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



Date Issued: 02/16/2018

SDS No: 234-250.01

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

## **Venus White Pro EVA Trays**

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

#### 1.1. Product identifier

Product code : 40005203 (#81232)

Product name : Venus White Pro EVA Trays

**Product description** : Tray Material

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

Relevant identified uses : Professional Dental Tray Material

## 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. This material is

not considered hazardous to health.

Health : Not Classified

#### 2.2. Label elements

This material is not considered hazardous to the health according to Regulation(EC) No 1272/2008[CLP].

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

#### Precautionary statement(s)

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

: P305: IF IN EYES: Response

P351: Rinse cautiously with water for several minutes. P302+P352: IF ON SKIN: Wash with plenty of soap & water. P332+P313: If skin irritation occurs: Get medical advice/attention.

: P210: Keep away from heat, hot surfaces, sparks, open flames and other Storage

ignition sources. No smoking.

Disposal : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-

20/11/2003)

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Dental Use



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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]
Ethylene Vinyl Acetate Copolymer	24937-78-8	NAP	< 100	Not classified

#### **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 : Remove contaminated clothing. Wash with soap and water. Get medical

attention if irritation develops or persists.

Following ingestion : Do not swallow. Material is not likely to cause any problems if swallowed. Seek

medical assistance if you feel unwell.

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 mechanical irritation.

**Skin** : At ambient temperatures this product is not hazardous. If material is heated may

cause thermal burns.

Ingestion : None expected for this product.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 : CO, CO2, Vinyl Acetate, and Acetic Acid

5.3. Advice for firefighters

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Dental Use



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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 : Not Applicable

6.3. Methods and material for containment and cleaning up

Small Spill : Shovel or vacuum spill and place in a container for disposal.Large Spill : Shovel or vacuum spill and place in a container for disposal.

6.4. Reference to other sections

Reference to other sections : NAP

### **SECTION 7: Handling and storage**

#### 7.1. Precautions for safe handling

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 Tray Material

## SECTION 8: Exposure controls / personal protection

#### 8.1. Control parameters

Control parameters : None

8.2. Exposure controls

**Eye/face protection**: Wear safety glasses with side shields (or goggles) and a face shield.

**Skin protection**: Wear suitable protective clothing and gloves.

#### **SECTION 9: Physical and chemical properties**

## 9.1. Information on basic physical and chemical properties

Appearance : Pellets

Odour : Odorless or no characteristic odor

Flash point :  $(500^{\circ}F)$ 

9.2. Other information

**Additional information**: No further relevant information available

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Dental Use



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SDS No: 234-250.01

## **Venus White Pro EVA Trays**

## **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 : Not determined

10.5. Incompatible materials

**Incompatible materials** : Sunlight, heat, sparks

10.6. Hazardous decomposition products

Hazardous decomposition products : Vinyl acetate, acetic acid, CO2, CO

#### **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)

96-hour LC50: Not determined48-hour EC50: Not determined96-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** : No data available.

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Dental Use



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SDS No: 234-250.01

## **Venus White Pro EVA Trays**

## **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 : 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

Prepared by : Anu Kattoju

**General statements** : NAP = Not Applicable **Additional SDS information** : This is the first SDS.

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and

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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.