

# Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/23/2016


Version US-EN-Rev 1

Reviewed on 11/23/2016

## 1 Identification

- **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(s) identification

- **Classification of the substance or mixture**  
Eye Irrit. 2A      H319 Causes serious eye irritation.  
Aquatic Acute 3      H402 Harmful 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**  
  
GHS07
- **Signal word** Warning
- **Hazard statements**  
Causes serious eye irritation.  
Harmful to aquatic life.  
Harmful to aquatic life with long lasting effects.
- **Precautionary statements**  
Wear eye protection / face protection.  
Avoid release to the environment.

(Contd. on page 2)

# Safety Data Sheet

## acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/23/2016

Version US-EN-Rev 1

Reviewed on 11/23/2016

**Trade name:** COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)

(Contd. of page 1)

Wash thoroughly after handling.

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)**



HEALTH 1 Health = 1  
FIRE 1 Fire = 1  
REACTIVITY 0 Reactivity = 0

· **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:**

	Kieselguhr, soda ash flux-calcined	50-70%
16919-27-0	dipotassium hexafluorotitanate	1-5%
1314-13-2	zinc oxide	1-5%
7722-88-5	tetrasodium pyrophosphate	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:**

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.

(Contd. on page 3)

# Safety Data Sheet

## acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/23/2016

Version US-EN-Rev 1

Reviewed on 11/23/2016

**Trade name:** COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)

(Contd. of page 2)

- **After eye contact:**  
Protect unharmed eye.  
Rinse opened eye for several minutes under running water. Then 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:**  
CO<sub>2</sub>, 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 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.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

1314-13-2	zinc oxide	10 mg/m <sup>3</sup>
7722-88-5	tetrasodium pyrophosphate	15 mg/m <sup>3</sup>
100-52-7	benzaldehyde	4 ppm

(Contd. on page 4)

# Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/23/2016

Version US-EN-Rev 1

Reviewed on 11/23/2016

**Trade name:** COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)

(Contd. of page 3)

75-07-0	acetaldehyde	45 ppm
<b>· PAC-2:</b>		
1314-13-2	zinc oxide	15 mg/m <sup>3</sup>
7722-88-5	tetrasodium pyrophosphate	130 mg/m <sup>3</sup>
100-52-7	benzaldehyde	9.9 ppm
75-07-0	acetaldehyde	270 ppm
<b>· PAC-3:</b>		
1314-13-2	zinc oxide	2,500 mg/m <sup>3</sup>
7722-88-5	tetrasodium pyrophosphate	790 mg/m <sup>3</sup>
100-52-7	benzaldehyde	59 ppm
75-07-0	acetaldehyde	840 ppm

## 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.  
Avoid contact with the eyes and skin.
- **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.  
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**
- **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.

### 1314-13-2 zinc oxide

PEL	Long-term value: 15* 5** mg/m <sup>3</sup> *total dust **respirable fraction and fume
-----	--

(Contd. on page 5)

US

# Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/23/2016

Version US-EN-Rev 1

Reviewed on 11/23/2016

**Trade name:** COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)

(Contd. of page 4)

REL	Short-term value: 10** mg/m <sup>3</sup> Long-term value: 5 mg/m <sup>3</sup> Ceiling limit value: 15* mg/m <sup>3</sup> *dust only **fume
TLV	Short-term value: 10* mg/m <sup>3</sup> Long-term value: 2* mg/m <sup>3</sup> *as respirable fraction
<b>7722-88-5 tetrasodium pyrophosphate</b>	
REL	Long-term value: 5 mg/m <sup>3</sup>
TLV	TLV withdrawn

· **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

· **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:	Pink (cherry) / White (mint)
Odor:	Product specific
Odor threshold:	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· **Flash point:** Not applicable.

(Contd. on page 6)

US

# Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/23/2016

Version US-EN-Rev 1

Reviewed on 11/23/2016

**Trade name:** COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)

(Contd. of page 5)

· <b>Flammability (solid, gaseous):</b>	Not determined.
· <b>Ignition temperature:</b>	Undetermined.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto igniting:</b>	Product is not self-igniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapor pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with Water:</b>	Insoluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· <b>Solvent content:</b>	
Organic solvents:	0.0 %
Solids content:	100.0 %
· <b>Other information</b>	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.

US

(Contd. on page 7)

# Safety Data Sheet

## acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/23/2016

Version US-EN-Rev 1

Reviewed on 11/23/2016

**Trade name:** COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)

(Contd. of page 6)

### 11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

<b>16919-27-0 dipotassium hexafluorotitanate</b>		
Oral	LD50	324 mg/kg (rat (f+m))
<b>1314-13-2 zinc oxide</b>		
Oral	LD50	7900 mg/kg (rat (f+m))

- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **on the eye:** 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	3
acetaldehyde	2B

- **NTP (National Toxicology Program)**

acetaldehyde	R
--------------	---

- **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.

- **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 (carcinogenicity, mutagenicity and toxicity for reproduction)**

No further relevant information available.

(Contd. on page 8)

# Safety Data Sheet

## acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/23/2016

Version US-EN-Rev 1

Reviewed on 11/23/2016

**Trade name:** COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)

No further relevant information available.

(Contd. of page 7)

### 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.
- **Ecotoxicological 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

- **Waste treatment methods**
- **Recommendation:**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                       |                 |
|---------------------------------------|-----------------|
| · <b>UN-Number</b>                    | Void            |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>    | Void            |
| · <b>UN proper shipping name</b>      | Void            |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>    | Void            |
| · <b>Transport hazard class(es)</b>   | Void            |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>    | Void            |
| · <b>Class</b>                        | Void            |
| · <b>Packing group</b>                | Void            |
| · <b>DOT, ADR, IMDG, IATA</b>         | Void            |
| · <b>Environmental hazards:</b>       |                 |
| · <b>Marine pollutant:</b>            | No              |
| · <b>Special precautions for user</b> | Not applicable. |

(Contd. on page 9)

US



# Safety Data Sheet

acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/23/2016

Version US-EN-Rev 1

Reviewed on 11/23/2016

**Trade name:** COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)

(Contd. of page 8)

- |  |                 |
|--|-----------------|
| <b>· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |
| <b>· UN "Model Regulation":</b>  | Void            |

## 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 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

**· Carcinogenic categories**

**· EPA (Environmental Protection Agency)**

zinc oxide

D, I, II

acetaldehyde

B2

**· TLV (Threshold Limit Value established by ACGIH)**

acetaldehyde

A3

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

acetaldehyde

**· 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**

Wear eye protection / face protection.

Avoid release to the environment.

(Contd. on page 10)

US

# Safety Data Sheet

## acc. to OSHA HCS 29 CFR 1910.1200

Printing date 11/23/2016

Version US-EN-Rev 1

Reviewed on 11/23/2016

**Trade name:** COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)

(Contd. of page 9)

Wash thoroughly after handling.

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** 11/23/2016 / -

· **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)

C.I.: Colour Index

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard – Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· **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](http://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.

(Contd. on page 11)

**Safety Data Sheet**  
**acc. to OSHA HCS 29 CFR 1910.1200**

Printing date 11/23/2016

Version US-EN-Rev 1

Reviewed on 11/23/2016

**Trade name:** COE ALGINATE (Set/Flavor: Fast/Mint, Fast/Wild Cherry, Normal/Mint, and Normal/Wild Cherry)

(Contd. of page 10)

· **Disclaimer:**

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

US