Heraeus Kulzer Mitsui Chemicals Group Page 1/6

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015 Reviewed on 05/12/2015 1 Identification · Product identifier Trade name: Xantasil Dynamix 5:1 (base + cat) · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available. · Application of the substance / the mixture Dental impression material · Details of the supplier of the safety data sheet Manufacturer/Supplier: Heraeus Kulzer GmbH Grüner Weg 11, D-63450 Hanau Tel.: 0800 4372522 · Information department: Marc Henn Tel. +1 (574) 2995444 / Fax: +1 (574) 2912542 e-mail: marc.henn@kulzer-dental.com · Emergency telephone number: Emergency CONTACT (24-Hour-Number) GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500 2 Hazard(s) identification Classification of the substance or mixture The product is not classified according to the Globally Harmonized System (GHS). · Label elements · GHS label elements Void Hazard pictograms Void · Signal word Void Hazard statements Void Classification system · NFPA ratings for USA (scale 0-4) Health = 0Fire = 10 Reactivity = 0· HMIS-Ratings (Scale 0-4) HEALTH 0 Health = 0FIRE 1 Fire = 1REACTIVITY 0 Reactivity = 0Results of PBT and vPvB assessment PBT: Not applicable. · vPvB: Not applicable. 3 Composition/information on ingredients Chemical characterization: Mixtures **Description:** 2-component silicone impression material comprising base paste and matching catalyst paste for

addition curing

· Dangerous components: Void

(Contd. on page 2)

USA

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Xantasil Dynamix 5:1 (base + cat)

(Contd. of page 1)

4 First-aid measures

Description of first aid measures

- General information No special measures required.
- After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact
- Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.
- · After eye contact
- Rinse opened eye for several minutes under running water. Then consult a doctor. After swallowing
- Rinse out mouth and then drink plenty of water.
- Seek immediate medical advice.
- · Most important symptoms and effects, both acute and delayed
- No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Fire-fighting measures

· Extinguishing media

- Suitable extinguishing agents
- CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Use fire fighting measures that suit the environment.
- · Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
 - Protective equipment: No special measures required.
 - · Additional information -

6 Accidental release measures

- · Personal precautions, protective equipment and emergency procedures Not required.
- · Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up:
- Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **Reference to other sections** See Section 7 for information on safe handling
- See Section 8 for information on personal protection equipment.
- See Section 13 for disposal information.

7 Handling and storage

- Precautions for safe handling Please observe the additional instructions in the product's instructions for use. Information about protection against explosions and fires: No special measures required.
- · Conditions for safe storage, including any incompatibilities
 - · 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.

(Contd. on page 3) USA

Heraeus Kulzer Mitsui Chemicals Group Page 3/6

Safety Data Sheet acc. to OSHA HCS

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Reviewed on 05/12/2015

Trade name: Xantasil Dynamix 5:1 (base + cat)

(Contd. of page 2)

• Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

· Control parameters

Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

• Additional information: The lists that were valid during the creation were used as basis.

· Exposure controls

- 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: recommended
 - · 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
 - For the permanent contact gloves made of the following materials are suitable: Nitrile rubber, NBR
 - Eye protection: Protective goggles are recommended.
 - · Body protection: Light weight protective clothing

9 Physical and chemical properties

 Information on basic physical and che General Information 	mical properties	
 Appearance: Form: Color: Odor: 	Pasty Light orange color White Odorless	
· Odour threshold:	Not determined.	
· pH-value:	Not determined.	
Change in condition Melting point/Melting range: Boiling point/Boiling range:	undetermined undetermined	
· Flash point:	> 130 °C (> 266 °F)	
 Flammability (solid, gaseous) 	Not applicable.	
 Ignition temperature: 		
 Decomposition temperature: 	Not determined.	
· Auto igniting:	Product is not selfigniting.	
· Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits: Lower: Upper:	Not determined. Not determined.	
	(Contd. on page 4)	

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Xantasil Dynamix 5:1 (base + cat)

(Contd. of page 3) 0.1 hPa · Vapor pressure at 20 °C (68 °F): · Density at 20 °C (68 °F): 1.35 g/cm3 (11.266 lbs/gal) Relative density Not determined. Not determined. Vapour density · Evaporation rate Not determined. · Solubility in / Miscibility with Not miscible or difficult to mix · Water: · Partition coefficient (n-octanol/water): Not determined. · Viscosity: · dynamic: Not determined. kinematic: Not determined. Other information No further relevant information available.

10 Stability and reactivity

· Possibility of hazardous reactions No dangerous reactions known

- **Conditions to avoid** No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: none
 - · Additional information: -

11 Toxicological information

· Information on toxicological effects

- 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.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

1318-02-1 Zeolith A

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
 - Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.

(Contd. on page 5)

3

Heraeus Kulzer Mitsui Chemicals Group Page 5/6

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Xantasil Dynamix 5:1 (base + cat)

(Contd. of page 4)

· Additional ecological information:

· General notes: Avoid transfer into the environment.

· Results of PBT and vPvB assessment

• PBT: Not applicable.

vPvB: Not applicable.

• Other adverse effects No further relevant information available.

13 Disposal considerations

Waste treatment methods

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.

Uncleaned packagings:

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

14 Transport information		
· UN-Number · DOT, ADR, ADN, IMDG, IATA	Void	
UN proper shipping name DOT, ADR, ADN, IMDG, IATA	Void	
 Transport hazard class(es) 		
· DOT, ADR, ADN, IMDG, IATA · Class	Void	
· Packing group · DOT, ADR, IMDG, IATA	Void	
• Environmental hazards: • Marine pollutant:	No	
 Special precautions for user 	Not applicable.	
 Transport in bulk according to Annex MARPOL73/78 and the IBC Code 	ll of Not applicable.	
· Transport/Additional information:	-	
UN "Model Regulation":	-	

15 Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture
 SARA Section 355 (extremely hazardous substances)

None of the ingredients is listed.

• **TSCA (Toxic Substances Control Act)** None of the ingredients is listed. Medical devices are exempted from TSCA.

· Cancerogenity categories

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· GHS label elements Void

(Contd. on page 6)

USA -

Heraeus Kulzer Mitsui Chemicals Group Page 6/6

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Xantasil Dynamix 5:1 (base + cat)

(Contd. of page 5)

USA

- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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. • Date of preparation / last revision 05/12/2015 / -

 Abbreviations and acronyms: ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) * Data compared to the previous version altered.