

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

Venus Comfort Gel

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

1.1. Product identifier

Product code : 40005240
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

Heraeus Kulzer, LLC (Mitsui Chemicals Group)
 300 Heraeus Way
 South Bend, IN 46614-2517
 USA
 (800) 431-1785

Distributor

Heraeus Kulzer, LLC (Mitsui Chemicals Group)
 300 Heraeus Way
 South Bend, IN 46614-2517
 USA
 (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 Directive 1999/45/EC

: 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.

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

Health : None

2.2. Label elements

Classification according to Directive 1999/45/EC : This material is not considered to be hazardous for the health.

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

Hazard statement(s) : 6298PYRE: This Material Is Not Considered To Be Hazardous For The Health.

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 and water.

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

Venus Comfort Gel

Storage : P332+P313: If skin irritation occurs: Get medical advice/attention.
Disposal : P273: Avoid release to the environment.
: P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

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 Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Sodium Hydroxide	1310-73-2	215-185-5	< 5	C; R34	Skin Corr.,Cat. 1A; H314
Sodium Fluoride	007681-49-4	231-667-8	< 1	T, Xi; R25; R32; R36/38	Acute Tox. (O),Cat. 3; Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; H301; H315; H319
Poly Acrylic acid	9003-01-4	N/A	< 10	Xi; R36/37/38	Not classified
Potassium Nitrate	7757-79-1	231-818-8	< 5	O, Xi; R36/37/38; R22	Oxid. Sol.,Cat. 2; Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; H272; H315; H319

For full text of H-statements and R-phrases: 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 : Wash with soap and water. Get medical attention if irritation develops

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

Venus Comfort Gel

- 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** : Not Applicable

SECTION 5: Fire fighting measures

- 5.1. Extinguishing media**
- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.
- 5.2. Special hazards arising from the substance or mixture**
- Hazardous combustion products** : None known.
- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined
- 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.
- Fire fighting equipment** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO₂)

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.

SAFETY DATA SHEET

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

Venus Comfort Gel

6.4. Reference to other sections

Reference to other sections : Not Applicable

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 : Not Determined

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

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

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

Date Issued : 12/15/2009
SDS No : V003
Date Revised : 05/28/2015
Revision No : 5

Venus Comfort Gel

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

Acute

Notes : 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)

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

Date Issued : 12/15/2009
SDS No : V003
Date Revised : 05/28/2015
Revision No : 5

Venus Comfort Gel

SECTION 14: Transport information

14.1. UN number

UN number : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : Not Dangerous Goods

RID - rail : Not Dangerous Goods

IMDG - sea : Not Dangerous Goods

IATA - air : Not Dangerous Goods

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

Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information

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

RoHS : 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 R-phrases and/or H-statements (number and full text)

- : R22: Harmful if swallowed.
- : R25: Toxic if swallowed.
- : R32: Contact with acids liberates very toxic gas.
- : R34: Causes burns.
- : R36/37/38: Irritating to eyes, respiratory system and skin.
- : R36/38: Irritating to eyes and skin.
- : Acute Tox. (O), Cat. 3: Acute Toxicity (Oral), Category 3
- : Eye Irr., Cat. 2: Eye Irritation, Category 2
- : Oxid. Sol., Cat. 2: Oxidizing Solids, Category 2
- : Skin Corr., Cat. 1A: Skin Corrosion, Category 1A
- : Skin Irr., Cat. 2: Skin Irritation, Category 2

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

Date Issued : 12/15/2009
SDS No : V003
Date Revised : 05/28/2015
Revision No : 5

Venus Comfort Gel

H272: May intensify fire; oxidizer.
H301: Toxic if swallowed.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H319: Causes serious eye irritation.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 01/21/2015 SDS. Revised: **Section 1:**
. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE
CONCERNS. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT -
SKIN. **Section 10:** HAZARDOUS POLYMERIZATION. **Section 11:**
ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section**
14: . **Section 15:** COMMENTS, SECTION 15: Regulatory information.

General statements

: N/A= Not Applicable

Manufacturer disclaimer

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