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

VENTURA HIGH VEST HIGH SPEED



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

1.1 Product identifier.

Product Name: VENTURA HIGH VEST HIGH SPEED

UFI: 3C00-X01K-K00N-FE84

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.

Auxiliar material for the casting of dental prostheses

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 Jarama, 120
City: 45007 - 45007 Toledo

Province: Toledo Telephone: 925 241 025

E-mail: calidad@madespa.com Web: www.madespa.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 1: Causes damage to organs through prolonged or repeated exposure.

2.2 Label elements.

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

Pictograms:



Signal Word:

Danger

Hazard statements:

H372 Causes damage to organs through prolonged or repeated exposure.

Precautionary statements:

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

P264 Wash any part of the body that has come into contact with the product thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P314 Get medical advice/attention if you feel unwell.

P501 Dispose of the content or the container in accordance with the regulations on hazardous waste or packaging and packaging waste respectively.

Contains:

crystalline silica: Quartz (SiO2) (respirable fraction)

2.3 Other hazards.

The mixture does not contain substances classified as PBT.

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The mixture does not contain substances classified as vPvB.

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:

			(*)Classification - Regulation (EC) No 1272/2008	
Identifiers	Name	Concentrate	Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 14808-60-7 EC No: 238-878-4	[2] crystalline silica: Quartz (SiO2) (respirable fraction)	10 - 75 %	STOT RE 1, H372	STOT RE 2, H373: 1% ≤ C < 10% STOT RE 1, H372: C ≥ 10%
CAS No: 14464-46-1 EC No: 238-455-4	[2] cristobalite	10 - 50 %	STOT RE 2, H373	-
CAS No: 1309-48-4 EC No: 215-171-9	[2] magnesium oxide	2.5 - 25 %	-	-

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

SECTION 4: FIRST AID MEASURES.

4.1 Description of first aid measures.

Delayed effects may occur after the exposure to the product.

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. Dont let the person to rub the affected eye.

Skin contact.

Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

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

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

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SECTION 5: FIREFIGHTING MEASURES.

The product is NOT classified as flammable, in case of fire the following measures should be taken:

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.

Exposure to combustion or decomposition products can be harmful to your health.

Fire can cause release of

- Ammonia (NH3)
- Nitrogen oxides (NOx)

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).

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Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

Work exposure limit for:

Name	CAS No.	Country	Limit value	ppm	mg/m³
		Éire [1]	Eight hours		0,1
		riie [1]	Short term		
		United States	Eight hours		0.05
		[2] (Cal/OSHA)	Short term		
		United States [3] (NIOSH)	Eight hours		Potential occupational carcinogens 0.05
			Short term		
crystalline silica: Quartz (SiO2) (respirable fraction)	14808-60-7	United States [4] (OSHA)	Eight hours		10 mg/m3/(%SiO2 +2), 250/(%SiO2+5) (mppcf:Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques. Conversion factors - mppcf X 35.3 = million particles per cubic meter = particles per c.c.)
			Short term		,
	14464-46-1	United States [2] (Cal/OSHA)	Eight hours		0.05 respirable dust
		[2] (Cai, OSI IA)	Short term		
cristobalite		United States [3] (NIOSH)	Eight hours		Potential occupational carcinogens 0.05 respirable dust, lowest feasible concentration (LFC).
			Short term		

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		United States [4] (OSHA)	Eight hours	1/2 the value calculated from the count or mass formulae for quartz: (Total Dust) 30 mg/m3/(%SiO2 +2), (Respirable) 10 mg/m3/(%SiO2 +2), 250/(%SiO2+5) (mppcf:Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques. Conversion factors - mppcf X 35.3 = million particles per cubic meter = particles per c.c.)
			Short term	
		United Kingdom [5]	Eight hours	10 (inhalable dust) 4 (fume and respirable dust)
			Short term	
magnesium oxide	1309-48-4	Éire [1]	Eight hours	4 (respirable dust) 5 (fume) 10(inhalable dust)
			Short term	10 (fume)
		United States [2] (Cal/OSHA)	Eight hours	10 (fume - Total Particulate)
			Short term	
		United States [4] (OSHA)	Eight hours	15 (fume - Total Particulate)
			Short term	
547.4 II O. J. CD. II C. IJ C.				

^[1] According Code of Practice for the Safety, Health and Welfare at Work (Chemicals Agents) Regulations adopted by Health and Safety Authority (HSA).

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:	Auxiliar material for the casting of dental prostheses			
Breathing protection:				
PPE:	Particle filter mask			
Characteristics:	«CE» marking, category III. Made of filtering material, it covers nose, mouth and chin.			

^[2] California Division of Occupational Safety and Health (Cal/OSHA) Permissible Exposure Limits (PELs).

^[3] National Institute for Occupational Safety and Health. NIOSH Recommendations for occupational safety and health, Compendium of Policy Documents and Statements, January, 1992, DHHS (NIOSH) Publication No. 92-100.

^[4] Occupational Safety and Health Administration, United States Department of Labor. Permissible Exposure limits (PELs), California Division of Occupational Safety and Health (Cal/OSHA) Permissible Exposure Limits (PELs).

^[5] According Limit Value (IOELV) list in 2nd Indicative Occupational Exposure adobted by Health and Safety Executive. The product does NOT contain substances with Biological Limit Values.

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CEN standards: EN 149

Check for any tears, defects, etc. before use. Since it is disposable individual protection equipment, it Maintenance:

should be replaced after use.

Does not protect worker unless properly adjusted. Follow the manufacturer's instructions regarding Observations:

suitable use of the equipment.

Filter Type needed: P2

Hand protection:

PPF. Non-disposable protective gloves against chemicals.

«CE» marking, category III. Check the list of chemicals for which the glove has been Characteristics:

tested.

CEN standards: EN 374-1, En 374-2, EN 374-3, EN 420

A schedule for the periodical replacement of gloves should be established in order to guarantee their Maintenance:

replacement before pollutants permeate them. The use of contaminated gloves could be more dangerous

than not using gloves, since the pollutant can gradually accumulate in the glove's material.

They are to be replaced whenever tears, cracks or deformations are observed or when exterior dirt could

reduce their strength.

Breakthrough time Material thickness PVC (polyvinyl chloride) > 480 0,35 Material: (min.): (mm):

Eye protection:

Observations:

Protective goggles against particle impacts. PPE:

Characteristics: «CE» marking, category II. Eye protector against dust and smoke.

EN 165, EN 166, EN 167, EN 168 CEN standards:

Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should Maintenance:

be disinfected periodically following the manufacturer's instructions.

Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, Observations:

scraping etc.

Skin protection: Chemical protective clothing PPF:

«CE» marking, category III. Clothing should fit properly. The level of protection

Characteristics: must be set according to a test parameter called BT (Breakthrough Time), which

indicates how long it takes for the chemical to pass through the material.

EN 464,EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034 CEN standards:

In order to guarantee uniform protection, follow the washing and maintenance instructions provided by Maintenance:

the manufacturer.

The protective clothing's design should facilitate correct positioning, staying in place without moving for

the period of use expected, bearing in mind environmental factors as well as any movement or position

the user might adopt while carrying out the activity.

PPE: Anti-static safety footwear against chemicals.

«CE» marking, category III. Check the list of chemicals against which the footwear Characteristics:

EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345 CEN standards:

For correct maintenance of this kind of safety footwear, it is necessary to observe the instructions specified by the manufacturer. The footwear should be replaced as soon as any sign of damage is Maintenance:

The footwear should be cleaned regularly and dried when damp, although it should not be placed too Observations:

close to a source of heat in order to avoid any sharp changes in temperature.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

9.1 Information on basic physical and chemical properties.

Physical state: Solid - Dust

Colour: Whittish Odour: Odourless

Observations:

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

Melting point: >1400 °C

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

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

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

Auto-ignition temperature: Not applicable/Not available due to the nature/properties of the product Decomposition temperature: REVES. SUPERFINO FIJA (25 x 160 g) + LIQ. 1000 ml- GRANEL

pH: 6

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

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

Hydrosolubility: Unsoluble

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

Explosives:

Explosive properties: not explosive

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 presesent the posibility of dangerous reactions.

At preheating temperature (250-300°C) slight odour like ammonia.

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.

No decomposition if used for the intended uses.

SECTION 11: TOXICOLOGICAL INFORMATION.

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

Toxicological information about the substances present in the composition.

Name		Acute toxicity			
ľ	Туре	Test	Kind	Value	
		Oral	LD50	Rat	>2000 mg/L
cristobalite		Dermal			
CAS No: 14464-46-1	EC No: 238-455-4	Inhalation	LC50	Rat	2.6 mg/L

a) acute toxicity;

Not conclusive data for classification.

b) irritation;

Not conclusive data for classification.

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c) corrosivity;

Primary irritant effect:

- On the skin: No irritant effect
- On the eye: Moderate irritation

d) sensitisation;

Not conclusive data for classification.

e) repeated dose toxicity;

Not conclusive data for classification.

Do not breathe dust.

Harmful: possible risk of irreversible effectos through inhalation.

f) carcinogenicity;

Not conclusive data for classification.

g) mutagenicity;

Not conclusive data for classification.

h) toxicity for reproduction;

Not conclusive data for classification.

11.2 Information on other hazards.

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.

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.

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Waste classification according to the European Waste Catalogue:

16 WASTES NOT OTHERWISE SPECIFIED IN THE LIST

16 03 off-specification batches and unused products

16 03 03 inorganic wastes containing hazardous substances

Waste classified as hazardous.

SECTION 14: TRANSPORT INFORMATION.

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

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.

Transportation is not dangerous.

SECTION 15: REGULATORY INFORMATION.

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

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.

Product classification according to Annex I of Directive 2012/18/EU (SEVESO III): N/A

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.

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:

H372 Causes damage to organs through prolonged or repeated exposure.

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

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Classification codes:

STOT RE 1: Specific target organ toxicity following a repeated exposure, Category 1 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).
- Modification of specific hazards (SECTION 2.3).
- Changes in the composition of the product (SECTION 3.2).
- Modification in the firefighting measures (SECTION 5.2).
- Modifications in the accidental release measures (SECTION 6.1).
- 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).

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

On basis of test data Physical hazards 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:

CFN: 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/

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.