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Safety Data Sheet in accordance with HSNO

Printing date 20.01.2021

Version number 2

Revision: 20.01.2021

1 Identification of the substance or mixture and of the supplier

· Product identifier

• Trade name: GC Dry Mouth Gel

• *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 23 William Pickering Drive, Albany Auckland 0632, NEW ZEALAND

PO Box 101140, NSMC Auckland 0745, 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

The product is not classified, according to the Globally Harmonised System (GHS).

- · Label elements
- · GHS label elements

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device. Hazard pictograms Void

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

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:			
9004-32-4 sodium carboxyl methyl cellulose (CMC-Na)	Aquatic Acute 3, H402	2.5-<5%	
• Additional information: For the wording of the listed hazard phrases refer to section 16.			

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4 First aid measures

· Description of first aid measures

• General information:

No special measures required.

- If symptoms persist consult doctor.
- After inhalation: Take affected persons into fresh air and keep quiet.
- · After skin contact: Immediately rinse with water.
- 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.

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Remove persons from danger area.
- 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.

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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
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- 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

· 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

9 Physical and chemical properties

Information on basic physical General Information		
Appearance:		
Form:	Fluid	
Colour:	Transparent	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value at 20 °C:	7	

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Change in condition Melting point/freezing point: Initial boiling point and boiling range	Undetermined. : 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: Upper:	Not determined. Not determined.	
Vapour pressure:	Not determined.	
Density at 20 °C: Relative density Vapour density Evaporation rate	1.2 g/cm ³ Not determined. Not determined. Not determined.	
Solubility in / Miscibility with water:	Fully miscible.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity: Dynamic: Kinematic:	Not determined. Not determined.	
Solvent content: Water: VOC (EC)	35.6 % 0.0 g/l	
• Other information	<i>No further relevant information available.</i>	

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.

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- 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: The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
- *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:

9004-32-4 sodium carboxyl methyl cellulose (CMC-Na)

EC50/48h 87.3 mg/l (daphnia magna)

- · Persistence and degradability No further relevant information available.
- · Behaviour in environmental systems:
- $\cdot \textit{Bioaccumulative potential No further relevant information available}.$
- · *Mobility in soil* No further relevant information available.
- Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.

- · 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

Must not be disposed together with household garbage. Do not allow product to reach sewage system. Contact waste processors for recycling information.

· Uncleaned packaging:

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

· UN-Number		
· ADR, ADN, IMDG, IATA	not regulated	
· UN proper shipping name		
· ADR, ADN, IMDG, IATA	not regulated	

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· Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· Packing group · ADR, IMDG, IATA	not regulated	
· Environmental hazards: · Marine pollutant:	No	
· Special precautions for user	Not applicable.	
• Transport in bulk according to Annex L and the IBC Code	I of Marpol Not applicable.	
· UN "Model Regulation":	not regulated	

15 Regulatory information

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

7732-18-5 Water

9004-32-4 sodium carboxyl methyl cellulose (CMC-Na)

9000-07-1 Carrageenan

6132-04-3 Sodium Citrate

120-47-8 ethyl 4-hydroxybenzoate

· HSNO Approval numbers

9004-32-4 sodium carboxyl methyl cellulose (CMC-Na)

· GHS label elements Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

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

16 Other information

• *Relevant phrases* H402 Harmful to aquatic life.

· Department issuing SDS: Regulatory affairs

· Contact: msds@gc.dental

· 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

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)

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(Contd. of page 6) 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 3: Hazardous to the aquatic environment - acute aquatic hazard - Category 3 · 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.

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