UN Globally Harmonised System of classification and labeling of chemicals (GHS), Article 58 (2)(a), and Article 59(2)(b) of (EC) No 1272/2008 (CLP), which amends REACH article 31(1), safety data sheets are only required for substances and mixtures that meet the harmonised criteria for physical, health or environmental hazards. Since **OPTISON™** does not meet these criteria; a safety data sheet is not issued. In order to communicate relevant HSE information, this product safety information (PSI) is provided instead.

REACH article 31(7) requires relevant exposure scenarios from the Chemical Safety Report (CSR) to be placed into the annex to the Safety Data Sheet. According to REACH Annex I, section 0., subsection 0.6. no 4 and 5 however, exposure scenarios are only required for hazard-classified substances or preparations. Since **OPTISON™ is** not hazard-classified; there is no requirement for exposure scenarios.

Updated: May 2014

GE Healthcare

September 25, 2014

Subject: Exemption to HR3204

To Whom It May Concern,

On Wednesday, November 27, 2013, President Obama signed into law H.R. 3204, the "Drug Quality and Security Act," which clarifies the authority of FDA to regulate specialty compounded (altered) drugs; creates a new voluntary program for FDA to regulate entities engaged in batch compounding that elect to register with the Agency; and establishes authority for FDA to develop a national track-and-trace system to secure the pharmaceutical supply chain and minimize opportunities for contamination, adulteration, diversion, or counterfeiting.

Subchapter H—Pharmaceutical Distribution Supply Chain of the bill begins the section in regard to FDA authority to develop a (US) national "track-and-trace system. On Page 38 of this subchapter (see excerpt provided with this letter) under the definition of Product, it is stated that:

> The term 'product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but … does not include…radioactive drugs or … imaging drugs…."

The exclusion noted in this definition covers all GE Healthcare Life Sciences – Core Imaging medical contrast and radiopharmaceutical imaging agents. Thus GE Healthcare medical imaging agents are excluded from the (US) national "track-and-trace requirements of HR3204.

Sincerely,

GE Healthcare Life Sciences – Core Imaging
Fred Longenecker
USCan Regulatory Site Head (Acting)

General Healthcare
Life Sciences – Core Imaging
101 Carnegie Center
Princeton, NJ 08540

"(13) PRODUCT.—The term 'product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (21(B)), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B.

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