

Safety Data Sheet

according to HPR, Schedule 1

Printing date 03/13/2018

Version CA-EN-Rev 1

Reviewed on 01/09/2018

- · Product identifier
- Trade name: COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)
- · Application of the substance / the mixture Dental impression 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 identification

· Classification of the substance or mixture

Eye Irritation - Category 2AH319Causes serious eye irritation.Aquatic Acute 3H402Harmful to aquatic life.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· 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

The product is classified and labeled according to the Globally Harmonized System (GHS). • Hazard pictograms



· Signal word Warning

· Hazard statements

Causes serious eye irritation. Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

• **Precautionary statements** Wash thoroughly after handling. Avoid release to the environment.

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Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· Classification system:

• NFPA ratings (scale 0 - 4)

Health = 1 Fire = 1 Reactivity = 0

· HMIS-ratings (scale 0 - 4)



3 Composition/Information on ingredients

· Chemical characterization: Mixtures

• **Description:** Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:				
CAS: 68855-54-9	Kieselguhr, soda ash flux-calcined	40 - 70% w/w		
CAS: 16919-27-0	dipotassium hexafluorotitanate	1 - 5% w/w		
CAS: 1314-13-2	zinc oxide	1 - 5% w/w		
CAS: 7722-88-5	tetrasodium pyrophosphate	0.5 - 1.5% w/w		
	-			

· 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:

Immediately remove any clothing soiled by the product. 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:
- Protect unharmed eye.

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

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• 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 Firefighting 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: 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.
 Avoid formation of dust.
 Avoid contact with the eyes and skin.
 Wear protective clothing.
 Environmental precautions:
 Do not allow product to reach sewage system or any water course.
- 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: Pick up mechanically. Prevent formation of dust. 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.

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- Avoid contact with the eyes and skin. • Information about protection against explosions and fires: Dust can combine with air to form an explosive mixture.
- · 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: Observe instructions for use / storage. Keep receptacle tightly sealed.
- 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

· Control parameters				
· Components with limit values that require monitoring at the workplace:				
CAS: 1314-13-2 zinc oxide				
EL Short-term value: 10 mg/m ³ Long-term value: 2 mg/m ³				
EV Short-term value: 10 mg/m ³ Long-term value: 2 mg/m ³ respirable				
CAS: 7722-88-5 tetrasodium pyrophosphate				
EV Long-term value: 5 mg/m ³				
· 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.				
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.				

· Breathing equipment:



Suitable respiratory protective device recommended.

· Protection of hands:



Protective gloves

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• 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 prop	erties			
 Information on basic physical and chemical properties General Information 				
 Appearance: Form: Color: Odor: Odor threshold: 	Powder Pink (cherry) / White (mint) Product specific Not determined.			
· pH-value:	Not applicable.			
 Change in condition Melting point/Melting range: Boiling point/Boiling range: 	Undetermined. Undetermined.			
· Flash point:	Not applicable.			
· Flammability (solid, gaseous):	Not determined.			
· 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: 	Not determined. Not determined.			
· Vapor pressure:	Not applicable.			
 Density: Relative density Vapor density Evaporation rate 	Not determined. Not determined. Not applicable. Not applicable.			
 Solubility in / Miscibility with Water: 	Insoluble.			
· Partition coefficient (n-octanol/wa	ter): Not determined.			
 Viscosity: Dynamic: 	Not applicable.			
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Kinematic: Solvent content: Not applicable.

Solids content: Other information 100.0 %

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:

CAS: 16919-27-0 dipotassium hexafluorotitanate

Oral LD50 324 mg/kg (rat (f+m))

CAS: 1314-13-2 zinc oxide

Oral LD50 7,900 mg/kg (rat (f+m))

- · Primary irritant effect:
- · on the skin: No irritant effect.
- on the eve: Irritating effect.
- · Sensitization: No sensitizing effects known.

· Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

- Irritant
- Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

C.I. Pigment Red 3

acetaldehyde

NTP (National Toxicology Program)

acetaldehyde

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.

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2B

R

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NTP K: Known to be human carcinogen.

NTP R: Reasonably anticipated to be human carcinogen.

Additional carcinogenic information:

The substance acetaldehyde is listed by IARC as a Group 1 carcinogen but associated with alcoholic beverage consumption. IARC Volume 100E (2012) "Personal Habits and Indoor Combustions" stated in its monograph "Consumption of Alcoholic Beverages" the following evaluation: "Acetaldehyde associated with the consumption of alcoholic beverages is carcinogenic to humans (Group 1)." GC products are not consumable alcoholic beverages.

When not associated with alcoholic beverage consumption, acetaldehyde is only possibly carcinogenic to humans. IARC Volume 71 (1999) (Re-evaluation of Some Organic Chemicals, Hydrazine and Hydrogen Peroxide) had in its monograph titled "Acetaldehyde" the following evaluation: "Acetaldehyde is possibly carcinogenic to humans (Group 2B)."

- 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.
- · Ecotoxical effects:
- · Remark: Harmful to fish
- · Additional ecological information:
- · General notes: Harmful to aquatic organisms
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

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

14 Transport information

- · UN-Number
- · DOT, TDG, ADN, IMDG, IATA
- · UN proper shipping name

Void Void

· DOT, TDG, ADN, IMDG, IATA

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· Transport hazard class(es)		
· DOT, TDG, ADN, IMDG, IATA		
Class	Void	
Packing group DOT, TDG, IMDG, IATA	Void	
Environmental hazards:		
Marine pollutant:	No	
Special precautions for user	Not applicable.	
Transport in bulk according to Annex	k II of	
MARPOL73/78 and the IBC Code	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): 	
zinc oxide	
· TSCA (Toxic Substances Control Act):	
Kieselguhr, soda ash flux-calcined	
potassium alginate	
dipotassium hexafluorotitanate	
zinc oxide	
tetrasodium pyrophosphate	
· Canadian substance listings:	
 Canadian Domestic Substances List (DSL) 	
Kieselguhr, soda ash flux-calcined	
potassium alginate	
dipotassium hexafluorotitanate	
zinc oxide	
tetrasodium pyrophosphate	
starch sodium octenylsuccinate	
benzaldehyde	
butyric acid ethyl ester	
vanillin	
acetaldehyde	
· Canadian Ingredient Disclosure list (limit 0.1%)	
None of the ingredients is listed.	
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 Canadian Ingredient Disclosure 	list (limit 1%)
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Kieselguhr, soda ash flux-calcined

zinc oxide

tetrasodium pyrophosphate

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms



GHS07

- · Signal word Warning
- Hazard statements
- Causes serious eye irritation.
- Harmful to aquatic life.

Harmful to aquatic life with long lasting effects.

Precautionary statements

Wash thoroughly after handling.

Avoid release to the environment.

Wear protective gloves/protective clothing/eye protection/face protection.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

- Dispose of contents/container in accordance with local/regional/national/international regulations.
- 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 03/13/2018 / -· 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) C.I.: Colour Index LEL: Lower Explosive Limit UEL: Upper Explosive Limit IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association CAS: Chemical Abstracts Service (division of the American Chemical Society) NFPA: National Fire Protection Association (USA) (Contd. on page 10)

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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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