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

· 1.1 Product identifier

· Trade name: ALVEOGYL

· Article number / formula: 283S

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

No further relevant information available.

· Application of the substance / the preparation : dental product

· 1.3 Details of the supplier of the safety data sheet

· Supplier:

IVOCLAR VIVADENT LTD.

12 Omega Street, Rosedale, Auckland 0632, New Zealand

PO Box 303011, North Harbour, Auckland 0751, New Zealand

Telephone: +649 914 9999

Fax: +649 914 9990

· orders.nz@ivoclarvivadent.com

http://www.ivoclarvivadent.co.nz

#### 1.4 Emergency telephone number:

0800 764 766 (National Poisons Centre)

#### SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008:



GHS07

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



GHS07

- · Signal word Warning
- · Hazard-determining components of labelling:

Eugenol

l-carvone

(S)-p-mentha-1,8-diene

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trans-p-Menthan-3-one

· Hazard statements

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements

P264 Wash hands thoroughly after handling.P273 Avoid release to the environment.

*P280* Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of water.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable. · **vPvB**: Not applicable.

### SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture: consisting of the following components.

Dangerous components:		
CAS: 97-53-0 EINECS: 202-589-1 Reg.nr.: 01-2119971802-33	Eugenol	10-25%
CAS: 6485-40-1 EINECS: 229-352-5 Index number: 606-148-00-8 RTECS: OS 8650000	l-carvone ••• Acute Tox. 4, H302; Skin Sens. 1, H317	5-10%
CAS: 151-21-3 EINECS: 205-788-1 RTECS: WT 1050000	sodium dodecyl sulphate  Acute Tox. 3, H311; Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Irrit. 2, H315	≤2.5%
CAS: 5989-54-8 EINECS: 227-815-6 Index number: 601-029-00-7 RTECS: OS 8350000	(S)-p-mentha-1,8-diene Flam. Liq. 3, H226;  Asp. Tox. 1, H304;  Aquatic Chronic 1, H410;  Skin Irrit. 2, H315; Skin Sens. 1, H317	≤2.5%
CAS: 89-80-5 EINECS: 201-941-1	trans-p-Menthan-3-one	<0.5%

- · SVHC No
- · Additional information: For the wording of the listed risk phrases, refer to section 16.

#### SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

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· After excessive inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient in a stable laying down side position for transportation.

- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: Call for a doctor immediately.
- · 4.2 Most important symptoms and effects, both acute and delayed:

No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed:

No further relevant information available.

### **SECTION 5: Firefighting measures**

· 5.1 Suitable extinguishing agents:

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

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

#### SECTION 6: Accidental release measures

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

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

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

· 6.3 Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· 6.4 Reference to other sections:

See Section 7 for information on safe handling.

See Section 8 for information on personal protective equipment.

See Section 13 for disposal information.

#### **SECTION 7: Handling and storage**

· 7.1 Precautions for safe handling:

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of dust.

- · Information about fire and explosion protection: No special measures required.
- · 7.2 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: Keep container tightly sealed.
- $\cdot$  7.3 *Specific end use*(s): *No further relevant information available.*

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## SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see section 7.
- · 8.1 Control parameters

· Ingredients with lin	nit values that require monitoring at the workplace:
CAS: 471-34-1 calc	ium carbonate (10-25%)
MAK (Switzerland)	Long-term value: 3 a mg/m³
CAS: 5989-27-5 (R)	)-p-mentha-1,8-diene (<0.1%)
MAK (Switzerland)	Short-term value: 80 mg/m³, 14 ppm Long-term value: 40 mg/m³, 7 ppm S SSc;
CAS: 80-56-8 alpho	n-Pinene (<0.1%)
MAK (Switzerland)	Short-term value: 224 mg/m³, 40 ppm Long-term value: 112 mg/m³, 20 ppm H S;

· Additional information:

The most current valid lists have been used as a basis for the production of this document.

- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Keep away from food, beverages and petfood.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· Respiratory protection:



In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Protection of hands:



Protective gloves

- · Gloves material: Butyl rubber, BR
- · Eye protection:



Safety glasses

Tightly sealed goggles

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9.1 Information on basic physical and che	emical properties
General Information	
Appearance: Form:	Destri
rorm: Colour:	Pasty Brown
Odour:	Characteristic
Odour threshold:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gas):	Not determined.
Ignition temperature:	340 °C
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not self igniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure at 20 °C:	23 hPa
Density:	Not determined.
Relative density:	Not determined.
Vapour density:	Not applicable.
Evaporation rate :	Not applicable.
Solubility in / Miscibility with	
water:	Fully soluble.
Segregation coefficient (n-octanol/water):	: Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solvent content:	
VOC (EC)	0.00 %
9.2 Other information:	No further relevant information available.

## SECTION 10: Stability and reactivity

- $\cdot \textbf{10.1 Reactivity} \ \textit{No further relevant information available}.$
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions: No dangerous reactions known.
- · 10.4 Conditions to avoid: No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.

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· 10.6 Hazardous decomposition products: No dangerous decomposition products known.

#### SECTION 11: Toxicological information

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

· LD/LC5	0 valu	es relevant for classification:
CAS: 97	7-53-0 I	Eugenol
Oral	LD50	1,930 mg/kg (rat)
CAS: 64	185-40-	1 l-carvone
Oral	LD50	1,640 mg/kg (rat)
CAS: 15	51-21-3	sodium dodecyl sulphate
	I	1,288 mg/kg (rat)
Dermal	<i>LD50</i>	300 mg/kg (ATE)

- · Primary irritant effect:
- · On the skin: Based on available data, the classification criteria are not met.
- · On the eyes:

Causes serious eye irritation.

· Respiratory or skin sensitization

May cause an allergic skin reaction.

- · CMR effects (carcinogenicity, 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.

#### SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability: No further relevant information available.
- · 12.3 Bioaccumulative potential: No further relevant information available.
- · 12.4 Mobility in soil: No further relevant information available.
- · Ecotoxical effects:
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water



Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground. Harmful to aquatic organisms

- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

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· 12.6 Other adverse effects: No further relevant information available.

# SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation:



Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· Europe	· European waste catalogue	
HP 4	Irritant - skin irritation and eye damage	
HP 6	Acute Toxicity	
HP 13	Sensitising	
HP 14	Ecotoxic	

- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

14.1 UN-Number ADR, ADN, IMDG, IATA	Not classified as hazardous for transport
14.2 UN proper shipping name ADR, ADN, IMDG, IATA	Not classified as hazardous for transport
14.3 Transport hazard class(es)	
ADR, ADN, IMDG, IATA Class	Not classified as hazardous for transport
14.4 Packing group ADR, IMDG, IATA	Not classified as hazardous for transport
14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Ann Marpol and the IBC Code	<b>ex II of</b> Not applicable.
UN "Model Regulation":	Not classified as hazardous for transport

## **SECTION 15: Regulatory information**

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.

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· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

#### **SECTION 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.

#### · Relevant phrases

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H410 Very toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

#### · Classification according to Regulation (EC) No 1272/2008

Serious eye damage/eye irritation

Skin sensitisation

Hazardous to the aquatic environment - long-term (chronic) aquatic hazard

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

#### · 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

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids - Category 3

Acute Tox. 4: Acute toxicity - Category 4

Acute Tox. 3: Acute toxicity - Category 3

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation - Category 1

Skin Sens. 1B: Skin sensitisation - Category 1B Asp. Tox. 1: Aspiration hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3