

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

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Publication: 08/03/2022

Revision: 03/07/2024

Version: 01



DINATRII EDETAS

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

1.1 Product identifier

Product name: Disodium edetate
Dinatrii edetas
Dinatriumedetaat
Edétate disodique
Natriumedetat

N° CAS: 6381-92-6

N° EC: 205-358-3

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV
Neerlandweg 24
2610 Wilrijk
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 4	H332
STOT RE 3	H373

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H332 Harmful if inhaled.

H373 May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure if inhaled.

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Precautionary statements:

P314

Get medical advice/ attention if you feel unwell.

Additional applicable label elements:

Not applicable.

2.3 Other hazards

Risk of dust explosion.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Disodium edetate
IUPAC name:	disodium;2-[2-[bis(carboxymethyl)amino]ethyl-(carboxylatomethyl)amino]acetate;dihydrate
Synonyms:	Ethylenediaminetetraacetic acid disodium salt dihydrate EDTA disodium salt
N° CAS:	6381-92-6
N° EC:	205-358-3
Molecular Formula:	$C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$
Content:	98.5 per cent to 101.0 per cent.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Move out of dangerous area. Consult a physician. Show this safety data sheet to the doctor in attendance.
After inhalation:	Remove to fresh air. Keep patient warm and at rest. Rinse nose and mouth with water.
After skin contact:	Take off contaminated clothing and shoes immediately.
After eye contact:	Rinse with plenty of water. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
After ingestion:	Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: The symptoms and effects are as expected from the hazards as shown in section 2. No specific product related symptoms are known.

Risks: Harmful if inhaled. May cause damage to organs through prolonged or repeated exposure if inhaled.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

Specific hazards during firefighting/Specific hazards arising from the chemical: Do not allow run-off from fire fighting to enter drains or water courses. Risks of ignition followed by flame propagation or secondary explosions shall be prevented by avoiding accumulation of dust, e.g. on floors and ledges.

Combustion products: Nitrogen oxides (NO_x).

5.3 Advice for firefighters

Surrounding fires: Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Protection against fire: In the event of fire, wear self-contained breathing apparatus.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Personal precautions: Use personal protective equipment. Wear respiratory protection. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

Emergency measures on accidental release: Evacuate personnel to safe areas. Only qualified personnel equipped with suitable protective equipment may intervene. Prevent unauthorised persons entering the zone.

For emergency responders

Personal precautions: Use personal protective equipment. Wear respiratory protection. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.

Emergency measures on accidental release: Evacuate personnel to safe areas. Only qualified personnel equipped with suitable protective equipment may intervene. Prevent unauthorised persons entering the zone.

6.2 Environmental precautions

Do not flush into surface water or sanitary sewer system.

If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust.

Sweep up and shovel.

Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal considerations, see section 13.

For personal protection, see section 8.

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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Avoid formation of respirable particles. Keep away from heat/sparks/open flames/hot surfaces. No sparking tools should be used. Smoking, eating and drinking should be prohibited in the application area.
Personal protection:	For personal protection, see section 8. Do not breathe vapours/dust.
Technical protective measures:	Provide sufficient air exchange and/or exhaust in work rooms. Provide appropriate exhaust ventilation at places where dust is formed.
Handling:	Dispose of rinse water in accordance with local and national regulations.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Prevent unauthorized access. Keep container tightly closed. No decomposition if stored and applied as directed.
Conditions for safe storage, including any incompatibilities:	Keep in a dry place. Store at room temperature in the original container.
Storage – away from:	Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters:

Dust: AGW: 10 mg/m³, basis: DE TRGS 900, form of exposure: inhalable fraction.

Dust: AGW: 1,25 mg/m³, basis: DE TRGS 900, form of exposure: alveolate fraction.

Dust: TWA: 6 mg/m³, basis: DE TRGS 900, form of exposure: total dust.

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Workers, inhalation, long-term local effects: 1,5 mg/m³

Workers, inhalation, acute local effects: 3 mg/m³

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Fresh water: 2.5 mg/l

Marine water: 0.25 mg/l

Intermittent water: 1.4 mg/l

Soil: 0.84 mg/kg dry weight

Sewage treatment plant: 50 mg/l

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8.2 Exposure controls

Appropriate engineering control

Provide appropriate exhaust ventilation at places where dust is formed. Handle in accordance with good industrial hygiene and safety practice. When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

Individual protection measures

Eye/face protection:	Tightly fitting safety goggles.
Skin protection:	Protective suit.
Hand protection:	Wash hands before breaks and at the end of workday.
Respiratory protection:	Half mask with a particle filter P2 (EN 143).
Thermal hazards:	Not determined.

Environmental exposure control

Do not flush into surface water or sanitary sewer system. If the product contaminates rivers and lakes or drains, inform respective authorities.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Odourless.
Odour threshold:	Not applicable.
pH:	4.0 to 5.0 (1% water)
Melting/freezing point:	Decomposes before melting.
Initial boiling point:	Not applicable.
Boiling range:	Not applicable.
Flash point:	Not applicable.
Evaporation rate:	Not applicable.
Flammability (solid/gas):	Not classified as a flammability hazard. May form combustible dust concentrations in air during processing, handling or other means.
Upper/lower flammability or explosive limits:	Lower explosion limit: $\geq 40 \text{ g/m}^3$. Upper explosion limit: Not applicable.
Vapour pressure:	Not applicable.
Vapour density:	Not applicable.
Relative density:	Not available.
Solubility:	Practically insoluble in ethanol (96%).
Solubility in water:	Soluble in water: ca. 100 g/l.
Partition coefficient (n-octanol/water):	Low Pow: < 0 .
Auto-ignition temperature:	$\geq 200 \text{ }^\circ\text{C}$ Method: Auto-ignition of a 5mm dust layer according to EN 50281-2-1

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Decomposition temperature:	Not available.
Viscosity:	Not applicable.
Explosive properties:	Not explosive.
Oxidising properties:	Not classified as oxidising.

9.2 Other information

This safety datasheet only contains information relating to safety and does not replace any product information or product specification.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Stable under normal conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Dust may form explosive mixture in air.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

Carbon oxides, nitrogen oxides (NO_x).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Harmful if inhaled. Inhalation toxicity: 1.66 mg/l (estimate) (4h), test atmosphere: dust/mist, method: calculation method. Oral LD50 (rat): > 2 000 mg/kg Inhalation LC50 (rat): > 1 – 5 mg/l, test atmosphere: dust/mist, method: OECD Test Guideline 412
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Skin corrosion/irritation:	Not classified based on available information.
Serious eye damage/irritation:	Not classified based on available information.
Respiratory/skin sensitisation:	Not classified based on available information.
Germ cell mutagenicity:	Not classified based on available information.
Carcinogenicity:	Not classified based on available information.
Reproductive toxicity:	Not classified based on available information.
Summary of evaluation of the CMR properties:	Not available.

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STOT-single exposure:	Not classified based on available information.
STOT-repeated exposure:	May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure if inhaled.
Aspiration Hazard:	Not classified based on available information.
Other:	Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Harmful if inhaled. May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure if inhaled.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish: LC50: > 100 mg/l (96h) (fish)

Toxicity to daphnia and other aquatic invertebrates: EC50 (calculated): 140 mg/l (48h) (*Daphnia magna*), method: DIN 38412

Toxicity to bacteria: EC50: > 500 mg/l (30 min) (activated sludge), test type: respiration inhibition, method: OECD Test Guideline 209

Toxicity to fish (chronic toxicity): NOEC: > 25,7 mg/l (35d) (*Danio rerio*), test type: flow-through test, method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (chronic toxicity): NOEC: > 25 mg/l (21d) (*Daphnia magna*)

12.2 Persistence and degradability

Not readily biodegradable, but will degrade after a longer period.

12.3 Bioaccumulative potential

Not expected considering the low log Pow value.

12.4 Mobility in soil

Adsorption to the solid soil particles is not expected.

12.5 Results of PBT and vPvB assessment

This substance contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Chemical Oxygen Demand (COD): 630 mg/g

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Do not dispose of waste into sewer. Do not contaminate ponds, waterways or ditches with chemical or used container. Hazardous waste. Dispose of contents/container in accordance with local regulation.

Contaminated packaging: Empty remaining contents. Dispose of as unused product.

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SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not classified.

14.6 Special precautions for user

Not classified as dangerous in the meaning of transport regulations.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not applicable for product as supplied.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R20 Harmful by inhalation.
R48 Danger of serious damage to health by prolonged exposure.

Safety phrases:

S45 In case of accident or if you feel unwell, seek medical advice immediately
(show the label where possible).

15.2 Chemical safety assessment

A chemical safety assessment has been carried out for this substance.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

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16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department

FAC SECUNDUM ARTEM NV

info@magis-pharma.be

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