

## **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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**Venus Comfort Gel**

**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 (CO<sub>2</sub>)

**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 <sup>3</sup> F TWA 2.5 mg/m <sup>3</sup> dust (vacated) TWA 2.5 mg/m <sup>3</sup>
ACGIH TLV	TWA 2.5 mg/m <sup>3</sup> F
NIOSH REL	TWA 2.5 mg/m <sup>3</sup>
NIOSH IDLH	250 mg/m <sup>3</sup> F TWA: 2.5 mg/m <sup>3</sup> F

Sodium Hydroxide CAS: 1310-73-2

Control Parameters	Exposure Limits
OSHA PEL General Industry	2 mg/m <sup>3</sup> TWA
OSHA PEL - Construction Industry	2 mg/m <sup>3</sup> TWA
OSHA PEL - Shipyard Employment	2 mg/m <sup>3</sup> TWA
NIOSH REL	2 mg/m <sup>3</sup> Ceiling
ACGIH TLV	2 mg/m <sup>3</sup> Ceiling
CAL/OSHA PEL	2 mg/m <sup>3</sup> 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 LC<sub>50</sub> : Not determined

48-hour EC<sub>50</sub> : Not determined

96-hour EC<sub>50</sub> : 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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## Venus Comfort Gel

### 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**

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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 = Permittable 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.