

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 : 224-250.01

Venus White Pro 16%, Venus White Pro 22%

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

1.1. Product identifier

Product code : 40005166, 40005167, 40005164, 40005165 (HV/71042, HW/71043)
Product name : Venus White Pro 16%, Venus White Pro 22%
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 : Eye Irritation, Category 2
 Skin Irritation, Category 2

2.2. Label elements

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

Hazard pictogram(s) : 
 Exclamation mark

Signal Word : WARNING

Hazard statement(s) : H315: Causes skin irritation.
 H319: Causes serious eye irritation.

Precautionary statement(s)

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

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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.

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 : NAP

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	< 24	Skin Irr.,Cat. 2; EYE DMG.,Cat. 1; STOT SE,Cat. 3; Oxid. Sol.,Cat 3; H272; H315; H318; H335
Potassium Nitrate	7757-79-1	231-818-8	3	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; STOT SE,Cat 3; H335; H315; H319
Sodium Hydroxide	1310-73-2	215-185-5	< 5	Skin Corr.,Cat. 1B; H314
Poly Acrylic acid	9003-01-4	618-347-7	< 10	Not classified

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 eyes with plenty of water for at least 15 minutes. Get immediate medical attention.

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 : Irritating to eyes.

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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 : 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.
: Water spray only.

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.
Handling : Use suitable protective equipment.
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 : Sodium Hydroxide CAS: 1310-73-2

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	3 Ceiling
CAL/OSHA PEL	2 mg/m ³ Ceiling

Sodium Hydroxide International Regulations

Country	Exposure Limits	Limit Values
Australia	Peak limitation(199)	2 mg/m ³
Federal Republic of Germany	Short term level	2 mg/m ³ , 4 mg/m ³ , 5 minutes. 8 times per shift (1990)
United Kingdom	10 min Short term exposure limit (STEL)	2 mg/m ³ (1991)

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 Minty

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pH : 6.0 to 7.5
Solubility in water : Partially Soluble

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

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 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

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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

General information : Professional Cosmetic (US) not sold in the EU.

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

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Additional information : This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant H-statements (number and full-text) : 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 Corr., Cat. 1B: Skin Corrosion, Category 1B
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 H272: May intensify fire; oxidizer.
 H314: Causes severe skin burns and eye damage.
 H315: Causes skin irritation.
 H318: Causes serious eye damage.
 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.