

Triclabendazole

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Version: 1.0

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

1.1. Product identifier

Product form : Substance
Substance name : Triclabendazole
Product code : 201600925
Synonyms : Triclabendazole, salts, hydrates, isomers and impurities where applicable

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

1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.
Use of the substance/mixture : For professional use only
Function or use category : Laboratory chemicals

1.2.2. Uses advised against

Restrictions on use : Do not use : Ingestion, Inhalation, Dermal

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe 7, Allée Kastner, CS30026
F- 67081 Strasbourg
France
T +33(0)388412035 - F +33(0)388412771
sds@edqm.eu - www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Specific target organ toxicity – Repeated exposure, Category 2 H373
Hazardous to the aquatic environment – Acute Hazard, Category 1 H400
Full text of H- and EUH-statements: see section 16

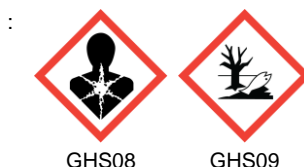
Adverse physicochemical, human health and environmental effects

Expert judgement and weight of evidence determination.

2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP)

: Warning

Hazard statements (CLP)

: H373 - May cause damage to organs through prolonged or repeated exposure.
H400 - Very toxic to aquatic life.

Precautionary statements (CLP)

: P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P273 - Avoid release to the environment.
P314 - Get medical advice/attention if you feel unwell.
P391 - Collect spillage.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

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Labelling according to: exemption for inner packaging where the contents do not exceed 10ml
Hazard pictograms (CLP) :



GHS08

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-----------------|--------------------|-------|---|
| Triclabendazole | - | ≤ 100 | STOT RE 2, H373 Aquatic Acute 1, H400 |

Full text of H- and EUH-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after skin contact : Wipe off as much as possible (using a clean, soft, absorbent material).
First-aid measures after eye contact : Rinse eyes with water as a precaution.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Extinguishing blanket.

5.2. Special hazards arising from the substance or mixture

Fire hazard : See Heading 2.2.

5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Avoid all unnecessary exposure.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

No additional information available

6.3. Methods and material for containment and cleaning up

No additional information available

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No additional information available

7.2. Conditions for safe storage, including any incompatibilities

No additional information available

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

No additional information available

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8.2.2.2. Skin protection

Skin and body protection:

Lab coat

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

No additional information available

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

No additional information available

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|--------------------|
| Physical state | : Solid |
| Colour | : Not available |
| Appearance | : Powder. |
| Odour | : Not available |
| Odour threshold | : Not available |
| Melting point | : Not available |
| Freezing point | : Not available |
| Boiling point | : Not available |
| Flammability | : Not available |
| Explosive limits | : Not applicable |
| Lower explosion limit | : Not applicable |
| Upper explosion limit | : Not applicable |
| Flash point | : Not applicable |
| Auto-ignition temperature | : Not applicable |
| Decomposition temperature | : Not available |
| pH | : Not available |
| pH solution | : Not available |
| Viscosity, kinematic | : Not applicable |
| Solubility | : Water: < 0.1 g/l |
| Partition coefficient n-octanol/water (Log Kow) | : Not available |
| Vapour pressure | : Not available |
| Vapour pressure at 50°C | : Not available |
| Density | : Not available |
| Relative density | : Not available |
| Relative vapour density at 20°C | : Not applicable |
| Particle size | : Not available |

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

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10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

None under normal use. See Section 7.

10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

SECTION 11: Toxicological information

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

| | |
|-----------------------------|---|
| Acute toxicity (oral) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (dermal) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (inhalation) | : Not classified (Lack of data) |

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| | |
|---------------|--------------|
| LD50 oral rat | > 2000 mg/kg |
|---------------|--------------|

| | |
|-----------------|--------------|
| LD50 dermal rat | > 2000 mg/kg |
|-----------------|--------------|

| | |
|-----------------------------------|--|
| Skin corrosion/irritation | : Not classified (Lack of data) |
| Serious eye damage/irritation | : Not classified (Lack of data) |
| Respiratory or skin sensitisation | : Not classified (Lack of data) |
| Germ cell mutagenicity | : Not classified (Lack of data) |
| Carcinogenicity | : Not classified (Lack of data) |
| Reproductive toxicity | : Not classified (Lack of data) |
| STOT-single exposure | : Not classified (Lack of data) |
| STOT-repeated exposure | : May cause damage to organs through prolonged or repeated exposure. |
| Aspiration hazard | : Not classified (Technical impossibility to obtain the data) |

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

| | |
|---|--|
| Ecology - general | : Presents no specific risk for the environment. |
| Hazardous to the aquatic environment, short-term (acute) | : Very toxic to aquatic life. |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified |

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

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

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

| ADR | IMDG | IATA |
|---|--|--|
| 14.1. UN number or ID number | | |
| UN 3077 | UN 3077 | UN 3077 |
| 14.2. UN proper shipping name | | |
| ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | Environmentally hazardous substance, solid, n.o.s. |
| Transport document description | | |
| UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-) | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT | UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III |
| 14.3. Transport hazard class(es) | | |
| 9 | 9 | 9 |
| | | |
| 14.4. Packing group | | |
| III | III | III |
| 14.5. Environmental hazards | | |
| Dangerous for the environment: Yes | Dangerous for the environment: Yes Marine pollutant: Yes | Dangerous for the environment: Yes |
| No supplementary information available | | |

14.6. Special precautions for user

Overland transport

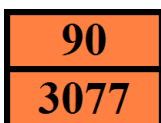
Classification code (ADR) : M7
Special provisions (ADR) : 274, 335, 375, 601
Limited quantities (ADR) : 5kg

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| | |
|---|---------------------------|
| Excepted quantities (ADR) | : E1 |
| Packing instructions (ADR) | : P002, IBC08, LP02, R001 |
| Special packing provisions (ADR) | : PP12, B3 |
| Mixed packing provisions (ADR) | : MP10 |
| Portable tank and bulk container instructions (ADR) | : T1, BK1, BK2, BK3 |
| Portable tank and bulk container special provisions (ADR) | : TP33 |
| Tank code (ADR) | : SGAV, LGBV |
| Vehicle for tank carriage | : AT |
| Transport category (ADR) | : 3 |
| Special provisions for carriage - Packages (ADR) | : V13 |
| Special provisions for carriage - Bulk (ADR) | : VC1, VC2 |
| Special provisions for carriage - Loading, unloading and handling (ADR) | : CV13 |
| Hazard identification number (Kemler No.) | : 90 |
| Orange plates | : |



| | |
|-------------------------------|-----|
| Tunnel restriction code (ADR) | : - |
|-------------------------------|-----|

Transport by sea

| | |
|-----------------------------------|---------------------------|
| Special provisions (IMDG) | : 274, 335, 966, 967, 969 |
| Limited quantities (IMDG) | : 5 kg |
| Excepted quantities (IMDG) | : E1 |
| Packing instructions (IMDG) | : LP02, P002 |
| Special packing provisions (IMDG) | : PP12 |
| IBC packing instructions (IMDG) | : IBC08 |
| IBC special provisions (IMDG) | : B3 |
| Tank instructions (IMDG) | : BK1, BK2, BK3, T1 |
| Tank special provisions (IMDG) | : TP33 |
| EmS-No. (Fire) | : F-A |
| EmS-No. (Spillage) | : S-F |
| Stowage category (IMDG) | : A |
| Stowage and handling (IMDG) | : SW23 |

Air transport

| | |
|--|-------------------------------|
| PCA Excepted quantities (IATA) | : E1 |
| PCA Limited quantities (IATA) | : Y956 |
| PCA limited quantity max net quantity (IATA) | : 30kgG |
| PCA packing instructions (IATA) | : 956 |
| PCA max net quantity (IATA) | : 400kg |
| CAO packing instructions (IATA) | : 956 |
| CAO max net quantity (IATA) | : 400kg |
| Special provisions (IATA) | : A97, A158, A179, A197, A215 |
| ERG code (IATA) | : 9L |

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

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

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REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not applicable.

POP Regulation (Persistent Organic Pollutants)

Not applicable.

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

Classification of the substance or mixture.

| Full text of H- and EUH-statements: | |
|-------------------------------------|--|
| Aquatic Acute 1 | Hazardous to the aquatic environment – Acute Hazard, Category 1 |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| STOT RE 2 | Specific target organ toxicity – Repeated exposure, Category 2 |

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.