SINERGIA DISK PMMA



Issued on 06/01/2015 - Rel. # 3 on 08/01/2023

In conformity to Regulation (EU) 2020/878

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

1.1. Product identifier

Product code: SINERGIA DISK TEMPO MULTI, TEMPO OPAL, CAST PMMA-based CAD/CAM discs.

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

Sectors of use: Only for professional dental technician

Uses advised against Do not use for purposes other than those listed

1.3. Details of the supplier of the safety data sheet

Nobil Metal Spa Strada San Rocco, 28 - 14018 Villafranca d'Asti - Italy tel. +39 0141 933811 fax +39 0141 943840

Email:contact@nobilmetal.it - Sito internet: www.nobilmetal.it

1.4. Emergency telephone number

+39 0141 933811 - 8.30-12,30 / 13.30-17.30

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008:

Pictograms: None

Hazard Class and Category Code(s): Nonhazardous

Hazard statement Code(s): Nonhazardous

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008:

Pictogram, Signal Word Code(s): None

Hazard statement Code(s): Nonhazardous

Supplemental Hazard statement Code(s): EUH210 - Safety data sheet available on request. EUH212 - Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

Precautionary statements: None in particular.

SINERGIA DISK PMMA



Issued on 06/01/2015 - Rel. # 3 on 08/01/2023

In conformity to Regulation (EU) 2020/878

2.3. Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100.

No information on other hazards.

SECTION 3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

Refer to paragraph 16 for full text of hazard statements.

* Titanium dioxide is inextricably bound within the polymer matrix of this product.

Note V - If the substance is to be placed on the market as fibres (with diameter < 3 μ m, length > 5 μ m and aspect ratio ≥ 3:1) or particles of the substance fulfilling the WHO fibre criteria or as particles with modified surface chemistry, their hazardous properties must be evaluated in accordance with Title II of this Regulation, to assess whether a higher category (Carc. 1B or 1A) and/or additional routes of exposure (oral or dermal) should be applied.

Note W - It has been observed that the carcinogenic hazard of this substance arises when respirable dust is inhaled in quantities leading to significant impairment of particle clearance mechanisms in the lung. This note aims to describe the particular toxicity of the substance; it does not constitute a criterion for classification according to this Regulation. Note 10 - The classification as a carcinogen by inhalation applies only to mixtures in powder form containing 1 % or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter \leq 10 µm.

Substance	Concentration[w/w]	Classification	Index	CAS	EINECS	REACh
polymethyl methacrylate	>= 75 < 100%	NC	ND	9011-14-7	618-466-4	ND
Titanium dioxide* Note: V W 10	< 0,1%	Carc. 2, H351	022-006-002	13463-67-7	236-675-5	ND

SECTION 4. First aid measures

4.1. Description of first aid measures

After inhalation: Provide fresh air.

After contact with skin:

Wash with plenty of water. Take off contaminated clothing and wash it before reuse. Get medical attention if irritation develops or persists.

After contact with eyes: Rinse immediately carefully and thoroughly with water. Get medical attention if irritation persists.

After ingestion: Rinse mouth immediately with water. If irritation or discomfort occurs, get medical attention.

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

Product dust may be mechanically irritating to eyes, skin and respiratory system.



SINERGIA DISK PMMA

Issued on 06/01/2015 - Rel. # 3 on 08/01/2023

In conformity to Regulation (EU) 2020/878

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

Treat symptomatically.

SECTION 5. Firefighting measures

5.1. Extinguishing media

Advised extinguishing agents: Water spray, CO2, foam, dry chemical, depending on the materials involved in the fire.

Extinguishing means to avoid:

Water jets. Use water jets only to cool the surfaces of the containers exposed to fire.

5.2. Special hazards arising from the substance or mixture

Decomposition may release oxides of carbon, methyl methacrylate, and irritating smoke and fumes.

5.3. Advice for firefighters

Wear self-contained breathing apparatus.

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel: Wear gloves and protective clothing.

6.1.2 For emergency responders: Wear gloves and protective clothing. Provision of sufficient ventilation.

6.2. Environmental precautions

No special environmental measures are necessary. Clean contaminated articles and floor according to the environmental legislation.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment: Recover the product for reuse, if possible, or the removal.

6.3.2 For cleaning up: After wiping up, wash with water the area and materials involved

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Refer to paragraphs 8 and 13 for more information





Issued on 06/01/2015 - Rel. # 3 on 08/01/2023

#4/9

In conformity to Regulation (EU) 2020/878

SECTION 7. Handling and storage

7.1. Precautions for safe handling

No special measures are necessary.

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Store in a cool place, away from sources of heat and `direct exposure of sunlight.

7.3. Specific end use(s)

Only for professional dental technician: Handle with care. Avoid formation of dust.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Related to the substances contained: Titanium dioxide 10 mg/m3 TWA ACGIH TLV 15 mg/m3 TWA OSHA PEL (Total Dust) 0.3 mg/m3 (respirable) TWA, 2.4 mg/m3 (respirable) STEL (15 min average value) DFG MAK 10 mg/m3 (Inhalable), 4 mg/m3 (Respirable) TWA UK WEL 10 mg/m3 TWA Belgium OEL

8.2. Exposure controls

Appropriate engineering controls: Use with adequate local exhaust ventilation to maintain exposures below excessive levels.

Only for professional dental technician : No specific monitoring foreseen

Individual protection measures:

(a) Eye / face protection Wear eye/face protection.

(b) Skin protection

(i) Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

(ii) Other Wear normal work clothing.

(c) Respiratory protection

SINERGIA DISK PMMA

Issued on 06/01/2015 - Rel. # 3 on 08/01/2023

In conformity to Regulation (EU) 2020/878

In case of inadequate ventilation wear respiratory protection. Do not breathe dust.

(d) Thermal hazards No hazard to report

Environmental exposure controls: Use according to good working practices to avoid pollution into the environment.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical and chemical properties	Value	Determination method	
Physical state	solid		
Colour	according to the markings on the package		
Odour	odorless		
Odour threshold	not determined		
Melting point/freezing point	not determined		
Boiling point or initial boiling point and boiling range	not determined		
Flammability	irrelevant		
Lower and upper explosion limit	not determined		
Flash point	irrelevant		
Auto-ignition temperature	not determined		
Decomposition temperature	not determined		
рН	irrelevant		
Kinematic viscosity	irrelevant		
Solubility(ies)	insoluble		
Water solubility	insoluble		
Partition coefficient n-octanol/water (log value)	irrelevant		
Vapour pressure	irrelevant		
Density and/or relative density	1,18		
Relative vapour density	irrelevant		
Particle characteristics	irrelevant		

9.2. Other information

9.2.1 Information with regard to physical hazard classes

Irrilevant

9.2.2 Other safety characteristics

Irrilevant



#5/9

SINERGIA DISK PMMA



Issued on 06/01/2015 - Rel. # 3 on 08/01/2023

#6/9

In conformity to Regulation (EU) 2020/878

SECTION 10. Stability and reactivity

10.1. Reactivity

No reactivity hazards.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Avoid extreme heat and direct sunlight.

10.5. Incompatible materials

Avoid oxidizing agents.

10.6. Hazardous decomposition products

Decomposition may release oxides of carbon, methyl methacrylate, and irritating smoke and fumes.

SECTION 11. Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞ ATE(mix) dermal = ∞ ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met.

(b) skincorrosion/irritation: based on available data, the classification criteria are not met.

(c) serious eye damage/irritation: based on available data, the classification criteria are not met.

(d) respiratoryorskinsensitisation: based on available data, the classification criteria are not met.

(e) germ cell mutagenicity: based on available data, the classification criteria are not met.

(f) carcinogenicity: based on available data, the classification criteria are not met.

(g) eproductivetoxicity: based on available data, the classification criteria are not met.

(h) specific target organ toxicity (STOT) single exposure: based on available data, the classification criteria are not met.

(i) specific target organ toxicity (STOT) repeated exposurebased on available data, the classification criteria are not met.

(j) aspiration hazard: based on available data, the classification criteria are not met.

Health hazards

Contact with eyes: Product dust may cause eye irritation.

Contact with skin: The product is not an irritant. Repeated and prolonged direct contact with product dust can irritate the skin and cause dermatitis in some cases.

Ingestion: Ingestion may cause product mucosal irritation of the throat and digestive system resulting in abnormal digestive symptoms and intestinal disorders.

Inhalation: Inhalation of product dust may cause mild irritation of the eyes, nose and upper respiratory tract. Symptoms include coughing, sneezing and difficulty in breathing.

SINERGIA DISK PMMA



Issued on 06/01/2015 - Rel. # 3 on 08/01/2023

#7/9

In conformity to Regulation (EU) 2020/878

Related to contained substances:

Titanium dioxide

LD50 oral, rat > 10.000 mg/kg

Titanium dioxide is not classified as an eye and skin irritant. However, under particular conditions, contact with the eyes could give rise to slight, short-term irritations attributable to mechanical effects (dust).

Titanium Dioxide is classified by IARC as a group 2B carcinogen (possible human carcinogen). However, the titanium dioxide in this product is inextricably bound within a polymer matrix and will not present a risk of exposure.

11.2. Information on other hazards

No data available.

SECTION 12. Ecological information

12.1. Toxicity

Use according to good working practices to avoid pollution into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100.

12.7. Other adverse effects

No adverse effects.

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Dispose of waste according to applicable legislation.

SECTION 14. Transport information

14.1. UN number or ID number

Not included in the scope of application regulations concerning the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO / IATA); by sea (IMDG).



SINERGIA DISK PMMA

Issued on 06/01/2015 - Rel. # 3 on 08/01/2023

#8/9

In conformity to Regulation (EU) 2020/878

14.2. UN proper shipping name

None

14.3. Transport hazard class(es)

None

14.4. Packing group

None

14.5. Environmental hazards

None

14.6. Special precautions for user

No data available.

14.7. Maritime transport in bulk according to IMO instruments

It is not intended to carry bulk

SECTION 15. Regulatory information

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

Substances in the Candidate List (REACH Article 59). Based on available data, no SVHC substances are present.

15.2. Chemical safety assessment

The supplier has not made an assessment of chemical safety.

SECTION 16. Other information

16.1. Other information

Description of the hazard statements exposed to point 3 H351 = Suspected of causing cancer .

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

No hazard to report. Classification procedure: Calculation method

GENERAL BIBLIOGRAPHY:

- 1. Directive 1999/45/EC and subsequent updates
- 2. Directive 67/548/EEC and subsequent amendments and adjustments
- 3. Council Regulation (EC) 1907/2006 of the European Parliament (REACH)
- 4. Regulation (EC) 1272/2008 of the European Parliament (CLP) and subsequent updates
- 5. Council Regulation (EC) no 758/2013 of the European Parliament
- 6. Regulation (EC) no 453/2010 of the European Parliament
- 7. Regulation (EC) No 528/2012 European Parliament and subsequent updates
- 8. Council Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- 9. The Merck Index And 10.
- 10. Handling Chemical Safety

SINERGIA DISK PMMA



Issued on 06/01/2015 - Rel. # 3 on 08/01/2023

#9/9

In conformity to Regulation (EU) 2020/878

11. Niosh Registry of Toxic Effects of Chemical Substances

12. INRS-Centre Piece

13. Patty-Industrial Hygiene and Toxicology

14. N.I. Sax-Dangerous properties of Industrial Materials-7 Ed., 1989

Note to the user:

the information in this tab are based on knowledge available to us on the date of the latest version.

The user must ensure the fitness and completeness of the information in relation to the specific use of the product.

You should not interpret it as a guarantee of any specific property of the product.

For the use of the product does not fall under our direct control, the obligation of the user to observe under their own liability laws and regulations on hygiene and safety. Do not assume liability for improper use.

This tab replaces and cancels all previous