Safety Data Sheet
according to 1907/2006/EC, Article 31

Date of issue: 17.08.2020 **Version: 1**
Printing date: 15.09.2020

1. Identification of the substance/mixture and of the company/undertaking

Product Identifier
Trade name: MARK3 Chroma Chameleon
Use of the preparation: Dental filling material
Details of the supplier of the safety data sheet:
Manufacturer/supplier:
Cargus International, Inc,
135 North Route 9W
Congers, New York, 10920
info@cargus.com
Emergency telephone number:
845-267-2600

2. Hazards identification

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 allergic skin reaction
Information concerning particular hazards for human and environment:
The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.
Label elements
Labeling according to Regulation (EC) 1272/2008:
Hazard pictograms

Signal word
Warning
Hazard statements
H319 Causes serious eye irritation
H317 May cause allergic skin reaction
Precautionary statements
P280 Wear protective gloves/protective clothing/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.
P302+P352 IF ON SKIN: Wash with plenty of soap and water
Labeling according to EU guidelines:
Medical devices as defined in Directive 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.
Other hazards
Results of PBT and vPvB assessment
PBT: not applicable
vPvB: not applicable

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3. Composition/Information on Ingredients

Chemical characterization:
Description:
Mixture of difunctional methacrylates, prepolymerized resin, fumed silica, photoinitiator, stabilizer, pigments
Hazardous components:
Methacrylates GHS07, GHS09 H319, H317, H411

4. First-aid measures

General information: Seek medical advice, if symptoms occur, which can be caused by the product
after skin contact: wash with plenty of water and soap
after inhalation: fresh air
after eye contact: rinse with plenty of water and consult a doctor
after swallowing: If symptoms persist consult a doctor

5. Fire fighting measures

Extinguishing media:
CO_2, powder, water spray.
Use extinguishing method and media suitable to surrounding fire.
Special hazards arising from the substance or mixture No further relevant information available
Protective equipment Wear self-contained respiratory protective equipment

6. Accidental release measures

Personal precautions: not required
Environmental precautions:
Do not allow to enter drains/surface water/ ground-water.
Methods for cleaning up:
Pick up mechanically. Clean up affected area.
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:
This product should only be supplied or handled to dentists or dental technicians or upon their instructions.
Information for safe handling: Observe normal care for working with chemicals.
Information about fire and explosion protection: No special measures required
Storage: Store at a dry place. Store tightly closed. Storage temperature <25 °C.
Requirements at storerooms and containers: Store only in the original containers
Further information on storage conditions:
Store away from food stuffs.
Specific end uses: No further relevant information available

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8. Exposure controls/personal protection

Components with limits of values to be supervised at the workplace:
The product contains no relevant quantities of components with limits of values to be supervised at the workplace.
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.
Keep away from foodstuffs and beverages. Avoid contact with eyes or skin
Hand protection: Protective gloves.
Due to missing tests no recommendation to the glove material can be given for the product.
Eye protection: Safety glasses
Respiratory protection: Required, when aerosols are generated

9. Physical and chemical properties

Information on basic physical and chemical properties
Appearance

Form:	paste
Color:	colorless
Odor:	odorless

	Value	Unit	Method
Safety relevant basic data			
Melting point/melting range:	n.a.		
Boiling point/boiling range:	n.a.		
Flash point:	n.d.		
Ignition temperature:	n.d.		
Danger of explosion:	none		
Density:	1.68 (20°C)	g/cm^3	
Vapor pressure:	n.a.		
pH:	neutral		
Solubility in/miscibility with:	Partially soluble in toluene, silicone oil		
Water:	insoluble		
Content of solvents:	none		
Organic solvents:	none		

10. Stability and reactivity

Thermal decomposition / conditions to be avoided
Possibility of hazardous reactions: no information available
Conditions to avoid: Heat, direct sunlight and radical starters. The product is stable by proper use. Avoid contact with alkali metals, hydrides, strong oxidizing agents, radical initiators.
Hazardous decomposition products: No information available.

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11. Toxicological information

Acute toxicity: no data available
Primary irritation:
skin: irritant
eye: irritant
Sensitization: sensitization by skin contact possible
Additional toxicological information:
Allergic reactions to the product after long-term exposure are possible. When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12. Ecological information

General information: Avoid transfer into environment
Classification of water endangerment: WGK=1 (slightly polluting substance).

13. Disposal considerations

Product:
Recommendation:
Small quantities can be disposed of with household waste.
Use proper landfill disposal or incineration in accordance with local, state and federal regulations.
Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations

14. Transport information

Land transport ADR/RID and GGVS/GGVE (Germany): no subject to transport regulations
Sea transport IMDG: no subject to transport regulations
Air transport ICAO-TI and IATA-DGR: no subject to transport regulations

15. Regulatory information

Classification according to EC-guidelines:
The product is a medical device according to EC-directive 93/42 EEC.
Chemical safety assessment:
A Chemical Safety Assessment has not been carried out.

16. Other information:

Changes compared with the previous version:

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 products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.
Preparation by
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