1 Identification

- Product identifier
  - **Trade name:** Saliva-Check Buffer (Wax)

- 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 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
    - Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device.

  - Hazard pictograms: Void
  - Signal word: Void
  - Hazard statements: Void

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

  - **HMIS-ratings (scale 0 - 4)**
    - Health = 0
    - Fire = 0
    - Reactivity = 0

(Contd. on page 2)
3 Composition/Information on ingredients

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

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.

- 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.
  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.

- 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.

- 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 product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- 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.
Trade name: Saliva-Check Buffer (Wax)

- 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:
  
  Manufacturing sites:
  Wear safety glasses with side shields (or goggles).
  Distribution, Workplace, and Household Settings:
  No special protective equipment required

9 Physical and chemical properties

- Information on basic physical and chemical properties

- General Information

- Appearance:
  
  Form: Solid
  
  Color: According to product specification
  
  Odor: Odorless
  
  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.

- 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: Not determined.
  
  Upper: Not determined.

- Vapor pressure:
  
  Not applicable.

- Density:
  
  Not determined.

- Relative density:
  
  Not determined.
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.
- 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
    - butylated hydroxytoluene (BHT) 3
  - NTP (National Toxicology Program)
    - 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.
Trade name: Saliva-Check Buffer (Wax)

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 (carcinogenicity, mutagenicity and toxicity for reproduction)
  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:
  - General notes:
    Water hazard class 1 (Self-assessment): slightly hazardous for water
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - 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:
    Dispose of contents / container in accordance with local / regional / national / international regulations.
- Uncleaned packagings:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - DOT, TDG, ADN, IMDG, IATA: Void
- UN proper shipping name
  - DOT, TDG, ADN, IMDG, IATA: Void
- Transport hazard class(es)
  - DOT, TDG, ADN, IMDG, IATA: Void
  - Class: Void
- Packing group
  - DOT, TDG, IMDG, IATA: 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):**
      None of the ingredients is listed.
- **TSCA (Toxic Substances Control Act):**
  - D-glucitol
  - xylitol
  - D-mannitol
  - silicon dioxide
  - calcium distearate, pure
  - Enzactin
- **Canadian substance listings:**
  - **Canadian Domestic Substances List (DSL)**
    - D-glucitol
    - D-mannitol
    - silicon dioxide
    - calcium distearate, pure
    - Glycerin fatty acid ester (POEM)
    - Enzactin
    - butylated hydroxytoluene (BHT)
  - **Canadian Ingredient Disclosure list (limit 0.1%)**
    None of the ingredients is listed.
  - **Canadian Ingredient Disclosure list (limit 1%)**
    - silicon 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: 03/13/2018 / -
· 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)
  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)
  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.
· 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.