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Safety Data Sheet in accordance with HSNO

Printing date 16.08.2024

Version number 4

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1 Identification of the substance or mixture and of the supplier

· Product identifier

· Trade name: AROMA FINE PLUS

• *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

Skin sensitisation Category 1 Specific target organ toxicity - repeated exposure Category 2 H317 May cause an allergic skin reaction.

H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

Hazardous to the aquatic environment chronic Category 3H412 Harmful 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



· Signal word Warning

• Hazard-determining components of labelling: Kieselguhr, soda ash flux-calcined l-Carvone

· Hazard statements

May cause an allergic skin reaction. May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation. Harmful to aquatic life with long lasting effects.

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· Precautionary statements

Do not breathe dust/fume/gas/mist/vapours/spray.

Contaminated work clothing should not be allowed out of the workplace.

Avoid release to the environment.

Wear protective gloves.

If skin irritation or rash occurs: Get medical advice/attention.

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.

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:			
CAS: 68855-54-9	Kieselguhr, soda ash flux-calcined	50-<75%	
EINECS: 272-489-0	Specific target organ toxicity - repeated exposure Category 2, H373		
CAS: 7778-18-9	calcium sulfate	10-<25%	
EINECS: 231-900-3			
CAS: 16919-27-0	dipotassium hexafluorotitanate	1-<2.5%	
EINECS: 240-969-9	Acute oral toxicity Category 4, H302		
CAS: 6485-40-1	<i>l-Carvone</i>	1-<2.5%	
EINECS: 229-352-5	Skin sensitisation Category 1, H317; Flammable liquids Category 4, H227		
CAS: 8008-79-5	spearmint oil	1-<2.5%	
EINECS: 283-656-2	Flammable liquids Category 4, H227		
CAS: 1314-13-2	zinc oxide	1-<2.5%	
EINECS: 215-222-5	Hazardous to the aquatic environment acute Category 1, H400; Hazardous to the aquatic environment chronic Category 1, H410		
CAS: 68551-13-3	Alkoxya	≥0.25-<0.5%	
	<i>Hazardous to the aquatic environment acute Category 1, H400; Hazardous to the aquatic environment chronic Category 1, H410</i>		
CAS: 26402-26-6	Monocaprylin	0.1-<0.2%	
	Acute oral toxicity Category 4, H302; Skin irritation Category 2, H315; Eye irritation Category 2, H319; Skin sensitisation Category 1, H317		
· Additional informati	ion: For the wording of the listed hazard phrases refer to section 16		

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*

4 First aid measures

· General information:

Immediately remove any clothing soiled by the product.

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.

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• After skin contact:

Immediately wash with water and soap and rinse thoroughly. Seek medical treatment.

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 Allergic reactions

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire fighting measures

• 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.

- 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. Avoid formation of dust. Avoid contact with the eyes and skin. 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: Pick up mechanically. Prevent formation of dust. 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

Prevent formation of dust.

Any unavoidable deposit of dust must be regularly removed.

Avoid contact with the eyes and skin.

· Information about fire - and explosion protection: Dust can combine with air to form an explosive mixture.

· 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 section 7.

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

68855-54-9 Kieselguhr, soda ash flux-calcined

WES (New Zealand) Long-term value: 10* mg/m³

*inspirable dust: no asbestos, < 1% free silica

7778-18-9 calcium sulfate

WES (New Zealand) Long-term value: 10 mg/m³

1314-13-2 zinc oxide

WES (New Zealand) Short-term value: 5 0.5* mg/m³ Long-term value: 2 0.1* mg/m³

*respirable dust

• Additional information: The lists valid during the making were used as basis.

· Personal protective equipment:

General protective and hygienic measures:

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

Do not inhale dust / smoke / mist.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

· 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.

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(Contd. of page 4) • Eye protection: Tightly sealed goggles 9 Physical and chemical properties · General Information · Appearance: · Form: Solid · Colour: According to product specification · Odour: Characteristic Not determined. • Odour threshold: · pH-value: Not applicable. · Change in condition Undetermined. • *Melting point/freezing point:* · Initial boiling point and boiling range: Undetermined. · Flash point: Not applicable. · Flammability (solid, gas): Not determined. Undetermined. • Auto-ignition temperature: • Decomposition temperature: Not determined. · Ignition temperature: Product is not selfigniting. Product does not present an explosion hazard. · Explosive properties: · Explosion limits: · Lower: Not determined. · Upper: Not determined. · Vapour pressure: Not applicable. Not determined. · Density: · Relative density Not determined. · Vapour density Not applicable. Not applicable. · Evaporation rate · Solubility in / Miscibility with Insoluble. · water: · Partition coefficient: n-octanol/water: Not determined. · Viscosity: Not applicable. · Dynamic: · Kinematic: Not applicable. · Other information No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

- · 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.

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· Hazardous decomposition products: No dangerous decomposition products known.

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11 Toxicological information

· Information on toxicological effects

· Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

16919-27-0 dipotassium hexafluorotitanate

Oral LD50 324 mg/kg (rat (f+m))

6485-40-1 l-Carvone

Oral LD50 1,640 mg/kg (rat (f+m))

26402-26-6 Monocaprylin

Oral LD50 23,625 mg/kg (mouse)

2,000 mg/kg (rat (f+m))

• 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** May cause an allergic skin reaction.
- · 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
- May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- **Repeated dose toxicity** May cause damage to organs through prolonged or repeated exposure.
- · 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: Harmful to fish
- 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. Harmful to aquatic organisms

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

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• 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 NZS, ADN, IMDG, IATA	not regulated	
UN proper shipping name NZS, ADN, IMDG, IATA	not regulated	
Transport hazard class(es)		
NZS, ADN, IMDG, IATA Class	not regulated	
Packing group NZS, 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

· New Zealand Inventory of Chemicals

All ingredients are listed.

· 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*



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• *Hazard-determining components of labelling: Kieselguhr, soda ash flux-calcined l-Carvone*

· Hazard statements

· Signal word Warning

May cause an allergic skin reaction. May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation. Harmful to aquatic life with long lasting effects.

 Precautionary statements

 Do not breathe dust/fume/gas/mist/vapours/spray.

 Contaminated work clothing should not be allowed out of the workplace.

 Avoid release to the environment.

 Wear protective gloves.

 If skin irritation or rash occurs: Get medical advice/attention.

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

· 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

H227 Combustible liquid.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H373 May cause damage to organs through prolonged or repeated exposure.
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 acronyms:

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) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flammable liquids Category 4: Flammable liquids - Category 4 Acute oral toxicity Category 4: Acute toxicity - Category 4 Skin irritation Category 2: Skin corrosion/irritation – Category 2 Eye irritation Category 2: Serious eye damage/eye irritation - Category 2 Skin sensitisation Category 1: Skin sensitisation – Category 1 Specific target organ toxicity - repeated exposure Category 2: Specific target organ toxicity (repeated exposure) – Category 2 Hazardous to the aquatic environment acute Category 1: Hazardous to the aquatic environment - acute aquatic hazard - Category 1 Hazardous to the aquatic environment chronic Category 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1 Hazardous to the aquatic environment chronic Category 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3 (Contd. on page 9)

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· Sources

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

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