

# 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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**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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| 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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### 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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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.