

Disodium edetate

Safety Data Sheet

256439

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
 Date of issue: 30/08/2012 Revision date 26/08/2020
 Supersedes 19/03/2019

Version: 4.1

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

1.1. Product identifier

Product form : Substance
 Substance name : Disodium edetate
 IUPAC name : Disodium dihydrogen (ethylenedinitrilo)tetraacetate dihydrate
 EC-No. : 205-358-3
 REACH registration No : 01-2119486775-20
 Product code : 256439
 Formula : $C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$
 Synonyms : EDTA Disodium salt dihydrate
 Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Professional use
 Use of the substance/mixture : Exipient
 Function or use category : Chelating agent

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - Nederland
 T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
 +31(0)23-5319093 (M-F 09:00-17:00)
 +31(0)6-30109355 (outside office hours)

| Organisation/Company | Address | Comment |
|---|---------------------------------|---------|
| Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust | Avonley Road SE14 5ER London | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP] Mixtures/Substances: SDS EU 2015, According to Regulation (EU) 2015/830 (REACH Annex I)

Acute toxicity (inhal.), Category 4 H332

Specific target organ toxicity — Repeated exposure, Category 2 H373

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display/Extra classification(s) to display

Hazard pictograms (CLP)



Signal word (CLP) : Warning

Hazard statements (CLP) : H332 - Harmful if inhaled.
H373 - May cause damage to organs through prolonged or repeated exposure.

Precautionary statements (CLP) : P260 - Do not breathe dust, vapours.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312 - Call a POISON CENTER/doctor if you feel unwell.

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 | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|------------------|---|----------|---|
| Disodium edetate | (EC-No.) 205-358-3 (REACH-no) 01-2119486775-20 | 90 - 100 | Acute Tox. 4 (Inhalation), H332 STOT RE 2, H373 |

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 | : If possible show this sheet, if not available show packaging or label. |
| First-aid measures after inhalation | : Allow affected person to breathe fresh air Rinse mouth out with water. |
| First-aid measures after skin contact | : Remove contaminated clothing and shoes Rinse with plenty of water. |
| First-aid measures after eye contact | : Rinse immediately with plenty of water If eye irritation persists, take medical advice. |
| First-aid measures after ingestion | : Give water to drink Rinse mouth. Never give anything by mouth to an unconscious person Immediately call a POISON CENTER/doctor. |

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

No additional information available

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 : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

| | |
|--|---|
| Explosion hazard | : Product is not explosive. |
| Hazardous decomposition products in case of fire | : On burning: release of harmful gases/vapours. |

5.3. Advice for firefighters

| | |
|--------------------------------|---|
| Precautionary measures fire | : Exercise caution when fighting any chemical fire. |
| Firefighting instructions | : Prevent fire fighting water from entering the environment. |
| Protection during firefighting | : Do not enter fire area without proper protective equipment, including respiratory protection. |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ensure adequate air ventilation.

6.1.2. For emergency responders

Protective equipment : Wear proper protective equipment.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly. Hose down area with water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Avoid inhalation of the product.

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area
Keep container tightly closed.
Protect from light.

Incompatible products : Strong bases. Strong oxidizing agent. Metals.

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| Disodium edetate | |
|--|-----------------------|
| DNEL/DNEL (Workers) | |
| Long-term - systemic effects, inhalation | 1.5 mg/m ³ |
| PNEC (Water) | |
| PNEC aqua (freshwater) | 2.5 mg/l |
| PNEC aqua (marine water) | 0.25 mg/l |
| PNEC aqua (intermittent, freshwater) | 1.4 mg/l |
| PNEC (Soil) | |
| PNEC soil | 0.84 mg/kg dwt |
| PNEC (STP) | |
| PNEC sewage treatment plant | 50 mg/l |

8.2. Exposure controls

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Safety glasses. Gloves. Dust production: dust mask with filter type P2.

Hand protection:

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| Type | Material | Permeation | Thickness (mm) | Standard |
|--------|----------------------|-------------------|----------------|------------|
| Gloves | Nitrile rubber (NBR) | 6 (> 480 minutes) | 0,11 | EN ISO 374 |

Eye protection:

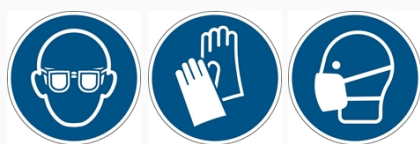
Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Wear suitable protective clothing.

Respiratory protection:

Dustmask with filtertype P2

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

| | |
|--|-----------------------------|
| Physical state | : Solid |
| Appearance | : Crystalline powder. |
| Molecular mass | : 372.2 g/mol |
| Colour | : White. |
| Odour | : odourless. |
| Odour threshold | : No data available |
| pH | : 4 - 5 (1% solution) |
| 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 | : > 252 °C |
| Flammability (solid, gas) | : No data available |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Density | : 0.7 g/cm ³ |
| Solubility | : Water: 100 g/l |
| Log Pow | : < 0 |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : Product is not explosive. |
| 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 additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

High temperature

Light (daylight).

10.5. Incompatible materials

Strong oxidizers

metals

Strong acids.

10.6. Hazardous decomposition products

Carbon dioxide

Carbon monoxide

Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Harmful if inhaled.

| Disodium edetate | |
|---------------------|--------------|
| LD50 oral rat | > 2000 mg/kg |
| LC50 inhalation rat | 1.68 mg/l/4h |

Skin corrosion/irritation : Not classified
pH: 4 - 5 (1% solution)

Serious eye damage/irritation : Not classified
pH: 4 - 5 (1% solution)

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

SECTION 12: Ecological information**12.1. Toxicity**

| Disodium edetate | |
|------------------|----------|
| LC50 fish 1 | 320 mg/l |
| EC50 Daphnia 1 | 140 mg/l |

12.2. Persistence and degradability

| Disodium edetate | |
|-------------------------------|-----------------------------------|
| Persistence and degradability | Minimally biodegradable. |
| Chemical oxygen demand (COD) | 0.6 g O ₂ /g substance |

12.3. Bioaccumulative potential

| Disodium edetate | |
|---------------------------|------------------------------------|
| Log Pow | < 0 |
| Bioaccumulative potential | No bioaccumulation data available. |

12.4. Mobility in soil

| Disodium edetate | |
|------------------|---|
| Ecology - soil | There are no available data for a classification. |

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste treatment methods : Avoid release to the environment.
Product/Packaging disposal : Dispose in a safe manner in accordance with local/national recommendations regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

| ADR | IATA |
|---|----------------|
| 14.1. UN number | |
| Not applicable | Not applicable |
| 14.2. UN proper shipping name | |
| Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | |
| Not applicable | Not applicable |
| Not applicable | Not applicable |
| 14.4. Packing group | |
| Not applicable | Not applicable |

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| ADR | IATA |
|--|------------------------------------|
| 14.5. Environmental hazards | |
| Dangerous for the environment : No | Dangerous for the environment : No |
| No supplementary information available | |

14.6. Special precautions for user**. Overland transport**

No data available

- Air transport

No data available

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

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

Disodium edetate is not on the REACH Candidate List

Disodium edetate is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

A chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

| | | | |
|---|--|-------|------------------|
| 1 | | Added | New company logo |
|---|--|-------|------------------|

Abbreviations and acronyms:

| | |
|-------|---|
| SDS | Safety Data Sheet |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| IMDG | International Maritime Dangerous Goods |
| IATA | International Air Transport Association |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |

Data sources : Handbook Of Pharmaceutical Excipients. Supplier.

Full text of H- and EUH-statements:

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| | |
|---------------------------|--|
| Acute Tox. 4 (Inhalation) | Acute toxicity (inhal.), Category 4 |
| STOT RE 2 | Specific target organ toxicity — Repeated exposure, Category 2 |
| H332 | Harmful if inhaled. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |

SDS EU (REACH Annex II) duchefa nieuwe logo

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.