

SAFETY DATA SHEET


Section 1: Identification	
Contents	Description
(a). Product identifier used on the label	Neuraceq® Solution for Injection
(b). Other means of identification	Florbetaben (18F)
(c). Recommended use of the chemical and restrictions on use	for intravenous diagnostic use, by authorized medical professionals only
(d). Responsible Party:	Lantheus Biosciences Ltd. 25 Barnes Wallis Road Fareham Hampshire PO15 5TT UK
(e). Manufacturer:	SOFIE CO. 21000 Atlantic Blvd., Suite 730 Dulles, Virginia 20166 USA Phone +1 703 787 7900
(f). Emergency Phone Number	ChemTrec (American Chemistry Council) Local phone number +1 703 527 3887 Toll-free phone number +1 800 424 9300
Section 2: Hazard(s) Identification	
Contents	Description
(a). Emergency Overview	<p>Combustible liquid. Flammable vapor. Slightly hazardous in case of skin contact (irritant, permeator), of eye contact (irritant), of ingestion, of inhalation. In high concentration, vapors and aerosol mists has a narcotic effect and may cause headache, fatigue, dizziness and nausea.</p> <p>The material is a radioactive diagnostic agent containing Fluorine¹⁸ and should be handled with appropriate safety measures to minimize radiation exposure during transport, storage, emergencies and administration. Radiopharmaceuticals should only be</p>

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	<p>administered to humans under the control of physicians who are qualified by specific training and experience in the safe use and handling of radioactive materials, and whose experience and training have been approved by the appropriate governmental agency authorized to license the administration of radiopharmaceuticals. Radioactive materials should only be handled by personnel who are qualified by specific training and experience in the safe use and handling of radioactive materials and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radioactive materials.</p>
(b). Hazard Components	<<0.1% Florbetaben (18F), CAS#: 902143-01-5
(c). Hazard Statements	Flammable, health hazard (respiratory sensitization), environmental hazard
(d). Pictograms	
(e). Precautionary statements:	Avoid eye and skin contact, avoid inhalation and ingestion
(f). Description of other hazards	<p>Potential Health Effects</p> <p>Route of exposure: Inhalation. Eye Contact. Ingestion.</p> <p>Eyes Causes eye irritation</p> <p>Skin May cause slight skin irritation</p> <p>Inhalation May cause central nervous system effects, headache, dizziness and nausea.</p> <p>Ingestion May result in central nervous system effects including headache, sleepiness, dizziness, slurred speech and blurred vision.</p>

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Section 3: Composition/Information on Ingredients			
Contents		Description	
(a). Ingredients:		Hazardous Components	
		<<0.1% Florbetaben (18F)	
	12%	Ethanol	CAS#: 64-17-5
Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.			
Section 4: First Aid Measures			
Contents		Description	
(a). Personal Precautions:		<p>Personal Protective Equipment Respiratory protection: None under normal conditions. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.</p> <p>Eye protection: Safety glasses with side-shields</p> <p>Skin and body protection: Disposable plastic, latex or rubber gloves; lab coat.</p>	
(b). Measures for environmental precaution:		<p>General advice: Do not allow to enter surface waters or groundwater.</p> <p>Toxicity to fish: Ethanol LC50 8.140 mg/L Test species: Leuciscus idus (Golden orfe)</p> <p>Duration of test: 48 h</p> <p>Toxicity to daphnia and other aquatic invertebrates: Ethanol EC50 > 7.800 mg/L Test species: Daphnia magna (Water flea)</p> <p>Toxicity to algae: Ethanol Toxic limit concentration 5.000 mg/L Test species: Scenedesmus quadricauda (Green algae)</p> <p>Toxicity to bacteria: Ethanol Toxic limit concentration 6.500 mg/L Test species: Pseudomonas putida</p> <p>Biodegradability: Ethanol Readily biodegradable.</p>	

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(c). Measures for cleaning / collecting:	<p>Routes of exposure</p> <p>Eye Contact: Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.</p> <p>Skin Contact: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.</p> <p>Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.</p> <p>Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.</p>
Section 5: Fire Fighting Measures	
Contents	Description
(a). Suitable Extinguishing agents:	<p>Flammable properties: Vapors are flammable. Vapors may travel to a source of ignition and flash back.</p> <p>Suitable extinguishing media: Water spray jet, foam, carbon dioxide (CO₂), Dry powder</p>
	<p>Unsuitable extinguishing media: High volume water jet</p>
(b). Special protective equipment for firefighters:	<p>Fire may cause evolution of: Carbon dioxide (CO₂), Carbon monoxide, Nitrogen oxides (NO_x), Sulphur oxides</p> <p>In the event of fire, wear full protection and self-contained breathing apparatus.</p>
(c). Measures for cleaning/collecting:	<p>Prevent fire extinguishing water from contaminating surface water or the ground water system.</p>
Section 6: Accidental Release Measures	
Contents	Description
(a). Personal Precautions:	<p>If the product is received in a leaking condition or any loss or release of the radioactive package contents occurs, notify your Radiation Safety Department and ChemTrec US emergency phone number (local number +1 703 527 3887; Toll-free +1 800 424 9300). All cleanup operations should be performed according to the Standard</p>

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	Operating Procedures (SOPs) established for your facility and by the NRC or other applicable local, state and federal regulations.						
Section 7: Handling and Storage							
Contents	Description						
(a). Handling:	Handling time should be kept to a minimum and appropriate shielding should be used. Handling devices such as syringe or vial shields and tongs should be used. Storage and disposal of product should be controlled in a manner, which is in compliance with the appropriate regulations of the federal or state government agency authorized to license the use of this radionuclide.						
(b). Storage:	Store in shielded locations. Keep containers tightly closed in a dry, cool and well-ventilated place. Store at room temperature. For storage, suitable stores with adequate product-reception volume must be used. Keep locked up or in an area accessible only to qualified or authorized persons. Keep only in original container.						
Section 8: Exposure Controls/Personal Protection							
Contents	Description						
Occupational Exposure Limits							
	<table border="0"> <tr> <td>Ethanol</td> <td>Type STEL</td> <td>1000 ppm (US ACGIH Threshold)</td> </tr> <tr> <td>Ethanol</td> <td>Type PEL</td> <td>1000 ppm (US OSHA Table Z-1 limit) 1900 mg/m³</td> </tr> </table>	Ethanol	Type STEL	1000 ppm (US ACGIH Threshold)	Ethanol	Type PEL	1000 ppm (US OSHA Table Z-1 limit) 1900 mg/m ³
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(b). Engineering Controls:	The following are recommended for manufacturing or other situations where exposure to contents may occur. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. During patient administration, use effective shielding, including lead-glass syringe shields when handling. Properly sealed containers are not expected to require any special ventilation.						
(c). Personal Protective Equipment	<p>Respiratory protection: None under normal conditions. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn.</p> <p>Eye protection: Safety glasses with side-shields</p>						

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	Skin and body protection: Disposable plastic, latex or rubber gloves; lab coat.																		
Section 9: Physical and Chemical Properties																			
Contents	Description																		
(a). Appearance:	Solution																		
(b). Form:	Liquid																		
(c). Colour:	Clear colorless; might turn slightly yellow upon longer storage																		
(d). Odour:	Alcoholic																		
(e). pH	4.5 – 7.0																		
(f). Freezing point:	Approx. -7°C(20F)																		
(g). Flash Point:	Approx. 47°C (117F)																		
(h). Boiling Point:	Approx. 89°C (192F)																		
(i). Autoignition temperature	> 425°C (797F)																		
(j). Density:	Approx. 1.03 g/mL																		
(k). Vapour pressure:	No data available																		
(l). Water Solubility:	Not applicable (aqueous solution)																		
(m). Radioactivity:	<= 5,000 MBq/mL / <= 135 mCi/mL																		
(n). Half-life:	110 minutes (Decayed after 24 hours)																		
Stability and Reactivity	<p>Conditions to avoid: Avoid heat, sparks, open flames and other ignition sources.</p> <p>Material to avoid: Avoid contact with oxidizing agents. Acids.</p> <p>Hazardous reactions: None known.</p> <p>Hazardous decomposition products: Decomposition of this product may emit oxides of nitrogen and carbon monoxide.</p> <p>Further information: The following applies in general to flammable organic substances and preparations: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.</p>																		
Toxicological Information	<p>Toxicological Data (Acute Toxicity)</p> <table border="0"> <tr> <td>Ethanol</td> <td></td> <td></td> </tr> <tr> <td>Dermal</td> <td>LD50(Rabbit)</td> <td>>5000mg/kg</td> </tr> <tr> <td>Inhalation</td> <td>LC50 (Rat)</td> <td>145 mg/L, 4h</td> </tr> <tr> <td>Oral</td> <td>LD50(Rat)</td> <td>7000 mg/kg</td> </tr> <tr> <td>Ascorbic Acid</td> <td>LD50 (Rat)</td> <td>11900 mg/kg</td> </tr> <tr> <td>Oral</td> <td></td> <td></td> </tr> </table>	Ethanol			Dermal	LD50(Rabbit)	>5000mg/kg	Inhalation	LC50 (Rat)	145 mg/L, 4h	Oral	LD50(Rat)	7000 mg/kg	Ascorbic Acid	LD50 (Rat)	11900 mg/kg	Oral		
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	<p>Macrogol 400 LD50 (Rat) >5000 mg/kg Oral</p> <p>Sensitization: No data available for this product. Not expected to be hazardous by OSHA criteria.</p> <p>Routes of exposure: Inhalation. Eye contact.</p> <p>Local Effects: (Ethanol) Moderate eye irritation. Mild skin irritation chronic effects. No compound-related histological findings were reported in rats and dogs administered intravenous doses for up to 28 days. Ingestion over a long period of time may cause damage to the liver and nervous system.</p> <p>Carcinogenicity: Neuraceq, similar to other radiopharmaceuticals, contributed to a patient’s overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. The ethanol carcinogenicity information reported below only applies when it is consumed in alcoholic beverages.</p> <p>ACGIH Carcinogens: (Ethanol) A3 confirmed animal carcinogen with unknown relevance to humans.</p> <p>IARC Monographs. Overall Evaluation of Carcinogenicity: (Ethanol) 1 Carcinogenic to humans.</p> <p>US NTP Report on Carcinogens: Known carcinogen: (Ethanol) known to be human carcinogen.</p> <p>Mutagenicity: Florabetaben F19 Results in genetic toxicity assays negative.</p> <p>Reproductive effects: (Ethanol) can cause adverse reproductive effect – such as birth defects, miscarriages, or infertility. All radiopharmaceuticals, including Neuraceq, have a potential to cause fetal harm. The likelihood of fetal harm depends on the stage of fetal development and the magnitude of the radiopharmaceutical dose.</p>
Ecological Information	General Advice: Do not allow to enter surface waters or groundwater



	<p>Toxicity to fish: Ethanol LC50 8.140 mg/L Test Species: Leuciscus idus (Golden orfe) Duration of test: 48 h</p> <p>Toxicity to daphnia and other aquatic invertebrates</p> <p>Ethanol EC50 > 7.800 mg/L Test Species: Daphnia magna (water flea)</p> <p>Toxicity to algae Ethanol toxic limit concentration 5.000 mg/L Test species: Scenedesmus quadricauda (Green algae)</p> <p>Toxicity to bacteria: Ethanol toxic limit concentration 6.500 mg/L Test Species: Pseudomonas putida</p> <p>Biodegradability Ethanol readily biodegradable</p>
<p>Disposal Considerations</p>	<p>Disposal Instructions: Radioactive waste must be handled in accordance with procedures established by your Radiation Safety Officer, NRC and other applicable regulations. Dispose of waste material according to Local, State, Federal, and Provincial Environmental Regulations. Unused Florbetaben solution for injection and objects touching Florbetaben solution for injection should be considered radioactive waste. The radioactivity in Florbetaben solution for injection will decay quickly but should be considered radioactive until surveyed and documented as no longer radioactive.</p> <p>Waste from residues / unused products: Dispose of waste and residues in accordance with local authority requirements.</p> <p>Contaminated packaging: Since emptied containers may retain product residue, follow label warnings even after container is emptied.</p>

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<p>Transport Information</p>	<p>DOT – basic shipping requirements (F-18, Ethanol) UN Number UN2915 Proper shipping name Radioactive material, Type A package Hazard Class 7 Subsidiary hazard class 3</p> <p>IATA (F-18, Ethanol) UN number UN2915 UN proper shipping name Radioactive material, Type A package</p> <p>Transport hazard class (es) 7 Subsidiary class (es) 3</p> <p>IMDG (F-18, Ethanol) UN Number UN2915 UN proper shipping name Radioactive material, Type A package Transport hazars class(es) 7 Subsidiary class (es) 3</p> <p>DOT</p> <div style="display: flex; justify-content: space-around; align-items: center;"> </div> <p>IATA/ IMDG</p> <div style="display: flex; justify-content: space-around; align-items: center;"> </div>
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Regulatory Information	<p>US Federal Regulations</p> <p>Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2) and Chemical Code Number: Not Listed.</p> <p>Drug Enforcement Administration (DEA). List 1&2 Exempt Chemical Mixtures (21 CFR 1310.12(c).): Not Regulated. DEA Exempt Chemical Mixtures Code Number: Not regulated.</p> <p>TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D): Not Regulated.</p> <p>OSHA Hazard Communication This product is considered hazardous under OSHA Hazard Communication Standard (29 CFR 1910-1200)</p> <p>CERCLA (Superfund) Reportable Quantities F-18 = 10,000 Ci (3.7×10^{14} Bq) releases to air, land and water of these hazardous substances, which exceed the reportable quantity, must be reported to the National Response Center at 800-424-8802. Ethanol=100</p> <p>Sara Title III Extremely Hazardous Substances: None Hazard Categories: Chronic Toxic substances subject to annual release reporting requirements: None</p> <p>RCRA Hazardous Waste Status Non-hazardous (See Section 13 for additional details)</p> <p>State Regulations</p> <p>US-California Proposition 65 Warning Ethanol (CAS 64-17-5) Listed: October 1, 1987 Developmental toxin. This product contains a substance known to the state of California to cause cancer.</p> <p>US – new Jersey RTK – Substances: Listed substance Ethanol (CAS 64-17-5) Listed.</p>
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	<p>US-Massachusetts RTK – Substance List Ethanol (CAS 64-17-5)</p> <p>US – Pennsylvania RTK – Hazardous Substances Ethanol (CAS 64-17-5) Listed.</p>
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Section 10: Additional Information

This information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

THE SAFETY DATA SHEET SHALL NOT BE DEMMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this material safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this material safety data sheet intended to be a substitute for product literature which may accompany the finished product.