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SECTION1: IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier:

Substance name:	Kaolinitic clay
Synonyms:	plastic clay, ball clay, fine clay
Chemical name and formula:	Hydrous aluminium silicate
Trade name:	Weichporzellan-Dreh- und Stanzmasse "Mont Blanc" Nr. 011, schnee- weiß, unschamottiert;
CAS number:	none – (999999-99-4: Naturally occurring substances)
EC number:	none – (310-127-6: Naturally occurring substances)
Molecular Weight:	unspecified for this UVCB substance
REACH Registration number:	Exempted in accordance with Annex V.7 of Regulation (EC) 1907/2006

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

1.2.1 Relevant identified uses

Main applications - non-exhaustive list: Ceramics (sanitaryware, floor tiles, wall tiles, roof tiles, tiles; porcelain, tableware, refractories, etc.) Enamels Glass Fillers Deposit sealing Paint Plastic & Rubber Adhesives and Sealant

Building material & Cement Fertilisers & Agricultural products

1.2.2 Uses advised against

There is no use advised against.

1.3 Details of the supplier of the safety data sheet:

Name:	Arno Witgert, Inh. DiplIng. (FH) Michael Liebig e. K.
Address:	Arno-Witgert-Str. 1, 56414 Herschbach/OT Wahnscheid, Germany
Phone N°:	0049 (0)6435/9223-0
Fax N°:	0049 (0)6435/9223-33

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E-mail of competent person responsible for SDS in the MS or in the EU:	m_liebig@witgert.de	
1.4 Emergency telephone number:		
European Emergency N°: Emergency telephone at the company Available outside office hours:	112 0049 (0)6435/9223-0 ☐ Yes	🖾 No
Other information (e.g. language of the phone service):	German/English	
SECTION 2: HAZARDS IDENTIFICATIO	N	
2.1 Classification of the substance:		
2.1.1 Classification according to Regulation (EC) No 1272/2008 [CLP] as amended		
Not classified as hazardous		
2.1.2 Additional information		
None.		
2.2 Label elements:		
Labelling according to Regulation (EC) No	o 1272/2008 [CLP]	

None

2.3 Other hazards:

The substance does not meet the criteria for PBT or vPvB substance according to Regulation (EC) No 1907/2006, Annex XIII.

No other hazards identified.

Kaolinitic clay is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances:

Kaolinitic clay is a UVCB substance sub-type 4. The purity of the product is 100 % w/w. This product contains less than 1% of quartz-fine fraction (CAS: 14808-60-7; EC: 238-878-4) which is self-classified as STOT RE1.

No M Factor assigned. No SCL assigned

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

Following inhalation:

Movement of the exposed individual from the area to fresh air is recommended.

<u>Following skin contact:</u> No special first aid measures necessary.

Following eye contact:

Rinse under water for at least one minute and seek medical attention if irritation persists.

Following ingestion:

No first aid measure required.

<u>Self-protection of the first aider</u>: No special precautions required

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

No acute and delayed symptoms and effects are observed.

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

No need for immediate medical attention; follow the advises given in section 4.1

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media:

<u>Suitable extinguishing media:</u> No specific extinguishing media is needed.

Unsuitable extinguishing media:

No restriction on the extinguishing media to be used.

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5.2 Special hazards arising from the substance or mixture:

None. The material is not flammable and it does not lead to hazardous thermal decomposition products.

5.3 Advice for fire fighters:

No specific fire-fighting protection is required.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel

Ensure adequate ventilation.

Keep dust levels to a minimum.

Keep unprotected persons away.

Avoid contact with skin, eyes, and personal clothing – wear suitable protective equipment (see section 8).

Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).

Take care of wet product on floor, which presents a slip hazard.

6.1.2 For emergency responders

Keep dust levels to a minimum.

Ensure adequate ventilation.

Keep unprotected persons away.

Avoid contact with skin, eyes, and personal clothing – wear suitable protective equipment (see section 8).

Avoid inhalation of dust – ensure that sufficient ventilation or suitable respiratory protective equipment is used, wear suitable protective equipment (see section 8).

Take care of wet product on floor, which presents a slip hazard.

6.2 Environmental precautions:

No special environmental measures are necessary.

6.3 Methods and material for containment and cleaning up:

Avoid dry sweeping and use water spraying or vacuum cleaning systems (with high-efficiency particulate air filter) to prevent airborne dust generation. Wear personal protective equipment in compliance with national legislation.

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6.4 Reference to other sections:

For more information on exposure controls/personal protection or disposal considerations, please refer to sections 8 and 13 of this safety data sheet.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

7.1.1 Protective measures

Keep dust levels to a minimum. Minimize dust generation.

Provide appropriate exhaust ventilation at places where airborne dust is generated. In case of insufficient ventilation, wear suitable respiratory protective equipment refer to section 8 of this safety data sheet. Other suitable controls may include enclosure, isolation, water suppression. Handle packaged products carefully to prevent accidental bursting. If you require advice on safe handling techniques, please contact your supplier or check the Good Practice Guide referred to in section 16.

7.1.2 Advice on general occupational hygiene

Keep dust levels to a minimum. Minimize dust generation.

General occupational hygiene measures are required to ensure safe handling of the substance. These measures involve good personal and housekeeping practices (i.e. regular cleaning with suitable cleaning devices), no drinking, eating and smoking in the work areas. Remove contaminated clothing and protective equipment before entering eating areas. Shower and change clothes at end of work shift. Do not wear contaminated clothing at home.

7.2 Conditions for safe storage, including any incompatibilities:

Minimise airborne dust generation and prevent wind dispersal during loading and unloading. Keep containers closed and store packaged products so as to prevent accidental bursting.

7.3 Specific end use(s):

If you require advice on specific uses, please contact your supplier.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

- 8.1 Control parameters
- 8.1.1 Components with occupational exposure limits rsp. biological occupational exposure limits requiring monitoring

8.1.1.1 Occupational exposure limit values:

A European Binding OEL (Occupational Exposure Limit) for respirable crystalline silica dust is set at 0.1 mg/m³ in the Directive (EU) 2017/2398, measured as an 8-hour TWA (Time Weighted Average). Maintain personal exposure below occupational exposure limits for dust (inhalable and respirable) as dictated in the national legislation.

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The OEL (Occupational Exposure Limit) for respirable crystalline silica dust is 0.5 mg/m³ in Germany, measured as an 8 hour TWA (Time Weighted Average). For the equivalent limits in other countries, please consult a competent occupational hygienist or the local regulatory authority.

Please refer to the Annex 1 of this SDS for the appropriate national exposure limit values lists for inhalable and respirable dust.

8.2 Exposure controls:

8.2.1 Appropriate engineering controls:

Minimise airborne dust generation. Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below specified exposure limits. If user operations generate dust, fumes or mist, use ventilation to keep exposure to airborne particles below the exposure limit. Apply organisational measures e.g. by isolating personnel from dusty areas. Remove and wash soiled clothing.

8.2.2 Individual protection measures such as personal protective equipment:

8.2.2.1 Eye/face protection

Wear safety glasses with side-shields, or tight-fitting full-vision goggles in circumstances where there is a risk of penetrative eye injuries. Do not wear contact lenses.

8.2.2.2 Skin & hands protection

For skin, normal work clothes are appropriate.

For hands, appropriate protection (e.g. PVC, neoprene or natural rubber gloves) is recommended for workers who suffer from dermatitis or sensitive skin. Wash hands at the end of each work session.

8.2.2.3 Respiratory protection

Local ventilation to control airborne dust levels below occupational exposure limits is recommended. In case of prolonged exposure to airborne dust concentrations wear a respiratory protective equipment that complies with the requirements of European and national legislation. The use of a suitable particle filter mask type FFP1, FFP2 or FFP3 is recommended. See EN 143: 2000 (Respiratory Protective devices – Particle filters) and EN149: 2001 (Respiratory protective devices - Filtering half masks to protect against particles).

8.2.2.4 Thermal hazards

The substance does not represent a thermal hazard, thus special consideration is not required.

8.2.3 Environmental exposure controls:

All ventilation systems should be filtered before discharge to atmosphere.

Avoid wind dispersal. Contain the spillage.

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solid (bulk, lumps, pellets, granulate or powder)

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 Information on basic physical and chemical properties:
 - a) Physical state:
 - b) Colour:
 - c) Odour:
 - white odourless d) Melting point: > 450 °C (study result, EU A.1 method)
 - e) Boiling point: not applicable (solid with a melting point > $450 \,^{\circ}C$)
 - not applicable (solid with a melting point > $450 \,^{\circ}C$)
 - f) Flash point:g) Evaporation rate: not applicable (solid with a melting point > $450 \,^{\circ}\text{C}$)

 - h) Flammability: non flammable (study result, EU A.10 method) do not apply to solids

3-7

- i) Explosive limits:
- Flash point: not applicable j)
- k) Auto-ignition temperature: do not apply to solids
- Decomposition temperature: not applicable (solid with a melting point > 450 °C) I)
- m) pH:
- n) Kinematic viscosity: do not apply to solids (solid with a melting point > 450 °C)
- o) Solubility in water: <1 mg/L at 20°C (study results, EU A.6 method)
- p) Partition coefficient n-oct./water: not applicable (inorganic substance)
- q) Vapour pressure: not applicable (solid with a melting point > 450 °C)
- r) Relative density: 2.6 g/cm³
- s) Vapour density: not applicable (solid with a melting point > $450 \,^{\circ}C$)
- Particle characteristics: mean particle size (d50): 0.5 - 2.5 µm by SediGraph t)

9.2 Other information:

None.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

Inert, not reactive.

10.2 Chemical stability:

Kaolinitic clay is chemically stable.

10.3 Possibility of hazardous reactions:

No hazardous reaction.

10.4 Conditions to avoid:

None.

10.5 Incompatible materials:

None.

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10.6 Hazardous decomposition products:

None.

SECTION 11: TOXICOLOGICAL INFORMATION

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

Toxicity endpoints	Outcome of the effects assessment	
Acute toxicity	Kaolinitic clay is not acutely toxic. By read-across with the substance kaolin.	
	Oral LD ₅₀ > 5000 mg/kg bw (OECD 401)	
	Dermal LD ₅₀ > 2000 mg/kg bw (OECD 402).	
	Inhalation $LC_{50}(4h) > 5.07 \text{ mg/L}$ air (OECD 436).	
Skin corrosion / irritation	Kaolinitic clay is not irritating to skin (OECD 404).	
Serious eye damage / irritation	Kaolinitic clay is not irritating to eye (OECD 405).	
Respiratory or skin sensitisation	Kaolinitic clay is not a skin sensitiser in accordance with the local lymph node assay (OECD 429). By read-across with the substance kaolin.	
Germ cell mutagenicity	Kaolinitic clay is not genotoxic (OECD 471, OECD 490). By read-across with the substance kaolin.	
Carcinogenicity	Read-across with the substance kaolin.	
	Epidemiological studies covering a large number of workers did not reveal an explicit association between kaolin exposure and tumour formation.	
Reproductive toxicity	No data available.	
STOT - single exposure	Read-across with the substance kaolin.	
	No organ toxicity is observed in acute tests.	
STOT - repeated exposure – inhalation	No adverse effects observed on kaolinitic clay in an in-vivo 14-day inhalation toxicity study at the tested doses up to 110 mg/m ³ .	
	Read-across with the substance kaolin	
	Prolonged and massive exposure to kaolin dust containing respirable crystalline silica may lead to pneumoconiosis. Results indicate that the severity of effects may increase with the amount of crystalline silica in the respirable dust.	

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Toxicity endpoints	Outcome of the effects assessment
Aspiration hazard	No data available

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Available data for the substance have been considered against the criteria laid down in Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605) and found not to apply

11.2.2 Other information

None

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity:

12.1.1 Acute/Prolonged toxicity to fish

LC₅₀ (96h) for freshwater fish (rainbow trout Oncorhynchus mykiss): >1000 mg/L (Method OECD 203)

12.1.2 Acute/Prolonged toxicity to aquatic invertebrates

EC₅₀ (48h) for aquatic invertebrates (Daphnia magna): >1000 mg/L (Method OECD 202)

12.1.3 Acute/Prolonged toxicity to aquatic plants

EC₅₀ (72h) for freshwater algae (Raphidocelis Subcapitata): > 1000 mg/L (Method OECD 201)

12.1.4 Toxicity to micro-organisms e.g. bacteria

No data available

12.1.5 Chronic toxicity to aquatic organisms

No data available

12.1.6 Toxicity to soil dwelling organisms

No data available

12.1.7 Toxicity to terrestrial plants

No data available

12.1.8 General effect

No specific adverse effects known.

12.2 Persistence and degradability:

Abiotic Degradation:

The substance is inorganic and therefore will not undergo abiotic degradation.

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Biodegradation:

The substance is inorganic and therefore will not undergo biodegradation.

12.3 Bioaccumulative potential:

Not relevant for inorganic substances. Bioaccumulation is not expected.

12.4 Mobility in soil:

Kaolinitic clay is almost insoluble and thus presents a low mobility in most soils.

12.5 Results of PBT and vPvB assessment:

This substance does not meet the criteria for classification as PBT or vPvB.

12.6 Endocrine disrupting properties:

Available data for the substance have been considered against the criteria laid down in Regulations ((EC) No 1907/2006, (EU) 2017/2100, (EU) 2018/605) and found not to apply.

12.7 Other adverse effects:

According to the criteria of the European classification and labelling system, the substance does not require classification as hazardous for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

- Wastes should be handled in accordance with local and national regulations.
- Dispose of waste in such a way to avoid dust generation. Where possible, recycling should be preferred to disposal.

Packaging treatment:

Dust formation from residues in packaging should be avoided and suitable worker protection assured. Store used packaging in enclosed receptacles. Recycling and disposal of packaging should be carried out in compliance with local regulations..

14 TRANSPORT INFORMATION

14.1 UN-Number or ID number:

Not relevant. No UN-number.

14.2 UN proper shipping name:

Not relevant.

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14.3 Transport hazard class(es):

ADR:	Not classified
IMDG:	Not classified
ICAO/IATA:	Not classified
RID:	Not classified

14.4 Packing group:

Not applicable.

14.5 Environmental hazards:

Not relevant.

14.6 Special precautions for user:

Avoid any release of dust during transportation, by using air-tight tanks for powders and covered trucks for pebbles.

14.7 Maritime transport in bulk according to IMO instruments:

IMSBC Code:

Bulk cargo shipping name (BCSN):	clay
Harmful to the marine environment (HME):	No.
Material hazardous only in bulk (MHB):	Not applicable.
Cargo group:	С

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance:

National legislations:

None.

Other EU or International regulations:

None.

15.2 Chemical safety assessment:

Kaolinitic clay is exempted from REACH registration in accordance with Annex V.7 of Regulation (EC) 1907/2006. Thus, no formal chemical safety assessment has been carried out for this substance by the supplier.

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SECTION 16: OTHER INFORMATION

Data are based on our latest knowledge but do not constitute a guarantee for any specific product features and do not establish a legally valid contractual relationship.

16.1 Indication of changes:

The SDS has been revised to comply with Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of REACH.

16.2 Abbreviations and acronyms:

- EC₅₀: median effect concentration
- LC₅₀: median lethal concentration
- LD₅₀: median lethal dose
- OEL: occupational exposure limit
- PBT: persistent bioaccumulative toxic
- TWA: time weighted average
- vPvB: very persistent, very bioaccumulative

16.3 Relevant H-phrases (number and full text):

None.

16.4 Further information:

Prolonged and/or massive exposure to respirable crystalline silica-containing dust may cause silicosis, a nodular pulmonary fibrosis caused by deposition in the lungs of fine respirable particles of crystalline silica.

In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans (human carcinogen category 1). However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated. (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France.). In 2009, in the Monographs 100 series, IARC confirmed its classification of Silica Dust, Crystalline, in the form of Quartz and Cristobalite (IARC Monographs, Volume 100C, 2012).

In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. "There is

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sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk..." (SCOEL SUM Doc 94-final, June 2003). So there is a body of evidence supporting the fact that increased cancer risk would be limited to people already suffering from silicosis. Worker protection against silicosis should be assured by respecting the existing regulatory occupational exposure limits and implementing additional risk management measures where required (see paragraph below).

A multi-sectoral social dialogue agreement on Workers Health Protection through the Good Handling and Use of Crystalline Silica and Products Containing it was signed on 25 April 2006. This autonomous agreement, which received the European Commission's financial support, is based on a Good Practices Guide. The requirements of the Agreement came into force on 25 October 2006. The Agreement was published in the Official Journal of the European Union (2006/C 279/02). The text of the Agreement and its annexes, including the **Good Practices Guide**, are available from http://www.nepsi.eu and provide useful information and guidance for the handling of products that may generate respirable dust of crystalline silica. Literature references are available on request from EUROSIL, the European Association of Industrial Silica Producers,

A source of information on how to manage the risks on respirable crystalline silica is the website <u>https://safesilica.eu/</u>. In addition, it provides a handy FAQs section, as well as information on the science behind crystalline silica.

Dioxins

The material may contain trace amounts (parts per trillion) of naturally occurring dioxin congeners (PCDD, PCDF) including TCDD. 2,3,7,8. TCDD has been classified as a known human carcinogen by the IARC in Monograph 69 (1997). If this material is used for food, feed, or cosmetic purposes, it is highly recommended to check whether it fulfils the requirements of relevant legislation, in particular with regards to dioxins content.

<u>Disclaimer</u>

This safety data sheet (SDS) is based on the legal provisions of the REACH Regulation (EC 1907/2006; article 31 and Annex II), as amended. Its contents are intended as a guide to the appropriate precautionary handling of the material. It is the responsibility of recipients of this SDS to ensure that the information contained therein is properly read and understood by all people who may use, handle, dispose or in any way come in contact with the product. Information and instructions provided in this SDS are based on the current state of scientific and technical knowledge at the date of issue indicated. It should not be construed as any guarantee of technical performance, suitability for particular applications, and does not establish a legally valid contractual relationship. This version of the SDS supersedes all previous versions.

End of the safety data sheet

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Annex 1

Occupational Exposure Limits in mg/m ³ 8 hours TWA dust			
Member State	Non specified (inert) dust INHALABLE	Non specified (inert) dust RESPIRABLE	
Austria	10	5	
Belgium	10	3	
Bulgaria		4	
Denmark	10	5	
Finland	10	/	
France	10	5	
Germany	10	0.51	
Greece	10	5	
Ireland	10	4	
Italy	10	3	
Lithuania		10	
Luxembourg	10	6	
Netherlands	10	5	
Norway	10	5	
Poland	10	/	
Portugal/	10	5	
Romania		10	
Slovakia	10		
Spain	10	3	
Sweden		5	
Switzerland		6	
UK	10	4	

¹ Defined for a density of 1 g/cm³, i.e. for minerals with a common density of 2,5 g/cm³, a calculated OEL of 1,25 mg/m³ applies.