

Printing date 11.04.2023 Version number 4 Revision: 11.04.2023

### 1 Identification of the substance or mixture and of the supplier

- · Product identifier
- · Trade name: Freegenol Base
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Auxillary for dental technology
- · Details of the supplier of the safety data sheet

Henry Schein Dental

243-249 Bush Road, Rosedale Auckland 0632, NEW ZEALAND

Free Phone: 0800 808 855

- · Further information obtainable from: Regulatory affairs
- · Emergency telephone number: 0800 764 766 (National Poisons Centre)

### 2 Hazards identification

· Classification of the substance or mixture

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

- · Label elements
- · GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · Exemptions

The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).

· Hazard pictograms



GHS09

- · Signal word Warning
- · Hazard statements

Very toxic to aquatic life with long lasting effects.

· Precautionary statements

Avoid release to the environment.

Collect spillage.

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

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

NZ

Printing date 11.04.2023 Version number 4 Revision: 11.04.2023

Trade name: Freegenol Base

(Contd. of page 1)

### 3 Composition/Information on ingredients

- · Chemical characterisation: Mixtures
- · Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

	· Dangerous components:		
Γ	011/01/10/1		75-<90%
	EINECS: 215-222-5	EINECS: 215-222-5 Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
Γ	CAS: 8007-18-9	antimony nickel titanium oxide yellow	0.5-<1%
	EINECS: 232-353-3		

· 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: If symptoms persist consult doctor.
- · After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist. Take affected persons into fresh air and keep quiet.

- · After skin contact: If skin irritation continues, consult a doctor.
- · After eye contact:

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

· After swallowing:

Rinse out mouth and then drink plenty of water.

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 Fire fighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

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

Use fire extinguishing methods suitable to surrounding conditions.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- · Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

No further relevant information available.

- · Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.
- · Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

ΝZ

Printing date 11.04.2023 Version number 4 Revision: 11.04.2023

Trade name: Freegenol Base

(Contd. of page 2)

### 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Remove persons from danger area.

Wear protective clothing.

· 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 to penetrate the ground/soil.

In case of seepage into the ground inform responsible authorities.

· Methods and material for containment and cleaning up:

Absorb liquid components with liquid-binding material.

Dispose of the material collected according to regulations.

· 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 precautions are necessary if used correctly.
- · Information about fire and explosion protection: No special measures required.
- Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: Store only in unopened original receptacles.
- · Information about storage in one common storage facility: Store away from foodstuffs.
- Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

#### 8 Exposure controls/personal protection

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

· Ingreatents	with iimii	values ind	u require	monitoring a	t the workplace:

#### 8007-18-9 antimony nickel titanium oxide yellow

WES (New Zealand) Long-term value: 0.02 0.005\* mg/m³

sen, suspected carc.; as Ni; \*respirable dust

BOELV (European Union) Long-term value: 0.1\* mg/m³

as Ni; sens. dermal/resp. \*inhalable

- · 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.

Wash hands before breaks and at the end of work.

- Respiratory protection: Suitable respiratory protective device recommended.
- · **Protection of hands:** Protective gloves

(Contd. on page 4)

Printing date 11.04.2023 Version number 4 Revision: 11.04.2023

Trade name: Freegenol\_Base

(Contd. of page 3)

· Material of gloves

The selection of the 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 break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

Information on basic physical and chen	nical properties	
General Information		
Appearance:		
Form:	Pasty	
Colour:	White	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range	: Undetermined.	
Flash point:	Not applicable.	
Flammability (solid, gas):	Not applicable.	
Ignition temperature:	Undetermined.	
Decomposition temperature:	Not determined.	
Auto-ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure:	Not determined.	
Density:	Not determined.	
Relative density	Not determined.	
Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
water:	Insoluble.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	

Printing date 11.04.2023 Version number 4 Revision: 11.04.2023

Trade name: Freegenol\_Base

(Contd. of page 4)

· Solvent content: VOC (EC)	0.0 g/l	
· 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
- LD/LC50 values relevant for classification: No further relevant information available.
- · Primary irritant effect:
- · Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation No irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.
- Additional toxicological information:
- · Repeated dose toxicity No further relevant information available.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

No further relevant information available.

### 12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 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.
- · Ecotoxical effects:
- · Remark: Very toxic for 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.

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

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

(Contd. on page 6)

Printing date 11.04.2023 Version number 4 Revision: 11.04.2023

Trade name: Freegenol\_Base

(Contd. of page 5)

· Other adverse effects No further relevant information available.

### 13 Disposal considerations

- · Waste treatment methods
- · Recommendation

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

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

Transport information	
UN-Number	171/2002
NZS, IMDG, IATA	UN3082
UN proper shipping name	
NZS	3082 ENVIRONMENTALLY HAZARDOUS SUBSTAN
	LIQUID, N.O.S. (zinc oxide)
IMDG	ENVIRONMENTALLY HAZARDOUS SUBSTANO
IATA	LIQUID, N.O.S. (zinc oxide), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANG
IAIA	LIQUID, N.O.S. (zinc oxide)
Transport hazard class(es)	English, 11.0.0. (and owner)
•	
NZS	
Class	9 (M6) Miscellaneous dangerous substances and articles.
Label	9
IMDG, IATA	
Class	9 Miscellaneous dangerous substances and articles.
Label	9
Packing group	
NZS, IMDG, IATA	III
Environmental hazards:	
Marine pollutant:	Yes
	Symbol (fish and tree)
Special marking (NZS):	Symbol (fish and tree)
Special marking (IATA):	Symbol (fish and tree)
Special precautions for user	Warning: Miscellaneous dangerous substances and article
Hazard identification number (Kemler code):	90

Printing date 11.04.2023 Version number 4 Revision: 11.04.2023

Trade name: Freegenol\_Base

	(Contd. of page			
EMS Number:	F-A,S-F			
Stowage Category	A			
ransport in bulk according to Annex II of Marpol				
and the IBC Code	Not applicable.			
Transport/Additional information:				
NZS				
Limited quantities (LQ)	5L			
Excepted quantities (EQ)	Code: E1			
	Maximum net quantity per inner packaging: 30 ml			
	Maximum net quantity per outer packaging: 1000 ml			
Transport category	3			
Tunnel restriction code	(-)			
· IMDG				
Limited quantities (LQ)	5L			
Excepted quantities $(\widetilde{EQ})$	Code: E1			
	Maximum net quantity per inner packaging: 30 ml			
	Maximum net quantity per outer packaging: 1000 ml			
UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOU			
S	SUBSTANCE, LIQUID, N.O.S. (ZINC OXIDE), 9, III			

# 15 Regulatory information

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

<i>y y</i>	8 1 1 1		
· New Zealand Inventory of Chemicals			
1314-13-2	zinc oxide		
25322-69-4	Propane-1,2-diol, propoxylated		
8007-18-9	antimony nickel titanium oxide yellow		
68611-44-9	Silane, dichlorodimethyl-, reaction products with silica		
· HSNO Approval numbers			

None of the ingredients is listed.

- · GHS label elements The product is classified and labelled according to the Globally Harmonised System (GHS).
- · Hazard pictograms



- · Signal word Warning
- · Hazard statements

Very toxic to aquatic life with long lasting effects.

· Precautionary statements

Avoid release to the environment.

Collect spillage.

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

(Contd. on page 8)

Printing date 11.04.2023 Version number 4 Revision: 11.04.2023

Trade name: Freegenol\_Base

(Contd. of page 7)

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category E1 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### 16 Other information

· Relevant phrases

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- · Department issuing SDS: Regulatory affairs
- · Contact: msds@gc.dental
- · Abbreviations and acronvms:

ADR: Accord relatif au transport international 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

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

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1

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

- ·Sources
- ECHA (http://echa.europa.eu/)
- EnviChem (www.echemportal.org)
- \* Data compared to the previous version altered.

This version replaces all previous versions.

Disclaimer:

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.