


Product name: Sulfobutyl- ether- β-cyclodextrin sodium salt	Product code: CY-2041.1, CY- 2041.2, CY-2041.3, CY-2041.4, 47 or 50	Revised date: 18.05.2023
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1. Identification of the Substance/Preparation and Company

Name of substance/preparation:

Chemical name: Sulfobutyl-ether-β-cyclodextrin sodium salt
Abbreviation: SBECD
Trade name: Dexolve™

Use of substance/preparation:

Industrial. Pharmaceutical excipient

Information about Manufacturer:

Cyclolab R&D. Ltd., Budapest, Hungary
H-1097 Budapest, IX. Illatos út 7, Hungary



Tel: (36-1)-347-60-70; e-mail: cyclolab@cyclolab.hu

2. Hazards Identification

Classification and labelling according to EC 1272/2008

H-phrase	H317	May cause an allergic skin reaction.
P-phrase	P261	Avoid breathing dust/fume/gas/mist/vapours/spray
	P272	Contaminated work clothing should not be allowed out of the workplace
	P280	Wear protective gloves/protective clothing/eye protection/face protection
	P302+P352	ON SKIN: Wash with plenty of soap and water
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P363	Wash contaminated clothing before reuse

Classification and labelling according to 67/548/EEC, EC 1999/45

R-phrase	R 43	May cause sensitisation by skin contact
S-phrase	S1/2	Keep locked up and out of the reach of children
	S 3	Keep in a cool place
	S 8	Keep container dry
	S 15	Keep away from food, drink and animal foodstuffs
	S 13	Keep away from heat
	S 20/21	When using do not eat, drink or smoke
	S 24/25	Avoid contact with skin and eyes
	S 28	After contact with skin, wash immediately with plenty of water
	S 43	In case of fire use water, extinguishing powder, alcohol-resistant foam, carbon dioxide
	S 47	Keep at temperature not exceeding 30 °C
	S 51	Use only in well-ventilated areas

Further information:

Risk of dust explosion. Minimum explosive concentration for dust/vapour is 75 - 80 g/m³

3. Composition/Information on ingredients


Chemical characterization:

EC-No.	CAS No.	Chemical characteristics
-	182410-00-0	Beta-cyclodextrin sulfobutyl ether, sodium salts

4. First-Aid Measures

General information

Potentially harmful; avoid prolonged or repeated exposure. Do not get in eye or skin or on clothing. In case of accident or if you feel unwell seek medical advice (show label or MSDS where possible).

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If inhaled

Provide fresh air. Lack of respiration oxygen must be administered in the respiratory equipment.

In case of skin contact

The contaminated clothes must be removed and the skin must be washed with water to remove the material and consult with physician.

In case of eye contact

Rinse thoroughly with plenty of water.

If swallowed

Rinse mouth with water. Drink several small portions of water. Do not induce vomiting. Never give anything by mouth to an unconscious person.

5. Fire Fighting Measures

Suitable extinguishing media:

Water, extinguishing powder, alcohol-resistant foam, carbon dioxide

Extinguishing media which must not be used for safety reasons:

n.d.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases:

At low oxygen level: carbon monoxide

Special protective equipment for fire fighters:

Use respiratory protection independent of recirculated air.

6. Accidental Release Measures

Personal precautions:

Avoid dust formation. Do not breathe dust.

Environmental precautions:

Cover any spilled material in accordance with regulations to prevent dispersal by wind. Observe local/state/federal regulations.

Methods for cleaning up:

Take up mechanically and dispose of according to local/state/federal regulations. Avoid formation of dust and dust deposition. Wash the surface with water.

7. Handling and Storage

Handling

Precaution for safe handling: Avoid dust formation. Gloves, protective clothing and eyewear should be worn and safe laboratory practices followed. Mechanical ventilation is recommended.

Precautions against fire and explosion: Observe the general rules for fire prevention. Avoid dust deposit, remove dust regularly. Take precautionary measures against electrostatic charging. Take precautionary measures against dust explosion.

Storage

Conditions for storage rooms and vessels: Observe precautionary measures against dust explosion.

Advice for storage of incompatible materials: none known

Further information for storage: Keep container tightly closed. Protect from direct light and source of heat.

Store under dry conditions below 30 °C, in well-ventilated place.

8. Exposure Control and Personal Protection Equipment


Exposure limits

No data

Exposure limited and controlled

Exposure in the workplace limited and controlled:

General protection and hygiene measures: Observe standard industrial hygiene practices for the handling of chemical substances.

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Personal protection equipment:

Respiratory protection: In case of dust formation: fine dust mask without protection rating.

Hand protection: rubber gloves

Eye protection: tight fitting protective goggles

Exposure to the environment limited and controlled:

Prevent material from entering surface waters and soil

Further information for system design and engineering measures

Observe information in section 7.

9. Physical and Chemical Properties

General information

Physical state/form	solid - powder
Colour	white or slightly yellow
Odour	n.a.

Important information about the protection of health, safety, and the environment

Ignition temperature	> 250°C
Phase transition	> 200°C (Floating Point)
Oxidizing properties	no
Lower explosion limit (LEL)	n.d.
Upper explosion limit (UEL)	n.d.
Bulk density	n.d.
Water solubility / miscibility	water soluble
pH- value (1% in water)	4.0-7.5

Other information

See Product Information Sheet.

10. Stability and Reactivity

General information:

If stored and handled in accordance with standard industrial practices no hazardous reactions are known.

Conditions to avoid:

None known

Materials to avoid:

Decomposes in strongly acidic solutions

Hazardous decomposition products:

None known

11. Toxicological Information

General information:

According to our present state of knowledge no damaging effect expected when treated in accordance with standard industrial practices and local regulations where applicable.

Toxicological tests:

Acute toxicity (LD50/LC50-values relevant to classification):

Oral; rat; Dose: >2000 mg/kg No effects.

Intravenous; rat; Dose: >2000 mg/kg No effects.

Intravenous; mouse; Dose: >2000 mg/kg No effects.

Teratogenicity:


Intravenous; rat; Dose: 3000/mg/kg/day No effect to embryo/fetal development.

Intravenous; rabbit; Dose: 1500/mg/kg/day No effect to embryo/fetal development.

Reproductive:

Intravenous; rat (male); Dose: 1500 mg/kg/day No effects.

Intravenous; rat (female); Dose: 1500 mg/kg/day No effects.

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Intravenous; rat (male); Dose: 3000 mg/kg/day Not applicable.
 Intravenous; rat (female); Dose: 3000 mg/kg/day Increased still births.
Synergistic Products: None identified.

Exposure Limits: OEL

Type	Value
TWA	3mg/m ³

Carcinogenicity:

Studies to evaluate the carcinogenic potential of this product have not been conducted.

NTP	IARC	OSHA
Not Classified	Not Classified	Not Classified

Primary irritation:

No data

Sensitization:

Topical; guinea pig; Dose 3.75% Sensitization to skin.

Topical; guinea pig; Dose 7.5% Sensitization to skin.

Substance to chronic toxicity:

Other Chronic Effects: None identified.

Reference points for mutagenic potential:

No effects.

Source of information: test reports

Experience with man:

Signs and Symptoms of Overexposure: Redness or irritation of the skin.

Medical Conditions Aggravated by Overexposure: Individuals with hypersensitivity to this material or other materials in its chemical class.

12. Ecological Information

Ecotoxicity

This substance was not acutely toxic to aquatic organisms at its maximum solubility.

Aquatic toxicity: None identified.

Mobility

In the environment, this substance is expected to remain in water or migrate through the soil to groundwater and persist.

Persistence and degradability

In the environment, this substance is expected to remain in water or migrate through the soil to groundwater and persist.

Biodegradation / further information:

This substance is not expected to inhibit wastewater treatment microorganisms.

Bio-accumulation potential

Long term effects and bioaccumulation are not expected.

13. Disposal Considerations

Material

Recommendation:

Observe local/state/federal regulations.

Uncleaned packaging

Recommendation:

Completely discharge containers (no powder rest, scraped carefully). Containers may be recycled or re-used.
 Observe local/state/federal regulations.

14. Transport Regulations


Land transport ADR and RID:

Road ADR:

Not regulated for transport.

Railway RID:

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Transport by sea IMDG-Code:

Sea IMDG-Code:

Not regulated for transport

Air transport ICAO-TI/IATA-DGR:

Air transport ICAO-TI/IATA-DGR:

Not regulated for transport

15. Regulatory Information

National and local regulations must be observed.

16. Other Information

Material

The above information describes exclusively the safety requirements of the product(s) and is based on our present-day knowledge. It does not represent a guarantee for the properties of the product(s) described in terms of the legal warranty regulations. Properties of the product are to be found in the respective product leaflet (if applicable).

Further information

This version supersedes all previous versions.