Nycodenz®

Safety Data Sheet

according to Regulation (EU) 2020/878

Date of issue: 15.11.2021 Revision date: - Version/Replaced version: 1.0/-

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance

Product name : Nycodenz®

IUPAC name : Iohexol

EC-No. : 266-164-2

CAS-No. : 66108-95-0

Synonyms : 5-[acetyl(2,3-dihydroxypropyl)amino]-N,N'-bis(2,3-dihydroxypropyl)-2,4,6-triiodoisophthalamide

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : Density gradient media

1.2.2. Uses advised against

Not intended for use as infusion solution

1.3. Details of the supplier of the safety data sheet

Supplier / Manufacturer
Serumwerk Bernburg AG
Hallesche Landstrasse 105 b
06406 Bernburg - Germany
T + 49 3471 860 0

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency telephone number
Germany	Giftinformationszentrum-Nord Zentrum Pharmakologie und Toxikologie der Universität Göttingen	Robert-Koch Strasse 40 D-37075 Göttingen	+49 551 19240

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Iohexol	CAS-No.: 66108-95-0 EC-No.: 266-164-2	96 – 100	Not classified

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Get medical advice/attention if you feel unwell. If possible show him this sheet. Failing this, show him the packaging or label. Place the affected person in the recovery position. Never give anything by mouth to an unconscious person.

First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing.

First-aid measures after skin contact : Wash with plenty of soap and water.

First-aid measures after eye contact : If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

First-aid measures after ingestion : Rinse mouth. Drink plenty of water as a precaution. Do NOT induce vomiting.

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Adapt extinguishing agents to the environment. Carbon dioxide. Dry extinguishing powder. Water spray. For a significant fire: Alcohol resistant foam.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Static unloading of dry powder may cause fire.

Hazardous decomposition products in case of fire : Toxic gases may be formed. Carbon dioxide. Carbon monoxide. Nitrogen oxides (NOx). Iodine vapour.

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Provide adequate ventilation. Stop leak if safe to do so. Avoid contact with skin and eyes. Do not breathe dust. Avoid dust formation.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection"

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product. Flush contaminated areas with plenty of water. Dispose of in accordance with relevant local regulations.

6.4. Reference to other sections

Exposure controls and personal protection, see section 8. Concerning disposal elimination after cleaning, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Do not breathe dust. Avoid dust formation.

Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. When using do not eat, drink or smoke. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Keep container tightly closed. Store in dry, cool, well-ventilated area. Store at room temperature. Protect from sunlight.

Prohibitions on mixed storage : Keep away from food, drink and animal feedingstuffs.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Provide adequate ventilation to minimize dust concentrations.

Hand protection:

Wear suitable gloves (EN 374). Nitrile rubber, ≥ 0.35 mm. The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Wear chemical goggles or safety glasses (EN 166).

Skin and body protection:

Wear suitable protective clothing (EN 13034, EN ISO 13982-1, EN14605, EN1149-5)

Respiratory protection:

Where exposure through inhalation may occur from use, respiratory protection is recommended. Breathing apparatus with filter P3 (EN 14387).

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid, crystalline powder
Colour	:	White to off-white
Odour	:	Odourless
Melting point/freezing point	:	174 – 180 °C
Boiling point or initial boiling point and boiling range	:	No data available
Flammability	:	No data available
Lower and upper explosion limit	:	No data available
Flash point	:	Not applicable
Auto-ignition temperature	:	> 400 °C (Method: LIT (Layer 5 mm ignition temperature)) No-ignition was observed up to 400 °C at atm. press. of 1.0 bar.
Decomposition temperature	:	170 – 180 °C (Method: ARC)
pH	:	No data available
Kinematic viscosity	:	No data available
Solubility	:	Water: 107 mg/l Soluble in water in all concentrations at 25 °C
Partition coefficient n-octanol/water (log value)	:	-0.5 (OECD 107 – shake flask method)
Vapour pressure	:	No data available
Density and/or relative density	:	No data available
Relative vapour density	:	Not applicable
Particle size	:	No data available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Explosive properties	:	No explosive properties (Method: EU Method A.14)
Flammable solids	:	From the preliminary screening test the sample was seen not to ignite, therefore further testing is not required. (Method: EU Method A.10)

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under use and storage conditions as recommended in section 7.

10.3. Possibility of hazardous reactions

None under normal use.

10.4. Conditions to avoid

Do not expose to temperatures exceeding 50 °C. Direct sunlight.

10.5. Incompatible materials

Strong oxidizing agents. Strong bases. Strong acids.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature. In case of fire: Toxic gases may be formed. Carbon dioxide. Carbon monoxide. Nitrogen oxides (NOx). Iodine vapour.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

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

Specific target organ toxicity (single exposure) : Not classified
Based on available data, the classification criteria are not met

Specific target organ toxicity (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

11.2. Information on other hazards

Potential adverse human health effects and symptoms : 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.

Acute aquatic toxicity : Not classified

Chronic aquatic toxicity : Not classified

Iohexol (66108-95-0)	
LC50 Fish	> 1000 mg/l 96h, Salmo salar
EC50 Crustacea	> 3200 mg/l 48 h, Daphnia magna
EC50 Algae	> 3200 mg/l 72 h, Pseudokirchneriella subcapitata

12.2. Persistence and degradability

Iohexol (66108-95-0)	
Persistence and degradability	Not readily biodegradable.
Biodegradation	0 % 28 d (ISO DIS 9408 and OECD 301 F)

12.3. Bioaccumulative potential

Iohexol (66108-95-0)	
Partition coefficient n-octanol/water (Log Pow)	-0.5 (OECD 107 – shake flask method)

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

This substance does not meet the PBT- or vPvB criteria of REACH regulation, annex XIII.

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Dispose in a safe manner in accordance with local/national regulations.

Waste code : The waste code number according to the Ordinance on the European Waste Catalogue depends on the waste producer and can therefore vary for any given product. The waste code number is therefore to be gleaned separately from each waste producer.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

14.1. UN number or ID number

UN-No. (ADR) : Not applicable

UN-No. (IMDG) : Not applicable

UN-No. (IATA) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : 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

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : 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

- Overland transport

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Iohexol is not on the REACH Candidate List

Iohexol is not on the REACH Annex XIV List
Iohexol is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 july 2012 concerning the export and import of hazardous chemicals.
Iohexol is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants
Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.1.2. 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 : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Changes compared to the previous version : -

Abbreviations and acronyms:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EC50	The effective concentration of substance that causes 50% of the maximum response (Median Effective Concentration)
IATA	International Air Transport Association
IMDG	“International Maritime Dangerous Goods Code” for the transport of dangerous goods by sea
LC50	Lethal Concentration to 50 % of a test population (Median Lethal Concentration)
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
LOAEL	Lowest Observed Adverse Effect Level
NOAEC/L	No Observed Adverse Effect Concentration/Level
NOEC/L	No Observed Effect Concentration/Level
OECD	Organisation for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic substance
PNEC	Predicted No-Effect Concentration
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
STP	Sewage Treatment Plant
UFI	Unique Formula Identifier
vPvB	Very Persistent and Very Bioaccumulative

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.