Revision date: 15/09/2018 Revision: 3

SAFETY DATA SHEET ESTELITE Σ QUICK

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

1.1. Product identifier

Product name ESTELITE Σ QUICK

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

Identified uses Resin-based Dental Restorative Material. For dental professionals only.

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 vapours.

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 (1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)]

BISMETHACRYLATE, 2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE, MEQUINOL

Supplementary precautionary

statements

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

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.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

(1-METHYLETHYLIDENE)BIS[4,1-PHENYLENEOXY(2-HYDROXY-3,1-PROPANEDIYL)] BISMETHACRYLATE

10-30%

Classification

Skin Sens. 1 - H317 Aquatic Chronic 3 - H412

2,2'-ETHYLENEDIOXYDIETHYL DIMETHACRYLATE

5-10%

CAS number: 109-16-0 EC number: 203-652-6

Classification

Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Skin Sens. 1 - H317

TITANIUM DIOXIDE

<1%

Classification

Acute Tox. 4 - H332 Carc. 2 - H351

MEQUINOL

<1%

CAS number: 150-76-5 EC number: 205-769-8

Classification

Acute Tox. 4 - H302 Eye Irrit. 2 - H319 Skin Sens. 1 - H317

<1% 2,6-DI-tert-BUTYL-p-CRESOL

CAS number: 128-37-0 EC number: 204-881-4

M factor (Chronic) = 1

Classification

Aquatic Chronic 1 - H410

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.

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

firefighting

No known hazardous decomposition products.

5.3. Advice for firefighters

Protective actions during

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 Eliminate all sources of ignition. No smoking, sparks, flames or other sources of ignition near

spillage. Provide adequate ventilation. Absorb in vermiculite, dry sand or earth and place into

containers.

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

Usage precautions All handling should only take place in well-ventilated areas.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in a cool and well-ventilated place. Store at temperatures between 0°C/25°F and

32°C/77°F. Keep away from heat, hot surfaces, sparks, open flames and other ignition

sources. No smoking. Avoid exposure to high temperatures or direct sunlight.

Storage class Chemical storage.

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

TITANIUM DIOXIDE

Long-term exposure limit (8-hour TWA): WEL 4 mg/m³ respirable dust Long-term exposure limit (8-hour TWA): WEL 10 mg/m³ inhalable dust

2,6-DI-tert-BUTYL-p-CRESOL

Long-term exposure limit (8-hour TWA): WEL 10 mg/m³

WEL = Workplace Exposure Limit

8.2. Exposure controls

Appropriate engineering

controls

Provide adequate general and local exhaust ventilation.

Eye/face protection The following protection should be worn: 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 smoke in work area. 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. Promptly remove any clothing that becomes contaminated. Use appropriate skin cream to

prevent drying of skin. When using do not eat, drink or smoke.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance Paste

Colour Yellow-white

Odour Not available.

Odour threshold Not available.

pH (concentrated solution): 7

Melting point Not available.

Initial boiling point and range Not available.

Flash point Not available.

Evaporation rate Not available.

Evaporation factor Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or

explosive limits

Not applicable.

Other flammability Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density 1.9

Solubility(ies) Not available.

Partition coefficient Not available.

Auto-ignition temperature Not available.

Decomposition Temperature Not available.

Viscosity Not available.

Explosive properties Not explosive.

Oxidising properties Not available.

9.2. Other information

Other information Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity May polymerise. See the other subsections of this section for further details.

10.2. Chemical stability

Stability Stable at normal ambient temperatures and when used as recommended.

10.3. Possibility of hazardous reactions

Possibility of hazardous

reactions

Not known.

10.4. Conditions to avoid

Conditions to avoid Keep away from heat, sparks and open flame. Protect against direct sunlight.

10.5. Incompatible materials

Materials to avoid Strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition

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

products

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Routes of exposure See section 4.2. Skin, Eyes, Ingestion, Inhalation

Acute toxicity - oral

Notes (oral LD50) Not available.

Acute toxicity - dermal

Notes (dermal LD50) Not available.

Acute toxicity - inhalation

Notes (inhalation LC₅₀) Not available.

Skin corrosion/irritation

Skin corrosion/irritation Not available. Animal data Not available.

Serious eye damage/irritation

Serious eye damage/irritation Not available.

Respiratory sensitisation

Respiratory sensitisation Not available.

Skin sensitisation

Skin sensitisation Sensitising.

Germ cell mutagenicity

Genotoxicity - in vitro Not available.

Genotoxicity - in vivo Not available.

Carcinogenicity

Carcinogenicity Not available.

IARC carcinogenicity Some of the ingredients are listed or exempt.

NTP carcinogenicity Some of the ingredients are listed or exempt.

Reproductive toxicity

Reproductive toxicity - fertility Not available.

Reproductive toxicity -Not available.

development

Specific target organ toxicity - single exposure STOT - single exposure Not available.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure Not available.

Aspiration hazard

Aspiration hazard Not available.

TITANIUM DIOXIDE

Acute toxicity - inhalation

ATE inhalation 1.5

(dusts/mists mg/l)

Carcinogenicity

IARC carcinogenicity IARC Group 2B Possibly carcinogenic to humans.

NTP carcinogenicity Reasonably anticipated to be a human carcinogen.

OSHA Carcinogenicity Not listed.

2,6-DI-tert-BUTYL-p-CRESOL

Carcinogenicity

IARC carcinogenicity IARC Group 3 Not classifiable as to its carcinogenicity to humans.

NTP carcinogenicity Reasonably anticipated to be a human carcinogen.

OSHA Carcinogenicity Not listed.

SECTION 12: Ecological Information

12.1. Toxicity

Acute toxicity - fish Not available.

Acute toxicity - aquatic

invertebrates

Not available.

Acute toxicity - aquatic plants Not available.

Chronic toxicity - fish early life Not available.

stage

Short term toxicity - embryo

and sac fry stages

Not available.

Chronic toxicity - aquatic

invertebrates

Not available.

12.2. Persistence and degradability

Persistence and degradability No data available.

12.3. Bioaccumulative potential

Bioaccumulative potential No data available on bioaccumulation.

Partition coefficient Not available.

12.4. Mobility in soil

Mobility No information available.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB

assessment

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

12.6. Other adverse effects

Other adverse effects Not known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal methods

Dispose of waste to licensed waste disposal site in accordance with the requirements of the

local Waste Disposal Authority.

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 15/09/2018

Revision 3

Hazard statements in full H302 Harmful if swallowed.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H351 Suspected of causing cancer.

H410 Very toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.

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.