SAFETY DATA SHEETS

This SDS packet was issued with item: 072088540

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

072088516 072088532 072088557 072088565 072088581 273012205



MS002614

MI PASTE PLUS material safety data sheet

Page 1 of 2

SECTION 1 - SOURCE/IDENTITY/USE INFORMATION

DISTRIBUTOR

GC AMERICA INC. 3737 West 127th St. Alsip, Illinois, 60803 Telephone: 708-597-0900 Hours: Mon.- Fri. 8:00 am. - 5:00 pm. C.S.T. Transportation Emergency No. 800-424-9300

COMMON NAME: MI PASTE PLUS

PRODUCT USE: Topical paste with bio-available calcium and phosphate

The following information is provided with regard to the toxicity and hazards the pure components present in this product. SECTION 2 - HAZARDOUS INGREDIENTS/IDENTITY INFORMATION

COMPONENT	C.A.S.	EXPOSURE LIMITS	LD50/LC50	%
Glycerol	56-81-5	TWA=10 mg/m ³	N.E.	10-20
•		(as mist) (ACGIH)		
Propylene glycol	57-55-6	TWA=10mg/m ³	LD50-20.0-33.7g/kg	0-2
		Dow (mist)	(oral rat)	
			LC50=N.E.	
Sodium fluoride	7681-49-4	5.6 g/Kg	LD50=2,000mg/kg	0.2
			(oral rat)	
CPP-ACP	691364-49-5	N.E.	N.E.	5-10
D-glucitol	50-70-4	N.E.	N.E.	0-5
Silicon dioxide	7631-86-9	TLV=10mg/m ³	LD50=>10,000mg/kg	0-2
		total dust (ACGIH)	(oral-rat)	
		PEL=80mg/m ³	LC50=N.E.	
		(OSHA)		
Titanium dioxide	13463-67-7	TWA=10mg/m ³	N.E.	0-2
		(respirable) (ACGIH)		
Ethyl-4-hydroxybenzoate	120-47-8	N.E.	N.E	< 0.1
Butyl-parahydroxybenzoate	94-26-8	N.E.	N.E	< 0.1
Propyl-4-hydroxybenzoate	94-13-3	N.E.	N.E.	< 0.1

SECTION 3 - PHYSICAL/CHEMICAL PROPERTIES

BOILING POINT:	100°C	SPECIFIC GRAVITY:	N.E.
VAPOR PRESSURE:	23.0 hPa	MELTING POINT:	1350°C
VAPOR DENSITY:	N.E.	EVAPORATION RATE:	N.E.
SOLUBILITY IN WATER	: partially miscible	ODOR THRESHOLD:	N.E.
COEFFICIENT OF OIL/W	ATER DISTRIBUTION: N.E.	APPEARANCE AND ODOR:	white paste with sweet odor

SECTION 4 - FIRE AND EXPLOSION DATA

FLASH POINT: 160°C

FLAMMABLE LIMITS: N.A.

EXTINGUISHING MEDIA: Chemical foam, carbon dioxide and dry chemical.

SPECIAL FIRE FIGHTING PROCEDURES: Water can be used to cool fire-exposed container and protect personnel. Use of normal protective equipment is recommended.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None

HAZARDOUS COMBUSTION PRODUCTS: None

SECTION 5 - REACTIVITY DATA

STABILITY:	Stable		
POLYMERIZATION:	Will Not Occur 🛛		
CONDITIONS TO AVOID:	Avoid high heat and humidity.		
INCOMPATIBILITY (Materials to Avoid): None			
HAZARDOUS DECOMPOS	SITION OR BY-PRODUCTS: None		

Unstable Unstable



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MI PASTE PLUS

SECTION 6 - HEALTH HAZARD DATA and FIRST AID INFORMATION - continued

	YES	NO	NE	NA	NTP	IARC	OSHA	OTHER
MUTAGENIC AFFECTS		X						
TERATOGENIC AFFECTS		X						
REPRODUCTIVE TOXIN		X						
CARCINOGENICITY		X						
SENSITIZER		X						

HEALTH HAZARD (Acute and Chronic): CPP-ACP is derived from milk casein, it should not be consumed by patients with milk

protein allergies or hydroxybenzoate allergies.

SIGNS AND SYMPTOMS OF OVEREXPOSURE: N.E.

CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE: N.E.

EMERGENCY FIRST AID PROCEDURES:

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EYECONTACT: Flush eyes with plenty of water, lifting lower and upper eyelids. If irritation persists, seek medical attention. **SAN CONTACT**: Remove with wet gauze or tissue. If irritation develops, seek medical attention. **INGESTION:** Do not induce vomiting. Give plenty of water. If irritation develops, seek medical attention.

INHALATION: Supply fresh air; consult doctor in case of complaints.

SECTION 7 - PRECAUTIONS for SAFE HANDLING and USE

IN CASE OF RELEASE OR SPILL: Cover with absorbent material.

WASTE DISPOSAL METHOD: Dispose of in accordance with local, state and federal guidelines.

STORAGE, HANDLING, AND SPECIAL PRECAUTIONS: Store at room temperature. Keep container closed when not in use. Keep away from heat and high humidity.

SECTION 8 -	CONTROL MEASURES			
RESPIRATORY F	PROTECTION: None required.			
VENTILATION:	Local Exhaust - Yes	Mechanical:	Special:	Other:
EYE PROTECTIC OTHER PROTEC WORK/HYGIENIC	OVES: Disposable vinyl gloves DN: Safety glasses recommende TIVE CLOTHING OR EQUIPMENT C PRACTICE: Observe good hyge PREPARATION INFORMATION	ed. r: N.A. gienic work practices.		
This data is supplied to comply with OSHA Hazard Communication Standard 29 CFR 1910,1200 and W.H.M.I.S. CPR.				
DATE: <u>16 Apr</u> REVIEWED: <u>2</u>	ril 2007 28 February 2012			
N.A. = NOT API N.E. = NOT EST	-			

The information herein is given in good faith but no warranty expressed or implied is made.

		NFPA		
FIRE – 0	TOXICITY - 0	REACTIVITY – 0	SPECIAL -	

, 'GC

Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 03/29/2016

Version US-EN-Rev 1

Reviewed on 03/29/2016

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1 Identification
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- · Product identifier
- Trade name: GC MI Paste Plus (Flavors: Melon [M], Mint [I], Strawberry [S], Tutti-Frutti [T], and Vanilla [V])
- · Application of the substance / the mixture Auxiliary for dental technology
- · 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.

Do not use this material on patients with a proven or suspected milk protein allergy and/or with a sensitivity or allergy to benzoate preservatives.

- · Label elements
- GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Additional information:

10 % of the mixture consists of component(s) of unknown toxicity.

- · Classification system:
- · NFPA ratings (scale 0 4)



Reactivity = 0

· HMIS-ratings (scale 0 - 4)

HEALTH 0	Health = 0
FIRE 0	Fire = 0
REACTIVITY 0	Reactivity = 0

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Trade name: GC MI Paste Plus (Flavors: Melon [M], Mint [I], Strawberry [S], Tutti-Frutti [T], and Vanilla [V])

(Contd. of page 1)

· 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:		
56-81-5	glycerol	10-20%
9004-32-4	sodium carboxyl methyl cellulose (CMC-Na)	1-5%
57-55-6	propylene glycol	1-5%
13463-67-7	titanium dioxide	1-5%

• 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:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

No special measures required.

If symptoms persist consult doctor.

After inhalation:

Supply fresh air; consult doctor in case of complaints.

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

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 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** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed** No further relevant information available.

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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
- 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:
- Mouth respiratory protective device.
- 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. Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:** Absorb liquid components with liquid-binding material. 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. Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols.
- · Information about protection against explosions and fires: No special measures required.
- · 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.
- Keep receptacle tightly sealed.
- Specific end use(s) No further relevant information available.

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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:

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

56-81-5 glycerol

PEL Long-term value: 15* 5** mg/m³

mist; *total dust **respirable fraction

TLV TLV withdrawn-insufficient data human occup. exp.

57-55-6 propylene glycol

WEEL Long-term value: 10 mg/m³

• 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. Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

- 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: Pasty Color: White · Odor: Product specific · Odor threshold: Not determined. · pH-value at 20 °C (68 °F): 7 · Change in condition Melting point/Melting range: Undetermined. (Contd. on page 5) US

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	(Contd. of page 4
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not self-igniting.
· Danger of explosion:	Product does not present an explosion hazard.
[·] Explosion limits: Lower: Upper:	0.9 Vol % 0.0 Vol %
· Vapor pressure:	Not determined.
 Density: Relative density Vapor density Evaporation rate 	Not determined. Not determined. Not determined. Not determined.
 Solubility in / Miscibility with Water: 	Fully miscible.
· Partition coefficient (n-octanol/water):	Not determined.
[·] Viscosity: Dynamic: Kinematic:	Not determined. Not determined.
 Solvent content: Organic solvents: Water: VOC content: 	22.0 % 56.1 % 2.0 %
Solids content: • Other information	21.6 % 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.

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(Contd. of page 5)

11 Toxicological information

- Information on toxicological effects
- Acute toxicity:
- · LD/LC50 values that are relevant for classification: No further relevant information available.
- · 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) 	
silicon dioxide	3
titanium dioxide	2B
sodium fluoride	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.

- Repeated dose toxicity. No further relevant information available.
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- No further relevant information available.
- No further relevant information available.

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:
- \cdot General notes: Not known to be hazardous to water.
- · 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: Smaller quantities can be disposed of with household waste.
- · Uncleaned packagings:
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 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 I MARPOL73/78 and the IBC Code 	l of Not applicable.
· UN "Model Regulation":	Void

15 Regulatory information

 $^{\cdot}$ Safety, health and environmental regulations/legislation specific for the substance or mixture $^{\cdot}$ SARA (Superfund Amendments and Reauthorization Act)

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

• Section 313 (Specific toxic chemical listings):

phosphoric acid

• TSCA (Toxic Substances Control Act):

glycerol

D-glucitol

sodium carboxyl methyl cellulose (CMC-Na)

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US

A4

A4

Safety Data Sheet acc. to OSHA HCS 29 CFR 1910.1200

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Trade name: GC MI Paste Plus (Flavors: Melon [M], Mint [I], Strawberry [S], Tutti-Frutti [T], and Vanilla [V])

propylene glycol titanium dioxide xylitol phosphoric acid sodium fluoride sodium saccharin		(Contd. of page 7)
titanium dioxide xylitol phosphoric acid sodium fluoride sodium saccharin	silicon dioxide	
xylitol phosphoric acid sodium fluoride sodium saccharin	propylene glycol	
phosphoric acid sodium fluoride sodium saccharin	titanium dioxide	
sodium fluoride sodium saccharin	xylitol	
sodium saccharin	phosphoric acid	
	sodium fluoride	
water distilled	sodium saccharin	
water, distined	water, distilled	

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

• TLV (Threshold Limit Value established by ACGIH)

titanium dioxide

sodium fluoride

· NIOSH-Ca (National Institute for Occupational Safety and Health)

titanium dioxide

- · 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 03/29/2016 / -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) VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent (Contd. on page 9) US

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us

LD50: Lethal dose, 50 percent PBT: Persistent. Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit **REL: Recommended Exposure Limit** BEI: Biological Exposure Limit · 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:

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

· Disclaimer:

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