Revision date: 15/12/2022 Revision: 4

SAFETY DATA SHEET TOKUYAMA REBASE II Powder

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

1.1. Product identifier

Product name TOKUYAMA REBASE II Powder

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

Identified uses [Medical device] Denture Liner, a component of kit. For dental professionals only.

Uses Not Recommended Use only for intended applications.

1.3. Details of the supplier of the safety data sheet

Supplier

Tokuyama Dental Italy S.r.l.

Via Chizzalunga, 1,

36066 Sandrigo, Vicenza, Italy

TEL: +39-0444-659650 FAX: +39-0444-750345

Contact person http://www.tokuyama-dental.com/tdc/contact.html

Manufacturer

Tokuyama Dental Corporation

38-9, Taitou 1-chome, Taitou-ku, Tokyo

110-0016, Japan TEL: +81-3-3835-2261 FAX: +81-3-3835-2265

1.4. Emergency telephone number

Emergency telephone Regional Medicines and Poisons Information Centre NI,

Pharmacy Department

Royal Hospital Suite, Grosvenor Road, Belfast

Emergency telephone: 844 892 0111 Telephone: +44 28 90 63 2032 Fax: +44 28 90 24 8030

E-mail address: nirdic.nirdic@belfasttrust.hscni.net

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Skin Sens. 1 - H317

Environmental hazards Not Classified

2.2. Label elements

Pictogram



Signal word Warning

Hazard statements H317 May cause an allergic skin reaction.

Precautionary statements P261 Avoid breathing dust.

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

P302+P352 IF ON SKIN: Wash with plenty of water.

P501 Dispose of contents/ container in accordance with local regulations.

Contains BENZOYL PEROXIDE

Supplementary precautionary

P272 Contaminated work clothing should not be allowed out of the workplace.

statements P321 Specific treatment (see medical advice on this label).

P333+P313 If skin irritation or rash occurs: Get medical advice/ attention. P362+P364 Take off contaminated clothing and wash it before reuse.

2.3. Other hazards This product does not contain any substances classified as PBT or vPvB.

Endocrine disrupting properties: Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

BENZOYL PEROXIDE 1-5%

CAS number: 94-36-0 EC number: 202-327-6

Classification

Org. Perox. B - H241 Eye Irrit. 2 - H319 Skin Sens. 1 - H317

The full text for all hazard statements is displayed in Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information Move affected person to fresh air at once. Get medical attention if any discomfort continues.

Inhalation Move affected person to fresh air at once.

Ingestion Try to induce vomiting. Get medical attention if any discomfort continues.

Skin contact Wash skin thoroughly with soap and water. Get medical attention if any discomfort continues.

Eye contact Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes

with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Get

medical attention if irritation persists after washing.

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

Skin contact Allergic rash.

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

Notes for the doctor No specific recommendations.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with the following media: Foam. Carbon dioxide or dry powder.

5.2. Special hazards arising from the substance or mixture

Specific hazards When heated and in case of fire, irritating vapours/gases may be formed.

Hazardous combustion

products

No known hazardous decomposition products.

5.3. Advice for firefighters

Protective actions during

firefighting

Avoid breathing fire gases or vapours.

Special protective equipment Wear chemical protective suit.

for firefighters

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet.

6.2. Environmental precautions

Environmental precautions No specific recommendations.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up No smoking, sparks, flames or other sources of ignition near spillage. Provide adequate

ventilation. Collect and place in suitable waste disposal containers and seal securely. Avoid

generation and spreading of dust.

6.4. Reference to other sections

Reference to other sections For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

All handling should only take place in well-ventilated areas. Avoid inhalation of dust and Usage precautions

contact with skin and eyes.

Advice on general occupational hygiene Do not eat, drink or smoke when using this product. Wash promptly with soap and water if skin becomes contaminated. Wash at the end of each work shift and before eating, smoking and using the toilet. Take off contaminated clothing and wash it before reuse. Wash at the end

of each work shift and before eating, smoking and using the toilet.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No

smoking. Protect from sunlight. Store in tightly-closed, original container in a dry, cool and

well-ventilated place. Store at temperatures between 0°C/32°F and 25°C/77°F.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

BENZOYL PEROXIDE

Long-term exposure limit (8-hour TWA): WEL 5 mg/m³

WEL = Workplace Exposure Limit

8.2. Exposure controls

Appropriate engineering

controls

Provide adequate ventilation. Observe any occupational exposure limits for the product or ingredients.

Eye/face protection The following protection should be worn: Dust-resistant, chemical splash goggles.

Hand protection Wear protective gloves.

Other skin and body

protection

Wear appropriate clothing to prevent any possibility of skin contact.

Hygiene measures Do not eat, drink or smoke when using this product. Wash at the end of each work shift and

before eating, smoking and using the toilet. Wash promptly with soap and water if skin becomes contaminated. Take off contaminated clothing and wash it before reuse.

Respiratory protection Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked.

Check that the respirator fits tightly and the filter is changed regularly. Gas and combination filter cartridges should comply with European Standard EN14387. Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136. Half mask and quarter mask respirators with replaceable filter cartridges should comply with European

Standard EN140.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance Powder

Colour Pink

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point Not available.

Initial boiling point and range Not available.

Flash point Not available.

Evaporation rate Not available.

Evaporation factor Not available.

Upper/lower flammability or

explosive limits

Not applicable.

Other flammability Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies) Not available.

Partition coefficient Not available.

Auto-ignition temperature Not available.

Decomposition Temperature Not available.

Viscosity Not available.

Explosive properties St2, strong

Oxidising properties The product contains a substance classified as oxidising. Organic peroxides/hydroperoxides.

9.2. Other information

Other information Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity Dust may form explosive mixture with air. See the other subsections of this section for further

details.

10.2. Chemical stability

Stability Dust may form explosive mixture with air.

10.3. Possibility of hazardous reactions

Possibility of hazardous

reactions

Dust may form explosive mixture with air.

10.4. Conditions to avoid

Conditions to avoid Keep away from heat, sparks and open flame. Avoid exposure to high temperatures or direct

sunlight. Avoid generation and spreading of dust.

10.5. Incompatible materials

Materials to avoid Strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition

products

Heating may generate the following products: Toxic gases or vapours.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity - Ingestion

Calculation method: Not classified.

Acute toxicity - Skin Contact

Calculation method: Not classified. No data.

Acute toxicity - Inhalation

Calculation method: Not classified. No data.

Skin corrosion/irritation

Calculation method: Not classified.

Serious eye damage/irritation

Calculation method: Not classified. Based on available data, the classification criteria are not met.

Skin sensitization

Calculation method: May cause an allergic skin reaction.

Respiratory sensitization

Calculation method: Not classified.

Germ cell mutagenicity

Calculation method: Not classified.

Carcinogenicity

Calculation method: Not classified.

Reproductive toxicity

Calculation method: Not classified.

Lactation

Calculation method: Not classified.

STOT - single exposure

Calculation method: Not classified.

STOT - repeated exposure

Calculation method: Not classified.

Aspiration hazard

Calculation method: Not classified. Not applicable.

11.2 Other information

Route(s) of entry Skin, Eyes, Ingestion, Inhalation, Health effects: See section 4.2.

Endocrine disrupting properties: Not known.

SECTION 12: Ecological Information

12.1 Toxicity

Toxicity - Aquatic invertebrates Not classified.

Toxicity - Fish Not classified.

Toxicity - Algae Not classified.

Toxicity - Sediment Compartment Not classified.

Toxicity - Terrestrial Compartment Not classified.

12.2 Persistence and degradability

Not known.

12.3 Bioaccumulative potential

Not known.

12.4 Mobility in soil

Not known.

12.5 Results of PBT and vPvB assessment

This product does not contain any substances classified as PBT or vPvB.

12.6 Endocrine disrupting properties

Not known.

12.7 Other adverse effects

Not known.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

Must not be disposed of together with household garbage. Dispose at suitable refuse site. Do not allow to enter drains, sewers or watercourses. Empty containers may retain some product residues and hence be potentially hazardous.

13.2 Additional Information

Disposal should be in accordance with local, state or national legislation.

SECTION 14: Transport information

General

The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78

and the IBC Code

SECTION 15: Regulatory information

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

EU legislation (EC) No 1907/2006 (REACH).

(EC) No 1272/2008 (CLP).

(EU) No 2015/830.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Classification procedures according to Regulation (EC)

Skin Sens. 1 - H317: Calculation method.

1272/2008

Training advice Ensure operatives are trained to minimise exposure. Only trained personnel should use this

material.

Revision comments

Revision date 15/12/2022

Revision 4

Hazard statements in full H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

The information which is contained in this document is based on available data. However, as such has been obtained from various sources, including independent laboratories, it is given without warranty or representation that is complete, accurate and can be replied upon. Tokuyama Dental Corp. has not attempted to conceal in any way the deleterious aspects of the product listed herein, but makes no warranty as to such information.