



Safety Data Sheet

VEL MIX Stone (White & Pink)

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
Issue date: 27/11/2013 Revision date: 21/09/2022 Supersedes version of: 10/03/2017 Version: 4.0

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

1.1. Product identifier

Product form : Mixture
Product name : VEL MIX Stone (White & Pink)

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

Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : Preparation intended for dental medical use
Function or use category : Dental materials.

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Kerr Italia S.r.l.
Via Passanti, 174
Scafati (SA) 84018 (Italy)
T +39 081 850 3511 / Information Phone Number: 1-800-841-1428 (Customer Service)
safety@envistaco.com

1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300
International and Maritime Telephone Number +1 (703) 527-3887

Country	Official advisory body	Address	Emergency number	Comment
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266	
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD 2090 Msida	+356 2545 6508	
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182 +44 191 2606180	Hours of operation: 24hrs

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

EUH-statements : EUH212 - Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

2.3. Other hazards

Other hazards which do not result in classification : Dust may cause painful eye irritation and tearing. Dust of the product, if present, may cause respiratory irritation after an excessive inhalation exposure.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

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The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or 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 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Calcium sulfate dihydrate	(CAS-No.) 10101-41-4 (EC-No.) 600-148-1 (REACH-no) 01-2119488953-20	< 1	Not classified
ironoxide	(CAS-No.) 1309-37-1 (EC-No.) 215-168-2 (REACH-no) 01-2119457614-35	< 0.5	Not classified
titanium dioxide	(CAS-No.) 13463-67-7 (EC-No.) 236-675-5 (EC Index-No.) 022-006-00-2 (REACH-no) 01-2119489379-17	< 0.5	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel unwell.
First-aid measures after skin contact	: Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: If swallowed, rinse mouth with water (only if the person is conscious). Call a POISON CENTER/doctor if you feel unwell.

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

Symptoms/effects	: In all cases of doubt, or when symptoms persist, seek medical attention.
Symptoms/effects after inhalation	: Dust from this product may cause irritation to the respiratory tract.
Symptoms/effects after skin contact	: Prolonged or repeated contact may cause skin to become dry.
Symptoms/effects after eye contact	: Dust from this product may cause eye irritation.

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

Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO2) and powder.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Non-flammable.
Explosion hazard	: Product is not explosive.
Hazardous decomposition products in case of fire	: Carbon dioxide. Carbon monoxide. Sulphur oxides.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper personal protective equipment, including respiratory protection (EN137).

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid dust formation. Do not breathe dust. Avoid contact with skin and eyes. Concerning personal protective equipment to use, see section 8.

6.1.1. For non-emergency personnel

Protective equipment : See Section 8.
Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup and emergency crew with proper protection.
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.
Methods for cleaning up : Sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.

6.4. Reference to other sections

For further information refer to section 13. See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Avoid contact with skin and eyes. Avoid dust formation. Do not breathe dust.
Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store in original container. Store in dry protected location to prevent any moisture contact.
Incompatible materials : reducing materials. Acids.
Storage area : Store in a well-ventilated place.

7.3. Specific end use(s)

No additional data.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Calcium sulfate dihydrate (10101-41-4)	
Ireland - Occupational Exposure Limits	
Local name	Gypsum
OEL TWA [1]	4 mg/m ³ respirable dust 10 mg/m ³ total inhalable dust
Regulatory reference	Chemical Agents Code of Practice 2021
United Kingdom - Occupational Exposure Limits	
Local name	Gypsum
WEL TWA (OEL TWA) [1]	10 mg/m ³ inhalable dust 4 mg/m ³ respirable
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

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ironoxide (1309-37-1)	
Ireland - Occupational Exposure Limits	
Local name	Iron oxide, fume (as Fe)
OEL TWA [1]	5 mg/m ³
OEL STEL	10 mg/m ³
Regulatory reference	Chemical Agents Code of Practice 2021
United Kingdom - Occupational Exposure Limits	
Local name	Iron oxide
WEL TWA (OEL TWA) [1]	5 mg/m ³ fume (as Fe) 4 mg/m ³ Rouge, respirable 10 mg/m ³ Rouge, total inhalable
WEL STEL (OEL STEL)	10 mg/m ³ fume (as Fe)

titanium dioxide (13463-67-7)	
Ireland - Occupational Exposure Limits	
Local name	Titanium dioxide
OEL TWA [1]	10 mg/m ³ total inhalable dust 4 mg/m ³ respirable dust
Regulatory reference	Chemical Agents Code of Practice 2021
United Kingdom - Occupational Exposure Limits	
Local name	Titanium dioxide
WEL TWA (OEL TWA) [1]	10 mg/m ³ total inhalable 4 mg/m ³ respirable
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Wear dust resistant safety goggles where there is danger of eye contact. STANDARD EN 166.

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Not required for normal conditions of use

8.2.2.3. Respiratory protection

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Respiratory protection:

Dust production: dust mask with filter type P2. Standard EN 143:2021

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Other information:

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke during use. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White, pink.
Appearance	: Powder.
Odour	: Odourless.
Odour threshold	: Not determined.
Melting point	: Not determined.
Freezing point	: Not determined.
Boiling point	: Not determined.
Flammability	: Not determined.
Explosive properties	: Product is not explosive.
Oxidising properties	: Non flammable.
Explosive limits	: Not determined.
Lower explosive limit (LEL)	: Not applicable
Upper explosive limit (UEL)	: Not applicable
Flash point	: Not determined.
Auto-ignition temperature	: Not determined.
Decomposition temperature	: Not determined.
pH	: Not determined.
pH solution	: 6 – 9
Viscosity, kinematic	: Not determined.
Viscosity, dynamic	: Not determined.
Solubility	: In water, material soluble. Water: 0.2 – 1 g/100ml
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: Not determined.
Vapour pressure	: Not determined.
Vapour pressure at 50 °C	: Not available
Density	: 2.3 – 2.7 g/cm³
Relative density	: Not determined.
Relative vapour density at 20 °C	: Not determined.
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Relative evaporation rate (butylacetate=1) : Not determined.

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

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10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No polymerization.

10.4. Conditions to avoid

Heat. No flames, no sparks. Eliminate all sources of ignition. Water, humidity.

10.5. Incompatible materials

Acids.

10.6. Hazardous decomposition products

No decomposition if stored and used normally.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Additional information	: Based on available data, the classification criteria are not met

Calcium sulfate dihydrate (10101-41-4)

LD50 oral rat	> 3000 mg/kg
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titanium dioxide (13463-67-7)

LD50 oral rat	> 10000 mg/kg
LC50 Inhalation - Rat (Dust/Mist)	> 6.82 mg/l/4h

Skin corrosion/irritation	: Not classified pH: Not determined.
Additional information	: Based on available data, the classification criteria are not met Repeated exposure may cause skin dryness or cracking.
Serious eye damage/irritation	: Not classified pH: Not determined.
Additional information	: Based on available data, the classification criteria are not met Dust from this product may cause eye irritation
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met Dust from this product may cause irritation to the respiratory tract
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

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Viscosity, kinematic	Not determined.
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11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or 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 at a concentration equal to or greater than 0,1 %

11.2.2 Other information

Potential adverse human health effects and symptoms : For further information see section 4

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

Calcium sulfate dihydrate (10101-41-4)

LC50 - Fish [1]	876 mg/l <i>Lepomis macrochirus</i> (Bluegill)
EC50 - Crustacea [1]	30000 mg/l

ironoxide (1309-37-1)

LC50 - Fish [1]	> 1000 mg/kg 96 h <i>Leuciscus idus</i> (golden orfe)
LC50 - Other aquatic organisms [1]	> 5000 mg/kg (24 hours - <i>Pseudomonas fluorescens</i>)

titanium dioxide (13463-67-7)

LC50 - Fish [1]	> 1000 mg/l <i>Fundulus heteroclitus</i>
EC50 - Crustacea [1]	> 1000 mg/l (48 hours - <i>Daphnia magna</i>)

12.2. Persistence and degradability

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Persistence and degradability	No data available.
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12.3. Bioaccumulative potential

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Partition coefficient n-octanol/water (Log Pow)	Not determined.
Bioaccumulative potential	No data.

12.4. Mobility in soil

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Ecology - soil	Solidifies on exposure to water(moist).
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12.5. Results of PBT and vPvB assessment

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This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

Other adverse effects : None to our knowledge.

Additional information : No other effects known

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	: Must not be disposed together with household garbage. Do not allow product to reach the sewage system.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Empty container completely. After cleaning, recycle or dispose of at an authorised site.
European List of Waste (LoW) code	: 18 01 07 - chemicals other than those mentioned in 18 01 06

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID /

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

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 Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

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SECTION 16: Other information

Indication of changes:

Section	Changed item	Change	Comments
2.2	EUH-statements	Added	

Data sources : 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 Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

EUH212

Warning! Hazardous respirable dust may be formed when used. Do not breathe dust.

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.