

Printing date 03/31/2015

Version US-EN-Rev 1

Reviewed on 03/31/2015

1 Identification

- · Product identifier
- · Trade name: Miracle Mix CAPSULE (Mixture of Alloy and Glass Ionomer Powder)
- Relevant identified uses of the substance or mixture and uses advised against

Dental material

The product is intended for professional use.

To avoid risks for humans and environment obtain instructions.

- · Application of the substance / the mixture Dental filling material
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

GC America Inc. 3737 W. 127th Street Alsip, IL 60803 **USA**

sds@gcamerica.com

- · Information department: Regulatory Affairs
- · Emergency telephone number:

During normal opening times (Mon.-Fri. 8:00 AM-5:00 PM CST): +1 (708) 597-0900 Transportation (CHEMTREC®) Emergency Telephone No. +1 (800) 424-9300

2 Hazard(s) identification

· Classification of the substance or mixture

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

· Additional information:

The information provided is in regards to the toxicity and hazard rating(s) of the individual component(s) in the formulation. The associated risk(s) depends on the route(s) of exposure. The hazard rating system is based entirely on the existence of the risk(s) and does not take into account the likelihood of reduced risk(s) through proper usage and handling.

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0Fire = 0Reactivity = 0

HMIS-ratings (scale 0 - 4)



Health = 0Fire = 0

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

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:			
7440-22-4	silver	25-50%	
7440-31-5	tin	10-20%	
7440-50-8	copper	5-10%	

· Additional information:

If a substance is marked with **, then substance is a trade secret. This is allowed under OSHA's Hazard Communication Standard (HCS) as a trade secret and under GHS as Confidential Business Information (CBI).

4 First-aid measures

- · Description of first aid measures
- General information:

No special measures required.

If symptoms persist consult doctor.

· After inhalation:

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Rinse with warm water.

If symptoms persist consult doctor.

· After eve 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, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire fighting measures that suit the environment.

For safety reasons unsuitable extinguishing agents: Water with full jet

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· Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- 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:

Pick up mechanically.

Dispose of the collected material 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.

7 Handling and storage

- · Handling:
- · Precautions for safe handling

Observe instructions for use.

Prevent formation of dust.

Any deposit of dust which cannot be avoided must be regularly removed.

Information about protection against explosions and fires:

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: Observe instructions for use / storage.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

7440-22-4 silver

PEL Long-term value: 0.01 mg/m³

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(Contd. of page 3) REL Long-term value: 0.01 mg/m³ TLV Long-term value: 0.1 mg/m³ metal: dust and fume 7440-31-5 tin PEL Long-term value: 2 mg/m³ metal REL Long-term value: 2 mg/m³ TLV Long-term value: 2 mg/m³ metal 7440-50-8 copper PEL Long-term value: 1* 0.1** mg/m³ as Cu *dusts and mists **fume REL Long-term value: 1* 0.1** mg/m³ as Cu *dusts and mists **fume TLV Long-term value: 1* 0.2** mg/m³ *dusts and mists; **fume; as Cu

- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed.

Do not inhale dust / smoke / mist.

Wash hands before breaks and at the end of work.

- · Breathing equipment: 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 and chemical properties
- · General Information
- · Appearance:

Form: Powder
Color: Light grey
Odor: Odorless
Odor threshold: Not determined.

· **pH-value**: Not applicable.

· Change in condition

Melting point/Melting range: Undetermined.

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Boiling point/Boiling range:	Undetermined.
Flash point:	Not applicable.
Flammability (solid, gaseous):	Not determined.
Ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not applicable.
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water:	Insoluble.
Partition coefficient (n-octanol/wa	ater): Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
Solvent content:	
Organic solvents:	0.0 %
Solids content:	100.0 %
Other information	No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable at ambient temperature.
- 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 that are relevant for classification: No further relevant information available.

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- · Primary irritant effect:
- · on the skin: No irritant effect.
- on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product is not subject to classification according to internally approved calculation methods for preparations:

Carcinogenic categories

· IARC (International Agency for Research on Cancer)	
antimony nickel titanium oxide yellow	3
iron(III) oxide	3
· NTP (National Toxicology Program)	

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Carcinogenic categories' legend:

IARC Group 1: The agent is carcinogenic to humans.

IARC Group 2A: The agent is probably carcinogenic to humans.

IARC Group 2B: The agent is possibly carcinogenic to humans.

IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.

IARC Group 4: The agent is probably not carcinogenic to humans.

NTP K: Known to be human carcinogen.

NTP R: Reasonably anticipated to be human carcinogen.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes:

Water hazard class 3 (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: Smaller quantities can be disposed of with household waste.

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· Uncleaned packagings:

None of the ingredients is listed.

· Recommendation: Disposal must be made according to official regulations.

Transport information	
· UN-Number · DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name · DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA · Class	Void
· Packing group · DOT, ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	· Not applicable.
· UN "Model Regulation":	-

15 Regulatory information · Safety, health and environmental regulations/legislation specific for the substance or mixture · SARA (Superfund Amendments and Reauthorization Act) · Section 355 (extremely hazardous substances): None of the ingredient is listed. · Section 313 (Specific toxic chemical listings): silver copper · TSCA (Toxic Substances Control Act): All ingredients are listed. · Carcinogenic categories · EPA (Environmental Protection Agency) D silver copper D TLV (Threshold Limit Value established by ACGIH) antimony nickel titanium oxide yellow A4 iron(III) oxide Α4 NIOSH-Ca (National Institute for Occupational Safety and Health)

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- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

- · Department issuing SDS: Regulatory Affairs
- · Contact:

Regulatory Affairs

Telephone No. +1 (708) 597-0900

sds@gcamerica.com

- · Date of preparation / last revision 03/31/2015 / -
- · Abbreviations and acronyms:

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

HCS: Hazard Communication Standard (USA)

MSDS: Material Safety Data Sheet

SDS: Safety Data Sheet

ADN: Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways)

ECHA: European Chemicals Agency

OSHA: Occupational Safety and Health Administration (USA)

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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

· Sources

- Manufacturers' MSDSs/SDSs
- OSHA (https://www.osha.gov/dts/chemicalsampling/toc/chmcas.html)
- TOXNET (http://toxnet.nlm.nih.gov/)
- ECHA (http://echa.europa.eu/)
- EnviChem (www.echemportal.org)

· Notes

CAS Registry Number is a Registered Trademark of the American Chemical Society. CHEMTREC® is a registered service mark of the American Chemistry Council, Inc.

· * Data compared to the previous version altered. This version replaces all previous versions.

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