

Colchicine for system suitability B

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 23/02/2024 Revision date: 08/01/2026 Supersedes version of: 23/02/2024 Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Colchicine for system suitability B
Chemical name : Colchicine
EC Index-No. : 614-005-00-6
EC-No. : 200-598-5
CAS-No. : 64-86-8
Product code : 202400006

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development
Technical testing and analysis
For professional use only
Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

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]

Germ cell mutagenicity, Category 1B H340
Acute toxicity (oral), Category 2 H300
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Fatal if swallowed. May cause genetic defects.

2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP)

: Danger

Hazard statements (CLP)

: H340 - May cause genetic defects.
H300 - Fatal if swallowed.

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Precautionary statements (CLP) :

- P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P264 - Wash hands, forearms and face thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.
- P308+P313 - IF exposed or concerned: Get medical advice/attention.
- P321 - Specific treatment (see supplemental first aid instruction on this label).
- P330 - Rinse mouth.
- P405 - Store locked up.
- P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP) :



2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Other information : Active substance (in pharmaceutical products).
Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Colchicine	CAS-No.: 64-86-8 EC-No.: 200-598-5 EC Index-No.: 614-005-00-6	≤ 100	Muta. 1B, H340 Acute Tox. 2 (Oral), H300 (ATE=26 mg/kg)

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). 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

Symptoms/effects after ingestion : Fatal if swallowed.

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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 | : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket. |
| Unsuitable extinguishing media | : Do not use a heavy water stream. |

5.2. Special hazards arising from the substance or mixture

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| Hazardous decomposition products in case of fire | : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released. |
|--|--|

5.3. Advice for firefighters

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|--------------------------------|--|
| Firefighting instructions | : Prevent fire fighting water from entering the environment. |
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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|------------------|---|
| General measures | : Avoid contact with skin, eyes and clothing. |
|------------------|---|

For non-emergency personnel

- | | |
|----------------------|-----------------------------------|
| Emergency procedures | : Evacuate unnecessary personnel. |
|----------------------|-----------------------------------|

For emergency responders

- | | |
|----------------------|---|
| Protective equipment | : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection". |
|----------------------|---|

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

- | | |
|-------------------------|---|
| For containment | : Absorb with an inert material and place in an appropriate waste disposal container. |
| Methods for cleaning up | : Clean contaminated surfaces with an excess of water. Clean with the help of detergents. |

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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|-----------------------------------|--|
| Additional hazards when processed | : Do not expose pregnant or breastfeeding women. |
| Precautions for safe handling | : Avoid all unnecessary exposure. Ensure good ventilation of the work station. |
| Hygiene measures | : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work. |

7.2. Conditions for safe storage, including any incompatibilities

- | | |
|---------------------|---|
| Storage conditions | : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight. |
| Packaging materials | : Keep in original containers. |

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7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: yellowish-white.
Appearance	: Powder.
Molecular mass	: 399,4 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: $\approx 157^{\circ}\text{C}$
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
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: > 1000 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

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Particle size : Not 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

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Fatal if swallowed.
Acute toxicity (dermal) : Not classified (Lack of data)
Acute toxicity (inhalation) : Not classified (Lack of data)

Colchicine (64-86-8)	
LD50 oral rat	26 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	: May cause genetic defects.
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Lack of data)

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Hazardous to the aquatic environment, long-term (chronic) : Not classified (Lack of data)

12.2. Persistence and degradability

Colchicine (64-86-8)

Persistence and degradability	Not rapidly degradable
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12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Colchicine (64-86-8)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

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 1544	UN 1544	UN 1544
14.2. UN proper shipping name		
ALKALOIDS, SOLID, N.O.S.	ALKALOIDS, SOLID, N.O.S.	Alkaloids, solid, n.o.s.
Transport document description		
UN 1544 ALKALOIDS, SOLID, N.O.S., 6.1, II, (D/E)	UN 1544 ALKALOIDS, SOLID, N.O.S., 6.1, II	UN 1544 Alkaloids, solid, n.o.s., 6.1, II
14.3. Transport hazard class(es)		
6.1	6.1	6.1

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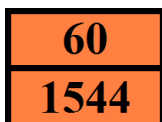
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
14.4. Packing group		
II	II	II
14.5. Environmental hazards		
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-A EmS-No. (Spillage): S-A	Dangerous for the environment: No
No supplementary information available		

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: T2
Special provisions (ADR)	: 43, 274
Limited quantities (ADR)	: 500g
Excepted quantities (ADR)	: E4
Packing instructions (ADR)	: P002, IBC08
Special packing provisions (ADR)	: B4
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAH, L4BH
Tank special provisions (ADR)	: TU15, TE19
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Special provisions for carriage - Packages (ADR)	: V11
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13, CV28
Special provisions for carriage - Operation (ADR)	: S9, S19
Hazard identification number (Kemler No.)	: 60
Orange plates	:



Tunnel restriction code (ADR)	: D/E
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Transport by sea

Special provisions (IMDG)	: 43, 274
Limited quantities (IMDG)	: 500 g
Excepted quantities (IMDG)	: E4
Packing instructions (IMDG)	: P002
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B21, B4
Tank instructions (IMDG)	: T3
Tank special provisions (IMDG)	: TP33
Stowage category (IMDG)	: A
Properties and observations (IMDG)	: A wide range of toxic solids, generally of vegetable origin. Toxic if swallowed, by skin contact or by inhalation.

Air transport

PCA Excepted quantities (IATA)	: E4
PCA Limited quantities (IATA)	: Y644
PCA limited quantity max net quantity (IATA)	: 1kg
PCA packing instructions (IATA)	: 669
PCA max net quantity (IATA)	: 25kg
CAO packing instructions (IATA)	: 676
CAO max net quantity (IATA)	: 100kg

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Special provisions (IATA) : A3, A5, A6, A801
ERG code (IATA) : 6L

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

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)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (2024/590)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Not listed on the Explosives Precursors list (EU)

Drug Precursors Regulation (EC 273/2004)

Not listed on the Drug Precursors list (EU)

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Special packing provisions (ADR)	Modified
	Special provisions (IATA)	Modified
	Supersedes version of	Added
	Revision date	Added
1.2	Main use category	Removed
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.2	Precautionary statements (CLP)	Modified
3	Composition/information on ingredients	Modified
4.1	First-aid measures after ingestion	Modified
4.1	First-aid measures after eye contact	Modified

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Indication of changes		
Section	Changed item	Comments
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after inhalation	Modified
4.1	First-aid measures general	Added
4.2	Symptoms/effects after skin contact	Removed
4.2	Symptoms/effects after inhalation	Removed
4.2	Symptoms/effects after eye contact	Removed
4.2	Symptoms/effects	Removed
4.2	Symptoms/effects after ingestion	Modified
4.3	Other medical advice or treatment	Removed
5.1	Suitable extinguishing media	Modified
5.1	Unsuitable extinguishing media	Added
5.2	Fire hazard	Removed
5.2	Hazardous decomposition products in case of fire	Added
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified
6.1	General measures	Modified
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Modified
6.4	Reference to other sections (8, 13)	Added
7.1	Hygiene measures	Modified
7.1	Additional hazards when processed	Modified
7.1	Precautions for safe handling	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.2	Storage conditions	Modified
7.3	Specific end uses	Removed
8.2	Eye protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
8.2	Respiratory protection	Modified
8.2	Hand protection	Modified
9	Odour	Removed
9	Molecular mass	Added
9	Melting point	Added

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Indication of changes		
Section	Changed item	Comments
9	Colour	Added
10.1	Reactivity	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	LD50 oral rat	Added
11.1	ATE CLP (oral)	Modified
12.1	Ecology - general	Removed
13.1	Regional waste regulation	Removed
13.1	Product/Packaging disposal recommendations	Removed
14.2	Proper Shipping Name (ADR)	Modified

Full text of H- and EUH-statements:	
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Muta. 1B	Germ cell mutagenicity, Category 1B
H300	Fatal if swallowed.
H340	May cause genetic defects.

Safety Data Sheet (SDS), EU

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