

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Dental Use



Date Issued : 08/28/2012
SDS No : 29-001.11
Date Revised : 09/16/2016
Revision No : 9

Sable Seek®

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

1.1. Product identifier

Product code : CO/11052
Product name : Sable Seek®
Product description : Caries Indicator

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

Relevant identified uses : Professional Dental Caries Indicator

1.3. Details of the supplier of the safety data sheet

Manufacturer

Ultradent Products, Inc.
505 W. 10200 S.
South Jordan, UT 84095

EC Responsible Person

Ultradent Products GmbH
Am Westhover Berg 30
51149 Cologne Germany
Email: infoDE@ultradent.com
Emergency Phone : +49(0)2203-35-92-0

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA) : (800) 424 - 9300
(INTERNATIONAL) : +1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Environmental : Flammable Liquids, Category 2

2.2. Label elements

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

Hazard pictogram(s) :



Flame

Signal Word : WARNING

Hazard statement(s) : H225: Highly flammable liquid and vapour.

Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response : P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P337+P313: If eye irritation persists: Get medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.

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P332+P313: If skin irritation occurs: Get medical advice/attention.

P304: IF INHALED:

P315: Get immediate medical advice/attention.

P341: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

Storage : P273: Avoid release to the environment.

Disposal : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

2.3. Other hazards

Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Regulation(EC) No 1272/2008 [CLP]
Ethyl Alcohol	64-17-5	200-578-6	10	Flam. Liq., Cat. 2; Eye Irr., Cat. 2; Skin Irr., Cat. 2; STOT SE, Cat. 3; H225; H319

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.

Following skin : Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion : If swallowed in small quantity the product is harmless, otherwise consult a doctor.

Following inhalation : Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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

Eyes : May cause mild irritation.

Skin : May cause slight irritation.

Ingestion : Maybe harmful if swallowed in large quantities.

Inhalation : May be harmful if inhaled.

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

Notes to physician : Not Applicable

SECTION 5: Fire fighting measures

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5.1. Extinguishing media

Extinguishing media : Foam, dry chemical, carbon dioxide (CO₂).

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : Not Available

5.3. Advice for firefighters

Fire fighting procedures : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

Water spill : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

Small Spill : Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.

Large Spill : Absorb with inert, damp non-combustible material, then flush area with water.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling : Follow all SDS/label precautions even after container is emptied because they may retain product residues.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Dental Caries Indicator

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Ethyl Alcohol CAS: 64-17-5

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Control Parameters	Exposure Limits
OSHA PEL General Industry	1000 ppm (1900 mg/m3) TWA
OSHA PEL - Construction Industry	1000 ppm (900 mg/m3) TWA
OSHA PEL Shipyard Employment	1000 ppm(1900 mg/m3) TWA
NIOSH REL	1000 ppm(1900 mg/m3) TWA
ACGIH TLV	1000 ppm(1880 mg/m3) STEL
CAL/OSHA PEL	1000 ppm(1900 mg/m3) TWA

8.2. Exposure controls

Eye/face protection : Wear eye protection

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : Good general ventilation should be sufficient to control airborne levels. In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid

Colour : Dark green

Odour : Odorless or no characteristic odor

Flash point : 49°C

Specific gravity : 1 to 1.1

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Heat, flames, and ignition sources

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10.5. Incompatible materials

Incompatible materials : Ignition sources

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : > 24000 mg/kg(Rabbit/Rat)

Notes : 12% of the mixture consists of components of unknown toxicity (Dermal).

Oral LD₅₀ : > 14500 mg/kg Rat

Notes : 2% of the mixture consists of components of unknown toxicity (Oral).

Inhalation LC₅₀ : > 350 mg/L/4H Vapor Rat

Notes : 69% of the mixture consists of components of unknown toxicity (Inhalation)

Other information : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

12.4. Mobility in soil

Mobility in soil : Not Available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : Do not allow to enter sewers or drains that may lead to waterways.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

SECTION 14: Transport information

14.1. UN number

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UN number : 1987

14.2. UN proper shipping name

UN proper shipping name : Alcohols, n.o.s. (Ethyl alcohol mixture)

14.3. Transport hazard class(es)

Primary hazard class/division : 3

Hazard classification : 3

14.4. Packing group

Packing group : III

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

General comments : Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.

SECTION 16: Other information

Relevant H-statements (number and full text) : Eye Irr., Cat. 2: Eye Irritation, Category 2
Flam. Liq., Cat. 2: Flammable Liquids, Category 2
STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3
Skin Irr., Cat. 2: Skin Irritation, Category 2
H225: Highly flammable liquid and vapour.
H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 04/16/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 3:** . **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 8:** . **Section 9:**

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FLASHPOINT AND METHOD, SPECIFIC GRAVITY. **Section 10:** INCOMPATIBLE MATERIALS. **Section 11:** ACUTE (DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

General statements

: NAP = Not Applicable
 NE = Not Established
 TLV = Threshold Limit Value
 PEL = Permittable exposure limits
 MAK = Maximum Workplace Concentration
 STEL = Short-term exposure limit
 STEV = Short-term exposure value
 TWA = Time Weighted Average
 PPE = Personal Protective Equipment

Manufacturer disclaimer

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.