according to Regulation (EC) No. 453/2010

Dental Use



Date Issued: 02/16/2018

SDS No: 321-250.01

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

Venus White Ultra Plus 15%

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

1.1. Product identifier

Product code : 660 60672 (MZ/71097)

Product name : Venus White Ultra Plus 15%

Product description : Pre-filled Bleaching Gel Trays

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

Relevant identified uses : Professional Dental Teeth Whitening 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.

Health: Eye Damage, Category 1

Acute Toxicity (Oral), Category 4

2.2. Label elements

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

Hazard pictogram(s) :



Exclamation mark

Signal Word : DANGER

Hazard statement(s) : H318: Causes serious eye damage.

H302: Harmful if swallowed.

Precautionary statement(s)

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

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Response: P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P313: 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.

P312: Call a POISON CENTER or doctor/physician if you feel unwell.

Storage : P273: Avoid release to the environment.

Disposal: P501: Dispose of container and unused contents in accordance with federal,

state, and local requirements.

2.3. Other hazards

Immediate concerns : May cause serious damage to the eyes.

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] |
|----------------------|-----------|---------------|------|--|
| Hydrogen Peroxide | 7722-84-1 | 231-765-0 | < 20 | EYE DMG.,Cat. 1; Acute Tox. (O),Cat. 4; Skin Irr.,Cat. 2; STOT SE,Cat. 3; H318; H332; H302; H315 |
| Polyvinylpyrrolidone | 9003-39-8 | 618-363-4 | < 10 | Not classified |
| Sodium Hydroxide | 1310-73-2 | 215-185-5 | < 5 | Skin Corr.,Cat. 1B; H314 |
| Potassium Nitrate | 7757-79-1 | 231-818-8 | ≤ 3 | Oxid. Sol.,Cat. 2; Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; STOT SE,Cat 3; H272; H335; H315; H319 |
| Glycerin | 56-81-5 | 200-289-5 | < 40 | Not classified |
| Potassium Hydroxide | 1310-58-3 | 215-181-3 | < 3 | Acute Tox. (O),Cat. 4; Skin Corr.,Cat. 1B; H302; H314 |

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.

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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 serious damage.

Skin : May cause skin irritation.

Ingestion: 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 : May cause severe eye damage.

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Extinguishing media : Water Spray Only 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 : 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

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

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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 Dental Teeth Whitening Gel

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : <u>Sodium Hydroxide CAS: 1310-73-2</u>

| 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 |

Hydrogen Peroxide CAS: 7722-84-1

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

Appearance : Highly viscous

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9.2. Other information

Solubility in water

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.

: Partially Soluble

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

Acute

 $\begin{array}{lll} \textbf{Der mal LD}_{50} & : \ \textbf{Not determined} \\ \textbf{Oral LD}_{50} & : \ \textbf{Not determined} \\ \textbf{Inhalation LC}_{50} & : \ \textbf{Not determined} \\ \end{array}$

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Not Determined

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

96-hour LC₅₀ : Not determined
48-hour EC₅₀ : Not determined
96-hour EC₅₀ : Not determined

12.2. Persistence and degradability

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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 available

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

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

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General information : Please refer to the United States Food, Drug, and Cosmetic Act.

15.2. Chemical safety assessment

: Not Determined Chemical safety assessment

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. 4: Acute Toxicity (Oral), Category 4

EYE DMG., Cat. 1: Eye Damage, Category 1 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 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract

Category 3

Skin Corr., Cat. 1B: Skin Corrosion, Category 1B Skin Irr., Cat. 2: Skin Irritation, Category 2

H272: May intensify fire; oxidizer. H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H315: Causes skin irritation.

H318: Causes serious eye damage. H319: Causes serious eye irritation.

H332: Harmful if inhaled.

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.