

VILLACRYL ORTHO POWDER

Creation date	06th May 2024	Version	2.0
Revision date			

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Substance / mixture	VILLACRYL ORTHO POWDER
Number	mixture
Other mixture names	V160P
	V1600P05 Villacryl Ortho powder 2kg
	V1600P06 Villacryl Ortho powder 4kg
	V1600P07 Villacryl Ortho powder 500 g

1.2. Relevant identified uses of the substance or mixture and uses advised against
Mixture's intended use

For professional use only. Solid component of material for making orthodontic appliances VILLACRYL ORTHO

Main intended use

PC-MED-OTH Other medical devices

Mixture uses advised against

The product should not be used in ways other than those referred in Section 1.

1.3. Details of the supplier of the safety data sheet**Importer**

Name or trade name	Everall7 Sp. z o.o.
Address	Augustówka 14, Warszawa , 02-981 Poland
Identification number (CRN)	002028511
VAT Reg No	PL5210124886
Phone	+48 22 858 82 72
E-mail	info@everall7.pl
Web address	everall7.pl

Supplier

Name or trade name	Everall7 Sp. z o.o.
Address	Augustówka 14, Warszawa , 02-981 Poland
Identification number (CRN)	002028511
VAT Reg No	PL5210124886
Phone	+48 22 858 82 72
E-mail	info@everall7.pl
Web address	everall7.pl

Competent person responsible for the safety data sheet

Name	Everall7 Sp. z o.o.
E-mail	info@everall7.pl

1.4. Emergency telephone number

European emergency number: 112

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification of the mixture in accordance with Regulation (EC) No 1272/2008**

The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008.

2.2. Label elements

none

Supplemental information

EUH210	Safety data sheet available on request.
EUH208	Contains dibenzoyl peroxide. May produce an allergic reaction.

2.3. Other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended. Dust may form explosive mixture with air.

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
Index: 617-008-00-0 CAS: 94-36-0 EC: 202-327-6	dibenzoyl peroxide	<1	Org. Perox. B, H241 Skin Sens. 1, H317 Eye Irrit. 2, H319	

Full text of all classifications and hazard statements is given in the section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

If on skin

Remove contaminated clothes.

If in eyes

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person.

If swallowed

Rinse out the mouth with clean water. In the event of issues, find medical help.

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

If inhaled

Not expected.

If on skin

Not expected.

If in eyes

Not expected.

If swallowed

Not expected.

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

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Usual extinguishing media: carbon dioxide, foam, extinguishing powders and coolant mist, sand.

Unsuitable extinguishing media

Water - full jet.

5.2. Special hazards arising from the substance or mixture

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

5.3. Advice for firefighters

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Follow the instructions in the Sections 7 and 8.

6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water.

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- 6.3. Methods and material for containment and cleaning up**
Place the product mechanically in an appropriate manner. Dispose of the collected material according to the instructions in the section 13.
- 6.4. Reference to other sections**
See the Section 7, 8 and 13.

SECTION 7: Handling and storage

- 7.1. Precautions for safe handling**
Before handling the product, read all directions in this SDS. Avoid releasing the product into the environment. Do not smoke, drink or eat during use. Remove contaminated clothing and protective equipment before eating meals in separate areas.
- 7.2. Conditions for safe storage, including any incompatibilities**
Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose.

Content	Packaging type	Material of package
500 g	talcum powder container	HDPE
2 kg	bucket	HDPE

Storage class 13 - Other non-combustible solids
Storage temperature min 5 °C, max 25 °C

- 7.3. Specific end use(s)**
not available

SECTION 8: Exposure controls/personal protection

- 8.1. Control parameters**
The mixture contains substances for which occupational exposure limits are set.

DNEL

dibenzoyl peroxide					
Workers / consumers	Route of exposure	Value	Effect	Value determination	Source
Workers	Inhalation	39 mg/m ³	Chronic effects systemic	Toxicity test	ECHA
Workers	Dermal	13.3 mg/kg bw/day	Chronic effects systemic	Toxicity test	ECHA
Workers	Dermal	34 µg/cm ²	Chronic effects local	Toxicity test	ECHA
Consumers	Oral	2 mg/kg bw/day	Chronic effects local	Toxicity test	ECHA

- 8.2. Exposure controls**
Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

It is not needed.

Skin protection

Hand protection: Protective gloves resistant to the product. When handling in long-term or repeatedly, use protective gloves.

Respiratory protection

It is not needed.

Thermal hazard

Data not available.

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

SECTION 9: Physical and chemical properties

- 9.1. Information on basic physical and chemical properties**

Physical state solid

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Colour	white
color intensity	light
Odour	without fragrance
Melting point/freezing point	>150 °C
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available
Lower and upper explosion limit	data not available
Flash point	390 °C
Auto-ignition temperature	465 °C
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	insoluble
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	
Density	1.1-1.18 g/cm ³
Relative vapour density	data not available
Particle characteristics	data not available

9.2. Other information

not available

SECTION 10: Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Unknown.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

SECTION 11: Toxicological information

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

not available

Acute toxicity

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

dibenzoyl peroxide								
Route of exposure	Parameter	Method	Value	Exposure time	Species	Sex	Value determination	Source
Oral	LD ₀	OECD 401	>2000 mg/kg		Mouse	F/M	Experimentally	ECHA
Inhalation (dust/mist)	LC ₀	OECD 403	24.3 mg/l of air	4 hours	Rat (Rattus norvegicus)	M	Experimentally	ECHA

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Skin corrosion/irritation

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

dibenzoyl peroxide						
Route of exposure	Result	Method	Exposure time	Species	Value determination	Source
Dermal	Not irritating	OECD 404	4 hours	Rabbit (New Zealand albino)	Experimentally	ECHA

Serious eye damage/irritation

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

dibenzoyl peroxide					
Route of exposure	Result	Exposure time	Species	Value determination	Source
Eye	Irritating	5 minutes	Rabbit (New Zealand White)	Experimentally	ECHA

Respiratory or skin sensitisation

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

dibenzoyl peroxide							
Route of exposure	Result	Method	Exposure time	Species	Sex	Value determination	Source
Dermal	Sensitizing	OECD 429		Mouse	F	Literary studies, Experimentally	ECHA

Germ cell mutagenicity

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

dibenzoyl peroxide							
Result	Method	Exposure time	Specific target organ	Species	Sex	Value determination	Source
Negative without metabolic activation, Negative with metabolic activation	OECD 471			Bacteria (Salmonella typhimurium)		Experimentally	ECHA
Negative	OECD 474	2 days		Mouse	M	Experimentally	ECHA

Carcinogenicity

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

dibenzoyl peroxide									
Route of exposure	Parameter	Method	Value	Exposure time	Result	Species	Sex	Value determination	Source
Oral	NOAEL		112-140 mg/kg bw/day	120 weeks	No carcinogenic effect	Rat (Albino)	F/M	Experimentally	ECHA

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Route of exposure	Parameter	Method	Value	Exposure time	Result	Species	Sex	Value determination	Source
Oral	NOAEC		11.2-14.0 mg/kg bw/day	120 weeks	No carcinogenic effect	Rat (Albino)	F/M	Experimentally	ECHA
Oral	LOAEL		112-140 mg/kg bw/day	120 weeks	Reduced body weight	Rat (Albino)	F/M	Experimentally	ECHA
Skin	NOEL	OECD 451	>2.6 mg/cm ²	co najmniej 104 weeks (7 days/week)	No carcinogenic effect	Rat (Rattus norvegicus)	F/M	Experimentally	ECHA
Skin	LOAEL	OECD 451	0.3 mg/cm ²	co najmniej 104 weeks (7 days/week)	No carcinogenic effect	Rat (Rattus norvegicus)	F/M	Experimentally	ECHA
Skin	NOAEL	OECD 451	>2.6 mg/cm ²	co najmniej 104 weeks (7 days/week)	No carcinogenic effect	Rat (Rattus norvegicus)	F/M	Experimentally	ECHA

Reproductive toxicity

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

dibenzoyl peroxide									
Effect	Parameter	Method	Value	Exposure time	Result	Species	Sex	Value determination	Source
Effects on fertility	NOAEL	OECD 422	500 mg/kg bw/day	51 days	No effect	Rat (Rattus norvegicus)	F/M	Experimentally	ECHA
Developmental toxicity	NOAEL	OECD 414	300 mg/kg bw/day	21 days	No effect	Rat (Rattus norvegicus)	F/M	Experimentally	ECHA

Toxicity for specific target organ - single exposure

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

Toxicity for specific target organ - repeated exposure

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

Repeated dose toxicity

dibenzoyl peroxide									
Route of exposure	Parameter	Result	Method	Value	Exposure time	Species	Sex	Value determination	Source
Oral	NOEL	No effect		19-23 mg/kg bw/day	120 weeks	Rat (Rattus norvegicus)	F/M	Literary studies, Experimentally	ECHA

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Route of exposure	Parameter	Result	Method	Value	Exposure time	Species	Sex	Value determination	Source
Oral	NOAEL	Loss of body weight		190-230 mg/kg bw/day	120 weeks	Rat (Rattus norvegicus)	F/M	Literary studies, Experimentally	ECHA
Dermal	NOAEL	No effect	OECD 451	>833 mg/kg bw/day	104 weeks (7 days/week)	Mouse	F/M	Experimentally	ECHA
Dermal	NOAEL	No effect	OECD 451	0.17 mg/kg bw/day	104 weeks (7 days/week)	Mouse	F/M	Experimentally	ECHA

Aspiration hazard

No data are available for either the mixture or the components. Based on the available data, the criteria for classification of the mixture are not met.

11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information

12.1. Toxicity

Data for the mixture are not available. Based on the available data, the criteria for classification of the mixture are not met.

Acute toxicity

dibenzoyl peroxide

Parameter	Method	Value	Exposure time	Species	Environment	Value determination	Source
LC ₅₀	OECD 203	60.2 µg/l	96 hours	Fish (Oncorhynchus mykiss)	Fresh water	Experimentally	ECHA
NOEC	OECD 203	31.6 µg/l	96 hours	Fish (Oncorhynchus mykiss)	Fresh water	Experimentally	ECHA
EC ₅₀	OECD 202	110 µg/l	48 hours	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA
NOEC	OECD 202	76.5 µg/l	48 hours	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA
EC ₅₀	OECD 201	42.2-71.1 µg/l	72 hours	Algae (Selenastrum capricornutum)	Fresh water	Experimentally	ECHA
EC ₅₀	OECD 209	35 mg/l	30 minutes	Bacteria (Salmonella typhimurium)	Activated sludge	Experimentally	ECHA

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Chronic toxicity

dibenzoyl peroxide							
Parameter	Method	Value	Exposure time	Species	Environment	Value determination	Source
EC ₁₀	OECD 211	1 µg/l	21 days	Daphnia (Daphnia magna)	Fresh water	Experimentally	ECHA

12.2. Persistence and degradability

Data for the mixture are not available.

Biodegradability

dibenzoyl peroxide							
Parameter	Method	Value	Exposure time	Environment	Value determination	Result	Source
	OECD 301D	71 %	28 days	Fresh water	Experimentally	Easily biodegradable	ECHA

12.3. Bioaccumulative potential

No data are available for either the mixture or the components.

12.4. Mobility in soil

No data are available for either the mixture or the components.

12.5. Results of PBT and vPvB assessment

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

Data not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorised for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended. Decision 2000/532/EC establishing a list of wastes, as amended.

Waste type code

20 03 01 mixed municipal waste

Packaging waste type code

20 01 39 Plastics

20 01 01 paper and cardboard

SECTION 14: Transport information

14.1. UN number or ID number

not subject to transport regulations

14.2. UN proper shipping name

not relevant

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14.3. Transport hazard class(es)

not relevant

14.4. Packing group

not relevant

14.5. Environmental hazards

not relevant

14.6. Special precautions for user

Reference in the Sections 4 to 8.

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information

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

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended. REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. 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 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out (mixture).

SECTION 16: Other information

A list of standard risk phrases used in the safety data sheet

H241	Heating may cause a fire or explosion.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.

A list of additional standard phrases used in the safety data sheet

EUH210	Safety data sheet available on request.
EUH208	Contains dibenzoyl peroxide. May produce an allergic reaction.

Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per the Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EC	Identification code for each substance listed in EINECS
EC ₁₀	Concentration of a substance when it is affected 10% of the population
EC ₅₀	Concentration of a substance when it is affected 50% of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization

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INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC ₀	Lethal concentration of a substance in which it can be expected death of 0% of the population
LC ₅₀	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD ₀	Lethal dose of a substance in which it can be expected death of 0% of the population
LOAEL	Lowest observed adverse effect level
log K _{ow}	Octanol-water partition coefficient
NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
NOEL	No observed effect level
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative
Eye Irrit.	Eye irritation
Org. Perox.	Organic peroxide
Skin Sens.	Skin sensitization

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No. 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.
REGULATION (EC) No. 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

The changes (which information has been added, deleted or modified)

Version 2.0 replaces the SDS version from 21.05.2021. Data updates and changes have been made to all sections of the SDS.

More information

Classification procedure - calculation method.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.