

Safety Data Sheet

OptiPrep™

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
alereotech.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
alereotech.no@alere.com - www.alere.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182/+44 191 2606180 24H

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.

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Iodixanol	(CAS-No.) 92339-11-2 (EC-No.) 618-837-0 (REACH-no) N/A	60	Not classified

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 (CO ₂). 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.
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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 vermikulit, 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

Heat. Direct sunlight. Frost.

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

Iodixanol (92339-11-2)	
LD50 oral rat	> 21000 mg/kg

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.

Iodixanol (92339-11-2)	
LC50 fish 1	> 1000 mg/l (96 hours)
EC50 Daphnia 1	> 2500 (48 hours - Daphnia magna)
IC50 algae	> 3200 mg/l (IC50, 72 hours - Selenastrum capricornutum)

12.2. Persistence and degradability

OptiPrep™	
Persistence and degradability	No data available.

Iodixanol (92339-11-2)	
Persistence and degradability	Not readily biodegradable.

12.3. Bioaccumulative potential

OptiPrep™	
Bioaccumulative potential	Unknown.

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated for transport				
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Dangerous for the environment : No	Dangerous for the environment : No Marine pollutant : No	Dangerous for the environment : No	Dangerous for the environment : No	Dangerous for the environment : No
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

EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Data sources	: EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.
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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.