

SAFETY DATA SHEETS

This SDS packet was issued with item:

074570214

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).

074570222

MATERIAL SAFETY DATA SHEET**SECTION 1 - PRODUCT IDENTIFICATION**

Product identifier: Venus Comfort Gel
Product Description: Teeth Desensitizing Gel
Product code: 40005240
Product use: Dental

Supplier's name and address:

HERAEUS KULZER, LLC
300 Heraeus Way
South Bend, IN
46614
Phone #: 1-800-431-1785

Manufacturer's name and address:

HERAEUS KULZER, LLC
300 Heraeus Way
South Bend, IN
46614
Phone #: 1-800-431-1785

Emergency Telephone: In the event of chemical emergency involving a spill, leak, fire, exposure, or accident involving chemicals call CHEMTREC (24 hours) (800) 424-9300

SECTION 2 - CHEMICAL COMPOSITION/HAZARDOUS INGREDIENTS

Chemical Name	CAS #	EINECS	Classification	Content %
Sodium Fluoride	007681-49-4	231-667-8	T; R25; R32; R36/38	0.25
Potassium Nitrate	007757-79-1	231-818-8	Xi; R36/37/38	3

(Full text of R-Phrases can be found in Sections 15 and 16)

SECTION 3 - HAZARDS IDENTIFICATION**HAZARD DESIGNATION:**

“O”- Oxidizing

R18: In use, may form flammable/explosive vapor air mixture.

“Xi”- Irritant

“T” - Toxic

R22: Harmful if swallowed.

EMERGENCY OVERVIEW

Physical Appearance: Gel

POTENTIAL HEALTH EFFECTS

Eyes: Mildly irritating to the eyes.

Skin: May cause skin irritation.

Ingestion: Substance may be harmful if swallowed.

SECTION 4 - FIRST AID MEASURES

Skin Contact: Wash with soap and water. Get medical attention if irritation develops or persists.

Eye Contact: Immediately remove any contact lenses, flush with plenty of water for 15 minutes. Seek immediate medical attention.

Ingestion: If swallowed, do **NOT** induce vomiting. Drink a glass of water or milk. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.

Inhalation: No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

SECTION 5 - FIRE FIGHTING MEASURES

Fire Fighting Procedures: General: Evacuate all personnel; use protective equipment for fire fighting. Use a self-contained breathing apparatus when the product is involved in fire.

Fire Fighting Equipment: Water spray, fog or mist, foam, dry chemical, carbon dioxide.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Small Spill: Wipe up with cloth, soap and water.

Large Spill: Collect in tightly closed containers.

ENVIRONMENTAL PRECAUTIONS:

Water Spill: Do not allow to enter sewers or drains that may lead to waterways.

SECTION 7 - HANDLING AND STORAGE

General Procedures: Avoid contact with eyes, skin and clothing.

Handling: Use suitable protective equipment.

Storage: Room temperature.

SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

PERSONAL PROTECTIVE EQUIPMENT:

Eyes and Face: Use chemical splash goggles and face shield (ANSI Z87.1 or approved equivalent).

Skin: S36/37: Wear suitable protective clothing and gloves.

Respiratory: S38: In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical Form: Gel

Color: Colorless

Odor: Odorless or no characteristic odor

SECTION 10 - REACTIVITY AND STABILITY DATA

Stability and Reactivity: Stable when stored and handled under recommended conditions

Conditions to Avoid: Excess heat and exposure to moist air or water, strong bases and metals.

Polymerization: Not Applicable

Incompatible Materials: Strong caustics, most metals.

SECTION 11 - TOXICOLOGICAL INFORMATION

Eye Effects; Severe eye irritation

Skin Effects: Prolonged skin contact may cause skin irritation.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental Data: Not defined

Ecotoxicological Information: Not yet determined.

SECTION 13 - WASTE DISPOSAL

Methods of Disposal: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

SECTION 14 - TRANSPORTATION INFORMATION

Road and Rail (ADR/RID)

Label: Not classified

Air (ICAO/IATA)

Label: Not Classified

Vessel (IMO/IMDG)

Label: Not Classified

SECTION 15 - REGULATORY INFORMATION

EUROPEAN COMMUNITY

ECC LABEL SYMBOL AND CLASSIFICATION:



“O”- Oxidizing

R18: In use, may form flammable/explosive vapor-air mixture.



“T” – Toxic

R22: Harmful if swallowed.



“Xi” – Irritant

SECTION 16 - OTHER INFORMATION

Relevant R-Phrases:

R36/37/38: Irritating to eyes, respiratory system and skin.

Prepared by: Cheryl Zimmerman

Telephone number: 800-431-1785

Preparation date: 2/2/10

Revision date: New

Additional notes or references: Not Applicable

We believe that the information contained herein is current as of the date of this Material Safety Data Sheet. Since the use of this information and these opinions and the conditions of use of the product are not within the control of Heraeus Kulzer, LLC, it is the user's obligation to determine the conditions of safe use of the product.

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010
Dental Use



Kulzer, LLC
4315 S. Lafayette Blvd.
South Bend, IN 46614 USA

Date Issued : 02/16/2018
SDS No : 368-250.01

Venus Comfort Gel

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : 40005240 (UV/41902)
Product name : Venus Comfort Gel
Product description : Teeth Desensitizing Gel

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Tooth Desensitizing Gel

1.3. Details of the supplier of the safety data sheet

Manufacturer

Kulzer, LLC (Mitsui Chemicals Group)
4315 S. Lafayette Blvd.
South Bend, IN 46614

Customer Support : (800) 431-1785

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA) : (800) 424 - 9300
(INTERNATIONAL) : +1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation(EC) No 1272/2008 [CLP]

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies. This material is not considered hazardous to health.

Health : Not Classified

2.2. Label elements

This material is not considered hazardous to the health according to Regulation(EC) No 1272/2008[CLP].

Classification according to Regulation(EC) No 1272/2008 [CLP]

Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response : P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P302+P352: IF ON SKIN: Wash with plenty of soap & water.
P332+P313: If skin irritation occurs: Get medical advice/attention.

Storage : P273: Avoid release to the environment.

Disposal : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

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2.3. Other hazards

Immediate concerns : None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Sodium Hydroxide	1310-73-2	215-185-5	< 5	Skin Corr.,Cat. 1B; H314
Sodium Fluoride	7681-49-4	231-667-8	< 1	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2A; Acute Tox. (O),Cat 3; H301; H315; H319
Poly Acrylic acid	9003-01-4	618-347-7	< 10	Not classified
Potassium Nitrate	7757-79-1	231-818-8	< 5	Oxid. Sol.,Cat. 2; Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; STOT SE,Cat 3; H272; H335; H315; H319

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Flush eyes with water. Get medical attention if irritation develops or persists.

Following skin : Remove contaminated clothing. Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion : If swallowed in small quantity the product is harmless, otherwise consult a doctor.

Following inhalation : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

4.2. Most important symptoms and effects, both acute and delayed

Eyes : May cause mild irritation.

Skin : Prolonged skin contact may cause skin irritation.

Ingestion : May be harmful if swallowed in large quantities.

Inhalation : None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed

Notes to physician : NAP

SECTION 5: Fire fighting measures

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Venus Comfort Gel

5.1. Extinguishing media

Extinguishing media : Water spray, fog, or mist, foam, dry chemical, carbon dioxide (CO₂)

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : None known.

5.3. Advice for firefighters

Fire fighting procedures : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General procedures : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

Water spill : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

Small Spill : Wipe up with cloth, soap and water.

Large Spill : Collect in tightly closed containers.

6.4. Reference to other sections

Reference to other sections : NAP

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General procedures : Avoid contact with eyes, skin and clothing.

Handling : Use suitable protective equipment.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Tooth Desensitizing Gel

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Sodium Fluoride CAS: 7681-49-4

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Venus Comfort Gel

Control Parameters	Exposure Limits
OSHA PEL	TWA 2.5 mg/m ³ F TWA 2.5 mg/m ³ dust (vacated) TWA 2.5 mg/m ³
ACGIH TLV	TWA 2.5 mg/m ³ F
NIOSH REL	TWA 2.5 mg/m ³
NIOSH IDLH	250 mg/m ³ F TWA: 2.5 mg/m ³ F

Sodium Hydroxide CAS: 1310-73-2

Control Parameters	Exposure Limits
OSHA PEL General Industry	2 mg/m ³ TWA
OSHA PEL - Construction Industry	2 mg/m ³ TWA
OSHA PEL - Shipyard Employment	2 mg/m ³ TWA
NIOSH REL	2 mg/m ³ Ceiling
ACGIH TLV	2 mg/m ³ Ceiling
CAL/OSH A PEL	2 mg/m ³ Ceiling

8.2. Exposure controls

Eye/face protection : Wear eye protection.

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gel

Colour : Colorless

Odour : Odorless or no characteristic odor

pH : 6.5 to 7.5

9.2. Other information

Additional information : No further relevant information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

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10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Avoid strong bases, metals, excess heat, exposure to moist air or water.

10.5. Incompatible materials

Incompatible materials : Strong caustics, most metals.

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Notes :

Other information : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Not Determined

Aquatic toxicity (acute)

96-hour LC₅₀ : Not determined

48-hour EC₅₀ : Not determined

96-hour EC₅₀ : Not determined

12.2. Persistence and degradability

Persistence and degradability : Not determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not determined

12.4. Mobility in soil

Mobility in soil : Not determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not determined

12.6. Other adverse effects

Environmental data : Not defined

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

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SECTION 14: Transport information

14.1. UN number

UN number : NAP

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : NAP

14.4. Packing group

Packing group : NAP

14.5. Environmental hazards

Marine pollutant #1 : NAP

14.6. Special precautions for user

ADR - road : NAP

RID - rail : NAP

IMDG - sea : NAP

IATA - air : NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

General information : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

Additional information : This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant H-statements (number and full-text) : Acute Tox. (O), Cat 3: Acute Toxicity (Oral), Category 3
Eye Irr., Cat. 2A: Eye Irritation, Category 2A
Eye Irr., Cat. 2: Eye Irritation, Category 2
Oxid. Sol., Cat. 2: Oxidizing Solids, Category 2
STOT SE, Cat 3: Target Organ Toxicity (Single exposure), Category 3
Skin Corr., Cat. 1B: Skin Corrosion, Category 1B
Skin Irr., Cat. 2: Skin Irritation, Category 2
H272: May intensify fire; oxidizer.
H301: Toxic if swallowed.
H314: Causes severe skin burns and eye damage.

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Venus Comfort Gel

H315: Causes skin irritation.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

Prepared by

: Anu Kattoju

General statements

: NAP = Not Applicable
NE = Not Established
TLV = Threshold Limit Value
PEL = Permissible exposure limits
MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment

Additional SDS information

: This is the first SDS.

Manufacturer disclaimer

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.