Captisol/Advasep 7/SBE-AE-Beta-CD

Safety Data Sheet


1. Product identifier

1.1. Product name

Captisol/Advasep 7/SBE-AE-Beta-CD

1.2. Substances

Chemical name: Oligosaccharide derivative

CAS No: 183410-00-0

1.3. Conversion between formaldehyde and Captisol

Captisol = n=5-6-8

Advasep = n=7-5.7

2. Identity and composition

2.1. Substance identification

Synonyms: Beta-cyclodextrin sulfobutyl ethers sodium salts (BCSBE); sulfobutyl ether-beta-cyclodextrin sodium (SBECD); C27H27ClO4Na; Beta-cyclodextrin sulfobutyl ethers sodium salts; Captisol, sodium salt; Captisol/Advasep 7/SBE-AE-Beta-CD

2.2. Use

Use of the substance/mixture

Typically used as an excipient.

Use of substances/mixture

No additional information available.

2.3. Details of the safety data sheet

Company: Cybulles Pharmaceuticals, Inc.

Address: 2020 Boxter Drive, Suite 217

Location: Lawrence, KS 66049

T (913) 402-3144

3. Hazards identification

3.1. Classification of the substance or mixture

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

Skin S1: H317

Full text of classification categories and in statement are visible in section 16.

Adverse physicochemical, human health and environmental effects

No additional information available.

3.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008

Hazard pictograms

CLP

Signal word [CLP]

Warning

Hazard statements [CLP]

H317 - May cause an allergic skin reaction

Precautionary measures [CLP]

Exposure limit values

No data available.

4. First aid measures

First aid measures after contact with eyes

Wear protective goggles. Do not mix with other materials. Avoid contact with skin, eyes and clothing. Avoid breathing dust. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, and other ignition sources. No smoking.

First aid measures after contact with skin

Avoid contact with skin, eyes and clothing. Avoid breathing dust. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, and other ignition sources. No smoking.

First aid measures after ingestion

Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

First-aid measures after skin contact

Wear suitable protective clothing.

4.2. Reactions in the event of mixture contact

None

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

If exposed or concerned, get medical advice/attention. If medical advice is needed, have product container or label at hand.

4.4. Symptoms and effects

Symptoms after inhalation

Redness, pain, swelling, itching, burning, dryness, and dermatitis.

4.5. Bioavailability

Intake of this substance is unlikely.

4.6. Stability and reactivity

Stability

None

Hazardous decomposition products

None

5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media

Unsuitable extinguishing media

Carbon dioxide, dry chemical, foam, water spray, fog.

5.2. Special hazards arising from the substance or mixture

Fire hazard

Explosion hazard

Reactivity

Hazardous decomposition products in case of fire

Combustible Dust

Fire: Fine dust clouds may form explosive mixtures with air. Dust explosion hazard in air.

Hazardous fumes will not occur under normal conditions.

Carbon dioxide, CO2; Sodium oxide, Sodium suflates.

5.3. Advice for firefighters

Precautionary measures fire

Fighting instructions

Fire fighting measures

None

5.4. Protective equipment for fire-fighters

None

5.5. Information on safety precautions and safe handling

Precautions to be taken when using

None

5.6. Control measures

Ventilation

Ventilation is not necessary.

6. Accidental release measures

6.1. Personal protective equipment, protective clothing and emergency procedures

General measures

Do not allow product to spread into the environment. Avoid breathing dust. Do not get in eyes, on skin, or on clothing. Avoid generating dust. Avoid keeping away from heat, hot surfaces, sparks, open flames, and other ignition sources.

6.2. Other information

Risk of fire explosion.

6.3. Exposure controls/Personal protective equipment

Respiratory protection

None

Eye protection

Chemically resistant materials and fabrics.

Personal protective equipment

Gloves, Protective clothing, Protective goggles.

7. Handling and storage

7.1. Precautions for safe handling

Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

Procedures for safe handling

Avoid contact with skin, eyes and clothing. Avoid breathing dust. Avoid creasing or spreading dust. Keep away from heat, sparks, open flames, hot surfaces. – No smoking. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures

Comply with applicable regulations. Avoid creasing or spreading dust. Use explosion-proof electrical, ventilation, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

Storage conditions

Keep container closed when not in use. Store in a dry, cool place. Keep away from direct sunlight, extremely high or low temperatures and incompatible materials.

7.3. Specific end use

Typically used as an excipient.

7.4. Transport information

Particular end use regulated [PGR]

Belgium Limit value (mg/m³)

3 mg/m³ (alveolar fraction)

3 mg/m³ (total dust)

France Limit value (mg/m³)

10 mg/m³ (respirable fraction)

10 mg/m³ (total dust)

USA OSHA ACGIH TLV (mg/m³)

3 mg/m³ (respirable fraction)

3 mg/m³ (total dust)

Spain Limit value (mg/m³)

10 mg/m³ (recommended limit, this value is for the particulate matter that is free from Asbestos and contains less than 2% of Crystalline silica inhalable fraction)

5 mg/m³ (inhalable fraction)

Ireland Limit value (mg/m³)

4 mg/m³ (respirable)

5 mg/m³ (total dust)

24 mg/m³ (alveolar respirable)

10 mg/m³ (total dust)

24 mg/m³ (total dust)

4.2.2. Uses advised against

Strong acids, strong bases, strong oxidizers.

4.2.3. Uses not advised

Keep container closed when not in use. Store in a dry, cool place. Keep away from heat, sparks, open flames, hot surfaces. – No smoking. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

4.2.4. Incompatible materials

Further information: see sections 16

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

If exposed or concerned, get medical advice/attention. If medical advice is needed, have product container or label at hand.

5. Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media

Unsuitable extinguishing media

Carbon dioxide, dry chemical, foam, water spray, fog.

5.2. Special hazards arising from the substance or mixture

Fire hazard

Explosion hazard

Reactivity

Hazardous decomposition products in case of fire

Combustible Dust

Fire: Fine dust clouds may form explosive mixtures with air. Dust explosion hazard in air.

Hazardous fumes will not occur under normal conditions.

Carbon dioxide, CO2; Sodium oxide, Sodium suflates.

5.3. Advice for firefighters

Precautionary measures fire

Fighting instructions

Fire fighting measures

None

5.4. Protective equipment for fire-fighters

None

5.5. Information on safety precautions and safe handling

Precautions to be taken when using

None

Procedures for safe handling

Avoid contact with skin, eyes and clothing. Avoid breathing dust. Avoid creasing or spreading dust. Keep away from heat, sparks, open flames, hot surfaces. – No smoking. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

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Technical measures

Comply with applicable regulations. Avoid creasing or spreading dust. Use explosion-proof electrical, ventilation, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

Storage conditions

Keep container closed when not in use. Store in a dry, cool place. Keep away from direct sunlight, extremely high or low temperatures and incompatible materials.

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4 mg/m³ (respirable)

5 mg/m³ (total dust)

24 mg/m³ (alveolar respirable)

10 mg/m³ (total dust)

24 mg/m³ (total dust)
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SECTION 10: Stability and reactivity

10.1. Reactivity
Hazardous reactions will not occur under normal conditions.

10.2. Chemical stability
Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions
Hazardous polymerisation will not occur.

10.4. Conditions to avoid
Exposure to heat, sparks, open flame, other sources of ignition.

10.5. Incompatible materials
Strong acids, strong base, strong oxidisers.

10.6. Hazardous decomposition products
None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
Acute toxicity: Not classified
Skin corrosivity/irritation: Not classified
Serious eye damage/irritation: Not classified
Respiratory or skin sensitisation: May cause an allergic skin reaction.
Germ cell mutagenicity: Not classified
Reproductive toxicity: Not classified
Specific target organ toxicity (single exposure): Not classified
Specific target organ toxicity (repeated exposure): Not classified
Aspiration hazard: May cause respiratory irritation. Dust may be harmful or cause irritation.
Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.
Symptoms/Injuries After Eye Contact: May cause eye irritation.
Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.
Chronic Symptoms: The chronic effects of this substance are unknown.

Potential adverse human/health effects and symptoms: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity
Ecology - general: Not classified.
12.2. Persistence and degradability: Not established.
12.3. Bioaccumulative potential: not established.
12.4. Mobility in soil: Not applicable.
12.5. Results of PBT and vPvB assessment: No additional information available.
12.6. Other adverse effects
Other adverse effects: Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Sewage disposal recommendations: Do not empty into drains; dispose of this material and its container in a safe way.
Waste disposal recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.
Additional information: Container may remain hazardous when empty. Continue to observe all precautions.
Ecology: Avoid release to the environment.

SECTION 14: Transport information

14.1. UN number: Not regulated for transport.
14.2. UN proper shipping name: Not applicable.
14.3. Transport hazard class(es): Not applicable.
14.4. Packing group: Not applicable.
14.5. Environmental hazards:
- Dangerous for the environment: No
- Marine pollutant: No

14.6. Special precautions for user: No additional information available.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code: 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
- Captisol/Advasep 7/SBE-AE-Beta-CD is not on the REACH Candidate List.
- Captisol/Advasep 7/SBE-AE-Beta-CD is not on the REACH Annex XIV List.
- Captisol/Advasep 7/SBE-AE-Beta-CD is not on the REACH Annex XV List.
- Captisol (182410-00-0) is not on the REACH Annex XIV List.
- Captisol (182410-00-0) is not on the REACH Candidate List.
- No REACH Annex XVI restrictions.
- Contains no REACH Annex XIV substances.
- Contains no substance on the REACH Candidate List.

15.1.2. National regulations: No additional information available.

15.2. Chemical safety assessment: No chemical safety assessment has been carried out.

SECTION 16: Other information

Revision date: 04/02/2016

Full text of H- and EUH-statements:
- H317: May cause an allergic skin reaction.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.