

Printing date 05/19/2015 Version number 4 Reviewed on 04/11/2015

### 1 Identification

- · Product identifier
- · Trade name: Telio Lab Opaquer Powder
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the mixture Auxiliary for manufacture of dental prothesis
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

175 Pineview Drive, Amherst, N.Y. 14228

USA

Tel. +1 800 533 6825

Fax +1 716 691 2285

Ivoclar Vivadent Inc.

1-6600 Dixie Road

Mississauga, Ontario

L5T 2Y2

Canada

Phone: +1 905 670 8499 Fax: +1 905 670 3102

- · Information department: Quality Assurance / Regulatory Affairs
- · Emergency telephone number:

24 Hour Emergency Assistance:

Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

### 2 Hazard(s) identification

· Classification of the substance or mixture

Skin Sens. 1 H317 May cause an allergic skin reaction.

Carc. 2 H351 Suspected of causing cancer.

- · Label elements
- · GHS label elements

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

· Hazard pictograms





GHS07

GHS08

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

dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

Suspected of causing cancer.

(Contd. on page 2)

Printing date 05/19/2015 Version number 4 Reviewed on 04/11/2015

## Trade name: Telio Lab Opaquer Powder

(Contd. of page 1)

#### · Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation or rash occurs: Get medical advice/attention.

- · Hazard description:
- · WHMIS-symbols:

D2B - Toxic material causing other toxic effects



- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0 Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



· Other hazards

Dust generation

Particular danger of slipping on leaked/spilled product.

- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

## 3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- Description: Mixture of the substances listed below with nonhazardous additions.

| · Dangerous o | components:              |           |
|---------------|--------------------------|-----------|
| 7727-43-7     | barium sulphate, natural | 25-40%    |
| 1344-28-1     | aluminium oxide          | 25-30%    |
| 94-36-0       | dibenzoyl peroxide       | ≤1%       |
| 13463-67-7    | titanium dioxide         | 0.1-<0.3% |

### 4 First-aid measures

- · Description of first aid measures
- · After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact:

Rinse with water.

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.

(Contd. on page 3)

Printing date 05/19/2015 Version number 4 Reviewed on 04/11/2015

## Trade name: Telio Lab Opaquer Powder

(Contd. of page 2)

If symptoms persist consult doctor.

- · Information for doctor:
- · 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.

#### 6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Particular danger of slipping on leaked/spilled product.

- · Environmental precautions: No special measures required.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · 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

- · Handling:
- · Precautions for safe handling

Only adequately trained personnel should handle this product.

For use in dentistry only.

- · 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: Store only in the original receptacle.
- · 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

- · Additional information about design of technical systems: No further data; see item 7.
- · Control parameters
- · Components with limit values that require monitoring at the workplace:

#### 7727-43-7 barium sulphate, natural

EL Long-term value: 10\* 3\*\* mg/m³ \*total dust, \*\*respirable fraction

(Contd. on page 4)

Printing date 05/19/2015 Version number 4 Reviewed on 04/11/2015

# Trade name: Telio Lab Opaquer Powder

(Contd. of page 3)

EV Long-term value: 10 mg/m<sup>3</sup> total dust

#### 1344-28-1 aluminium oxide

EL Long-term value: 1.0 mg/m³

respirable, as Al

EV Long-term value: 10 mg/m³

total dust

#### 94-36-0 dibenzoyl peroxide

EL Long-term value: 5 mg/m<sup>3</sup> EV Long-term value: 5 mg/m<sup>3</sup>

- · Additional information: The lists that were valid during the creation were used as basis.
- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Usual hygienic measures for dental practice.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Avoid contact with the skin.

- · Breathing equipment: Use respiratory protective device against the effects of dust.
- · Protection of hands:



Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

### 9 Physical and chemical properties

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

Form: Powder

Color: According to product specification

Odor: Characteristic
 Odour threshold: Not determined.

· pH-value: Not applicable.

· Change in condition

Melting point/Melting range:Undetermined.Boiling point/Boiling range:Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gaseous): Not determined.

(Contd. on page 5)

Printing date 05/19/2015 Version number 4 Reviewed on 04/11/2015

Trade name: Telio Lab Opaquer Powder

|                                       |   | (Contd. of page |
|---------------------------------------|---|-----------------|
| · Auto igniting:                      | Product is not selfigniting.                  |                 |
| · Danger of explosion:                | Product does not present an explosion hazard. |                 |
| · Explosion limits:                   |   |                 |
| Lower:                                | Not determined.                               |                 |
| Upper:                                | Not determined.                               |                 |
| · Vapor pressure:                     | Not applicable.                               |                 |
| · Density:                            | Not determined.                               |                 |
| Relative density                      | Not determined.                               |                 |
| · Vapour density                      | Not applicable.                               |                 |
| Evaporation rate                      | Not applicable.                               |                 |
| · Solubility in / Miscibility with    |   |                 |
| Water:                                | Nearly insoluble.                             |                 |
| · Partition coefficient (n-octanol/wa | tter): Not determined.                        |                 |
| · Viscosity:                          |   |                 |
| Dynamic:                              | Not applicable.                               |                 |
| Kinematic:                            | Not applicable.                               |                 |
| · Other information                   | No further relevant information available.    |                 |

## 10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable under normal handling and storage conditions.
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 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 under normal conditions of storage and use.

## 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: Sensitization possible through skin contact.
- · Additional toxicological information: No further relevant information available.
- · Carcinogenic categories

| IARC (International Agency for Research on Cancer) |   |
|--|---|
| 9011-14-7 polymethylmethacrylate                   | 3 |
| 94-36-0 dibenzoyl peroxide                         | 3 |
| NTP (National Toxicology Program)                  |   |

None of the ingredients is listed.

(Contd. on page 6)

Printing date 05/19/2015 Version number 4 Reviewed on 04/11/2015

## Trade name: Telio Lab Opaquer Powder

(Contd. of page 5)

· 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.
- · Behavior in environmental systems:
- $\cdot \textbf{\it Bioaccumulative potential} \ No \ further \ relevant \ information \ available.$
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes: Generally not hazardous for water
- · 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:

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

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

| T131 31 1   |  |
|---|--|
| · UN-Number<br>· DOT, TDG, ADN, IMDG, IATA        | Void   |
|   | . 0100   |
| UN proper shipping name DOT, TDG, ADN, IMDG, IATA | Void   |
| Transport hazard class(es)                        |  |
| DOT, TDG, ADN, IMDG, IATA                         |  |
| • Class   | Void   |
| Packing group                                     |  |
| DOT, TDG, IMDG, IATA                              | Void   |
| Environmental hazards:                            |  |
| Marine pollutant:                                 | No   |
| Special precautions for user                      | Not applicable.  |
| Transport in bulk according to Annex              | II of  |
| MARPOL73/78 and the IBC Code                      | Not applicable.  |
| Transport/Additional information:                 | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |

n page 7)

Printing date 05/19/2015 Version number 4 Reviewed on 04/11/2015

Trade name: Telio Lab Opaquer Powder

(Contd. of page 6)

· 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.

· Section 313 (Specific toxic chemical listings):

94-36-0 dibenzoyl peroxide

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

- · Proposition 65
- · Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

94-36-0 dibenzoyl peroxide

A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements

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

· Hazard pictograms





GHS07 G

GHS08

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

dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

Suspected of causing cancer.

· Precautionary statements

 $We ar \ protective \ gloves/protective \ clothing/eye \ protection/face \ protection.$ 

(Contd. on page 8)

Printing date 05/19/2015 Version number 4 Reviewed on 04/11/2015

## Trade name: Telio Lab Opaquer Powder

(Contd. of page 7)

If skin irritation or rash occurs: Get medical advice/attention.

- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

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

## 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- · Date of preparation / last revision 05/19/2015 / 3
- · Abbreviations and acronyms:

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)

WHMIS: Workplace Hazardous Materials Information System (Canada)

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1 Carc. 2: Carcinogenicity, Hazard Category 2

\* Data compared to the previous version altered.

CA-