

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Orthalgenat Duo

Revision date: 28.02.2017

Product code: 150-100

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Orthalgenat Duo

Further trade names

Article No.:

150-501-20, 150-509-20, 150-520-20,

150-501-30, 150-509-30, 150-520-30

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

Health services.

1.3. Details of the supplier of the safety data sheet

Company name: DENTAURUM GmbH & Co. KG

Street: Turnstr. 31

Place: D-75228 Ispringen

Telephone: +49 7231 803 0

Telefax: +49 7231 803 295

e-mail: info@dentaurum.de

Internet: www.dentaurum.com

Further Information

Emergency telephone:

07:00 - 16:15 (Mo - Do), 07:00 - 13:15 (Fr) +49 7231 803 213

16:15 - 18:00 (Mo - Do), 13:15 - 18:00 (Fr) +49 7231 803 0

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:

Specific target organ toxicity - repeated exposure: STOT RE 2

Hazard Statements:

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements**Regulation (EC) No. 1272/2008****Hazard components for labelling**

cristobalite

Signal word: Warning

Pictograms:**Hazard statements**

H373 May cause damage to organs (lung) through prolonged or repeated exposure if inhaled.

Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P314 Get medical advice/attention if you feel unwell.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Additional advice on labelling

As a medical device that is invasive or used in direct physical contact with the human body, the product is

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exempted from classification and labeling according to the Directive EC 1272/2008 (CLP) (Art. 1.5.d). Please see the indications in further chapters.

The product was dedusted by a special process. Hazardous dusts do not occur.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
14464-46-1	cristobalite			1-8 %
	STOT RE 2; H373			
68855-54-9	Kieselgur, gebrannt			60-100 %
16919-27-0	Kaliumhexafluorotitanat(IV)			1-5 %

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures**4.1. Description of first aid measures****After inhalation**

Provide fresh air. Medical treatment necessary.

After contact with skin

Wash with plenty of water. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. In case of eye irritation consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water. Induce vomiting when the affected person is not unconscious. Medical treatment necessary.

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

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings. The product itself does not burn.

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5.2. Special hazards arising from the substance or mixture

Non-flammable.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Suppress gases/vapours/mists with water spray jet.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

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

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust. Conditions to avoid: Generation/formation of dust, Dust deposits.

Advice on protection against fire and explosion

No special measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaust at critical locations.

Advice on storage compatibility

No special measures are necessary.

Further information on storage conditions

Keep container tightly closed and dry.

Protect against: moisture. Water.

7.3. Specific end use(s)

Health services.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls



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Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme.

Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink. Do not breathe dust.

Eye/face protection

Wear eye protection/face protection.

Hand protection

Recommendation:

Dermatril 740 Single-use gloves. NBR (Nitrile rubber). 0,11 mm penetration time (maximum wearing period): 480 min.

REF 162-907-00 (7/S), REF 162-908-00 (8/M), REF 162-909-00 (9/L)

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.

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Powder
Colour:	bright green, violet
Odour:	characteristic

pH-Value (at 20 °C):

6

Test method

Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Pour point:	not determined
Flash point:	not applicable
Sustaining combustion:	No data available

Flammability

Solid:	not determined
Gas:	not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Ignition temperature:	not determined

Auto-ignition temperature

Solid:	not determined
Gas:	not applicable

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Decomposition temperature: not determined

Oxidizing properties

Not oxidising.

Vapour pressure: not determined

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Density: 1,76 g/cm³

Bulk density: not determined

Water solubility: not determined

Solubility in other solvents

not determined

Partition coefficient: not determined

Viscosity / dynamic: not determined

Viscosity / kinematic: not determined

Flow time: not determined

Vapour density: not determined

Evaporation rate: not determined

Solvent separation test: not determined

Solvent content: not determined

9.2. Other information

Solid content: not determined

Solubility(ies) Water: Gelling.

Odour threshold: not applicable

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No risks worthy of mention.

10.4. Conditions to avoid

none

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

none

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

Irritation and corrosivity

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

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Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

May cause damage to organs through prolonged or repeated exposure. (cristobalite)

Aspiration hazard

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

Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

Further information

Toxicological data are not available.

SECTION 12: Ecological information**12.1. Toxicity**

The product is not: Ecotoxic.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The product has not been tested.

12.6. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations**13.1. Waste treatment methods****Advice on disposal**

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation. May be disposed of in household waste landfill.

Waste disposal number of used product

200301 MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS; other municipal wastes; mixed municipal waste

Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information**14.5. Environmental hazards**

ENVIRONMENTALLY HAZARDOUS: no

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14.6. Special precautions for user

No information available.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

Other applicable information

Not a hazardous material with respect to transportation regulations.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information****Additional information**

According to EC directives or the corresponding national regulations the product does not have to be labelled.

National regulatory information**Employment restrictions:**

Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water contaminating class (D):**15.2. Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information**Changes**This data sheet contains changes from the previous version in section(s):
1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16.**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 Labelling of Chemicals
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service
 LC50: Lethal concentration, 50%
 LD50: Lethal dose, 50%

Relevant H and EUH statements (number and full text)

H373 May cause damage to organs (lung) through prolonged or repeated exposure if inhaled.

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations. The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights.

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(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)