

Safety Data Sheet

According to 1907/2006/EC, Article 31

This version: 1.0 substituts version -
Revision: 22.02.2021
Printing date: 22.02.2021

Section 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: ArtOral ® Chroma FILL in syringes and tips

REF: ACX1000, X depends on syringe S or tip T

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

Light-cure, dental restoration material (composite)

1.3 Details of the supplier of the safety data sheet

Manufacturer: R-dental Dentalerzeugnisse GmbH
Winterhuder Weg 88
D-22085 Hamburg
Germany
Phone: +49-(0)40-30 70 70 73-0
Fax: +49-(0)40-30 70 70 73-73
E-mail: info@r-dental.com
Web: www.r-dental.com

1.4 Emergency telephone number

R-dental Dentalerzeugnisse GmbH,
Phone: +49-(0)40-30 70 70 73-0

Section 2: Hazards identification

2.1 Classification of the substance or mixture

Skin Irr. 2 H315 Causes skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Eye Irr. 2 H319 Causes serious eye irritation.

See Section 15.

2.2 Label elements

according to (EC) No. 1272/2008

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

Hazard pictograms:



GHS07

Signal word:

Attention

Additional information: Medical Devices as defined in MDD 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards Irritating to eyes and skin. Avoid contact with skin and eyes.

Section 3: Composition/information on ingredients

3.1 Substances Methacrylates – GHS07, GHS09, H317, H319, H411.

3.2 Mixtures Mixture of difunctional methacrylates, prepolymerized resin, fumed silica, photoinitiator, catalysts and stabilizer.

Additional information: None.

Section 4: First-aid measures

4.1 Description of first aid measures

General information after inhalation: Supply fresh air; consult physician in case of complaints.
General information after skin contact: Wash with plenty of water and soap. Remove contaminated clothes.

General information after eye contact: Rinse with the eyelid held wide open with plenty of water and consult a physician.

General information after swallowing: Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed See subsection 4.1. Consult physician when in doubt.

4.3 Indication of any immediate medical attention and special treatment needed See subsection 4.1.

Section 5: Fire fighting measures

5.1 Extinguishing media Suitable to surrounding conditions.

Extinguishing media: Water, CO₂ or foam.

Unsuitable extinguishing media: Not known. Suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture Not known.

5.3 Advice for firefighters Protecting actions in use with extinguishing media, see subsection 5.1.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Supply fresh air to working area, fresh working clothes.

6.2 Environmental precautions Do not let unpolymerized material come into contact with the environment.

6.3 Methods and material for containment and cleaning up

Pick-up the material. Dispose contaminated material as waste according to section 13.

6.4 Reference to other sections

See section 13.

Section 7: Handling and storage

7.1 Precautions for safe handling

This product should only be used by a dentist and/or a licensed professional. Store away from food stuffs. When in use do not eat, drink or smoke.

7.2 Conditions for safe storage, including any incompatibilities

Store tightly closed in dry place at temperature 48-68 °F and light protected and away from food stuffs.

7.3 Special end use(s)

Store under 77 °F, dry and light protected.

Section 8: Exposure controls/personal protection

8.1 Control parameters

The mixture does not contain any relevant quantities of substances with workplace-related, to be monitored limit values. Good ventilation is sufficient.

8.2 Exposure controls

See down.

General protective and hygienic measures

Usual hygienic measures for dental practice. Wash hands before breaks and at the end of work. Keep away from food and beverages.

Eyes:

Eye glasses are recommended.

Hands:

Wear protective gloves. Commercial gloves will not guarantee sufficient protection in every case. Quality of gloves can differ and are tested before use. Penetration times can be verified at gloves manufacturers.

Respiration:

Not applicable.

Pregnancy:

None.

Thermal driven:

None.

Environmental exposure:

See subsection 6.2.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

a) Appearance:

Paste.

aa) Colour:

Colourless.

b) Odour:

Odourless.

c) Odour threshold:

Not estimated.

d) pH:

Neutral.

e) Melting point/freezing point:

Not estimated.

f) Initial boiling point and boiling range:

Not estimated.

g) Flash point:

Not applicable.

h) Evaporation rate:

Not applicable.

i) Flammability (solid/gas):

Not applicable.

j) Upper/lower flammability or explosive limits:

Not applicable.

k) Vapour pressure:

Not applicable.

l) Vapour density:	Not applicable.
m) Relative density:	1,68 g/cm ³ (68 °F)
n) Solubility(ies):	
Water solubility:	Unsoluble.
Soluble in/miscible with:	Slightly in toluene and silicone oil.
o) Partition coefficient:	Not applicable.
p) Auto-ignition temperature:	Not applicable.
q) Decomposition temperature:	Not applicable.
r) Viscosity:	Paste.
s) Explosive properties:	Not applicable.
t) Oxidising properties:	Not applicable.
9.2 Other information	None.

Section 10: Stability and reactivity

10.1 Reactivity	See section 2.
10.2 Chemical stability	Stable when storing dry and light protected at 77 °F taking into account expiration date.
10.3 Possibility of hazardous reactions	Reacts in the presence of peroxides, metal powders, metal oxides and and free radical initiators.
10.4 Conditions to avoid	Avoid heat and direct sunlight. Contact with peroxides, metal powders, metal oxides and and free radical initiators.
10.5 Incompatible materials	See subsection 10.4.
10.6 Hazardous decomposition products	None when storing at normal conditions.

Section 11: Toxicological information

11.1 Information on toxicological effects	
a) acute toxicity:	No information available.
b) irritation:	Allergic reactions to the product after long-term exposure to methacrylates are possible, see subsection 2.3.
c) corrosivity:	Not known.
d) sensitisation:	See b).
e) repeated dose toxicity:	Not applicable.
f) carcinogenicity:	Not known.
g) mutagenicity:	Not known.
h) toxicity for reproduction	Not known.
Toxicological tests:	None.
Experience in practice:	Slightly irritating to the skin; irritating to the eye.
Informations on ingredients:	See section 3.
Additional toxicological information:	During the long period of use no health diseases are reported.

Section 12: Ecological information

12.1 Toxicity	Do not let the material come in contact with the environment.
---------------	---

12.2 Persistence and degradability	No data available.
12.3 Bioaccumulative potential	No data available.
12.4 Mobility in soil	No data available.
12.5 Results of PBT and vPvB assessment	Not applicable.
12.6 Other adverse effects	Do not let the material come in contact with the environment.

Section 13: Disposal considerations

13.1 Waste treatment methods	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.
Disposal key number:	Not known.
Uncleaned packaging:	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.
Cleaned packaging:	Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Section 14: Transport information

14.1 UN Number	Not applicable.
14.2 UN proper shipping name	Not applicable.
14.3 Transport hazard class(es)	
Land transport ADR/RID, GGVS/GGVE:	Not classified as dangerous goods.
Sea transport IMDG/GGVSea:	Not classified as dangerous goods.
Air transport ICAO-TI and IATA-DGR:	Not classified as dangerous goods.
14.4 Packing group	Not applicable.
14.5 Environmental hazards	Not applicable.
14.6 Special precautions for user	Not applicable.
Kemler-Code:	Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

Section 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	The product is a class IIa medical device according to the MDD 93/42/EEC.
15.2 Chemical safety assessment	No.

Section 16: Other informations

a) Changes to previous version: Revision of Material Safety Data Sheet according to 1907/2006/EC, Article 31.

b) Legend to abbreviations:

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)

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

c) Literature references: Not applicable.

d) Methods of evaluation information: Not applicable.

e) Phrases, stated:

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H412 Harmful to aquatic life with long term effect.

f) Training advices: Not applicable.

Data sheet producing area: R-dental Dentalerzeugnisse GmbH, Hamburg.

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to product properties. However users of the product should satisfy themselves that the information given above is sufficient and correct for their circumstances of use.

Prepared by: Dr. Andreas Sprafke, R-dental Dentalerzeugnisse GmbH.