

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 08/28/2012

SDS No : 29-001.10

Date Revised : 04/16/2015

Revision No : 8

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

Distributor

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 Directive 1999/45/EC**

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

Danger symbols : F

R phrases : R11

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

Environmental : Flammable Liquids, Category 2

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : F



Highly
flammable

R&S statement(s) : R11: Highly flammable.

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

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ULTRADENT
 PRODUCTS, INC.

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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.
 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(1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns

: Flammable

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Dehydrated Alcohol	64-17-5	200-578-6	10	F; R11	Flam. Liq., Cat. 2; H225

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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- 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** : Maybe 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

5.1. Extinguishing media

- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : Not Determined
- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined

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.
- Fire fighting equipment** : Foam, dry chemical, carbon dioxide (CO₂).

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,

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Large spill : flush away traces with water.
 : 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 : Not Determined

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

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.

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Sable Seek®**10.3. Possibility of hazardous reactions****Hazardous polymerization** : None**10.4. Conditions to avoid****Conditions to avoid** : Heat, flames, and ignition sources**10.5. Incompatible materials****Incompatible materials** : Not Determined**10.6. Hazardous decomposition products****Hazardous decomposition products** : None known.**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute****Notes** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.**SECTION 12: Ecological information****12.1. Toxicity****Aquatic toxicity (acute)****96-hour LC₅₀** : Not Determined**48-hour EC₅₀** : Not Determined**96-hour EC₅₀** : Not Determined**12.2. Persistence and degradability****Persistence and degradability** : Not Determined**12.3. Bioaccumulative potential****Bioaccumulative potential** : Not Determined**12.4. Mobility in soil****Mobility in soil** : Not Determined**12.5. Results of PBT and vPvB assessment****Results of PBT and vPvB assessment** : Not Determined**12.6. Other adverse effects****Environmental data** : No data available.**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

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Sable Seek®**SECTION 14: Transport information****14.1. UN number****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** : N/A**14.6. Special precautions for user****ADR - road** : N/A**RID - rail** : N/A**IMDG - sea** : N/A**IATA - air** : N/A**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code****Transport in bulk** : N/A**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****RoHS** : Please refer to Medical Devices Directive 93/42/EEC**15.2. Chemical safety assessment****Chemical safety assessment** : See Section 11**SECTION 16: Other information**

Relevant R-phrases and/or H-statements (number and full text) : R11: Highly flammable.
 Flam. Liq., Cat. 2: Flammable Liquids, Category 2
 H225: Highly flammable liquid and vapour.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 01/29/2015 SDS. Revised: **Section 1:**
 . **Section 2:** . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT -
 SKIN. **Section 10:** HAZARDOUS POLYMERIZATION,
 STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀
 (rat) ACUTE. **Section 15:** SECTION 15: Regulatory information.

General statements : N/A= Not Applicable**Manufacturer disclaimer** : FOR DENTAL USE ONLY: Use as directed. The information and

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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.