

Page 1/6

Safety Data Sheet acc. to OSHA HCS

Printing date 05/12/2015

Reviewed on 05/12/2015

Tel.: 0800 4372522

1 Identification

- · Product identifier
 - Trade name: Flexitime Dynamix Monophase Pro Scan (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

· 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

Carc. 2 H351 Suspected of causing cancer.

H227 Combustible liquid.

- · Label elements
 - · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labeling:

Titanium dioxide

· Hazard statements

Combustible liquid.

Suspected of causing cancer.

Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Wear protective gloves/protective clothing/eye protection/face protection.

Use personal protective equipment as required.

Store locked up.

Store in a well-ventilated place. Keep cool.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· Classification system

· NFPA ratings for USA (scale 0-4)



Health = 0 Fire = 2 Reactivity = 0

(Contd. on page 2)



Page 2/6

(Contd. of page 1)

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· HMIS-Ratings (Scale 0-4)

HEALTH 0
FIRE 2 Health = 0
Fire = 2
REACTIVITY 0 Reactivity = 0

- · Results 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:

27306-78-1 modified heptamethyltrisiloxane with polyalkylene oxide

0-5%

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. If symptoms persist, 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.

- · 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).

(Contd. on page 3)



Page 3/6

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(Contd. of page 2)

· Reference to other sections

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.
- · 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: Not absolutely necessary.
 - · 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: Natural rubber, NR
- · Eye protection: Not absolutely necessary.
- · Body protection: Light weight protective clothing

9 Physical and chemical properties

- · Information on basic physical and chemical properties
 - · General Information
 - · Appearance:

· Form: Pasty
· Color: Pink
· Odor: Odorless

· pH-value: Not determined.

· Change in condition

· Melting point/Melting range: undetermined

(Contd. on page 4)



Page 4/6

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(Contd. of page 3) · Boiling point/Boiling range: undetermined · Flash point: 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: Not determined. Not determined. · Upper: · Vapor pressure: Not determined. · Density at 20 °C (68 °F): 1.2-1.6 g/cm3 (10.014-13.35 lbs/gal) · Solubility in / Miscibility with Water: Insoluble 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

	RC (International Agency for Research on Cancer)	
13463-67-7	Titanium dioxide	2B
1318-02-1	Zeolith A	3
· N7	P (National Toxicology Program)	
None of the	ingredients is listed.	
· OS	SHA-Ca (Occupational Safety & Health Administration)	
None of the	ingredients is listed.	
		0

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(Contd. on page 5)



Page 5/6

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(Contd. of page 4)

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.
 - · 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.

4 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 II MARPOL73/78 and the IBC Code	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.

(Contd. on page 6)



Page 6/6

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(Contd. of page 5)

· 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)

13463-67-7 Titanium dioxide

Α4

GHS label elements

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· Hazard pictograms



- · Signal word Warning
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Combustible liquid.

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Precautionary statements

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Store in a well-ventilated place. Keep cool.

Dispose of contents/container in accordance with local/regional/national/international

· 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 ADR: Accord europeen sur le transport des marchandises dangereuses par 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

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
: Flammable liquids, Hazard Category 4
Carc. 2: Carcinogenicity, Hazard Category 2

* Data compared to the previous version altered.