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

VA-Nr

1.1. Product identifier

Trade name Lucitone HIPA powder

REACH Registration No.: if available listed in Chapter. 3

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

Relevant applications identified For dental use only.

1.3. Details of the supplier of the safety data sheet

Company DeguDent GmbH

Postfach 1364 D-63403 Hanau

Telephone +49 (0)6181/59-5576 Telefax +49 (0)6181/59-5879

Email address SDB.Degudent-DE@dentsplysirona.com

1.4. Emergency telephone number

Emergency information +49 (0)6181/59-50 (This telephone number is available during office

hours only.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not a hazardous mixture according to Regulation (EC) No 1272/2008.

2.2. Label elements

Labelling as per (EU) 1272/2008

Statutory basis Labelling not required according to EU-CLP Ordinance (1272/2008).

2.3. Other hazards

Mechanical irritation of skin and mucous linings of eyes and respiratory tract may occur., Danger of dust explosion.

A PBT/vPvB evaluation is not available, since a chemical safety evaluation is not required / has not been carried out.

SECTION 3: Composition/information on ingredients

Chemical nature

The mixture contains:, Traces of:, Dibenzoylperoxide

3.1. Substances

-

3.2. Mixtures

Information on ingredients / Hazardous components as per EU-CLP Regulation (EC) No. 1272/2008

• Poly(methyl methacrylate) >= 95% - <= 100%

CAS-No. 9011-14-7

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• Titanium dioxide >= 0.05% - <= 0.5%

CAS-No. 13463-67-7 EC-No. 236-675-5

Carcinogenicity Category 2 H351

Texts of H phrases, see in Chapter 16

SECTION 4: First aid measures

4.1. Description of first aid measures

Remove contaminated or saturated clothing.

Inhalation

In case product dust is released:

Move victims into fresh air.

In case of persistent discomfort

Obtain medical attention.

Skin contact

Wash off with soap and plenty of water.

Eve contact

Possible discomfort is due to foreign substance effect.

Rinse thoroughly with plenty of water keeping eyelid open.

In case of persistent discomfort

Consult an ophthalmologist.

Ingestion

Rinse mouth.

After absorbing large amounts of substance:

Consult a physician.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

After absorbing large amounts of substance:

Acceleration of gastrointestinal passage

If skin sensitisation has developed and a causal relationship has been confirmed, further exposure should not beallowed

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: mist

Foam

quenching powder Carbon dioxide (CO2)

Unsuitable extinguishing media: High volume water jet

5.2. Special hazards arising from the substance or mixture

May be released in case of fire: carbon monoxide, carbon dioxide, organic products of decomposition.

5.3. Advice for firefighters

In the event of fire, wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No particular measures required.

6.2. Environmental precautions

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Do not allow entrance in sewage water, soil stretches of water, groundwater, drainage systems.

6.3. Methods and material for containment and cleaning up

Pick up mechanically and collect in a suitable container. Avoid formation of dust.

Sweep up to prevent slipping hazard.

Clean up promptly by scoop or vacuum.

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Additional advice

Danger of slipping due to leaking or spilt product.

Ensure explosion proofness. Dispose of contaminated material as a waste in a correct manner.

6.4. Reference to other sections

Disposal considerations: see section 13.

Wear personal protective equipment; see section 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid dust formation.

7.2. Conditions for safe storage, including any incompatibilities

Advice on protection against fire and explosion

Danger of dust explosion.

Caution - electrostatic charge may occur.

Take precautionary measures against static discharges.

Keep away from sources of ignition - No smoking.

Storage

Keep in a dry place.

German storage class

13 - Non Combustible Solids

7.3. Specific end use(s)

We are unaware of any specific end uses which go beyond the data reported in Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

exposure limit for dust			
CAS-No. Control parameters type of exposure	10 mg/m3 Inhalable fraction.		(EH40 WEL)
Control parameters type of exposure	4 mg/m3 Respirable fraction.		(EH40 WEL)
Titanium dioxide			
CAS-No. Control parameters type of exposure	13463-67-7 4 mg/m3 Respirable.	EC-No.	236-675-5 Time Weighted Average (TWA):(EH40 WEL)
Control parameters type of exposure	10 mg/m3 Inhalable		Time Weighted Average (TWA):(EH40 WEL)

8.2. Exposure controls

Engineering measures

In case product dust is released:, Local ventilation.

Personal protective equipment

Respiratory protection

If workplace exposure limit is exceeded apply Dust mask with P2 particle filter.

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Hand protection

Wear protective gloves made of the following materials:.

Glove material butyl-rubber
Material thickness 0.5 mm
Break through time 60 min

The suitability for a specific workplace should be discussed with the producers of the protective gloves., The exact break through time can be obtained from the protective glove producer and this has to be observed.

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Preventive skin protection, Use barrier cream regularly.

Eye/face protection

Safety glasses with side-shields, If dust occurs: basket-shaped glasses

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice., Do not eat, drink, smoke, or sniff while at work. Wash your hands and/or face before breaks and before termination of work., If workplace exposure limits are exceeded and/or larger amounts are released (leakage, spilling, dust) the indicated respiratory protection should be used.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Form powder

Colour depending on staining result

Odour characteristic

Odour threshold: no data available

pH not applicable

(solid)

Melting point/range > 210 °C

Boiling point/range no data available

Flash point not applicable

(solid)

Evaporation rate not applicable, (solid)

Flammability (solid, gas) no data available

Lower explosion limit no data available

Upper explosion limit no data available

Vapour pressure not applicable

(solid)

Density no data available

Water solubility insoluble

Partition coefficient: n-

octanol/water

not applicable

Autoinflammability Not capable of spontaneous combustion or heating.

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Thermal decomposition 250 °C

Viscosity, dynamic not applicable

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(solid)

Explosiveness Dusts might form explosive mixtures with air.

Oxidizing properties no data available

9.2. Other information

Bulk density no data available

Other information No further physicochemical data were determined.

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reaction known under conditions of normal use.

10.2. Chemical stability

Stable under recommended storage conditions.

0.3. Possibility of hazardous reactions

Possibility of hazardous

No hazardous reactions are known if properly handled and stored.

reactions

10.4. Conditions to avoid

None known

10.5. Incompatible materials

None known

10.6. Hazardous decomposition products

decomposition products if heated above 250°C

irritative gases/vapours, Carbon monoxide, Carbon dioxide (CO2), organic products of decomposition

SECTION 11: Toxicological information

11.1. Information on toxicological effects

No results of animal experiments with the product available.

Acute oral toxicity no data available

Acute inhalation toxicity no data available

Acute dermal toxicity no data available

Skin irritation no data available

Eye irritation no data available

Sensitization no data available

Assessment of STOT single

exposure

e no data available

Assessment of STOT repeat

exposure

no data available

Risk of aspiration toxicity not applicable

Mutagenicity assessment no data available

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Dentsply

Carcinogenicity No data available

Toxicity to reproduction No data available

Human experience Mechanical irritation of skin and mucous linings of eyes and respiratory

tract may occur.

Toxicology Assessment

Acute effects An Expert Judgment stated that no classification is necessary based on

present knowledge.

SECTION 12: Ecological information

12.1. Toxicity

Page:

Ecotoxicological tests with this preparation are not available.

12.2. Persistence and degradability

Biodegradability No data available

12.3. Bioaccumulative potential

Bioaccumulation No data available

12.4. Mobility in soil

Mobility Is absorbed by the soil and is not mobile.

The product is a high-molecular-weight, water insoluble, solid polymer.

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12.5. Results of PBT and vPvB assessment

A PBT/vPvB evaluation is not available, since a chemical safety evaluation is not required / has not been carried out.

12.6. Other adverse effects

Further Information The product is a solid, insoluble in water, chemically inert and virtually not

> biologically degradable. No negative effects known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product

Disposal according to local authority regulations.

Uncleaned packaging

Disposal according to local authority regulations.

SECTION 14: Transport information

Not dangerous according to transport regulations.

14.1. UN number:

14.2. UN proper shipping name:

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14.3. Transport hazard class(es): -14.4. Packing group: -14.5. Environmental hazards: -14.6 Special precautions for user: No

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture National legislation

15.2. Chemical safety assessment

Chemical safety assessment No Chemical Safety Report as per Articles 2(8), 2(9) or 14 of the REACH

Regulatione is required for this product.

SECTION 16: Other information

Classification and applied procedure to derive the classification of mixtures according to EU Regulation (EC) No. 1272/2008 (CLP)

Relevant H phrases from chapter 3

H351 : Suspected of causing cancer.

Further information

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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Legend

ADR European Agreement concerning the International Carriage of Dangerous Goods by

Road

ADN European Agreement concerning the International Carriage of Dangerous Goods by

Inland Waterways

ASTM American Society for Testing and Materials

ATP Adaptation to Technical Progress

BCF Bioconcentration factor

BetrSichV German Ordinance on Industrial Safety and Health

c.c. closed cup

CAS Chemical Abstract Services

CESIO European Committee of Organic Surfactants and their Intermediates

ChemG German Chemicals Act

CMR carcinogenic-mutagenic-toxic for reproduction

DIN German Institute for Standardization

DMEL Derived minimum effect level

DNEL Derived no effect level

EINECS European Inventory of Existing Commercial Chemical Substances

EC50 half maximal effective concentration

GefStoffV German Ordinance on Hazardous Substances

GGVSEB German ordinance for road, rail and inland waterway transportation of dangerous

goods

GGVSee German ordinance for sea transportation of dangerous goods

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GLP Good Laboratory Practice
GMO Genetic Modified Organism

IATA International Air Transport Association
 ICAO International Civil Aviation Organization
 IMDG International Maritime Dangerous Goods
 ISO International Organization For Standardization

LOAEL Lowest observed adverse effect level

LOELLowest observed effect levelNOAELNo observed adverse effect levelNOECno observed effect concentration

NOEL no observed effect level

o. c. open cup

OECD Organisation for Economic Cooperation and Development

OEL Occupational Exposure Limit
PBT Persistent, bioaccumulative, toxic
PEC Predicted effect concentration
PNEC Predicted no effect concentration

REACH REACH registration

RID Convention concerning International Carriage by Rail

STOT Specific Target Organ Toxicity
SVHC Substances of Very High Concern

TA Technical Instructions

TPR Third Party Representative (Art. 4)

TRGS Technical Rules for Hazardous Substances
VCI German chemical industry association
vPvB very persistent, very bioaccumulative

VOC volatile organic compounds

VwVwS German Administrative Regulation on the Classification of Substances Hazardous to

Waters into Water Hazard Classes

WGK Water Hazard Class
WHO World Health Organization