



Safety Data Sheet

acc. to OSHA HCS

Printing date 03/03/2021

Reviewed on 03/03/2021

1 Identification

· **Product identifier**

· **Product name: Duloxetine-d3 Maleate**

· **Part number: TRC-D721004-IMG**

· **Application of the substance / the mixture** Reference material for laboratory use only

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

VHG

LGC Standards

276 Abby Road

Manchester, NH 03103

UNITED STATES OF AMERICA

Tel : +1 (603) 622-7660

Fax : +1 (603) 622-5180

Email : lgcusa@lgcgroup.com

Web : lgcstandards.com

· **Information department:**

Product safety department

eMail : sds-request@lgcgroup.com

· **Emergency telephone number:**

For Hazardous Materials or Dangerous Goods Incident
Spill, Leak, Fire Exposure, or Accident

Call CHEMTREC:

USA & Canada 1-800-424-9300

Rest of the world +1 703-741-5970

2 Hazard(s) identification

· **Classification of the substance or mixture**



GHS08 Health hazard

Repr. 2 H361-H362 Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.



GHS07

Acute Tox. 4 H302 Harmful if swallowed.

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

STOT SE 3 H335 May cause respiratory irritation.

· **Label elements**

· **GHS label elements**

The substance is classified and labeled according to the Globally Harmonized System (GHS).

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· Hazard pictograms

GHS07 GHS08

· Signal word Warning**· Hazard statements**

H302 Harmful if swallowed.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H361-H362 Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.

H335 May cause respiratory irritation.

· Precautionary statements

P260 Do not breathe dusts or mists.

P263 Avoid contact during pregnancy/while nursing.

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

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

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· Classification system:**· NFPA ratings (scale 0 - 4)**

Health = 2

Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)

Health = 2

Fire = 0

Reactivity = 0

· Other hazards**· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Substances**· CAS No. Description**

Duloxetine-d3 Maleate

· Identification number(s) -**· RTECS:** -

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· Additional information:

This product has been isotopically labelled with deuterium, a stable isotope of hydrogen.

4 First-aid measures

· Description of first aid measures**· General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· After inhalation: *Supply fresh air; consult doctor in case of complaints.***· After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing:

Rinse mouth. Do not induce vomiting.

Seek medical treatment.

· Information for doctor:

· Most important symptoms and effects, both acute and delayed *No further relevant information available.*

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

· Extinguishing media**· Suitable extinguishing agents:** *Use fire fighting measures that suit the environment.***· Special hazards arising from the substance or mixture**

Formation of toxic gases is possible during heating or in case of fire.

· Advice for firefighters**· Protective equipment:** *Wear self-contained respiratory protective device.*

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures *Avoid formation of dust.***· Environmental precautions:** *Do not allow to enter sewers/ surface or ground water.***· Methods and material for containment and cleaning up:**

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

· Protective Action Criteria for Chemicals**· PAC-1:** *Substance is not listed.*

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- **PAC-2:** Substance is not listed.
- **PAC-3:** Substance is not listed.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Store in cool, dry place in tightly closed receptacles.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Please refer to the manufacturers certificate for specific storage and transport temperature conditions.
Store only in the original receptacle unless other advice is given on the CoA.
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374



Protective gloves

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- **Material of gloves** Butyl rubber, BR
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:**



Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Solid
· Color:	White
· Odor:	Odorless
· Odor threshold:	Not determined.

· **pH-value:** Not applicable.

· Change in condition

· Melting point/Melting range:	128-130 °C (262.4-266 °F)
· Boiling point/Boiling range:	Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not determined.

· **Ignition temperature:** Not determined

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Not determined.

· **Danger of explosion:** Not determined.

· Explosion limits:

· Lower:	Not determined.
· Upper:	Not determined.

· **Vapor pressure:** Not applicable.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapor density** Not applicable.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with** Chloroform (Slightly), Methanol (Slightly)

· **Water:** Not determined.

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· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

Dynamic: Not applicable.

Kinematic: Not applicable.

· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity**

Stable under normal conditions.

No further relevant information available.

· **Chemical stability** Stable under normal conditions.

· **Thermal decomposition / conditions to be avoided:**

Formation of toxic gases is possible during heating or in case of fire.

· **Possibility of hazardous reactions** No dangerous reactions known.

· **Conditions to avoid** Heat.

· **Incompatible materials:** Strong oxidizing agents.

· **Hazardous decomposition products:** Formation of toxic gases is possible during heating or in case of fire.

11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **Primary irritant effect:**

· **on the skin:** Irritant to skin and mucous membranes.

· **on the eye:** Irritating effect.

· **Sensitization:** Based on available data, the classification criteria are not met.

· **Additional toxicological information:**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)** Substance is not listed.

· **NTP (National Toxicology Program)** Substance is not listed.

· **OSHA-Ca (Occupational Safety & Health Administration)** Substance is not listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Dispose in accordance with national regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT, ADR, IMDG, IATA | Not applicable |
| · DOT, ADR, IMDG, IATA | Not applicable |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Not applicable |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Not applicable |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Not applicable |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
No further relevant information available.
- **Sara**
- **Section 355 (extremely hazardous substances):** Substance is not listed.

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- **Section 313 (Specific toxic chemical listings):** Substance is not listed.
- **TSCA (Toxic Substances Control Act):** Substance is not listed.
- **Hazardous Air Pollutants** Substance is not listed.
- **Proposition 65**
- **Chemicals known to cause cancer:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
- **Chemicals known to cause reproductive toxicity for males:** Substance is not listed.
- **Chemicals known to cause developmental toxicity:** Substance is not listed.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** Substance is not listed.
- **TLV (Threshold Limit Value established by ACGIH)** Substance is not listed.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed.
- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Warning
- **Hazard statements**
 - H302 Harmful if swallowed.
 - H315 Causes skin irritation.
 - H319 Causes serious eye irritation.
 - H361-H362 Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.
 - H335 May cause respiratory irritation.
- **Precautionary statements**
 - P260 Do not breathe dusts or mists.
 - P263 Avoid contact during pregnancy/while nursing.
 - P280 Wear protective gloves/protective clothing/eye protection/face protection.
 - P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - P405 Store locked up.
 - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

The information in this Safety Data Sheet meets the requirements of the United States OCCUPATIONAL SAFETY AND HEALTH ACT and regulations promulgated thereunder (29 CFR 1910.1200 et. seq.) This document is intended only as a guide to the appropriate precautionary handling of the material by a person trained in, or supervised by a person trained in, chemical handling. The user is responsible for determining the application. Depending on usage, protective clothing including eye and face guards and respirators must be used to avoid contact with material or breathing chemical vapors/fumes. Exposure to this product may have serious adverse health effects. This chemical may interact with other substances. Since the potential uses are so varied, we cannot warn of all of the potential dangers of use or interaction with other chemicals or materials. We warrant that the chemical meets the specifications set forth on the label. We (LGC/VHG/ARMI)

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disclaim any other warranties, expressed or implied with regard to the product supplied hereunder, its merchantability or its fitness for a particular purpose. The user should recognize that this product can cause severe injury and even death, especially if improperly handled or the known dangers of use are not heeded. Read all precautionary information.

· Contact:**· Date of preparation / last revision** 03/03/2021 / -**· Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· Sources

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

· Data compared to the previous version altered. All sections have been updated.