

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 6 Nov 2024

Print date: 26 Nov 2024

Version: 3



dentona vivatemp / dentona vivapink - Pulver

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

* 1.1. Product identifier

Trade name/designation:

dentona vivatemp / dentona vivapink - Pulver

Article No.:

53333 / 53334 / 53343

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

Use of the substance/mixture:

Dental resin for the fabrication of flexible dental therapeutic splints of all kinds

1.3. Details of the supplier of the safety data sheet

Supplier (manufacturer/importer/only representative/downstream user/distributor):

dentona AG

Feldbachacker 16

44149 Dortmund

Germany

Telephone: 0231-5556-0

Telefax: 0231-5556-30

E-mail: info@dentona.de

Website: www.dentona.com

1.4. Emergency telephone number

No data available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Hazardous to the aquatic environment (Aquatic Chronic 1)	H410: Very toxic to aquatic life with long lasting effects.	Calculation method.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms:



GHS09

Environment

Signal word: Warning

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 6 Nov 2024

Print date: 26 Nov 2024

Version: 3



dentona vivatemp / dentona vivapink - Pulver

Hazard components for labelling:

dibenzoyl peroxide; 1-benzyl-5-phenylbarbituric acid

Hazard statements for environmental hazards

H410	Very toxic to aquatic life with long lasting effects.
------	---

Supplemental hazard information

EUH208	Contains dibenzoyl peroxide. May produce an allergic reaction.
--------	--

Precautionary statements Prevention

P264	Wash ... thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.

Precautionary statements Response

P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor/... if you feel unwell.
P330	Rinse mouth.
P391	Collect spillage.

Special rules for supplemental label elements for certain mixtures:

98,0 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (oral).

98,0 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (dermal).

98,0 % percent of the mixture consists of ingredient(s) of unknown acute toxicity (inhalative).

99,0 % percent of the mixture consists of components of unknown hazards to the aquatic environment.

2.3. Other hazards

No data available

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 72846-00-5 EC No.: 276-940-2	1-benzyl-5-phenylbarbituric acid Acute Tox. 4 (H302) Warning	0 - ≤ 1 weight-%
CAS No.: 94-36-0 EC No.: 202-327-6 Index No.: 617-008-00-0 REACH No.: 01-2119511472-50	dibenzoyl peroxide Aquatic Acute 1 (H400), Eye Irrit. 2 (H319), Org. Perox. B (H241), Skin Sens. 1 (H317) Danger M-factor (acute): 10 M-factor (chronic): 10	0 - < 0.99 weight-%

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information:

When in doubt or if symptoms are observed, get medical advice. In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

In case of irritation of the respiratory tract by the product: Consult a doctor Provide fresh air.

In case of skin contact:

Wash off with plenty of soap and water and rinse. After contact with skin, wash immediately with plenty of water and soap. Take off immediately all contaminated clothing.

After eye contact:

In case of contact with eyes, remove contact lenses and immediately rinse with running water for 10 to 15 minutes with the eyelids open and consult an ophthalmologist.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 6 Nov 2024

Print date: 26 Nov 2024

Version: 3



dentona vivatemp / dentona vivapink - Pulver

Following ingestion:

Rinse mouth. Let 1 glass of water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell. Never give anything by mouth to an unconscious person or a person with cramps. Avoid vomiting

Self-protection of the first aider:

Remove contaminated, saturated clothing. Use personal protection equipment. No direct artificial respiration to be given by first aider.

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

Skin contact: May cause allergic skin reactions.

Allergic reactions: Severe eye irritation/irritation

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

Note to doctor: Treat symptomatically. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

Water spray, foam, dry extinguisher or carbon dioxide. Water spray jet alcohol resistant foam
Extinguishing powder Carbon dioxide (CO₂)

Unsuitable extinguishing media:

Do not use water jet as extinguishing agent as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition or combustion products may contain the following substances: Carbon oxides.
Combustible

Hazardous combustion products:

In case of fire: Gases/vapours, toxic

5.3. Advice for firefighters

Protective measures during firefighting: No actions should be taken without appropriate training or that involve personal risk. Wear a self-contained breathing apparatus and chemical protective clothing.

5.4. Additional information

Special protective equipment for fire fighters: Wear positive pressure breathing apparatus (SCBA) and suitable protective clothing. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Personal precautions:

Wear suitable protective clothing, including gloves, goggles / face shield, respirator, boots, clothing or apron, as appropriate, when working. Wear suitable respiratory protection if ventilation is inadequate. Remove persons to safety.

Protective equipment:

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

6.1.2. For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2. Environmental precautions

Environmental precautions Avoid release to the environment. Do not allow to enter drains or water courses. Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

For cleaning up:

Do not smoke, no sparks, flames or other sources of ignition near spills. Bind spilled material with sand or other inert absorbent. Collect and place in a suitable disposal container and seal securely. Containers

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 6 Nov 2024

Print date: 26 Nov 2024

Version: 3



dentona vivatemp / dentona vivapink - Pulver

with collected spilled material must be properly hazard labelled. Spills must be collected and disposed of according to the instructions in chapter 13.

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

6.5. Additional information

Use appropriate container to avoid environmental contamination.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures

Advices on safe handling:

Protective measures during use: Avoid contact with eyes and skin. Wash contaminated skin thoroughly after handling. Wear suitable protective equipment at work in case of prolonged exposure and / or high concentrations of the vapours, spray or mist.

Wear personal protection equipment (refer to section 8).

Fire prevent measures:

Keep away from heat, sparks and open flame. Mechanical extraction is required if dust is released during handling. Open and handle containers with care.

Advices on general occupational hygiene

Do not eat, drink or smoke when using this product. Do not eat, drink, smoke or snort in the workplace. Avoid contact with skin, eyes and clothing.

When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

Requirements for storage rooms and vessels:

Store at temperatures between 5°C and 30°C. Protect from frost and direct sunlight. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Do not smoke.

Storage class (TRGS 510, Germany): 11 - Combustible solids that cannot be assigned to any of the above storage classes

7.3. Specific end use(s)

Recommendation:

The intended uses of this product are described in section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. Occupational exposure limit values

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
DFG (DE) from 1 Jul 2023	dibenzoyl peroxide CAS No.: 94-36-0 EC No.: 202-327-6	① 4 mg/m ³ ② 8 mg/m ³ ⑤ (Aerosol und Dampf, einatembare Fraktion)
DFG (DE) from 1 Jul 2023	dibenzoyl peroxide CAS No.: 94-36-0 EC No.: 202-327-6	① 1 mg/m ³ ② 4 mg/m ³ ⑤ (Aerosol und Dampf, alveolengängige Fraktion)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 6 Nov 2024

Print date: 26 Nov 2024

Version: 3



dentona vivatemp / dentona vivapink - Pulver

Limit value type (country of origin)	Substance name	① Long-term occupational exposure limit value ② Short-term occupational exposure limit value ③ Instantaneous value ④ Monitoring and observation processes ⑤ Remark
TRGS 900 (DE)	dibenzoyl peroxide CAS No.: 94-36-0 EC No.: 202-327-6	① 5 mg/m ³ ② 5 mg/m ³ ⑤ (einatembare Fraktion) DFG

8.1.2. Biological limit values

No data available

8.1.3. DNEL-/PNEC-values

No data available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure sufficient room ventilation and local exhaust ventilation. The occupational exposure limits of the product or the ingredients must be observed.

8.2.2. Personal protection equipment



Eye/face protection:

Eye protection conforming to a recognised standard should be worn if a risk assessment indicates that eye contact is possible. The following personal protective clothing should be worn: Frame goggles with side shields. DIN EN 166

Eye glasses with side protection EN 166

Skin protection:

Avoid contact with the skin. Wear suitable clothing to prevent possible skin contact.

Wear protective gloves. According to the data provided by the protective glove manufacturers, it is necessary to check during their use whether the gloves retain their repellent properties and to change them as soon as damage is detected. For exposures up to 8 hours, wear protective gloves made of the following material: nitrile rubber.

Tested protective gloves must be worn EN ISO 374 Suitable material: Breakthrough time: min In the case of wanting to use the gloves again, clean them before taking off and air them well.

Respiratory protection:

Suitable respiratory protection must be worn if ventilation is inadequate. Wear a respirator with full face shield and the following filter cartridge: Filter against organic vapours. High efficiency particulate filters.

Other protection measures:

Wash contaminated skin thoroughly after handling. Wash contaminated clothing and skin immediately with plenty of water before removing clothing. Remove all contaminated clothing immediately and wash before wearing again. Do not wear contaminated work clothing outside the workplace. Do not eat, drink or smoke when using this product.

8.2.3. Environmental exposure controls

No data available

SECTION 9: Physical and chemical properties

* 9.1. Information on basic physical and chemical properties

Appearance

Physical state: Powder

Colour: various

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 6 Nov 2024

Print date: 26 Nov 2024

Version: 3



dentona vivatemp / dentona vivapink - Pulver

Odour: not determined

Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	No data available		
Initial boiling point and boiling range	No data available		
Evaporation rate	No data available		
Upper/lower flammability or explosive limits	No data available		
Vapour pressure	No data available		
Relative density	1.11	25 °C	
Bulk density	not applicable		
Water solubility	No data available		

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

There is no information available Combustible

10.2. Chemical stability

Stable at normal room temperatures

10.3. Possibility of hazardous reactions

Can polymerise

10.4. Conditions to avoid

Reaction with light, risk of polymerisation. Protect from heat, flames and other ignition sources.
Do not expose to high temperatures or direct sunlight.
Avoid contact with strong oxidising agents.

10.5. Incompatible materials

Keep away from free-radical initiators, peroxides, strongly alkaline substances and reactive metals to avoid exothermic polymerisation reactions.

10.6. Hazardous decomposition products

Carbon oxides

Gases/vapours, toxic

SECTION 11: Toxicological information

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

dibenzoyl peroxide CAS No.: 94-36-0 EC No.: 202-327-6
LD₅₀ oral: 7,710 mg/kg (Ratte)
LD₅₀ dermal: 7,710 mg/kg (Rat)
LC₅₀ Acute inhalation toxicity (dust/mist): 24.3 mg/L 4 h (Ratte)

Acute oral toxicity:

Harmful if swallowed.

Acute dermal toxicity:

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

Acute inhalation toxicity:

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

Skin corrosion/irritation:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 6 Nov 2024

Print date: 26 Nov 2024

Version: 3



dentona vivatemp / dentona vivapink - Pulver

Serious eye damage/irritation:

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

Respiratory or skin sensitisation:

Contains dibenzoyl peroxide. May produce an allergic reaction.

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.

Additional information:

No data available

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

dibenzoyl peroxide CAS No.: 94-36-0 EC No.: 202-327-6
--

LC ₅₀ : 0.0602 mg/L 4 d (fish, <i>Oncorhynchus mykiss</i> (Regenbogenforelle)) OECD TG 203

EC ₅₀ : 0.0711 mg/L 3 d (Algae/water plant, <i>Pseudokirchneriella subcapitata</i> (Grünalge)) OECD TG 201

EC ₅₀ : 35 mg/L OECD 209

LC ₅₀ : 0.0602 mg/L 4 d (fish, <i>Oncorhynchus mykiss</i> (Rainbow trout)) OECD TG 203

EC ₅₀ : 0.0711 mg/L 3 d (Algae/water plant, <i>Pseudokirchneriella subcapitata</i> (Grünalge)) OECD TG 201

Aquatic toxicity:

Very toxic to aquatic life with long lasting effects.

12.2. Persistence and degradability

No data available

12.3. Bioaccumulative potential

1-benzyl-5-phenylbarbituric acid CAS No.: 72846-00-5 EC No.: 276-940-2

Log K _{ow} : < 3

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

1-benzyl-5-phenylbarbituric acid CAS No.: 72846-00-5 EC No.: 276-940-2

Results of PBT and vPvB assessment: —

dibenzoyl peroxide CAS No.: 94-36-0 EC No.: 202-327-6
--

Results of PBT and vPvB assessment: —

12.6. Endocrine disrupting properties

No data available

12.7. Other adverse effects

No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 6 Nov 2024

Print date: 26 Nov 2024

Version: 3



dentona vivatemp / dentona vivapink - Pulver

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of waste according to applicable legislation.

Waste treatment options

Appropriate disposal / Product:

Consult the appropriate local waste disposal expert about waste disposal.

Appropriate disposal / Package:

Contact the responsible, authorised waste disposal company about waste disposal.

Other disposal recommendations:

Avoid release to the environment.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
14.1. UN number or ID number			
UN 3077	UN 3077	UN 3077	UN 3077
14.2. UN proper shipping name			
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
14.3. Transport hazard class(es)			
14.4. Packing group			
III	III	III	III
14.5. Environmental hazards			
		MARINE POLLUTANT	
14.6. Special precautions for user			
Special Provisions: 274 335 375 601 Limited quantity (LQ): 5 kg Excepted Quantities (EQ): E1 Hazard identification number (Kemler No.): 90 Classification code: M7 Tunnel restriction code: (-)	Special Provisions: 274 335 375 601 Limited quantity (LQ): 5 kg Excepted Quantities (EQ): E1 Classification code: M7	Special Provisions: 274 335 966 967 969 Limited quantity (LQ): 5 kg Excepted Quantities (EQ): E1 EmS-No.: F-A, S-F	Special Provisions: A97 A158 A179 A197 A215 Limited quantity (LQ): Y956 Excepted Quantities (EQ): E1

14.7. Maritime transport in bulk according to IMO instruments

No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 6 Nov 2024

Print date: 26 Nov 2024

Version: 3



dentona vivatemp / dentona vivapink - Pulver

SECTION 15: Regulatory information

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

15.1.1. EU legislation

Authorisations:

EU regulations

Other regulations (EU):

Hazard categories:

- E1 Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

15.1.2. National regulations

[DE] National regulations

Restrictions of occupation

There is no information available

Störfallverordnung (12. BImSchV)

for substances contained in the product:

Hazard categories:

- E1 Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

Not subject to the Major Accidents Ordinance

Technische Anleitung zur Reinhaltung der Luft (TA-Luft)

Klasse 1:

No subject to TA-Luft.

Water hazard class

WGK:

3 - highly hazardous to water

15.2. Chemical Safety Assessment

Chemical safety assessments for substances in this mixture have not been carried out

SECTION 16: Other information

* 16.1. Indication of changes

1.1.	Product identifier
9.1.	Information on basic physical and chemical properties
16.1.	Indication of changes

16.2. Abbreviations and acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging
DIN	German Institute for Standardization / German Industrial Standard
DNEL	derived no-effect level
EC ₅₀	Effective Concentration 50%
EN	European Standard
ES	Exposure scenario
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
LC ₅₀	Lethal (fatal) Concentration 50%
LD ₅₀	Lethal (fatal) Dose 50%
MAK	Maximum concentration in the workplace air (CH)
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety & Health
OECD	Organisation for Economic Cooperation and Development

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH)

Revision date: 6 Nov 2024

Print date: 26 Nov 2024

Version: 3



dentona vivatemp / dentona vivapink - Pulver

OSHA Occupational Safety & Health Administration
PBT persistent and bioaccumulative and toxic
PNEC Predicted No Effect Concentration
REACH Registration, Evaluation and Authorization of Chemicals
RID Dangerous goods regulations for transport by rail
TRGS Technische Regeln für Gefahrstoffe
UN United Nations

16.3. Key literature references and sources for data

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008

on classification, labelling and packaging of substances and mixtures, amending and repealing of Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006.

16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

Hazard classes and hazard categories	Hazard statements	Classification procedure
Hazardous to the aquatic environment (Aquatic Chronic 1)	H410: Very toxic to aquatic life with long lasting effects.	Calculation method.

16.5. List of relevant hazard statements and/or precautionary statements from sections 2 to 15

Hazard statements	
H241	Heating may cause a fire or explosion.
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.

16.6. Training advice

As from 24 August 2023 adequate training is required before industrial or professional use.

16.7. Additional information

This information is based on our current knowledge and is intended to describe the product in terms of health, safety and environmental conditions only. It should therefore not be construed as a guarantee of any specific property of the product.

DISCLAIMER We have obtained the information contained in this data sheet from sources we believe to be reliable. The accuracy of the information, whether expressed or implied, cannot be guaranteed. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and possibly beyond our knowledge. For these and other reasons, we assume no responsibility and expressly disclaim liability for any loss, damage or expense which may arise from or be in any way connected with the handling, storage, use or disposal of the product. This safety data sheet has been prepared for this product and may only be used for this product. If the product is used as a component of another product, the information given in the data sheet may not apply. End of safety data sheet

End of safety data sheet

* Data changed compared with the previous version.

* Data changed compared with the previous version.