

SAFETY DATA SHEET

ACCORDING TO 1907/2006/EC

SINTODENT DISCS AND CUBES

Update: 09.09.2022

Version: 4.0 - EN



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

1.1 PRODUCT IDENTIFIER

Trade name

SINTODENT DISCS AND CUBES

Product type

Acrylic polymer resistant to bacterial colonization derived from the polymerization of methyl methacrylate monomer and polymethyl methacrylate.

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

Applications in dentistry: realization of prosthetic artefacts resistant to bacterial colonization by milling with CAD CAM technique.

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.: +39 06.4131555

E-mail: info@sintodent.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

None

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

None

Signal word

None

Hazard-determining components of labeling

None

Hazard statements

None

Precautionary statements

None

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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

Description

Acrylic polymer resistant to bacterial colonization derived from the polymerization of methyl methacrylate monomer and polymethyl methacrylate.

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: In case of eye irritation, resulting from the mechanical processing of PMMA, wash them thoroughly with plenty of water and if irritation persists consult a doctor (possible with processing and removal of chips, polishing, sanding, grinding).

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 information available.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No information available.

5. FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing agents: water jet, foam, extinguishing powder, CO₂.

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.

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6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Collect mechanically. Dispose of according to the prescriptions.

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.

In case of thermal processing and / or machining with chip removal, it is necessary localized removal on machines.

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: none.

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

Further information about storage conditions: keep in a dry place; avoid direct exposure to the sun's rays.

7.3. SPECIFIC END USE(S)

No information available.

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.

Respiratory protection: it is not necessary with normal use; during machining with chip removal, it may be necessary to use the dust mask.

Protection of hands: gloves also to protect themselves from mechanical and cutting risks, according to EN 388 standards.

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 during shaving removal.

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

Form..... disc and cube
Color..... according to product specification
Smell..... odorless
Odor threshold..... not determined
pH value not applicable
Softening temperature..... > 130°C
Melting point/Melting range undetermined
Boiling point/Boiling range..... undetermined
Ignition temperature..... > 400° C (ASTM D1929-68)
Self-igniting undetermined
Danger of explosion product does not present an explosion hazard
Vapour pressure..... not applicable
Density at 20 °C..... 1,18 g/cm³
Solubility in / Miscibility with water (20°C) insoluble

9.2 OTHER INFORMATION

No further relevant information available.

10. STABILITY AND REACTIVITY

10.1 REACTIVITY

No information available.

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 information available.

10.5. INCOMPATIBLE MATERIALS

No information available.

10.6. HAZARDOUS DECOMPOSITION PRODUCTS

None.

11. TOXICOLOGICAL INFORMATION

The product has passed all the biocompatibility tests required by the Medical Devices Directive (Dir. 93/42/CEE). The product, based on the studies carried out by us, does not cause damage to health.

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity

Based on the available data, Sintodent products do not present critical elements.

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Primary irritant effect

On the skin: based on the available data, Sintodent products do not present critical elements.

On the eye: based on the available data, Sintodent products do not present critical elements.

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.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Germ cell mutagenicity / Carcinogenicity: the components of SINTODENT products (both for characteristics and quantity) does not fall under the classification of carcinogens / mutagens.

Reproductive toxicity: based on the available data, Sintodent products do not present critical elements.

STOT-single exposure

Based on the available data, Sintodent products do not present critical elements.

STOT-repeated exposure

Based on the available data, Sintodent products do not present critical elements.

Aspiration hazard

Based on the available data, Sintodent products do not present critical elements.

12. INFORMAZIONI ECOLOGICHE

12.1 TOXICITY

Aquatic toxicity: no information available.

12.2 PERSISTENCE AND DEGRADABILITY

No information available.

12.3 BIOACCUMULATIVE POTENTIAL

No information available.

12.4 MOBILITY IN SOIL

No information available.

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 information available.

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

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

14. TRANSPORT INFORMATION

14.1 UN-NUMBER

ADR, ADN, IMDG, IATA not applicable

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14.2 UN PROPER SHIPPING NAME

ADR, ADN, IMDG, IATA not applicable

14.3 UN PROPER SHIPPING NAME

ADR, ADN, IMDG, IATA
Class not applicable

14.4 PACKAGING GROUP

ADR, IMDG, IATA not applicable

14.5 ENVIRONMENTAL HAZARDS:

Marine pollutant none

14.6 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": -

15. REGULATORY INFORMATION

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

No information available.

Other regulations, limitations and prohibitive regulations: the product is a medical device according to the 93/42/EEC Directive.

15.2 CHEMICAL SAFETY ASSESSMENT

A Chemical Safety Assessment has not been carried out.

16. OTHER INFORMATION

The information in this safety data sheet is correct to the best of our knowledge, information and opinions at the time of its publication. This information is provided for the sole purpose of allowing safe handling, use, storage, transport, disposal and release. They must not be considered a guarantee or a quality specification and do not justify any contractual legal relationship. The information refers only to the specific material and may not be valid for such material used in combination with other materials or in other processes not specifically indicated in the text.

For each product batch, Sintodent guarantees the execution of the appropriate internal verification tests and guarantees that the product will be placed on the market only they have been successfully obtained. For each product lot, Sintodent guarantees the execution of the appropriate internal verification tests and guarantees the placing on the market of the products only upon obtaining a positive test result.

Relevant phrases

None.

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