This SDS packet was issued with item: 074570305

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

074570248 074570339

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 : 306-250.01

Venus White Pro 35%

| SECTION 1 : Identification of the subs   | stance/preparation and of the company/undertaking  |
|--|--|
| 1.1. Product identifier  |  |
| Product code   | : 40005460, 40005462, 40005465 (OH/71059)  |
| Product name   | : Venus White Pro 35%  |
| Product description  | : Bleaching Gel  |
| 1.2. Relevant identified uses of the sul   | bstance or mixture and uses advised against  |
| Relevant identified uses   | : Professional Dental Teeth Whitening Gel  |
| 1.3. Details of the supplier of the safet  | y data sheet   |
| Manufacturer<br>Kulzer, LLC (Mitsui Chemicals Group)<br>4315 S. Lafayette Blvd.<br>South Bend, IN 46614<br>Customer Support              | : (800) 431-1785   |
| 1.4. Emergency telephone number  |  |
| CHEMTREC (NORTH AMERICA) :(800<br>(INTERNATIONAL) :+1(7  | •  |
| SECTION 2: Hazards identification  |  |
|  |  |
| 2.1. Classification of the substance or  | mixture  |
| 2.1. Classification of the substance or<br>Classification according to Regulation  |  |
|  |  |
|  | <b>(EC) No 1272/2008 [CLP]</b><br>: The mixture has been assessed and/or tested for its physical, health and   |
| Classification according to Regulation   | <ul> <li>h(EC) No 1272/2008 [CLP]</li> <li>The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.</li> <li>Skin Irritation, Category 2<br/>Eye Damage, Category 1</li> </ul>   |
| Classification according to Regulation<br>Health   | <ul> <li><b>(EC) No 1272/2008 [CLP]</b></li> <li>: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.</li> <li>: Skin Irritation, Category 2<br/>Eye Damage, Category 1<br/>Acute Toxicity (Oral), Category 4</li> </ul>   |
| Classification according to Regulation<br>Health<br>2.2. Label elements  | <ul> <li><b>(EC) No 1272/2008 [CLP]</b></li> <li>: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.</li> <li>: Skin Irritation, Category 2<br/>Eye Damage, Category 1<br/>Acute Toxicity (Oral), Category 4</li> </ul>   |
| Classification according to Regulation<br>Health<br>2.2. Label elements<br>Classification according to Regulation                        | <ul> <li>h(EC) No 1272/2008 [CLP]</li> <li>The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.</li> <li>Skin Irritation, Category 2<br/>Eye Damage, Category 1<br/>Acute Toxicity (Oral), Category 4</li> </ul>   |
| Classification according to Regulation<br>Health<br>2.2. Label elements<br>Classification according to Regulation<br>Hazard pictogram(s) | <ul> <li><b>h(EC) No 1272/2008 [CLP]</b></li> <li>The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.</li> <li>Skin Irritation, Category 2<br/>Eye Damage, Category 1<br/>Acute Toxicity (Oral), Category 4</li> </ul> <b>h(EC) No 1272/2008 [CLP]</b> Exclamation mark |

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### Venus White Pro 35%

| Prevention        | : P280: Wear protective gloves/protective clothing/eye protection/face protection.          |
|-------------------|---|
| Response          | : P305: IF IN EYES:   |
|                   | P351: Rinse cautiously with water for several minutes.                                      |
|                   | P337+P313: If eye irritation persists: Get medical advice/attention.                        |
|                   | P302+P352: IF ON SKIN: Wash with plenty of soap & water.                                    |
|                   | P332+P313: If skin irritation occurs: Get medical advice/attention.                         |
|                   | P301: IF SWALLOWED:   |
|                   | P330: Rinse mouth.  |
|                   | P331: Do NOT induce vomiting.   |
|                   | P312: Call a POISON CENTER or doctor/physician if you feel unwell.                          |
| Storage           | : P273: Avoid release to the environment.   |
| Disposal          | : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-<br>20/11/2003) |
| .3. Other hazards |   |

#### 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<br>No. | Wt.% | Classification according to Regulation(EC) No 1272/2008 [CLP]                                  |
|-----------------------|-------------|---------------|------|--|
| Carbamide<br>Peroxide | 000124-43-6 | 204-701-4     | < 25 | Skin Irr.,Cat. 2; EYE DMG.,Cat. 1; STOT SE,Cat. 3; Oxid. Sol.,Cat 3; H272;<br>H315; H318; H335 |
| Hydrogen<br>Peroxide  | 007722-84-1 | 231-765-0     | < 10 | Acute Tox. (O),Cat. 4; Eye Irr.,Cat. 2; Acute Tox. (I),Cat. 4; H302; H332; H319                |
| Potassium Nitrate     | 007757-79-1 | 231-818-8     | < 5  | Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; STOT SE,Cat 3; H315; H319; H335                             |

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

#### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

| Following eyes      | : Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and tested by medical personnel. |
|---------------------|--|
| 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.  |

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Kulzer, LLC

Eyes

Skin

Venus White Pro 35% **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 : Irritating to eyes. : May cause skin irritation. Indestion : 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 : NAP Notes to physician **SECTION 5: Fire fighting measures** 5.1. Extinguishing media Extinguishing media : Water Spray Only 5.2. Special hazards arising from the substance or mixture : Not determined Hazardous combustion products 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 small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water. Large Spill : Absorb with inert, damp non-combustible material, then flush area with water. 6.4. Reference to other sections Reference to other sections : NAP **SECTION 7: Handling and storage** 7.1. Precautions for safe handling : Keep away from heat sources and direct sunlight.

Handling Storage

: See product labeling.

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| 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 Dental Teeth Whitening Gel

#### **SECTION 8: Exposure controls / personal protection**

#### 8.1. Control parameters

**Control parameters** 

: Hydrogen Peroxide CAS: 7722-84-1

| Control Parameters             | Exposure Limits                  |
|--------------------------------|----------------------------------|
| OSHA PEL General Industry      | 1 ppm, 1.4 mg/m <sup>3</sup> TWA |
| OSHA PEL Construction Industry | 1 ppm, 1.4 mg/m <sup>3</sup> TWA |
| OSHA PEL Maritime Industry     | 1ppm, 1.4 mg/m <sup>3</sup> TWA  |
| ACGIH TLV                      | 1ppm, 1.4 mg/m <sup>3</sup> TWA  |
| NIOSH REL                      | 1ppm, 1.4 mg/m <sup>3</sup> TWA  |

| 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                                       | : Mint  |  |
| рН  | : 5.7 to 7.5  |  |
| Solubility in water                         | : Partially Soluble   |  |
| 9.2. Other information                      |   |  |
| Percent volatile                            | : Not Volatile  |  |
| 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 react        | tions   |  |

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|--|--|
| ,  | Venus White Pro 35%  |
| Hazardous polymerization   | : None   |
| 10.4. Conditions to avoid  |  |
| Conditions to avoid  | : Strong acids, strong bases, and oxidizing agents.                                      |
| 10.5. Incompatible materials                                       |  |
| Incompatible materials   | : Strong caustics, most metals.  |
| 10.6. Hazardous decomposition produc                               | ts   |
| Hazardous decomposition products                                   | : None known.  |
| SECTION 11: Toxicological information                              | 1  |
| 11.1. Information on toxicological effect                          | ts   |
| Notes  | :  |
| Other information  | : Device is biocompatible when used as directed by dental professionals per ISO 10993-1. |
| SECTION 12: Ecological information                                 |  |
| 12.1. Toxicity   |  |
| Aquatic toxicity (acute)   | : Do not allow to enter sewers or drains that may lead to waterways.                     |
| 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 assessm                              | nent   |
| Results of PBT and vPvB assessment                                 | : Not determined   |
| 12.6. Other adverse effects  |  |
| Environmental data   | : Biodegradability - Not established   |
| SECTION 13: Disposal considerations                                |  |
| 13.1. Waste treatment methods                                      |  |
| Disposal method  | : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)        |
| SECTION 14: Transport information                                  |  |
| 14.1. UN number  |  |
| UN number  | : NAP  |
| 14.2. UN proper shipping name                                      |  |



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| South Bend, IN 46614 USA                     |   |
|--|---|
|  | Venus White Pro 35%   |
| UN proper shipping name                      | : Not Dangerous Goods   |
| 14.3. Transport hazard class(es)             |   |
| Hazard classification                        | : NAP   |
| 14.4. Packing group                          |   |
| 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 A       | nnex 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                          | : US Cosmetic (not sold in the EU)  |
| 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) | <ul> <li>Acute Tox. (I), Cat. 4: Acute Toxicity (Inhalation), Category 4</li> <li>Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4</li> <li>EYE DMG., Cat. 1: Eye Damage, Category 1</li> <li>Eye Irr., Cat. 2: Eye Irritation, Category 2</li> <li>Oxid. Sol., Cat 3: Oxidizing Solids, Category 3</li> <li>STOT SE, Cat 3: Target Organ Toxicity (Single exposure), Category 3</li> <li>STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3</li> <li>Skin Irr., Cat. 2: Skin Irritation, Category 2</li> <li>H272: May intensify fire; oxidizer.</li> <li>H302: Harmful if swallowed.</li> <li>H315: Causes skin irritation.</li> <li>H318: Causes serious eye damage.</li> <li>H319: Causes serious eye irritation.</li> <li>H332: Harmful if inhaled.</li> <li>H335: May cause respiratory irritation.</li> </ul> |
| Prepared by                                  | : Anu Kattoju   |

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### Venus White Pro 35%

| General statements         | : NAP = Not Applicable<br>NE = Not Established<br>TLV = Threshold Limit Value<br>PEL = Permittable exposure limits<br>MAK = Maximum Workplace Concentration<br>STEL = Short-term exposure limit<br>STEV = Short-term exposure value<br>TWA = Time Weighted Average<br>PPE = Personal Protective Equipment  |
|----------------------------|--|
| Additional SDS information | : This is the first SDS.   |
| Manufacturer disclaimer    | : FOR DENTAL USE ONLY: Use as directed. The information and<br>recommendations are taken from sources (raw material SDS(s) and<br>manufacturer's knowledge) believed to be accurate; however, the manufacturer,<br>makes no warranty with respect to the accuracy of the information or the<br>suitability of the recommendation and assumes no liability to any user thereof.<br>Each user should review these recommendations in the specific context of the<br>intended use and determine whether they are appropriate. |