

# Safety Data Sheet

## OptiPrep

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

#### 1.1. Product identifier

Product form : Mixture  
Product name : OptiPrep  
Product group : Products

#### 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 : Isolation of mononuclear cells from human blood using centrifugation techniques.

##### Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Axis-Shield PoC AS (trading name of Alere Technologies AS)  
Kjelsåsveien 161, P.O. Box 6863, Rodeløkka  
NO-0504 Oslo - Norway  
T +47 24 05 60 00 - F +47 24 05 60 10  
[pocweb@no.axis-shield.com](mailto:pocweb@no.axis-shield.com) - [www.axis-shield-density-gradient-media.com](http://www.axis-shield-density-gradient-media.com)

##### Manufacturer

Axis-Shield PoC AS (trading name of Alere Technologies AS)  
Kjelsåsveien 161, P.O. Box 6863, Rodeløkka  
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[pocweb@no.axis-shield.com](mailto:pocweb@no.axis-shield.com) - [www.axis-shield-density-gradient-media.com](http://www.axis-shield-density-gradient-media.com)

Contact person : Remy Hagnar ([remy.hagnar@no.axis-shield.com](mailto:remy.hagnar@no.axis-shield.com))

#### 1.4. Emergency telephone number

Emergency number : 112 # The UK National Poisons Emergency number: +44 870 600 6266 WEB:  
<http://www.toxbase.org>

### 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 labelling to display

No labelling applicable

#### 2.3. Other hazards

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

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

Full text of H-phrases: see section 16

## 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. Allow breathing of fresh air.
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/injuries : No specific symptoms noted.

### 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.

### 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 <sub>2</sub> ). Carbon monoxide (CO). Nitrogen oxides. Corrosive vapours.

### 5.3. Advice for firefighters

Firefighting instructions	: No specific fire fighting procedure given.
Protection during firefighting	: Do not enter fire area without proper 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 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.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Precautions for safe handling	: Avoid spilling, skin and eye contact.
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 : < 20 °C

**7.3. Specific end use(s)**

Consult the supplier for further information.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1. Control parameters**

No additional information available

**8.2. Exposure controls**

Appropriate engineering controls : Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal protective equipment : In case of splash hazard: safety glasses.

Hand protection : For exposure of 1 to 4 hours use gloves made of: Nitril. Suitable gloves can be recommended by the glove supplier. STANDARD EN 374.

Eye protection : Chemical goggles or safety glasses. STANDARD EN 166.

Skin and body protection : Wear suitable protective clothing

Respiratory protection : Normally not required.



Other information : 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 at 20 °C

Solubility : 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. Freezing.

**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 : Ingestion of large quantities may cause discomfort.

<b>Iodixanol (92339-11-2)</b>	
LD50 oral rat	> 21000 mg/kg
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

**SECTION 12: ECOLOGICAL INFORMATION****12.1. Toxicity**

Ecology - general : Not regarded as dangerous to the environment. This does not, however, rule out the possibility that large or frequent smaller emissions of the product may be harmful to the environment.

<b>Iodixanol (92339-11-2)</b>	
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**

<b>OptiPrep</b>	
Persistence and degradability	No data available.

<b>Iodixanol (92339-11-2)</b>	
Persistence and degradability	Not readily biodegradable.

**12.3. Bioaccumulative potential**

<b>OptiPrep</b>	
Bioaccumulative potential	Unknown.

<b>Iodixanol (92339-11-2)</b>	
Log Pow	0,7
Bioaccumulative potential	Low bioaccumulation potential.

**12.4. Mobility in soil**

<b>OptiPrep</b>	
Ecology - soil	The product is water soluble and may spread in water systems.

**12.5. Results of PBT and vPvB assessment**

<b>OptiPrep</b>	
PBT: not relevant – no registration required	
vPvB: not relevant – no registration required	

**12.6. Other adverse effects**

Other adverse effects : No information.  
 Additional information : Avoid release to the environment

**SECTION 13: DISPOSAL CONSIDERATIONS****13.1. Waste treatment methods**

Regional legislation (waste) : Product is not hazardous waste.  
 Waste treatment methods : Dispose of waste and residues in accordance with local authority requirements.  
 Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.  
 European List of Waste (LoW) code : 18 01 07 - chemicals other than those mentioned in 18 01 06

**SECTION 14: TRANSPORT INFORMATION**

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

**14.1. UN number**

Not regulated for transport

**14.2. UN proper shipping name**

Proper Shipping Name (ADR) : Not applicable  
 Proper Shipping Name (IMDG) : Not applicable  
 Proper Shipping Name (IATA) : Not applicable  
 Proper Shipping Name (ADN) : Not applicable  
 Proper Shipping Name (RID) : Not applicable

**14.3. Transport hazard class(es)****ADR**

Transport hazard class(es) (ADR) : Not applicable

**IMDG**

Transport hazard class(es) (IMDG) : Not applicable

**IATA**

Transport hazard class(es) (IATA) : Not applicable

**ADN**

Transport hazard class(es) (ADN) : Not applicable

**RID**

Transport hazard class(es) (RID) : Not applicable

**14.4. Packing group**

Packing group (ADR) : Not applicable  
 Packing group (IMDG) : Not applicable  
 Packing group (IATA) : Not applicable  
 Packing group (ADN) : Not applicable  
 Packing group (RID) : Not applicable

**14.5. Environmental hazards**

Dangerous for the environment : No  
 Marine pollutant : No  
 Other information : 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

**- Inland waterway transport**

Carriage prohibited (ADN) : No  
Not subject to ADN : No

**- Rail transport**

Carriage prohibited (RID) : No

**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 substances with Annex XVII restrictions  
Contains no substance on the REACH candidate list  
Contains no REACH Annex XIV substances

**National regulations**

No additional information available

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

**SECTION 16: OTHER INFORMATION**

Data sources : EC-regulation 453/2010/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 : Roy E. Lunde

*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.*