

# Safety Data Sheet

## Nycodenz

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

#### 1.1. Product identifier

Substance name : Nycodenz

#### 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.

##### 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](mailto:alereotech.no@alere.com) - [www.alere.com](http://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](mailto:alereotech.no@alere.com) - [www.alere.com](http://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]

EUH-statements : EUH210 - Safety data sheet available on request.

Extra phrases : In vitro diagnostic medical devices, EU-regulation 1272/2008/EC, article 1, paragraph 5d.

#### 2.3. Other hazards

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substances

Name : Nycodenz

Name	Product identifier	%
Iohexol	(CAS-No.) 66108-95-0 (EC-No.) 266-164-2 (REACH-no) 01-2119941692-34	100

Full text of H-statements: see section 16

#### 3.2. Mixtures

Not applicable

**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	: No specific first aid measures noted.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Immediately flush with plenty of water or eyewash solution for up to 10 minutes. Obtain medical attention if pain, blinking or redness persists.
First-aid measures after ingestion	: If swallowed, rinse mouth with water (only if the person is conscious). Drink a few glasses of water or milk. Call a poison center or a doctor if you feel unwell.

**4.2. Most important symptoms and effects, both acute and delayed**

Symptoms/effects after inhalation	: Dust from this product may cause irritation to the respiratory tract.
Symptoms/effects after skin contact	: Dust may cause mechanical irritation.
Symptoms/effects after eye contact	: Dust from this product may cause eye irritation.
Symptoms/effects after ingestion	: Ingestion may cause nausea, vomiting and diarrhea.

**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 <sub>2</sub> ). Carbon monoxide (CO).

**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. Store in original container according to temperature stated on container and in package inser. Protect from sunlight.

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

For professional use only.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1. Control parameters****Exposure limit values for the other components**

dust, respirable			
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	4 mg/m <sup>3</sup>	

**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 : Solid

Appearance : Powder.

Colour : Off-white.

Odour : No characteristic odour.

Odour threshold : No data available

pH : 5 - 7

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 : > 400 °C

Decomposition temperature : 177 - 187 °C

Flammability (solid, gas) : Non flammable.

Vapour pressure : No data available

Relative vapour density at 20 °C : No data available

Relative density : 2.1 at 20 °C

Solubility : Miscible with water.

Log Pow : -0.5 (OECD 107 method)

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.

**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

<b>lohexol (66108-95-0)</b>	
LD50 oral rat	> 11000 mg/kg

Skin corrosion/irritation : Not classified  
Based on available data, the classification criteria are not met  
pH: 5 - 7

Serious eye damage/irritation : Not classified  
Based on available data, the classification criteria are not met  
pH: 5 - 7

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 : 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.

**12.2. Persistence and degradability**

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

**12.3. Bioaccumulative potential**

<b>Nycodenz</b>	
Log Pow	-0.5 (OECD 107 method)
Bioaccumulative potential	Unknown.

**12.4. Mobility in soil**

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

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

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

**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
<b>14.1. UN number</b>				
Not regulated for transport				
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
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**

No REACH Annex XVII restrictions  
 Nycodenz is not on the REACH Candidate List  
 Nycodenz is not on the REACH Annex XIV List

**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.  
 Date of issue : 01/06/2015  
 Revision date : 01/10/2018  
 Supersedes : 01/06/2015  
 Version : 2.0  
 Signature : K. Dyreskog

Full text of H- and EUH-statements:

EUH210	Safety data sheet available on request.
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*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.*