according to Regulation (EC) No. 453/2010

Dental Use



Date Issued: 02/16/2018

SDS No: 306-250.01

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

Venus White Pro 35%

SECTION 1: Identification of the substance/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 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 : Skin Irritation, Category 2

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) : H315: Causes skin irritation.

H318: Causes serious eye damage.

H302: Harmful if swallowed.

Precautionary statement(s)

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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-

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 Regulation(EC) No 1272/2008 [CLP]
Carbamide 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; H315; H318; H335
Hydrogen 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

Following eyes

4.1. Description of first aid measures

+. 1. Description of mst aid measures

: 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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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 : Irritating to eyes.

Skin: 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

5.1. Extinguishing media

Extinguishing media : Water Spray Only 5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : 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.

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

Handling : Keep away from heat sources and direct sunlight.

Storage : See product labeling.

according to Regulation (EC) No. 453/2010

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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 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
Colour : Colorless
Odour : Mint
pH : 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 reactions

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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 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

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 assessment

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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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 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 : 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)

: Acute Tox. (I), Cat. 4: Acute Toxicity (Inhalation), Category 4

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 3: Oxidizing Solids, Category 3

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 Irr., Cat. 2: Skin Irritation, Category 2

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

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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.