

AE00151 - D-Malate dehydrogenase (R)

Date of compilation: 12/05/2020

Revised: 13/05/2020

Version: 2 (Replaced 1)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1 Product identifier:** AE00151 - D-Malate dehydrogenase (R)**1.2 Relevant identified uses of the substance or mixture and uses advised against:**

Relevant uses: Laboratory. For professional user only.

Uses advised against: All uses not specified in this section or in section 7.3

1.3 Details of the supplier of the safety data sheet:

NZYTech

Estrada do Paco do Lumiar Campus do Lumiar - Edif. E, r/c

1649-038 Lisboa - Lisboa - Portugal

info@nzytech.com

www.nzytech.com

1.4 Emergency telephone number: +351 213 643 514

Local time: Monday to Friday 9.00 am to 18.00

National Poison Information Centre (Europe UK): +44 0845 4647 (this service is only available to health professionals)

SECTION 2: HAZARDS IDENTIFICATION ****2.1 Classification of the substance or mixture:****CLP Regulation (EC) No 1272/2008:**

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Eye Irrit. 2: Eye irritation, Category 2, H319

Repr. 1B: Reproductive toxicity, Category 1B, H360

Resp. Sens. 1: Sensitisation, respiratory, Category 1, H334

Skin Irrit. 2: Skin irritation, Category 2, H315

2.2 Label elements:**CLP Regulation (EC) No 1272/2008:**

Danger

**Hazard statements:**

Eye Irrit. 2: H319 - Causes serious eye irritation

Repr. 1B: H360 - May damage fertility or the unborn child

Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Skin Irrit. 2: H315 - Causes skin irritation

Precautionary statements:

P201: Obtain special instructions before use

P280: Wear protective gloves/protective clothing/eye protection/face protection

P302+P352: IF ON SKIN: Wash with plenty of water

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P308+P313: IF exposed or concerned: Get medical advice/attention

P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician

P501: Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively

Substances that contribute to the classification

Dehydrogenase, malate; Imidazole

Additional Labelling (Annex XVII, REACH):

Restricted to professional users

2.3 Other hazards:

Product fails to meet PBT/vPvB criteria

*** Changes with regards to the previous version*

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS **

3.1 Substance:



Non-applicable

3.2 Mixture:

Chemical description: Mixture of substances

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

| Identification | Chemical name/Classification | | Concentration |
|---|--|--|----------------------|
| CAS: 9001-64-3 EC: 232-622-5 Index: Non-applicable REACH: Non-applicable | Dehydrogenase, malate⁽¹⁾ Self-classified | | 1 - <2,5 % |
| | Regulation 1272/2008 | Resp. Sens. 1: H334 - Danger  | |
| CAS: 288-32-4 EC: 206-019-2 Index: Non-applicable REACH: 01-2119485825-24-XXXX | Imidazole⁽¹⁾ Self-classified | | 1 - <2,5 % |
| | Regulation 1272/2008 | Acute Tox. 4: H302; Eye Dam. 1: H318; Repr. 1B: H360; Skin Corr. 1C: H314 - Danger  | |

⁽¹⁾ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2015/830

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

** Changes with regards to the previous version

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use full jet water as an extinguishing agent.

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SECTION 5: FIREFIGHTING MEASURES (continued)**5.2 Special hazards arising from the substance or mixture:**

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures:**

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilled product (See section 8). Evacuate the area and keep out those who do not have protection.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE**7.1 Precautions for safe handling:**

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, handling and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

PREGNANT WOMEN SHOULD NOT BE EXPOSED TO THIS PRODUCT. Transfer in designated areas that comply with the necessary safety conditions (emergency showers and eyewash stations in close proximity), using personal protection equipment, especially on the hands and face (See section 8). Limit manual transfers to small amounts only. Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

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SECTION 7: HANDLING AND STORAGE (continued)

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace
There are no occupational exposure limits for the substances contained in the product

DNEL (Workers):

| Identification | | Short exposure | | Long exposure | |
|---|------------|------------------------|----------------|------------------------|----------------|
| | | Systemic | Local | Systemic | Local |
| Imidazole CAS: 288-32-4 EC: 206-019-2 | Oral | Non-applicable | Non-applicable | Non-applicable | Non-applicable |
| | Dermal | 25 mg/kg | Non-applicable | 1,5 mg/kg | Non-applicable |
| | Inhalation | 5583 mg/m ³ | Non-applicable | 10,6 mg/m ³ | Non-applicable |

DNEL (General population):

Non-applicable

PNEC:

| Identification | | | | |
|---|--------------|----------------|-------------------------|----------------|
| Imidazole CAS: 288-32-4 EC: 206-019-2 | STP | 10 mg/L | Fresh water | 0,13 mg/L |
| | Soil | 0,0425 mg/kg | Marine water | 0,013 mg/L |
| | Intermittent | 1,3 mg/L | Sediment (Fresh water) | 0,336 mg/kg |
| | Oral | Non-applicable | Sediment (Marine water) | Non-applicable |



8.2 Exposure controls:

A.- General security and hygiene measures in the work place



As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|---|-----------------------------------|---|---------------------|--|
|  Mandatory respiratory tract protection | Filter mask for gases and vapours |  | EN 405:2001+A1:2009 | Replace when there is a taste or smell of the contaminant inside the face mask. If the contaminant comes with warnings it is recommended to use isolation equipment. |

C.- Specific protection for the hands

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|--|---|---|---|--|
|  Mandatory hand protection | NON-disposable chemical protective gloves |  | EN ISO 374-1:2016 EN 16523-1:2015 EN 420:2003+A1:2009 | The Breakthrough Time indicated by the manufacturer must exceed the period during which the product is being used. Do not use protective creams after the product has come into contact with skin. |

"As the product is a mixture of several substances, the resistance of the glove material can not be predicted in advance with total reliability and has therefore to be checked prior to the application"

D.- Ocular and facial protection

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|--|-------------|---|---|---|
|  Mandatory face protection | Face shield |  | EN 166:2001 EN 167:2001 EN 168:2001 EN ISO 4007:2018 | Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. |

E.- Body protection

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|---|---|---|--|---|
|  Mandatory complete body protection | Disposable clothing for protection against chemical risks |  | EN 13034:2005+A1:2009 EN 168:2001 EN ISO 13982-1:2004/A1:2010 EN ISO 6529:2013 EN ISO 6530:2005 EN 464:1994 | For professional use only. Clean periodically according to the manufacturer's instructions. |
|  Mandatory foot protection | Safety footwear for protection against chemical risk |  | EN ISO 20345:2011 EN 13832-1:2019 | Replace boots at any sign of deterioration. |

F.- Additional emergency measures

| Emergency measure | Standards | Emergency measure | Standards |
|--|---|---|--|
|  Emergency shower | ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011 |  Eyewash stations | DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011 |

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

| | |
|---------------------------|-----------------------------|
| V.O.C. (Supply): | 0 % weight |
| V.O.C. density at 20 °C: | 0 kg/m ³ (0 g/L) |
| Average carbon number: | Non-applicable |
| Average molecular weight: | Non-applicable |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

| | |
|--------------------------|------------------|
| Physical state at 20 °C: | Liquid |
| Appearance: | Not available |
| Colour: | Not available |
| Odour: | Not available |
| Odour threshold: | Non-applicable * |

Volatility:

| | |
|--|-------------------------|
| Boiling point at atmospheric pressure: | 100 °C |
| Vapour pressure at 20 °C: | 2350 Pa |
| Vapour pressure at 50 °C: | 12381,01 Pa (12,38 kPa) |
| Evaporation rate at 20 °C: | Non-applicable * |

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Product description:

| | |
|--|--------------------------|
| Density at 20 °C: | 1283,3 kg/m ³ |
| Relative density at 20 °C: | 1,283 |
| Dynamic viscosity at 20 °C: | 2,23 cP |
| Kinematic viscosity at 20 °C: | 1,74 cSt |
| Kinematic viscosity at 40 °C: | Non-applicable * |
| Concentration: | Non-applicable * |
| pH: | Non-applicable * |
| Vapour density at 20 °C: | Non-applicable * |
| Partition coefficient n-octanol/water 20 °C: | Non-applicable * |
| Solubility in water at 20 °C: | Non-applicable * |
| Solubility properties: | Non-applicable * |
| Decomposition temperature: | Non-applicable * |
| Melting point/freezing point: | Non-applicable * |
| Explosive properties: | Non-applicable * |
| Oxidising properties: | Non-applicable * |

Flammability:

| | |
|----------------------------|------------------------|
| Flash Point: | Non Flammable (>60 °C) |
| Flammability (solid, gas): | Non-applicable * |
| Autoignition temperature: | 480 °C |
| Lower flammability limit: | Non-applicable * |
| Upper flammability limit: | Non-applicable * |

Explosive:

| | |
|------------------------|------------------|
| Lower explosive limit: | Non-applicable * |
| Upper explosive limit: | Non-applicable * |

9.2 Other information:

| | |
|---------------------------|------------------|
| Surface tension at 20 °C: | Non-applicable * |
| Refraction index: | Non-applicable * |

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

| Shock and friction | Contact with air | Increase in temperature | Sunlight | Humidity |
|--------------------|------------------|-------------------------|----------------|----------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

10.5 Incompatible materials:

| Acids | Water | Oxidising materials | Combustible materials | Others |
|--------------------|----------------|---------------------|-----------------------|-------------------------------|
| Avoid strong acids | Not applicable | Precaution | Not applicable | Avoid alkalis or strong bases |

10.6 Hazardous decomposition products:

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SECTION 10: STABILITY AND REACTIVITY (continued)

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION ****11.1 Information on toxicological effects:**

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Produces skin inflammation.
- Contact with the eyes: Produces eye damage after contact.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: May damage fertility or the unborn child

E- Sensitizing effects:

- Respiratory: Prolonged exposure can result in specific respiratory hypersensitivity.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

** Changes with regards to the previous version

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SECTION 11: TOXICOLOGICAL INFORMATION ** (continued)

| Identification | Acute toxicity | | Genus |
|--|-----------------|------------------|-------|
| | LD50 oral | LD50 dermal | |
| Dehydrogenase, malate CAS: 9001-64-3 EC: 232-622-5 | >2000 mg/kg | >2000 mg/kg | |
| Imidazole CAS: 288-32-4 EC: 206-019-2 | LC50 inhalation | Non-applicable | |
| | LD50 oral | 500 mg/kg (ATEi) | |
| | LD50 dermal | >2000 mg/kg | |
| | LC50 inhalation | >5 mg/L (4 h) | |

Acute Toxicity Estimate (ATE mix):

| ATE mix | | Ingredient(s) of unknown toxicity |
|------------|-------------------------------------|-----------------------------------|
| Oral | 42977,04 mg/kg (Calculation method) | 0 % |
| Dermal | >2000 mg/kg (Calculation method) | Non-applicable |
| Inhalation | >20 mg/L (4 h) (Calculation method) | Non-applicable |

** Changes with regards to the previous version

SECTION 12: ECOLOGICAL INFORMATION **

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

| Identification | Acute toxicity | | Species | Genus |
|---|----------------|-------------------|-------------------------|------------|
| | LC50 | EC50 | | |
| Imidazole CAS: 288-32-4 EC: 206-019-2 | LC50 | 240 mg/L (48 h) | Leuciscus idus | Fish |
| | EC50 | 341.5 mg/L (48 h) | Daphnia magna | Crustacean |
| | EC50 | 130 mg/L (72 h) | Scenedesmus subspicatus | Algae |

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Product fails to meet PBT/vPvB criteria

12.6 Other adverse effects:

Not described

** Changes with regards to the previous version

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

| Code | Description | Waste class (Regulation (EU) No 1357/2014) |
|------|---|--|
| | It is not possible to assign a specific code, as it depends on the intended use by the user | Dangerous |

Type of waste (Regulation (EU) No 1357/2014):

HP10 Toxic for reproduction

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

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SECTION 13: DISPOSAL CONSIDERATIONS (continued)

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2019 and RID 2019:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Environmental hazards:** No
- 14.6 Special precautions for user**
Special regulations: Non-applicable
Tunnel restriction code: Non-applicable
Physico-Chemical properties: see section 9
Limited quantities: Non-applicable
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 39-18:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Environmental hazards:** No
- 14.6 Special precautions for user**
Special regulations: Non-applicable
EmS Codes:
Physico-Chemical properties: see section 9
Limited quantities: Non-applicable
Segregation group: Non-applicable
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2020:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Environmental hazards:** No
- 14.6 Special precautions for user**
Physico-Chemical properties: see section 9
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

SECTION 15: REGULATORY INFORMATION

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SECTION 15: REGULATORY INFORMATION (continued)**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Seveso III:

Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Product classified hazardous under the CMR. Sale and distribution to the general public is prohibited. Due to its CMR category, it is essential to apply the specific measures for workplace hazard prevention covered in articles 4 and 5 of the 2004/37/EC Directive and later modifications.

Shall not be used in:

- ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
- tricks and jokes,
- games for one or more participants, or any article intended to be used as such, even with ornamental aspects.

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION ****Legislation related to safety data sheets:**

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (Regulation (EC) No 2015/830)

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

COMPOSITION/INFORMATION ON INGREDIENTS (SECTION 3, SECTION 11, SECTION 12):

- New declared substances
 - Dehydrogenase, malate (9001-64-3)
 - Imidazole (288-32-4)

Substances that contribute to the classification (SECTION 2):

- New declared substances
 - Dehydrogenase, malate (9001-64-3)
 - Imidazole (288-32-4)

CLP Regulation (EC) No 1272/2008 (SECTION 2, SECTION 16):

- Pictograms
- Hazard statements
- Precautionary statements

Texts of the legislative phrases mentioned in section 2:

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled

H315: Causes skin irritation

H360: May damage fertility or the unborn child

H319: Causes serious eye irritation

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:*** Changes with regards to the previous version*

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Version: 2 (Replaced 1)

SECTION 16: OTHER INFORMATION ** (continued)

Acute Tox. 4: H302 - Harmful if swallowed
Eye Dam. 1: H318 - Causes serious eye damage
Repr. 1B: H360 - May damage fertility or the unborn child
Resp. Sens. 1: H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
Skin Corr. 1C: H314 - Causes severe skin burns and eye damage

Classification procedure:

Resp. Sens. 1: Calculation method
Skin Irrit. 2: Calculation method
Repr. 1B: Calculation method
Eye Irrit. 2: Calculation method

Advice related to training:

Minimal training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>
<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road
IMDG: International maritime dangerous goods code
IATA: International Air Transport Association
ICAO: International Civil Aviation Organisation
COD: Chemical Oxygen Demand
BOD5: 5-day biochemical oxygen demand
BCF: Bioconcentration factor
LD50: Lethal Dose 50
LC50: Lethal Concentration 50
EC50: Effective concentration 50
Log-POW: Octanol-water partition coefficient
Koc: Partition coefficient of organic carbon

*** Changes with regards to the previous version*

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -