

# SAFETY DATA SHEET

ACCORDING TO 1907/2006/EC



SINTODENT POLYMER

Update: 01.04.2016

Version: 3.0 - EN

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1 PRODUCT IDENTIFIER

**Trade name**

SINTODENT POLYMER

**Product type**

Resin for dental prosthesis resistant to bacterial colonization

### 1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

**Applications:** manufacturing of dentures resistant to bacterial colonization, mixed with SINTODENT monomer.

**Undesirable use:** all those not mentioned in the relevant uses.

### 1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

**Manufacturer:**

SINTODENT S.r.l. Via Castelbottaccio, 22 - 00131 Roma

Ph.: 06.53270547 Fax 06.53275875

Email: info@welltrade.it

### 1.4 EMERGENCY TELEPHONE NUMBER

+39 337 1463354

## 2. HAZARDS IDENTIFICATION

### 2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

**Classification according to Regulation (EC) n. 1272/2008**

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

### 2.2 LABEL ELEMENTS

**Labeling according to Regulation (EC) n. 1272/2008**

The product is classified and labeled according to the CLP regulation.

**Hazard pictograms**



GHS07

**Signal word**

Warning

**Hazard-determining components of labeling**

Dibenzoyl peroxide

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### Hazard statements

H317 May cause an allergic skin reaction.

### Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

P262 Do not get in eyes, on skin, or on clothing.

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

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

## 2.3 OTHER HAZARDS

### Results of PBT and vPvB assessment

PBT: not applicable.

vPvB: not applicable.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 CHEMICAL CHARACTERISATION

Mixtures.

#### Description

Mixture of substances with nonhazardous additions

Dangerous components		
CAS: 94-36-0 EINECS: 202-327-6	Dibenzoyl peroxide Org. Perox. CD, H242; Repr. 2, H361fd, Eye Irrit. 2, H319; Skin Sens. 1, H317, Aquatic Acute, H400, Aquatic Chronic 3, H412	1-<3%*

For the wording of the listed hazard phrases refer to section 16.

\* Specific chemical weight has been withheld as a trade secret.

## 4. FIRST AID MEASURES

### 4.1 DESCRIPTION OF FIRST AID MEASURES

**General information:** no special measures required.

**After skin contact:** the product is not skin irritating.

**After eye contact:** rinse opened eye for several minutes under running water.

**After swallowing:** rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.

### 4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

No further relevant information available.

### 4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No further relevant information available.

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## 5. FIREFIGHTING MEASURES

### 5.1 EXTINGUISHING MEDIA

**Suitable extinguishing agents:** CO<sub>2</sub>, extinguishing powder or water jet. Fight larger fires with water jet or alcohol-resistant foam.

### 5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

No further relevant information available.

### 5.3 ADVICE FOR FIREFIGHTERS

**Protective equipment:** no special measures required.

**Additional information:** -

## 6. ACCIDENTAL RELEASE MEASURES

### 6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Not required.

### 6.2. ENVIRONMENTAL PRECAUTIONS

No special measures required.

### 6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Collect mechanically.

### 6.4. 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

### 7.1. PRECAUTIONS FOR SAFE HANDLING

For use in dentistry only.

No special measures required.

**Information about fire - and explosion protection:** no special measures required.

### 7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

**Storage**

**Requirements to be met by storerooms and receptacles:** store only in the original packs.

**Information about storage in one common storage facility:** not required.

**Further information about storage conditions:** keep the product at a temperature lower than 30°C/86°F.

### 7.3. SPECIFIC END USE(S)

No further relevant information available.

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. CONTROL PARAMETERS

**Ingredients 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 valid during the making were used as basis.

### 8.2 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.

**Respiratory protection:** 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

### 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Form .....	powder
Colour .....	according to product specification
Smell .....	characteristic
Odour threshold .....	not determined
pH value .....	not applicable
Melting point/Melting range.....	undetermined
Boiling point/Boiling range.....	undetermined
Ignition temperature .....	400°C
Self-igniting .....	product is not self igniting
Danger of explosion .....	product does not present an explosion hazard
Vapour pressure .....	not applicable
Density at 20 °C.....	0 g/cm <sup>3</sup>
Solubility in / Miscibility with water .....	insoluble

### 9.2 OTHER INFORMATION

No further relevant information available.

## 10. STABILITY AND REACTIVITY

### 10.1 REACTIVITY

No further relevant information available.

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## 10.2. CHEMICAL STABILITY

No decomposition if used and stored according to specifications.

## 10.3. POSSIBILITY OF HAZARDOUS REACTIONS

No dangerous reactions known.

## 10.4. CONDITIONS TO AVOID

No further relevant information available.

## 10.5. INCOMPATIBLE MATERIALS

No further relevant information available.

## 10.6. HAZARDOUS DECOMPOSITION PRODUCTS

None.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

#### Acute toxicity

Based on available data, the classification criteria are not met.

#### Primary irritant effect

**On the skin:** based on available data, the classification criteria are not met.

**On the eye:** based on available data, the classification criteria are not met.

#### Respiratory or skin sensitization

May cause an allergic skin reaction.

#### CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

**Germ cell mutagenicity:** based on available data, the classification criteria are not met.

**Carcinogenicity:** based on available data, the classification criteria are not met.

**Reproductive toxicity:** based on available data, the classification criteria are not met.

#### STOT-single exposure

Based on available data, the classification criteria are not met.

#### STOT-repeated exposure

Based on available data, the classification criteria are not met.

#### Aspiration hazard

Based on available data, the classification criteria are not met.

## 12. ECOLOGICAL INFORMATION

### 12.1 TOXICITY

**Aquatic toxicity:** no further relevant information available.

### 12.2 PERSISTENCE AND DEGRADABILITY

No further relevant information available.

### 12.3 BIOACCUMULATIVE POTENTIAL

No further relevant information available.

### 12.4 MOBILITY IN SOIL

No further relevant information available.

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**Additional ecological information:** do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

### 12.5 RESULTS OF PBT AND VPVB ASSESSMENT

**PBT:** not applicable.

**vPvB:** not applicable.

### 12.6 OTHERS ADVERSE EFFECTS

No further relevant information available.

## 13. DISPOSAL CONSIDERATIONS

### 13.1 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. Larger quantities must be disposed of following the regulations of the local authorities.

**European waste catalogue:** 18 01 06 chemicals consisting of or containing dangerous substance.

**Uncleaned packaging**

**Recommendation:** dispose of packaging according to regulations on the disposal of packagings.

## 14. TRANSPORT INFORMATION

### 14.1 UN-NUMBER

ADR, ADN, IMDG, IATA                      Void

### 14.2 UN PROPER SHIPPING NAME

ADR, ADN, IMDG, IATA                      Void

### 14.3 TRANSPORT HAZARD CLASS(ES)

ADR, ADN, IMDG, IATA  
Class    Void

### 14.4 PACKAGING GROUP

ADR, IMDG, IATA                              Void

### 14.5 ENVIRONMENTAL HAZARDS

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

Not applicable.

**Transport/Addition information:** -

**UN "Model Regulation":** -

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## 15. REGULATORY INFORMATION

### 15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATION/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

No further relevant information available.

#### Other regulations, limitations and prohibitive regulations

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

### 15.2 CHEMICAL SAFETY ASSESSMENT

A Chemical Safety Assessment has not been carried out.

## 16. OTHER INFORMATION

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release. It is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

### Relevant phrases

H317 May cause an allergic skin reaction.

### Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labeling of Chemicals

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)

Org. Perox. B: Organic Peroxides, Type B

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitization - Skin, Hazard Category 1