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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 19.01.2016

Version number 2

Revision: 18.01.2016

| SECTION 1. Ide | entification of the substance/mixture an | nd of the company |
|--|---|--|
| undertaking | | iu or the company |
| · 1.1 Product identifie | r | |
| · Trade name: Xai | ntalgin select, Xantalgin crono | |
| | ed uses of the substance or mixture and uses advise | ed against |
| · Application of the | substance / the mixture Dental impression material | |
| •• | oplier of the safety data sheet oplier: mbH | Tel.: 0800 437252 |
| 1.4 Emergency telep | nent: E-Mail: msds@kulzer-dental.com hone number: T (24-Hour-Number):GBK GmbH +49 (0)6132-84463 | |
| SECTION 2: Haza | ards identification | |
| Classification acc Eye Irrit. 2 H319 Skin Sens. 1 H317 STOT RE 2 H373 Case A constraints 2.2 Label elements Labelling accordi | | peated exposure. |
| Kieselguhr, soo dipotassium he. • Hazard statem H319 Causes s H317 May caus H373 May caus • Precautionary P280 P305+P351+P3 P321 P363 P333+P313 | a ash flux-calcined xafluorotitanate ents erious eye irritation. se an allergic skin reaction. se damage to organs through prolonged or repeated exp statements Wear protective gloves/protective clothing/eye protect 338 IF IN EYES: Rinse cautiously with water for several lenses, if present and easy to do. Continue rinsing. Specific treatment (see on this label). Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice/at | ction/face protection. I minutes. Remove conta ttention. |
| P337+P313 · 2.3 Other hazards - | If eye irritation persists: Get medical advice/attention |). |
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· Results of PBT and vPvB assessment

• **PBT:** Not applicable.

• vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

· 3.2 Chemical characterisation: Mixtures

Description: -

| · Dangerous com | ponents: | |
|---------------------|---|--------|
| | Kieselguhr, soda ash flux-calcined | 50-75% |
| EINECS: 272-489-0 | STOT RE 2, H373 | |
| | dipotassium hexafluorotitanate | 0-5% |
| EINECS: 240-969-9 | Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317; STOT SE 3, H335 | |
| · Additional inform | mation For the wording of the listed hazard phrases refer to section 16. | |

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - After inhalation Supply fresh air; consult doctor in case of symptoms.
 - · After skin contact instantly wash with water and soap and rinse thoroughly.
 - After eye contact Rinse opened eye for several minutes under running water.
 - · After swallowing
 - Rinse out mouth and then drink plenty of water.
 - In case of persistent symptoms consult doctor.
 - Seek immediate medical advice.
- 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.

SECTION 5: Firefighting measures

· 5.1 Extinguishing media

- · Suitable extinguishing agents
- CO2, 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
- Formation of toxic gases is possible during heating or in case of fire.
- 5.3 Advice for firefighters
 - · Protective equipment: No special measures required.
 - · Additional information -

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- 6.2 Environmental precautions: No special measures required.
 6.3 Methods and material for containment and cleaning up:
- Collect mechanically.

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Send for recovery or disposal in suitable containers.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 13 for information on disposal.

See Section 8 for information on personal protection equipment.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling Wear protective equipment. Keep unprotected persons away. Information about protection against explosions and fires: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage

Requirements to be met by storerooms and containers: No special requirements.

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

- Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see item 7.

8.1 Control parameters

Components with critical values that require monitoring at the workplace:

14807-96-6 Talc (Mg3H2(SiO3)4)

WEL Long-term value: 1 mg/m³

8002-74-2 Paraffin waxes and Hydrocarbon waxes

WEL Short-term value: 6 mg/m³

Long-term value: 2 mg/m³

1309-48-4 magnesium oxide

WEL Long-term value: 10* 4** mg/m³

· Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

· Personal protective equipment

General protective and hygienic measures

Keep away from foodstuffs, beverages and food. Instantly remove any soiled and impregnated garments.

- Wash hands during breaks and at the end of the work.
- · Breathing equipment: Not required. Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

If skin contact cannot be avoided, protective gloves are recommended to avoid possible sensitization.

Check protective gloves prior to each use for their proper condition.

recommended

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance

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and has therefore to be checked prior to the application. • **Penetration time of glove material** The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- For the permanent contact of a maximum of 15 minutes gloves made of the following *materials are suitable:* Butyl rubber, BR Nitrile rubber, NBR

· Eye protection: Safety glasses

· Body protection: Light weight protective clothing

| 9.1 Information on basic physical and · General Information · Appearance: | d chemical properties | |
|--|---|--|
| · Form: · Colour: · Smell: · Odour threshold: | Solid. According to product specification Aromatic Not determined. | |
| · pH-value: | Not applicable. | |
| Change in condition Melting point/Melting range: Boiling point/Boiling range: | Not determined Not determined | |
| · Flash point: | Not applicable | |
| Inflammability (solid, gaseous) | Not determined. | |
| · Ignition temperature: | | |
| Decomposition temperature: | Not determined. | |
| · Self-inflammability: | Product is not selfigniting. | |
| · Danger of explosion: | Product is not explosive. | |
| Critical values for explosion: Lower: Upper: | Not determined. Not determined. | |
| · Steam pressure: | Not applicable. | |
| · Density | Not determined | |
| Settled apparent density Relative density Vapour density Evaporation rate | 250-500 kg/m3 Not determined. Not applicable. Not applicable. | |
| Solubility in / Miscibility with Water: | Insoluble | |

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Viscosity:
 dynamic:
 kinematic:

9.2 Other information

Not applicable. Not applicable. No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
 - · Conditions to be avoided: 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

· Additional information: -

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects

- Acute toxicity Based on available data, the classification criteria are not met.
 - · Primary irritant effect:
 - · Skin corrosion/irritation Based on available data, the classification criteria are not met.
 - · Serious eye damage/irritation
 - Causes serious eye irritation.
 - · Respiratory or skin sensitisation
 - Guinea-Pig Maximisation Test (OECD 406): negative

May cause an allergic skin reaction. • Additional toxicological information:

The product contains no relevant dust particles (particel size > 100 micrometer) because the surface of the kieselguhr is coated with paraffin wax.

- CMR effects (carcinogenity, 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
- May cause damage to organs through prolonged or repeated exposure.

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

SECTION 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.
- · 12.5 Results of PBT and vPvB assessment
 - · **PBT:** Not applicable.
 - **vPvB:** Not applicable.

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· 12.6 Other adverse effects No further relevant information available.

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SECTION 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. Disposal must be made according to official regulations.

· Uncleaned packagings:

· Recommendation: Disposal must be made according to official regulations.

| SECTION 14: Transport information | n | |
|--|-----------------------------------|--|
| 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 Packing 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 Marpol and the IBC Code | x II of Not applicable. | |
| · Transport/Additional information: | - | |
| UN "Model Regulation": | Void | |

SECTION 15: Regulatory information

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

No further relevant information available.

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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 • Relevant phrases
 H302 Harmful if swallowed.
 H317 May cause an allergic skin reaction.
 H317 May cause an allergic skin reaction.
 H318 Causes serious eye damage.
 H335 May cause respiratory irritation.
 H373 May cause damage to organs through prolonged or repeated exposure.
 Abbreviations and acronyms:
 Aps: 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 Harmonised System of Classification and Labelling of Chemicals
 EINECS: European List of Notified Chemical Substances
 ELINECS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 PBT: Persistent and very Bioaccumulative
 Acute Tox. 4: Acute toxicity, Hazard Category 1
 Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
 Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
 Striot Se 3: Specific target organ toxicity - Single exposure, Hazard Category 3
 STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2
 * Data compared to the previous version altered.