This SDS packet was issued with item:

074570149

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

074570024 074570255 074570271 074570321

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

074492542 074492591 074492609 074492674 074492682 074570107 074570131 074570156 074570164 074570172 074570313 272438901



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Material Safety Data Sheet acc. to ISO/DIS 11014

Printing date 08/24/2010

Reviewed on 08/23/2010

Tel.: 0800 4372522

1 Identification of substance:

- · Product details:
 - Trade name: Flexitime (base + cat)

Easy Putty, Heavy Tray, Monophase, Correct Flow, Dynamix Putty, Dynamix Heavy Tray, Dynamix Monophase

- · Application of the substance / the preparation Dental impression material
- · Manufacturer/Supplier:

Heraeus Kulzer GmbH Grüner Weg 11, D-63450 Hanau

· Information department:

USA:

Cheryl Zimmerman

Tel. +1 (574) 2996662 / Fax: +1 (574) 2996614 e-mail: cheryl.zimmerman@heraeus.com

· Emergency information:

Call "Poisining Emergency Center Berlin": +49 30 30686 790 (24 hours, support in english and german language)

2 Hazards identification

- · Hazard description: not applicable
- Information pertaining to particular dangers for man and environment not applicable
- · Classification system

The classification was made according to the latest editions of the EU-lists, and expanded upon from company and literature data.

NFPA ratings for USA (scale 0-4)



Health = 0 Fire = 0 Reactivity = 0

· HMIS-Ratings (Scale 0-4)



Health = 0 Fire = 0 Reactivity = 0

3 Composition/Data on components:

- · Chemical characterization
 - · Description:

2-component material comprising base paste and matching catalyst paste for addition curing

- · Dangerous components: Void
- · Additional information For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- · General information No special measures required.
- · After skin contact Generally the product does not irritate the skin.
- · After eye contact Rinse opened eye for several minutes under running water.
- · After swallowing

Rinse out mouth and then drink plenty of water.

(Contd. on page 2)

USA



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Material Safety Data Sheet acc. to ISO/DIS 11014

Printing date 08/24/2010 Reviewed on 08/23/2010

Trade name: Flexitime (base + cat)

Seek immediate medical advice.

(Contd. of page 1)

5 Fire fighting measures

Suitable extinguishing agents

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · Protective equipment: No special measures required.
- · Additional information -

6 Accidental release measures

- · Person-related safety precautions: Not required.
- · Measures for environmental protection: No special measures required.
- · Measures for cleaning/collecting:

Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).

· Additional information:

See Section 13 for disposal information.

See Section 8 for information on personal protection equipment.

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7 Handling and storage

- · Handling
 - · Information for safe handling: No special measures required.
 - Information about protection against explosions and fires: No special measures required.
- Storage
 - · Requirements to be met by storerooms and receptacles: No special requirements.
 - · Information about storage in one common storage facility: Not required.
 - · Further information about storage conditions: None.

8 Exposure controls and personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Components with limit values that require monitoring at the workplace:

1317-65-3 Calciumcarbonat, nat., gem.

PEL () 15*; 5** mg/m³

*Total dust **Respirable fraction
REL () 10*; 5** mg/m³

*Total dust **Respirable fraction
TLV () 10 mg/m³

(e)

- · Additional information: The lists that were valid during the creation were used as basis.
- · Personal protective equipment
 - General protective and hygienic measures

The usual precautionary measures for handling chemicals should be followed.

- · Breathing equipment: Not required.
- Protection of hands: Not required.
 - · Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

(Contd. on page 3)

USA



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Material Safety Data Sheet acc. to ISO/DIS 11014

Printing date 08/24/2010 Reviewed on 08/23/2010

Trade name: Flexitime (base + cat)

(Contd. of page 2)

· Penetration time of glove material

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- · For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable: PVC or PE gloves
- · Eye protection: Not absolutely necessary.
- · Body protection: Light weight protective clothing

9 Physical and chemical properties:

· General Informati

· Form: Pasty

· Color: According to product specification

· Odor: Odorless

Change in condition

Melting point/Melting range: undetermined
 Boiling point/Boiling range: undetermined

· Flash point: Not applicable

· **Auto igniting:** Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

• **Density at 20°C (68°F):** 1.6 g/cm³

· Solubility in / Miscibility with

· Water: Not miscible or difficult to mix

10 Stability and reactivity

- · Dangerous reactions No dangerous reactions known
- · Dangerous products of decomposition: none

11 Toxicological information

- · Acute toxicity:
 - · Primary irritant effect:
 - on the skin: No irritant effect.
 - · on the eye: No irritating effect.
 - · Sensitization: No sensitizing effects known.
- · Additional toxicological information:

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12 Ecological information:

· General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

USA

(Contd. on page 4)



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Material Safety Data Sheet acc. to ISO/DIS 11014

Printing date 08/24/2010 Reviewed on 08/23/2010

Trade name: Flexitime (base + cat)

(Contd. of page 3)

13 Disposal considerations

- · Product:
 - Recommendation

Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.

- · Uncleaned packagings:
 - · Recommendation: Disposal must be made according to official regulations.

14 Transport information

- · DOT regulations:
 - · Hazard class:
- · Land transport ADR/RID (cross-border)
 - · ADR/RID class:
- · Maritime transport IMDG:
 - · IMDG Class:
 - · Marine pollutant: No
- · Air transport ICAO-TI and IATA-DGR:
 - · ICAO/IATA Class: -
- · Transport/Additional information: -

· SARA Section 355 (extremely hazardous substances)	
None of the ingredients is listed.	
SARA Section 313 (specific toxic chemical listings)	
None of the ingredients is listed.	
· Prop 65 - Chemicals known to cause cancer	
None of the ingredients is listed.	
· Cancerogenity categories	
· EPA (Environmental Protection Agency)	
None of the ingredients is listed.	
· IARC (International Agency for Research on Cancer)	
14808-60-7 Quartz (SiO2)	
· NTP (National Toxicology Program)	
14808-60-7 Quartz (SiO2)	
· TLV (Threshold Limit Value established by ACGIH)	
14808-60-7 Quartz (SiO2)	
· NIOSH-Ca (National Institute for Occupational Safety and H	lealth)
14808-60-7 Quartz (SiO2)	
OSHA-Ca (Occupational Safety & Health Administration)	



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Material Safety Data Sheet acc. to ISO/DIS 11014

Printing date 08/24/2010

Reviewed on 08/23/2010

Trade name: Flexitime (base + cat)

(Contd. of page 4)

· Markings according to EU guidelines:
Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (GefStoffV).

The product is not subject to classification according to the calculation methods of the "General Classification Guideline for Preparations of the EU" as issued in the latest valid version.

16 Other information:

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Départment issuing MSDS: Safety department
- · Contact:

Dr. Thiele Tel.: (+49) 6181 35-3012 email: ruediger.thiele@heraeus.com

* Data compared to the previous version altered.

USA

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued: 02/16/2018

SDS No: 224-250.01

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

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.

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%

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.

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%

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.

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%

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

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%

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 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

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%

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

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%

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.