

SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)

VENTURA IMPRESS 2.0 PUTTY SOFT REGULAR SET



Version 1 Date of compilation: 24/07/2015

Version 8 (replaces version 7)

Revision date: 22/05/2024

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING.

1.1 Product identifier.

Product Name: VENTURA IMPRESS 2.0 PUTTY SOFT REGULAR SET
MSDS valid of all kind of packagings of the same product.

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

For dental use

Uses advised against:

Uses other than those recommended.

1.3 Details of the supplier of the safety data sheet.

Company: **MADESPA, S.A.**
Address: Calle Río Torviscal, 8
City: 45007 - Toledo
Province: Toledo
Telephone: 925 241 025
E-mail: calidad@malespa.com
Web: www.malespa.com

1.4 Emergency telephone number: 925 241 025 (Only available during office hours; Monday-Friday; 07:00-15:00)

SECTION 2: HAZARDS IDENTIFICATION.

2.1 Classification of the substance or mixture.

In accordance with Regulation (EC) No 1272/2008:

STOT RE 2 : May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements.

Labelling in accordance with Regulation (EC) No 1272/2008:

Pictograms:



Signal Word:

Warning

Hazard statements:

H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements:

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P314 Get medical advice/attention if you feel unwell.
P501 Dispose of contents/container to ...

Contains:
cristobalite

Although classified according to EC criteria, this product is exempt from labelling according to article 23 and Annex 1 (section 1.3.4.1) of regulation CE No. 1272/2008.

2.3 Other hazards.

The mixture does not contain substances classified as PBT.
The mixture does not contain substances classified as vPvB.

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The mixture does not contain any endocrine disrupting properties substances.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

3.1 Substances.

Not applicable.

3.2 Mixtures.

Substances posing a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, assigned a Community exposure limit in the workplace, and classified as PBT/vPvB or included in the Candidate List:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 14464-46-1 EC No: 238-455-4	cristobalite	10 - 100 %	STOT RE 2, H373	-
CAS No: 68855-54-9 EC No: 272-489-0 Registration No: 01- 2119488518-22-XXXX	Kieselguhr, soda ash flux-calcined	1 - 10 %	STOT RE 2, H373	-

(*) The complete text of the H phrases is given in section 16 of this Safety Data Sheet.

[2] Substance with a national workplace exposure limit (see section 8.1).

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Eye contact.

Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact.

Remove contaminated clothing and shoes. Wash with soap and water.

Ingestion.

Do not induce vomiting. Rinse mouth thoroughly.

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

Long-term chronic exposure may result in injury to certain organs or tissues.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

SECTION 5: FIREFIGHTING MEASURES.

The product does not present any particular risk in case of fire.

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5.1 Extinguishing media.

Suitable extinguishing media:

Extinguisher powder or CO₂. In case of more serious fires, also alcohol-resistant foam and water spray.

Unsuitable extinguishing media:

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

5.2 Special hazards arising from the substance or mixture.

Special risks.

None known. For further information, refer to section 10: "Stability and Reactivity".

5.3 Advice for firefighters.

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

Fire protection equipment.

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

SECTION 6: ACCIDENTAL RELEASE MEASURES.

6.1 Personal precautions, protective equipment and emergency procedures.

For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions.

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up.

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

SECTION 7: HANDLING AND STORAGE.

7.1 Precautions for safe handling.

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

7.2 Conditions for safe storage, including any incompatibilities.

Store according to local legislation. Observe indications on the label. Store the containers between 5 and 25 °C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

7.3 Specific end use(s).

Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

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8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls.

Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Concentration:	100 %		
Uses:	For dental use		
Breathing protection:			
PPE:	Particle filter mask		
Characteristics:	«CE» marking, category III. Made of filtering material, it covers nose, mouth and chin.		
CEN standards:	EN 149		
Maintenance:	Check for any tears, defects, etc. before use. Since it is disposable individual protection equipment, it should be replaced after use.		
Observations:	Does not protect worker unless properly adjusted. Follow the manufacturer's instructions regarding suitable use of the equipment.		
Filter Type needed:	P2		
Hand protection:			
PPE:	Protective gloves against chemicals.		
Characteristics:	«CE» marking, category III.		
CEN standards:	EN 374-1, En 374-2, EN 374-3, EN 420		
Maintenance:	Keep in a dry place, away from any sources of heat, and avoid exposure to sunlight as much as possible. Do not make any changes to the gloves that may alter their resistance, or apply paints, solvents or adhesives.		
Observations:	Gloves should be of the appropriate size and fit the user's hand well, not being too loose or too tight. Always use with clean, dry hands.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.):	> 480
		Material thickness (mm):	0,35
Eye protection:			
PPE:	Protective goggles against particle impacts.		
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
Skin protection:			
PPE:	Protective clothing.		
Characteristics:	«CE» marking, category II. Protective clothing should not be too tight or loose in order not to obstruct the user's movements.		
CEN standards:	EN 340		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing should offer a level of comfort in line with the level of protection provided in terms of the hazard against which it protects, bearing in mind environmental conditions, the user's level of activity and the expected time of use.		
PPE:	Work footwear.		
Characteristics:	«CE» marking, category II.		
CEN standards:	EN ISO 13287, EN 20347		
Maintenance:	This product adapts to the first user's foot shape. That is why, as well as for hygienic reasons, it should not be used by other people.		
Observations:	Work footwear for professional use includes protection elements aimed at protecting users against any injury resulting from an accident		

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

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9.1 Information on basic physical and chemical properties.

Physical state: Solid

Colour: Blanco grisáceo

Odour: Odourless

Odour threshold: Not applicable/Not available due to the nature/properties of the product

Melting point: Not applicable/Not available due to the nature/properties of the product

Freezing point: Not applicable/Not available due to the nature/properties of the product

Boiling point or initial boiling point and boiling range: Not applicable/Not available due to the nature/properties of the product

Flammability: Not applicable/Not available due to the nature/properties of the product

Lower explosion limit: Not applicable/Not available due to the nature/properties of the product

Upper explosion limit: Not applicable/Not available due to the nature/properties of the product

Flash point: >200 °C

Auto-ignition temperature: >400 °C

Decomposition temperature: >200ADICION PUTTY 2 FAST-300 ml - GRANEL °C

pH: Not applicable/Not available due to the nature/properties of the product

Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product

Solubility: Diethylether: Miscible, Chlorinated solvents: miscible, Aromatic hydrocarbons: Miscible, Aliphatic hydrocarbons: miscible, Acetone: Very slightly soluble, Ethanol: Very slightly soluble

Hydrosolubility: Practically insoluble

Liposolubility: Not applicable/Not available due to the nature/properties of the product

Partition coefficient n-octanol/water (log value): Not applicable/Not available due to the nature/properties of the product

Vapour pressure: <0,1 hPa

Absolute density: Not applicable/Not available due to the nature/properties of the product

Relative density: 1.55

Relative vapour density: Not applicable/Not available due to the nature/properties of the product

Particle characteristics: Not applicable/Not available due to the nature/properties of the product

9.2 Other information

Information with regard to physical hazard classes

Oxidizing solids:

Oxidizing properties: According to the data on the componentes not considered as oxidizing (evaluation by structure-activity).

SECTION 10: STABILITY AND REACTIVITY.

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under the recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling.

10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products.

Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors. Amorphous silica.

SECTION 11: TOXICOLOGICAL INFORMATION.

11.1 Information on hazard classes as defined in Regulation (EC) N° 1272/2008.

Toxicological information about the substances present in the composition.

Name	Acute toxicity			
	Type	Test	Kind	Value

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cristobalite CAS No: 14464-46-1 EC No: 238-455-4	Oral	LD50	Rat	>2000 mg/L
	Dermal			
	Inhalation	LC50	Rat	2.6 mg/L
Kieselguhr, soda ash flux-calcined CAS No: 68855-54-9 EC No: 272-489-0	Oral	LD50	Rat	>2000 mg/kg
	Dermal			
	Inhalation	CL50	Rat	>2.6 mg/l

Acute toxicity:

Oral:

Product:

Not classified for acute toxicity based on available data.

Dermal:

Product:

Not classified for acute toxicity based on available data.

Inhalation:

Product:

No effects expected (assessment based on ingredients).

Repeated dose toxicity:

Product:

No effects expected (assessment based on ingredients).

Skin Corrosion/Irritation:

Product:

No effects expected (assessment based on ingredients).

Serious Eye Damage/Eye Irritation:

Product:

No effects expected (assessment based on ingredients).

Respiratory or Skin Sensitization:

Product:

No effects expected (assessment based on ingredients).

Germ Cell Mutagenicity:

In vitro:

Product:

No effects expected (assessment based on ingredients).

In vivo:

Product:

No effects expected (assessment based on ingredients).

Carcinogenicity:

Product:

No effects expected (assessment based on ingredients).

Reproductive toxicity:

Product:

No effects expected (assessment based on ingredients).

Reproductive toxicity (Fertility):

Product:

No data available.

Developmental toxicity (Teratogenicity):

Product:

No data available.

Specific Target Organ Toxicity - Single Exposure:

Product:

No effects expected (assessment based on ingredients).

Specific Target Organ Toxicity - Repeated Exposure:

Product:

No effects expected (assessment based on ingredients).

Aspiration Hazard:

Product:

No effects expected (assessment based on ingredients).

11.2 Information on other hazards.

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Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

There is no information available on other adverse health effects.

SECTION 12: ECOLOGICAL INFORMATION.

12.1 Toxicity.

No information is available regarding the ecotoxicity of the substances present.

12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.

No information is available on the degradability of the substances present.

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation of the substances present.

12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects.

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

No information is available about other adverse effects for the environment.

SECTION 13: DISPOSAL CONSIDERATIONS.

13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

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14.1 UN number or ID number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Description:

ADR/RID: Not classified as hazardous for transport.

IMDG: Not classified as hazardous for transport.

ICAO/IATA: Not classified as hazardous for transport.

14.3 Transport hazard class(es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): Not applicable.

14.6 Special precautions for user.

Transportation is not dangerous.

14.7 Maritime transport in bulk according to IMO instruments.

Not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles:

Designation of the substance, of the group of substances or of the mixture	Conditions of restriction
3. Liquid substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F; (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10; (c) hazard class 4.1; (d) hazard class 5.1.	1. Shall not be used in: - ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays, - tricks and jokes, - games for one or more participants, or any article intended to be used as such, even with ornamental aspects, 2. Articles not complying with paragraph 1 shall not be placed on the market. 3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they: - can be used as fuel in decorative oil lamps for supply to the general public, and, - present an aspiration hazard and are labelled with H304, 4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN). 5. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of dangerous substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met: (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: 'Keep lamps filled with this liquid out of the reach of children'; and, by 1 December 2010, 'Just a sip of lamp oil - or even sucking the wick of lamps - may lead to life-threatening

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	lung damage'; (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: 'Just a sip of grill lighter may lead to life threatening lung damage'; (c) lamp oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010. .
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15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: OTHER INFORMATION.

Complete text of the H phrases that appear in section 3:

H373 May cause damage to organs through prolonged or repeated exposure.

Classification codes:

STOT RE 2 : Specific target organ toxicity following a repeated exposure, Category 2

Changes regarding to the previous version:

- Changes in the information of the supplier (SECTION 1.3).
- Change in the hazard classification (SECTION 2.1).
- Removal of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Addition of precautionary statements/hazard statements/pictograms/signal word (SECTION 2.2).
- Modification of specific hazards (SECTION 2.3).
- Changes in the composition of the product (SECTION 3.2).
- Modifications in the first aid measures (SECTION 4.1).
- Modification of the symptoms (SECTION 4.2).
- Modification of the medical attention measures (SECTION 4.3).
- Modification in the firefighting measures (SECTION 5.3).
- Modifications in the accidental release measures (SECTION 6.1).
- Modifications in the handling and storage precautions (SECTION 7.1).
- Modifications in the handling and storage precautions (SECTION 7.2).
- Addition of personal protective equipment (SECTION 8.2).
- Modifications of the personal protective equipment (SECTION 8.2).
- Modification in the values of the physical and chemical properties (SECTION 9).
- Change in the hazard classification (SECTION 11.1).
- Modification of the classification ADR/IMDG/ICAO/IATA/RID (SECTION 14).
- National legislative changes (SECTION 15.1).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

Abbreviations and acronyms used:

CEN: European Committee for Standardization.

PPE: Personal protection equipment.

Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>

<http://echa.europa.eu/>

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Regulation (EU) 2020/878.

Regulation (EC) No 1907/2006.

Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.