

Printing date 24.05.2019 Revision: 15.01.2019

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

· Product identifier

· Trade name: <u>Seek™</u>

· Article number: 11050

· Index number: SDS 28-001.12

· Relevant identified uses of the substance or mixture and uses advised against

Professional Dental Caries Indicator

· Application of the substance / the mixture Professional Dental Caries Indicator

Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Ultradent Products Inc.

505 W. Ultradent Drive (10200 S)

South Jordan, UT 84095-3942

USA

onlineordersupport@utradent.com

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

· Further information obtainable from: Customer Service

· Emergency telephone number:

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

2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008
 The product is not classified, according to the CLP regulation.
- · Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The Regulation EC 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5(d). Therefore, the product is exempted from the CLP labelling requirements, and no SDS is required by Regulation 1907/2006, Art 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

GB2

Printing date 24.05.2019 Revision: 15.01.2019

Trade name: Seek™

(Contd. of page 1)

3 Composition/information on ingredients

- · Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

CAS: 57-55-6 Propylene Glycol substance with a Community workplace exposure limit <100% EINECS: 200-338-0

· Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Seek medical treatment in case of complaints.
- · After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: If symptoms persist consult doctor.
- Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters:
- · Protective equipment: No special measures required.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/surface or ground water.

· Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- · Handling:
- · Precautions for safe handling: No special measures required.
- · Information about fire and explosion protection: No special measures required.

(Contd. on page 3)

Printing date 24.05.2019 Revision: 15.01.2019

Trade name: Seek™

(Contd. of page 2)

- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- Further information about storage conditions: See product labelling.
- · Specific end use(s) Professional Dental Caries Indicator

8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters
- Ingredients with limit values that require monitoring at the workplace:

57-55-6 Propylene Glycol

WEL (Great Britain) Long-term value: 474* 10** mg/m³, 150* ppm *total vapour and particulates **particulates

- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

- · Respiratory protection: Not required.
- Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- · Eve protection: Goggles recommended during refilling
- · Body protection: Protective work clothing

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Liquid
Colour: Dark red
Odour: Odourless
Odour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/freezing point: -68 °C

(Contd. on page 4)

Printing date 24.05.2019 Revision: 15.01.2019

Trade name: Seek™

	(Contd. of	fpage
Initial boiling point and boiling range	2: Undetermined.	
Flash point:	99 ℃	
Flammability (solid, gas):	Not applicable.	
Ignition temperature:	371 °C	
Decomposition temperature:	Not determined.	
Auto-ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	2.6 Vol %	
Upper:	12.6 Vol %	
Vapour pressure at 20 °C:	0.11 hPa	
Density at 20 °C:	1.04 g/cm³	
Relative density	Not determined.	
Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
water:	Fully miscible.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
Solvent content:		
Organic solvents:	<100 %	
VOC (EC)	<99 %	
Solids content:	<10.0 %	
Other information	No further relevant information available.	

10 Stability and reactivity

- · Reactivity No further relevant information available.
- Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions: No dangerous reactions known.
- · Conditions to avoid: No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.

(Contd. on page 5)

Printing date 24.05.2019 Revision: 15.01.2019

Trade name: Seek™

(Contd. of page 4)

· LD/LC50 values relevant for classification:			
57-55-6	Propylene (Glycol	
Oral	LD50	18,000 mg/kg (rabbit)	
	LC50 Fish	>5,000 mg/l (Fish)	
Dermal	LD50	20,800 mg/kg (rabbit)	

- Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

12 Ecological information

- · Toxicity
- · Aquatic toxicity:

57-55-6 Propylene Glycol

EC50 18,100 mg/l (Algae)

>100,000 mg/l (daphnia)

- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation Smaller quantities can be disposed of with household waste.
- · Uncleaned packaging:
- **Recommendation:** Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

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Printing date 24.05.2019 Revision: 15.01.2019

Trade name: Seek™

(Contd. of page 5)

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UN-Number ADR, ADN, IMDG, IATA	not regulated	
ADK, ADN, IMDG, IATA	noi regulalea	
UN proper shipping name ADR, ADN, IMDG, IATA	not regulated	
ADN, ADN, IMDU, IATA	noi reguiatea	
Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
Class	not regulated	
Packing group		
ADR, IMDG, IATA	not regulated	
Environmental hazards:	Not applicable.	
Special precautions for user	Not applicable.	_
Transport in bulk according to Annex I	I of Marpol	
and the IBC Code	Not applicable.	
UN "Model Regulation":	not regulated	

15 Regulatory information

· Chemical safety assessment:

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Department issuing SDS: Regulatory Affairs
- · Contact: Customer Service
- · Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

GB2