

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

Date Issued : 08/28/2012
SDS No : 29-001.12
Date Revised : 06/25/2018
Revision No : 10

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. Ultradent Drive (10200 South)
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 3

2.2. Label elements

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

Hazard pictogram(s) :



Flame

Signal Word : WARNING

Hazard statement(s) : H226: Flammable liquid and vapour.

Precautionary statement(s)

Prevention

: P280: Wear protective gloves/protective clothing/eye protection/face protection.
P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233: Keep container tightly closed.
P240: Ground and bond container and receiving equipment.
P243: Take action to prevent static discharges.

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Response : P241: Use explosion-proof [electrical/ventilating/lighting/] equipment.
P242: Use non-sparking tools.
: P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P370+P378: In case of fire: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Storage : P403+P235: Store in a well-ventilated place. Keep cool.

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. 2A; Skin Irr.,Cat. 2; Acute Tox. (O),Cat. 4; STOT SE,Cat. 1; H225; H319
Dimethicone	NAP	NAP	≤ 1	STOT SE,Cat. 2; Rep. Tox.,Cat. 2; H361f; H373-1

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 : Remove contaminated clothing. 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.

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

Notes to physician : NAP

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water spray, alcohol-resistant foam, dry chemical or carbon dioxide

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 : NAP

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 (1900 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** : 47.5°C
- Specific gravity** : 1 to 1.1

9.2. Other information

- Additional information** : No further relevant information available.

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 : ~11% of the mixture consists of components of unknown toxicity (Dermal).

Oral LD₅₀ : > 14500 mg/kg Rat

Notes : ~ 4% 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)

Germ cell mutagenicity : The components in this product are not reported to produce mutagenic effects in humans.

Carcinogenicity : None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

Reproductive toxicity : WARNING! This product contains a chemical known to cause birth defects or other reproductive harm. Dimethicone

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

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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

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 : WARNING! This product contains a reproductive toxin. Dimethicone.

SECTION 16: Other information

Relevant H-statements (number and full-text) : Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
Eye Irr., Cat. 2A: Eye Irritation, Category 2A
Flam. Liq., Cat. 2: Flammable Liquids, Category 2
Rep. Tox., Cat. 2: Reproductive Toxicity, Category 2
STOT SE, Cat. 1: Target Organ Toxicity (Single exposure), Category 1
STOT SE, Cat. 2: Target Organ Toxicity (Single exposure), Category 2
Skin Irr., Cat. 2: Skin Irritation, Category 2
H225: Highly flammable liquid and vapour.

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H319: Causes serious eye irritation.
 H361f: Suspected of damaging fertility.
 H373-1: May cause damage to organs through prolonged or repeated exposure.

Prepared by

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Revision summary

: This SDS replaces the 09/16/2016 SDS. Revised: **Section 1:** MSDS No. **Section 4:** NOTES TO PHYSICIAN. **Section 5:** EXTINGUISHING MEDIA. **Section 6:** . **Section 9:** COMMENTS, FLASHPOINT AND METHOD, PERCENT VOLATILE. **Section 11:** CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 15:** COMMENTS.

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
 AMU = Atomic Mass Unit

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.