

# Safety Data Sheet

## Nycograde Polysucrose 400

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

#### 1.1. Product identifier

Substance name : Nycograde Polysucrose 400

#### 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

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

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

Name : Nycograde Polysucrose 400

Name	Product identifier	%
$\alpha$ -D-Glucopyranoside, $\beta$ -D-fructofuranosyl, polymer with 2-(chloromethyl)oxirane	(CAS-No.) 26873-85-8 (EC-No.) 200-334-9 (REACH-no) N/A	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	: No specific symptoms noted.
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**

- 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. 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 : 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 : No data available
- Solubility : Miscible with 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.

**10.5. Incompatible materials**

None to our knowledge.

**10.6. Hazardous decomposition products**

Stable under normal temperature conditions and recommended use.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**11.1. Information on toxicological effects**

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

Nycograde Polysucrose 400	
Persistence and degradability	No data available.

**12.3. Bioaccumulative potential**

Nycograde Polysucrose 400	
Bioaccumulative potential	Unknown.

**12.4. Mobility in soil**

Nycograde Polysucrose 400	
Ecology - soil	The product is water soluble and may spread in water systems.

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

**Nycograde Polysucrose 400**

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
<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

Nycograde Polysucrose 400 is not on the REACH Candidate List

Nycograde Polysucrose 400 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.  
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 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.*