

## Safety data sheet according to UK REACH

Printing date 16.08.2024

Version number 4 (replaces version 3)

Revision: 16.08.2024

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

- **1.1 Product identifier**
- **Trade name:** *AROMA FINE PLUS*
- **1.2 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*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
*GC EUROPE N.V.  
Interleuvenlaan 33  
B-3001 Leuven  
Tel. +32/(0)16/74.10.00  
Fax +32/(0)16/40.26.84  
msds@gc.dental*
- **Further information obtainable from:** *Regulatory affairs*
- **1.4 Emergency telephone number:**  
*National poison center for United Kingdom of Great Britain and Northern Ireland:  
Belfast: +44 28 90 63 2032  
Birmingham: +44 121 507 4123  
Edinburgh: +44 131 242 1383  
Newcastle Upon Tyne: +44 191 2606182/+44 191 2606180  
Penarth: +44 292 071 55 54*

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
*Eye Irrit. 2            H319 Causes serious eye irritation.  
Skin Sens. 1        H317 May cause an allergic skin reaction.  
STOT RE 2         H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.  
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 GB CLP regulation.*
- **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**



GHS07    GHS08

- **Signal word** *Warning*

(Contd. on page 2)

## Safety data sheet according to UK REACH

Printing date 16.08.2024

Version number 4 (replaces version 3)

Revision: 16.08.2024

Trade name: AROMA\_FINE\_PLUS

(Contd. of page 1)

- **Hazard-determining components of labelling:**

Kieselguhr, soda ash flux-calcined

l-Carvone

Monocaprylin

- **Hazard statements**

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

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

H412 Harmful to aquatic life with long lasting effects.

- **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection / face protection.

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 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 EINECS: 272-489-0	Kieselguhr, soda ash flux-calcined STOT RE 2, H373	50-<75%
CAS: 16919-27-0 EINECS: 240-969-9	dipotassium hexafluorotitanate Eye Dam. 1, H318; Acute Tox. 4, H302	1-<2.5%
CAS: 6485-40-1 EINECS: 229-352-5 Index number: 606-148-00-8	l-Carvone Skin Sens. 1, H317	1-<2.5%
CAS: 8008-79-5 EINECS: 283-656-2	spearmint oil Asp. Tox. 1, H304; Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319	1-<2.5%
CAS: 1314-13-2 EINECS: 215-222-5 Index number: 030-013-00-7	zinc oxide Aquatic Acute 1, H400; Aquatic Chronic 1, H410	1-<2.5%
CAS: 68551-13-3	Alkoxya Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0.25-<0.5%
CAS: 26402-26-6	Monocaprylin Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	0.1-<0.2%

(Contd. on page 3)

## Safety data sheet according to UK REACH

Printing date 16.08.2024

Version number 4 (replaces version 3)

Revision: 16.08.2024

Trade name: AROMA\_FINE\_PLUS

(Contd. of page 2)

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

### SECTION 4: First aid measures

#### · 4.1 Description of 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.

##### · **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:**

Protect unharmed eye.

Rinse opened eye for several minutes under running water. Then consult a doctor.

##### · **After swallowing:**

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

#### · 4.2 Most important symptoms and effects, both acute and delayed Allergic reactions

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

No further relevant information available.

### SECTION 5: Firefighting measures

#### · 5.1 Extinguishing media

##### · **Suitable extinguishing agents:**

CO<sub>2</sub>, 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

#### · 5.2 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.

#### · 5.3 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.

### SECTION 6: Accidental release measures

#### · 6.1 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.

#### · 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.

(Contd. on page 4)

## Safety data sheet according to UK REACH

Printing date 16.08.2024

Version number 4 (replaces version 3)

Revision: 16.08.2024

Trade name: AROMA\_FINE\_PLUS

(Contd. of page 3)

- Do not allow to penetrate the ground/soil.*
- In case of seepage into the ground inform responsible authorities.*
- **6.3 Methods and material for containment and cleaning up:**
  - Pick up mechanically.*
  - Prevent formation of dust.*
  - Dispose of the material collected according to regulations.*
- **6.4 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.*

### SECTION 7: Handling and storage

- **7.1 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.*
- **7.2 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.*
- **7.3 Specific end use(s)** *No further relevant information available.*

### SECTION 8: Exposure controls/personal protection

- **8.1 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.*
- **8.2 Exposure controls**
  - **Appropriate engineering controls** *No further data; see section 7.*
  - **Individual protection measures, such as 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.*
  - **Hand protection**



Protective gloves

(Contd. on page 5)

## Safety data sheet according to UK REACH

Printing date 16.08.2024

Version number 4 (replaces version 3)

Revision: 16.08.2024

Trade name: AROMA\_FINE\_PLUS

(Contd. of page 4)

- **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/face protection**



Tightly sealed goggles

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Physical state**

Solid

- **Colour:**

According to product specification

- **Odour:**

Characteristic

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

Undetermined.

- **Boiling point or initial boiling point and boiling range**

Undetermined.

- **Flammability**

Not determined.

- **Lower and upper explosion limit**

- **Lower:**

Not determined.

- **Upper:**

Not determined.

- **Flash point:**

Not applicable.

- **Auto-ignition temperature:**

Undetermined.

- **Decomposition temperature:**

Not determined.

- **pH**

Not applicable.

- **Viscosity:**

- **Kinematic viscosity**

Not applicable.

- **Dynamic:**

Not applicable.

- **Solubility**

- **water:**

Insoluble.

- **Partition coefficient n-octanol/water (log value)**

Not determined.

- **Vapour pressure:**

Not applicable.

- **Density and/or relative density**

- **Density:**

Not determined.

- **Relative density**

Not determined.

- **Vapour density**

Not applicable.

- **9.2 Other information**

- **Appearance:**

- **Form:**

Solid

- **Important information on protection of health and environment, and on safety.**

- **Ignition temperature:**

Product is not selfigniting.

- **Explosive properties:**

Product does not present an explosion hazard.

(Contd. on page 6)

## Safety data sheet according to UK REACH

Printing date 16.08.2024

Version number 4 (replaces version 3)

Revision: 16.08.2024

Trade name: AROMA\_FINE\_PLUS

(Contd. of page 5)

- **Change in condition**
- **Evaporation rate** Not applicable.

- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void
- **Oxidising gases** Void
- **Gases under pressure** Void
- **Flammable liquids** Void
- **Flammable solids** Void
- **Self-reactive substances and mixtures** Void
- **Pyrophoric liquids** Void
- **Pyrophoric solids** Void
- **Self-heating substances and mixtures** Void
- **Substances and mixtures, which emit flammable gases in contact with water** Void
- **Oxidising liquids** Void
- **Oxidising solids** Void
- **Organic peroxides** Void
- **Corrosive to metals** Void
- **Desensitised explosives** Void

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** 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.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **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))

- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.

(Contd. on page 7)

## Safety data sheet according to UK REACH

Printing date 16.08.2024

Version number 4 (replaces version 3)

Revision: 16.08.2024

Trade name: AROMA\_FINE\_PLUS

(Contd. of page 6)

- **STOT-repeated exposure**  
May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Additional toxicological information:**
- **Repeated dose toxicity** May cause damage to organs through prolonged or repeated exposure.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
No further relevant information available.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties**  
None of the ingredients is listed.

### 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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse 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

### SECTION 13: Disposal considerations

- **13.1 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.

### SECTION 14: Transport information

- **14.1 UN number or ID number**
- **ADR, ADN, IMDG, IATA** not regulated
- **14.2 UN proper shipping name**
- **ADR, ADN, IMDG, IATA** not regulated

(Contd. on page 8)

GB



## Safety data sheet according to UK REACH

Printing date 16.08.2024

Version number 4 (replaces version 3)

Revision: 16.08.2024

Trade name: AROMA\_FINE\_PLUS

(Contd. of page 7)

- |   |                 |
|---|-----------------|
| <b>· 14.3 Transport hazard class(es)</b>                              |                 |
| · ADR, ADN, IMDG, IATA  |                 |
| · Class   | not regulated   |
| <b>· 14.4 Packing group</b>   |                 |
| · ADR, IMDG, IATA   | not regulated   |
| <b>· 14.5 Environmental hazards:</b>                                  |                 |
| · Marine pollutant:   | No              |
| <b>· 14.6 Special precautions for user</b>                            | Not applicable. |
| <b>· 14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| <b>· UN "Model Regulation":</b>                                       | not regulated   |

### SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Poisons Act

<b>· Regulated explosives precursors</b>	
--	--

None of the ingredients is listed.
------------------------------------

<b>· Regulated poisons</b>	
----------------------------	--

None of the ingredients is listed.
------------------------------------

<b>· Reportable explosives precursors</b>	
---	--

None of the ingredients is listed.
------------------------------------

<b>· Reportable poisons</b>	
-----------------------------	--

None of the ingredients is listed.
------------------------------------

- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

- **Relevant phrases**

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

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.

H411 Toxic to aquatic life with long lasting effects.

- **Classification according to Regulation (EC) No 1272/2008 Calculation method**

- **Department issuing SDS: Regulatory affairs**

(Contd. on page 9)



## Safety data sheet according to UK REACH

Printing date 16.08.2024

Version number 4 (replaces version 3)

Revision: 16.08.2024

**Trade name: AROMA\_FINE\_PLUS**

(Contd. of page 8)

· **Contact:** [msds@gc.dental](mailto: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*

*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)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Acute Tox. 4: Acute toxicity – Category 4*

*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*

*STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2*

*Asp. Tox. 1: Aspiration hazard – Category 1*

*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*

*Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2*

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

· **Sources**

• ECHA (<http://echa.europa.eu/>)

• EnviChem ([www.echemportal.org](http://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.*