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
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</td>
<td>+44 191 2606182/+44 191</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Newcastle-upon-Tyne, Newcastle</td>
<td>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]
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

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>α-D-Glucopyranoside, β-D-fructofuranosyl,</td>
<td>(CAS-No.) 26873-85-8</td>
</tr>
<tr>
<td>polymer with 2-(chloromethyl)oxirane</td>
<td>(EC-No.) 200-334-9</td>
</tr>
<tr>
<td></td>
<td>(REACH-no) N/A</td>
</tr>
<tr>
<td></td>
<td>100</td>
</tr>
</tbody>
</table>

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 (CO2). 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.

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

<table>
<thead>
<tr>
<th>dust, respirable</th>
<th>United Kingdom</th>
<th>WEL TWA (mg/m³)</th>
<th>4 mg/m³</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Effect</th>
<th>Classification</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Skin corrosion/irritiation</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Classification</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nycograde Polysucrose 400</td>
<td>No data available.</td>
<td></td>
</tr>
</tbody>
</table>

12.3. Bioaccumulative potential

<table>
<thead>
<tr>
<th>Product</th>
<th>Classification</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nycograde Polysucrose 400</td>
<td>Unknown.</td>
<td></td>
</tr>
</tbody>
</table>

12.4. Mobility in soil

<table>
<thead>
<tr>
<th>Product</th>
<th>Ecology - soil</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nycograde Polysucrose 400</td>
<td>The product is water soluble and may spread in water systems.</td>
<td></td>
</tr>
</tbody>
</table>
12.5. Results of PBT and vPvB assessment

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></td>
<td></td>
<td></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>
</tbody>
</table>

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

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

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


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: 01/06/2015

Version: 2.0

Signature: K. Dyreskog

Full text of H- and EUH-statements:

EUH210 Safety data sheet available on request.

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.