1 Identification

- **Product identifier**
- **Trade name:** COE HYDROPHILIC GEL (Set/Flavor: Fast/Wild Cherry and Normal/Wild Cherry)

- **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 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.

- **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.
- **Precautionary statements**
  - Wear eye protection / face protection.
  - Wash thoroughly after handling.

(Contd. on page 2)
Trade name: COE HYDROPHILIC GEL (Set/Flavor: Fast/Wild Cherry and Normal/Wild Cherry)

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.

- **Additional information:**
  - 4.2 % of the mixture consists of component(s) of unknown toxicity.

- **Classification system:**
  - NFPA ratings (scale 0 - 4)
    - Health = 1
    - Fire = 1
    - Reactivity = 0

- HMIS-ratings (scale 0 - 4)

- 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:**
  - 1309-48-4 magnesium oxide 1-5%
  - 16919-27-0 dipotassium hexafluorotitanate 1-5%
  - 7722-88-5 tetrasodium pyrophosphate 1-5%
  - 56-95-1 chlorhexidine acetate 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).

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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 eye contact:**
  - Protect unharmed eye.

(Contd. on page 3)
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: 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.
  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.
  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.
Trade name: COE HYDROPHILIC GEL (Set/Flavor: Fast/Wild Cherry and Normal/Wild Cherry)

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.
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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>PEL</th>
<th>Long-term value: 15* mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>fume; *total particulate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TLV</td>
<td>Long-term value: 10* mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>*as inhalable fraction</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>REL</th>
<th>Long-term value: 5 mg/m³</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TLV</td>
<td>TLV withdrawn</td>
</tr>
</tbody>
</table>

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.
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

(Contd. on page 5)
Trade name: COE HYDROPHILIC GEL (Set/Flavor: Fast/Wild Cherry and Normal/Wild Cherry)

## 9 Physical and chemical properties

<table>
<thead>
<tr>
<th>Information on basic physical and chemical properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Information</td>
</tr>
<tr>
<td><strong>Appearance:</strong></td>
</tr>
<tr>
<td>Form: Powder</td>
</tr>
<tr>
<td>Color: Whitish</td>
</tr>
<tr>
<td>Odor: Characteristic</td>
</tr>
<tr>
<td>Odor threshold: Not determined.</td>
</tr>
<tr>
<td><strong>pH-value:</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Change in condition</strong></td>
</tr>
<tr>
<td>Melting point/Melting range: Undetermined.</td>
</tr>
<tr>
<td>Boiling point/Boiling range: Undetermined.</td>
</tr>
<tr>
<td><strong>Flash point:</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Flammability (solid, gaseous):</strong> Not determined.</td>
</tr>
<tr>
<td><strong>Ignition temperature:</strong> Undetermined.</td>
</tr>
<tr>
<td><strong>Decomposition temperature:</strong> Not determined.</td>
</tr>
<tr>
<td><strong>Auto igniting:</strong> Product is not selfigniting.</td>
</tr>
<tr>
<td><strong>Danger of explosion:</strong> Product does not present an explosion hazard.</td>
</tr>
<tr>
<td><strong>Explosion limits:</strong></td>
</tr>
<tr>
<td>Lower: Not determined.</td>
</tr>
<tr>
<td>Upper: Not determined.</td>
</tr>
<tr>
<td><strong>Vapor pressure:</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Density:</strong> Not determined.</td>
</tr>
<tr>
<td><strong>Relative density</strong> Not determined.</td>
</tr>
<tr>
<td><strong>Vapour density</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong> Not applicable.</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with</strong> Water: Insoluble.</td>
</tr>
<tr>
<td><strong>Partition coefficient (n-octanol/water):</strong> Not determined.</td>
</tr>
<tr>
<td><strong>Viscosity:</strong></td>
</tr>
<tr>
<td>Dynamic: Not applicable.</td>
</tr>
<tr>
<td>Kinematic: Not applicable.</td>
</tr>
<tr>
<td><strong>Solvent content:</strong></td>
</tr>
<tr>
<td>Organic solvents: 0.0 %</td>
</tr>
<tr>
<td>Solids content: 100.0 %</td>
</tr>
<tr>
<td>Other information No further relevant information available.</td>
</tr>
</tbody>
</table>

## 10 Stability and reactivity

<table>
<thead>
<tr>
<th>Reactivity</th>
<th>No further relevant information available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical stability</td>
<td>Stable at ambient temperature.</td>
</tr>
</tbody>
</table>
\textbf{Trade name:} COE HYDROPHILIC GEL (Set/Flavor: Fast/Wild Cherry and Normal/Wild Cherry)

\begin{itemize}
  \item Thermal decomposition / conditions to be avoided:  
  No decomposition if used according to specifications.
  \item Possibility of hazardous reactions No dangerous reactions known.
  \item Conditions to avoid No further relevant information available.
  \item Incompatible materials: No further relevant information available.
  \item Hazardous decomposition products: No dangerous decomposition products known.
\end{itemize}

\section*{11 Toxicological information}

\begin{itemize}
  \item Information on toxicological effects
  \item Acute toxicity:
  \item LD/LC50 values that are relevant for classification: No further relevant information available.
  \item Primary irritant effect:
  \item on the skin: No irritant effect.
  \item on the eye: Irritating effect.
  \item Sensitization: No sensitizing effects known.
  \item Additional toxicological information:
  The product shows the following dangers according to internally approved calculation methods for preparations:
  Irritant

  \item Carcinogenic categories

  \begin{itemize}
    \item IARC (International Agency for Research on Cancer)
      \begin{tabular}{ll}
        silicon dioxide & 3 \\
        C.I. Pigment Red 3 & 3 \\
        acetaldehyde & 1 \\
      \end{tabular}
    \item NTP (National Toxicology Program)
      \begin{tabular}{ll}
        acetaldehyde & R \\
      \end{tabular}
    \item OSHA-Ca (Occupational Safety & Health Administration)
      None of the ingredients is listed.
  \end{itemize}

  \item Carcinogenic categories' legend:
  \begin{itemize}
    \item IARC Group 1: The agent is carcinogenic to humans.
    \item IARC Group 2A: The agent is probably carcinogenic to humans.
    \item IARC Group 2B: The agent is possibly carcinogenic to humans.
    \item IARC Group 3: The agent is not classifiable as to its carcinogenicity to humans.
    \item IARC Group 4: The agent is probably not carcinogenic to humans.
    \item NTP K: Known to be human carcinogen.
    \item NTP R: Reasonably anticipated to be human carcinogen.
  \end{itemize}

  \item Additional carcinogenic information:
  \begin{itemize}
  \end{itemize}
\end{itemize}
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)."

### 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:** 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

- **UN-Number**
  - DOT, ADR, ADN, IMDG, IATA Void
- **UN proper shipping name**
  - DOT, ADR, ADN, IMDG, IATA Void
Trade name: COE HYDROPHILIC GEL (Set/Flavor: Fast/Wild Cherry and Normal/Wild Cherry)

- Transport hazard class(es)
  - DOT, ADR, ADN, IMDG, IATA
    - Class: Void

- Packing group
  - DOT, ADR, IMDG, IATA
    - Packing group: 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):
    - None of the ingredients is listed.

- TSCA (Toxic Substances Control Act):
  - silicon dioxide
  - potassium alginate
  - oxirane, methyl-, polymer with oxirane, ether with 1,2,3-propanetriol (3:1)
  - magnesium oxide
  - dipotassium hexafluorotitanate
  - tetrasodium pyrophosphate

- Carcinogenic categories

  - EPA (Environmental Protection Agency)
    - acetaldehyde: B2

  - TLV (Threshold Limit Value established by ACGIH)
    - magnesium oxide: A4
    - 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).
Trade name: COE HYDROPHILIC GEL (Set/Flavor: Fast/Wild Cherry and Normal/Wild Cherry)

- **Hazard pictograms**

  ![GHS07]

- **Signal word** Warning
- **Hazard statements**
  Causes serious eye irritation.
- **Precautionary statements**
  Wear eye protection / face protection.
  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.
- **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** 04/23/2015  
- **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)
  - 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
  - Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A
- **Sources**
  - Manufacturers’ MSDSs/SDSs  
  - EnviChem ([www.echemportal.org](http://www.echemportal.org))
Trade name: COE HYDROPHILIC GEL (Set/Flavor: Fast/Wild Cherry and Normal/Wild Cherry)

- 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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