

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

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EC) No. 453/2010

Revision date: 04/02/2016

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Version: 1.0

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

1.1. Product identifier

Product form	: Substance
Substance name	: Captisol/Advasep 7/SBE-AE-Beta-CD
Chemical name	: Oligosaccharide derivative
CAS No	: 182410-00-0
Formula	: $C_{42}H_{70-n}O_{35} \cdot (C_4H_8SO_3Na)_n \cdot xH_2O$ Captisol: n=6.2-6.9 Advasep 7: n=5.5-7.5 SBE-AE-Beta-CD: Beta-CD-(O-CH ₂ -CH ₂ -CH ₂ -CH ₂ -SO ₃) _n (O-CH ₂ -CH ₃) _{n2} ; n=3-10, n2=3-10
Synonyms	: Beta-cyclodextrin sulfobutyl ethers, sodium salts (BCDSBE) Sulfobutyl ether Beta-cyclodextrin sodium (SBECD) CP-217, 816-02 Betadex Sulfobutyl Ether Sodium

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Typically used as an excipient.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Company

CyDex Pharmaceuticals, Inc.
2029 Becker Drive, Suite 217
Lawrence, KS 66047
T (913) 402-3514
info@captisol.com

1.4. Emergency telephone number

Emergency number : (913) 402-3514; (913) 685-8850 (Hours: 8-5 EST)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin Sens. 1 H317

Full text of classification categories and H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP)	: Warning
Hazard statements (CLP)	: H317 - May cause an allergic skin reaction
Precautionary statements (CLP)	: P261 - Avoid breathing vapors, mist, or spray. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves, protective clothing, and eye protection. P302+P352 - IF ON SKIN: Wash with plenty of water. P321 - Specific treatment (see section 4 on this SDS). P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse. P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

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2.3. Other hazards

Other hazards not contributing to the classification : Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

SECTION 3: Composition/information on ingredients

3.1. Substance

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

CAS No : 182410-00-0

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Captisol	(CAS No) 182410-00-0 (EC no) 417-710-5	100	Skin Sens. 1, H317

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service.

First-aid measures after skin contact : Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid measures after eye contact : Do not rub. Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : May cause an allergic skin reaction. Dust may cause mechanical irritation to eyes, nose, throat, and lungs.

Symptoms/injuries after inhalation : 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.

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

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

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Carbon dioxide, dry chemical, foam, water spray, fog.

Unsuitable extinguishing media : Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Combustible Dust.

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

Reactivity : Hazardous reactions will not occur under normal conditions.

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO₂). Sodium oxides. Sulphur oxides.

5.3. Advice for firefighters

Precautionary measures fire : Exercise caution when fighting any chemical fire.

Firefighting instructions : Use water spray or fog for cooling exposed containers.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

Other information : Risk of dust explosion.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment 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. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.

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6.1.1. For non-emergency personnel

Protective equipment : Use appropriate personal protection equipment (PPE).
Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.
Methods for cleaning up : Clean up spills immediately and dispose of waste safely. Use explosion proof vacuum during clean-up, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools. Contact competent authorities after a spill.

6.4. Reference to other sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : 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.
Precautions for safe handling : Avoid contact with skin, eyes and clothing. Avoid breathing dust. Avoid creating 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.
Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Comply with applicable regulations. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, 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/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.
Incompatible products : Strong acids, strong bases, strong oxidizers.

7.3. Specific end use(s)

Typically used as an excipient.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Particulates not otherwise regulated (PNOR)		
Belgium	Limit value (mg/m ³)	3 mg/m ³ (alveolar fraction) 10 mg/m ³ (inhalable fraction)
France	VME (mg/m ³)	10 mg/m ³ (restrictive limit) 5 mg/m ³ (restrictive limit)
USA ACGIH	ACGIH TWA (mg/m ³)	3 mg/m ³ Respirable fraction 10 mg/m ³ Total Dust
Spain	VLA-ED (mg/m ³)	10 mg/m ³ (recommended limit, this value is for the particulate matter that is free from Asbestos and contains less than 1% of Crystalline silica-inhalable fraction) 3 mg/m ³ (recommended limit, this value is for the particulate matter that is free from Asbestos and contains less than 1% of Crystalline silica-respirable fraction)
Ireland	OEL (8 hours ref) (mg/m ³)	10 mg/m ³ (total inhalable) 4 mg/m ³ (respirable)
Ireland	OEL (15 min ref) (mg/m ³)	30 mg/m ³ (calculated-total inhalable) 12 mg/m ³ (calculated-respirable)

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Particulates not otherwise regulated (PNOR)		
Norway	Grenseverdier (AN) (mg/m ³)	10 mg/m ³ (total dust) 5 mg/m ³ (respirable dust)
Norway	Grenseverdier (Korttidsverdi) (mg/m ³)	20 mg/m ³ (total dust) 10 mg/m ³ (respirable dust)
Slovakia	NPHV (priemerná) (mg/m ³)	10 mg/m ³
Portugal	OEL TWA (mg/m ³)	10 mg/m ³ (inhalable fraction, particulate matter containing no Asbestos and <1% Crystalline silica) 3 mg/m ³ (respirable fraction, particulate matter containing no Asbestos and <1% Crystalline silica)

8.2. Exposure controls

Appropriate engineering controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

Personal protective equipment

: Gloves. Protective clothing. Protective goggles.



Materials for protective clothing

: Chemically resistant materials and fabrics.

Hand protection

: Wear protective gloves.

Eye protection

: Chemical safety goggles.

Skin and body protection

: Wear suitable protective clothing.

Respiratory protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn.

Other information

: When using, do not eat, drink or smoke.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White to off-white powder
Odour	: None
Odour threshold	: No data available
pH	: 4.0 - 6.8
Evaporation rate	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Solubility	: Soluble in water
Partition coefficient: n-octanol/water	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

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Explosive limits	: No data available
Molecular weight	: 2163
MAIT (minimum autoignition temperature)	: 770 °F (410 °C) ASTM E1491
9.2. Other information	
VOC content	: < 1 %

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 polymerization will not occur.

10.4. Conditions to avoid

Excessive dust accumulation. Direct sunlight, extremely high or low temperatures, incompatible materials. Sparks, heat, open flame, other sources of ignition.

10.5. Incompatible materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/Injuries After Inhalation	: 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 No additional information available

12.5. Results of PBT and vPvB assessment No additional information available

12.6. Other adverse effects

Other information : 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 - waste materials	: Avoid release to the environment.

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SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

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

No REACH Annex XVII restrictions

Captisol/Advasep 7/SBE-AE-Beta-CD is not on the REACH Candidate List

Contains no substance on the REACH candidate list

Captisol/Advasep 7/SBE-AE-Beta-CD is not on the REACH Annex XIV List

Contains no REACH Annex XIV substances

Captisol (182410-00-0)

Listed on ELINCS (European List of Notified Chemical Substances)

VOC content : < 1 %

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

Data sources : According to Regulation (EC) No. 1907/2006 (REACH) with its amendment
Regulation (EC) No. 453/2010

Full text of H- and EUH-statements:

Skin Sens. 1	Sensitisation — Skin, Category 1
H317	May cause an allergic skin reaction

EU GHS SDS

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.