SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier
Product name: OptiPrep™

1.2. Relevant identified uses of the substance or mixture and uses advised against
Relevant identified uses
Main use category: Professional use
Use of the substance/mixture: A general centrifugation medium for isolation of cells, cellular membranes, viruses and macromolecules.

Uses advised against
No additional information available

1.3. Details of the supplier of the safety data sheet
Supplier: Alere Technologies AS
Kjelsåsveien 161, P.O. Box 6863 Rodeløkka
NO-0504 Oslo - Norway
T +47-24056000 - F +47-24056010
aleretech.no@alere.com - www.alere.com

Manufacturer: Alere Technologies AS
Kjelsåsveien 161, P.O. Box 6863 Rodeløkka
NO-0504 Oslo - Norway
T +47-24056000 - F +47-24056010
aleretech.no@alere.com - www.alere.com

1.4. Emergency telephone number
<table>
<thead>
<tr>
<th>Country</th>
<th>Organisation/Company</th>
<th>Address</th>
<th>Emergency number</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom</td>
<td>National Poisons Information Service (Newcastle Unit)</td>
<td>Claremont Place, Newcastle-upon-Tyne, Newcastle</td>
<td>+44 191 2606182/+44 191 2606180 24H</td>
</tr>
</tbody>
</table>

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture
Classification according to Regulation (EC) No. 1272/2008 [CLP]
Not classified

2.2. Label elements
Labelling according to Regulation (EC) No. 1272/2008 [CLP]
Extra phrases: In vitro diagnostic medical devices, EU-regulation 1272/2008/EC, article 1, paragraph 5d.

2.3. Other hazards
Other hazards not contributing to the classification
None under normal conditions.
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances
Not applicable

3.2. Mixtures
Comment: The product is a kit containing one calibration fluid and one internal standard.
SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures
   First-aid measures general: Never give anything by mouth to an unconscious person.
   First-aid measures after inhalation: Remove person to fresh air and keep comfortable for breathing. Assure fresh air breathing.
   First-aid measures after skin contact: Wash skin with soap and water. Get medical attention if any discomfort continues.
   First-aid measures after eye contact: Immediately flush with plenty of water for up to 15 minutes. Remove any contact lenses and open eyes wide apart. Get medical attention if any discomfort continues.
   First-aid measures after ingestion: Rinse nose, mouth and throat with water. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed
   Symptoms/effects: No specific symptoms noted.
   Symptoms/effects after inhalation: No effects known.
   Symptoms/effects after skin contact: No effects known.
   Symptoms/effects after eye contact: Liquid splashes in the eye may cause irritation.
   Symptoms/effects after ingestion: Ingestion may cause nausea and vomiting.

4.3. Indication of any immediate medical attention and special treatment needed
   No specific first aid measures noted.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media
   Suitable extinguishing media: Use extinguishing media appropriate for surrounding fire.
   Unsuitable extinguishing media: None to our knowledge.

5.2. Special hazards arising from the substance or mixture
   Fire hazard: Not flammable according to national regulations concerning flammable goods.
   Hazardous decomposition products in case of fire: Thermal decomposition generates: Carbon dioxide (CO2), Carbon monoxide (CO), Nitrogen oxides. Corrosive vapours.

5.3. Advice for firefighters
   Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
   Protection during firefighting: Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures
   General measures: Avoid contact with skin and eyes. Wear appropriate personal protective equipment - see Section 8.

   For non-emergency personnel
   Protective equipment: Wear protective clothing as described in Section 8 of this safety data sheet.
   Emergency procedures: No special precautions required.

   For emergency responders
   Protective equipment: Equip cleanup and emergency crew with proper protection.
   Emergency procedures: Ventilate area.

6.2. Environmental precautions
   Prevent discharge of larger quantity to drain.

6.3. Methods and material for containment and cleaning up
   For containment: Collect all waste in suitable and labelled containers and dispose according to local legislation.
   Methods for cleaning up: Pick up mechanically or absorbed with inert material vermiculit, sand, dolomite, diatoms, etc.

6.4. Reference to other sections
   See section 13 for waste handling. For further information refer to section 8: "Exposure controls/personal protection".
SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling
Precautions for safe handling: Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Wear appropriate personal protective equipment - see Section 8.

Hygiene measures: Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities
Storage conditions: Store in a closed container. Protect from sunlight. Store in a well-ventilated place. Keep above the chemical’s freezing point. Protect against frost.

Storage temperature: 4 - 30 °C

7.3. Specific end use(s)
For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters
No additional information available

8.2. Exposure controls
Appropriate engineering controls: Provide eyewash station.
Hand protection: Wear suitable gloves resistant to chemical penetration. Neoprene or nitrile rubber gloves. Layer thickness: 0,1mm. Breakthrough time: >480min. STANDARD EN 374.
Eye protection: Not necessary under the recommended storage and handling conditions. Use splash goggles when eye contact due to splashing is possible. STANDARD EN 166.
Skin and body protection: Lab coat.
Respiratory protection: Respiratory protection not applicable.
Other information: Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment. Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties
Physical state: Liquid
Colour: Colourless.
Odour: No characteristic odour.
Odour threshold: No data available
pH: No data available
Relative evaporation rate (butylacetate=1): No data available
Melting point: No data available
Freezing point: No data available
Boiling point: No data available
Flash point: No data available
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Flammability (solid, gas): Non flammable.
Vapour pressure: No data available
Relative vapour density at 20 °C: No data available
Relative density: 1.32 g/ml at 20 °C
Solubility: Very soluble in water.
Log Pow: No data available
Viscosity, kinematic: No data available
Viscosity, dynamic: No data available
Explosive properties: No data available
Oxidising properties: No data available
Explosive limits: No data available

9.2. Other information
No additional information available
SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity
No incompatible groups noted.

10.2. Chemical stability
Stable under normal temperature conditions and recommended use.

10.3. Possibility of hazardous reactions
Will not polymerise.

10.4. Conditions to avoid

10.5. Incompatible materials
No contact with: strong acids, strong bases and strong oxidants.

10.6. Hazardous decomposition products
Stable under normal temperature conditions and recommended use. Avoid temperatures > 245 °C.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity: Not classified
   Based on available data, the classification criteria are not met

<table>
<thead>
<tr>
<th>Iodixanol (92339-11-2)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 oral rat</td>
<td>&gt; 21000 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Not classified
   Based on available data, the classification criteria are not met

Serious eye damage/irritation: Not classified
   Based on available data, the classification criteria are not met

Respiratory or skin sensitisation: Not classified
   Based on available data, the classification criteria are not met

Germ cell mutagenicity: Not classified
   Based on available data, the classification criteria are not met

Carcinogenicity: Not classified
   Based on available data, the classification criteria are not met

Reproductive toxicity: Not classified
   Based on available data, the classification criteria are not met

STOT-single exposure: Not classified
   Based on available data, the classification criteria are not met

STOT-repeated exposure: Not classified
   Based on available data, the classification criteria are not met

Aspiration hazard: Not classified
   Based on available data, the classification criteria are not met

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity
Ecology - general: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

<table>
<thead>
<tr>
<th>Iodixanol (92339-11-2)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 fish 1</td>
<td>&gt; 1000 mg/l (96 hours)</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>&gt; 2500 (48 hours - Daphnia magna)</td>
</tr>
<tr>
<td>IC50 algae</td>
<td>&gt; 3200 mg/l (IC50, 72 hours - Selenastrum capricornutum)</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>OptiPrep™</th>
<th>Persistence and degradability</th>
<th>No data available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iodixanol (92339-11-2)</td>
<td>Persistence and degradability</td>
<td>Not readily biodegradable.</td>
</tr>
</tbody>
</table>

12.3. Bioaccumulative potential

<table>
<thead>
<tr>
<th>OptiPrep™</th>
<th>Bioaccumulative potential</th>
<th>Unknown.</th>
</tr>
</thead>
</table>
Iodixanol (92339-11-2)

Log Pow 0.7
Bioaccumulative potential Low bioaccumulation potential.

12.4. Mobility in soil

OptiPrep™
Ecology - soil
The product is water soluble and may spread in water systems.

12.5. Results of PBT and vPvB assessment

OptiPrep™
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Other adverse effects : None to our knowledge.
Additional information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste) : Dispose of contents/container in accordance with licensed collector’s sorting instructions. Used device to be handled as infectious.
Additional information : The given LoW-code is a guiding, and the code depends on how the waste is formed. User must evaluate the choice of correct code.
European List of Waste (LoW) code : 18 01 03* - wastes whose collection and disposal is subject to special requirements in order to prevent infection

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

<table>
<thead>
<tr>
<th>ADR</th>
<th>IMDG</th>
<th>IATA</th>
<th>ADN</th>
<th>RID</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1. UN number</td>
<td>Not regulated for transport</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.2. UN proper shipping name</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.3. Transport hazard class(es)</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.4. Packing group</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>14.5. Environmental hazards</td>
<td>Dangerous for the environment : No</td>
<td>Dangerous for the environment : No</td>
<td>Dangerous for the environment : No</td>
<td>Dangerous for the environment : No</td>
</tr>
</tbody>
</table>

No supplementary information available

14.6. Special precautions for user

Special transport precautions : No particular precautions.

- Overland transport
  No data available
- Transport by sea
  No data available
- Air transport
  No data available
- Rail transport
  No data available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

IBC code : No IBC-code for bulk transport offshore (MARPOL).
SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU-Regulations
Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

National regulations

15.2. Chemical safety assessment
No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Date of issue : 01/06/2015
Revision date : 01/10/2018
Supersedes : 04/10/2017
Version : 3.0
Signature : K. Dyreskog

The information in this safety data sheet is based on information from the manufacturer/supplier, present European and national legislation, and presupposes that the product is used within the specified area of application.