

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

1.1. Product identifier

Code:	V1000P03; V1000P04; V100V210; V100V217; V100V218; V100V219; V100V413; V100V414; V100V415; V100V416
Product name:	VILLACRYL H PLUS POWDER

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

Intended use:	For professional use only. Powder component of heat-curing acrylic resin for denture bases VILLACRYL H PLUS.
---------------	--

1.3. Details of the supplier of the safety data sheet

Name	Everall7. z o.o
Full address	Augustówka 14
District and Country	02-950 Warszawa
	Poland
	tel. +48 22 858 82 72
	fax +48 22 642 07 14
e-mail address of the competent person responsible for the Safety Data Sheet	andrzej.ceglinski@everall7.pl

1.4. Emergency telephone number

For urgent inquiries refer to:	Fire Service tel. 998, 112 or nearest local branch of Fire Brigade. Toxicological information in Poland 042 631 47 24
--------------------------------	--

SECTION 2. Hazard identification

2.1. Classification of the substance or mixture

EC Regulation 1272/2008 (CLP) and subsequent amendments and adjustments.

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments

Hazard classification and indications:	-
Hazard pictograms:	-
Signal words:	-
Hazard statements:	-
EUH208:	Contains: BENZOYL PEROXIDE May cause skin allergic reaction
Precautionary statements:	-

Safety data sheet available for professional users on request.

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB.

SECTION 3. Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Contains:

Identification / Ingredients	Classification	Conc. %
Benzoyl peroxide		
CAS No. 94-36-0	Org. Perox. B; Skin Sens 1; Eye Irrit. 2; Aquatic Acute 1; H241, H317, H319; H400	<1%
EC No. 202-327-6		
INDEX No. -		
Reg. No. 01-2119511472-50-XXXX		

Note: Upper limit is not included into the range.

The full wording of the Risk (R) and hazard (H) phrases are given in section 16 the Safety Data Sheet.

SECTION 4. First aid measures

4.1. Description of first aid measures

EYES:	Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN:	Remove contaminated clothing. Immediately wash skin with plenty of soap and water. Flush for 10 minutes. In the event of persistent irritation, get medical advice/attention. Wash contaminated clothing before using it again
INHALATION:	Remove person to fresh air and keep comfortable for breathing. If the person stops breathing, administer artificial respiration. Get medical advice/attention.
INGESTION:	Do not give anything by mouth to an unconscious person. Immediately rinse mouth with water and, then drink 200 – 300 ml of water. Do not induce vomiting. Get immediate medical advice/attention. (show the packaging or label).

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

Direct inhalation exposure to dust released into the atmosphere may cause irritation of the respiratory system. Repeated frequent exposure to humans may lead to decreased immunity and the formation of allergic reactions. In sensitive people there may be severe allergic reactions to very small amounts of the mixture.

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

Treat symptomatically. In the event of swallowed call a poison center.

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

Ordinary extinguishing equipment: carbon dioxide, foam, extinguishing powder and coolant mist, sand

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Combustible but not readily ignited. Combustion or thermal decomposition will evolve toxic, irritant and flammable vapours. This product can form flammable dust clouds at elevated temperatures. The minimum ignition temperature of a dust cloud of a similar polymer has been measured at approximately 480°C (IEC 1241-2-1).

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire-fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.

Do not breathe vapours. Provide proper ventilation. Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the Safety Data Sheet) to prevent any contamination of skin, eyes and personal clothing.

TEMPLATE No.	EA7-WI EHS-001-01 TEM-02	REVISION LEVEL	1
--------------	--------------------------	----------------	---

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Use spark-proof mechanical equipment to collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.

Use ventilation in contaminated place with releases. Evaluate the incompatibility of the container materials referred to under Section 7 of the Safety Data Sheet. Disposal of contaminated material should be carried out in accordance with guidelines referred to under Section 13 of the Safety Data Sheet.

6.4. Reference to other section

Any other information about personal protection and disposal is provided in sections 8 and 13 of the Safety Data Sheet.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Before handling the product, consult all the other sections of the Safety Data Sheet. Avoid leakage of the product into the environment. Avoid contamination of skin, eyes and respiratory system. Avoid forming dust. Use only in well ventilated places. Provide appropriate exhaust ventilation in the workplace. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory references:

OEL EU	Directive (EU) 2017/2398; Directive (EU) 2017/164; Commission Directive 2009/161/EU; Commission Directive 2006/15/EC; Directive 2004/37/EC; Commission Directive 2000/39/EC; Commission Directive 91/322/EEC
TLV-ACGIH	ACGIH 2016

Substance name	Nr. CAS	NDS (mg/m ³)	NDSCh (mg/m ³)
Benzoyl peroxide	94-36-0	5	10
Dust (total)	-	10	-
Dust (respirable)	-	4	-

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

In case of choosing the personal protective equipment seek advice from chemical suppliers if it is needed.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

HAND PROTECTION

Use protective gloves of category III (see standard EN 374).

The choice of the material from which the protective gloves are made depends on: compatibility, degradation, break time and permeation.

In the case of preparations, the resistance of protective gloves must be tested before using them, because their durability is not predictable. The glove wear time depends on the exposure time and the circumstances of use..

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing the protective clothing.

EYE PROTECTION

Wear face shields (visors) and safety glasses. To protect the eyes use equipment certified use in accordance with applicable regulations such as NIOSH (USA) or EN 166 (EC).

RESPIRATORY PROTECTION

If the limit value (eg NDS-NDN) of a given substance or one or more substances contained in the product is exceeded, it is recommended to use a dust mask or a respirator with a P3 or FFP3 filter (EN 143 or EN149). In the unlikely event of high dust concentrations, a self contained breathing apparatus may be used.

The use of respiratory protection measures is obligatory in the presence of engineering solutions not capable of limiting the employee's exposure to the recommended limit values. In any case, the use of protective masks is limited.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odorless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Powder
Color	white or light pink (depending on the color version of the product)
Odour	Information not available
Odour threshold	Not available.
pH	Not available.
Melting point / freezing point	ok. 150 °C
Initial boiling point	Not available.
Boiling range	Not available.
Flash point	~390 °C
Evaporation Rate	Not available.
Flammability (solid, gas)	Not available.
Lower flammability limit	Not available.
Upper flammability limit	Not available.
Lower explosive limit	Not available.
Upper explosive limit	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	1.1 - 1.18 g/cm ³ .
Solubility in water	Insoluble
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature	~465 °C
Self-accelerating decomposition temperature (SAPT)	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Powder

9.2. Other information

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 in normal conditions of use and storage.

10.3. Possibility of hazardous reaction

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

Avoid dust formation. Comply with the chemical safety regulations

10.5. Incompatible materials

The product contains residual benzoyl peroxide. It can react with oxidizing agents, reducing agents, acids and amines leading to degradation

10.6. Hazardous decomposition products

Methyl methacrylate, Dibenzoyl peroxide, Carbon dioxide, Carbon monoxide

SECTION 11. Toxicological information

11.1. Information on toxicological effects

Toxicological information on the interaction of substances in mixture are not available, possible health effects are listed based on the properties of the substances contained in the mixture in accordance with the applicable regulations regarding classification. Information on possible health effects shall be included regarding concentrations of hazardous substances referred to under Section 3 of the Safety Data Sheet.

Metabolism, toxicokinetics, mechanism of action and other information: Data for mixture is not available.

Information on probable routes of exposure: WORKERS: inhalation, skin contact.

Delayed, immediate and chronic effects of short and long term exposure

Inhalation: If dust is inhaled, coughing, sneezing and lack of breathing may occur - mechanical irritation of the mucous membranes.

Ingestion: Slight irritation of the mouth, throat and stomach, nausea, vomiting.

Skin: Virtually no clinical symptoms when in contact with the skin. The polymer used in the preparation contains post-condensation impurities (methyl methacrylate: CAS No. 80-62-6 and benzoyl peroxide: CAS No. 94-36-0) with a concentration above 0.1%. It does not cause irritation under normal conditions. After dissolving the polymer in organic solvents, substances can be released and cause allergic reactions in sensitive persons. There may be redness and itching of the skin at the point of contact.

Eyes: May cause mechanical irritation with dust (source: literature). Stinging and burning in the eyes after dusting, characteristic of fine crystalline foreign substances

Interaction effects: None

Acute toxicity

Ingestion: LD50 oral (rat) > 5.000 mg/kg (Calculated based on known LD50 values of essential components observing the additivity rule). Based on available data, it does not meet the classification criteria for this hazard class.

Skin corrosion / irritation: Virtually no clinical symptoms when in contact with the skin. Based on the available data, it does not meet the classification criteria for this hazard class

Serious eye damage / eye irritation: May cause mechanical irritation with dust (source: literature). Based on the available data, it does not meet the classification criteria for this hazard class

Respiratory or skin sensitization: It is not sensitizing agent. Based on the available data, it does not meet the classification criteria for this hazard class.

CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction)

Mutagenicity: It does not contain substances that are mutagenic on reproductive cells. Based on the available data, it does not meet the classification criteria for this hazard class..

Carcinogenicity: No component of this product present in an amount above 0.1% is identified by IARC as probable, possible or confirmed human carcinogen. Based on available data, it does not meet the classification criteria for this hazard class.

Toxicity to reproduction: Based on available data, it does not meet the classification criteria for this hazard class.

Toxic effects on target organs – single exposure: No data available

Toxic effects on target organs – repeated exposure: No data available

Aspiration hazards: Based on available data, it does not meet the classification criteria for this hazard class.

DIBENZOYL PEROXIDE

Acute toxicity

LD0 (oral): >2000 mg/kg, (mouse, OECD 401) - ECHA Dossier,

LC0 (inhalation): 24.3 mg/L (rat, 4h, OECD 403) - ECHA Dossier.
Skin corrosion / irritation Skin irritation: Not irritating (rabbit, 72h, OECD Guideline 404) - ECHA Dossier. Eye irritation: Irritating (rabbit, 72h, US FDA, 21 CFR, Part 191,) - ECHA Dossier
Respiratory or skin sensitization <u>Skin sensitization:</u> It sensitizes the skin (mouse, equivalent or similar method to OECD 429) - ECHA Dossier
Toxic effects on target organs <u>STOT - single exposure:</u> Based on the available data, it does not meet the classification criteria for this hazard class. ECHA Dossier , Supplier MSDS <u>STOT - repeated exposure</u> Based on the available data, it does not meet the classification criteria for this hazard class. ECHA Dossier
CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction) <u>Genetic toxicity in vitro:</u> Based on the available data, it does not meet the classification criteria for this hazard class. ECHA Dossier <u>Genetic toxicity in vivo:</u> Based on the available data, it does not meet the classification criteria for this hazard class. ECHA Dossier
Carcinogenicity: Based on the available data, it does not meet the classification criteria for this hazard class. ECHA Dossier
Toxicity to reproduction: Based on the available data, it does not meet the classification criteria for this hazard class. ECHA Dossier
Aspiration toxicity: No data available.
SECTION 12. Ecological information When using the product comply with good working practices, avoid releasing of the substance to environment. Inform the competent authorities in case of penetrate into the soil, sewer system or come into contact with surface water, ground water or vegetation.
12.1. Toxicity
<i>DIBENZOYL PEROXIDE</i>
EC50 for freshwater fish: 0.06 mg / l, 96h, OECD Test Guideline 203, ECHA Dossier NOEC = 0.0316 mg / l, 96h for freshwater fish, OECD Test Guideline 203, ECHA Dossier EC50 for freshwater invertebrates: 0.11 mg / L, 48h (Daphnia magna), ECHA Dossier NOEC = 0.0765 mg / L, 48h (Daphnia magna), ECHA Dossier EC10 for freshwater invertebrates: 011 mg / l, 21d; OECD Test Guideline 211, ECHA Dossier EC50 for algae = 42.2 - 71.1 µg / L, 72 h (aquatic freshwater algae) OECD Test Guideline 201, ECHA Dossier NOEC for algae = 20 µg / L 72 h (aquatic freshwater algae) OECD Test Guideline 201, ECHA Dossier EC50 for microorganisms = 35 mg / L, 30 min; OECD Test Guideline 209, ECHA Dossier
12.2. Persistence and degradability
The polymer is not biodegradable in soil. There is no evidence of biodegradation in soil and water.
<i>DIBENZOYL PEROXIDE</i>
Dibenzoyl peroxide should be classified as readily biodegradable. ECHA Dossier
12.3. Bioaccumulative potential.
The product shows low bioaccumulation potential
<i>DIBENZOYL PEROXIDE</i>
Benzoyl peroxide has a low bioaccumulation potential.
12.4. Mobility in soil
Information not available.
12.5. Results of PBT and vPvB assessment
On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.
12.6. Other adverse effects
Information not available.
SECTION 13. Disposal considerations 13.1. Waste treatment methods If possible, send for recycling. The remains of the product belong to non-hazardous waste. Waste disposal should be handed over to a company with appropriate waste management permits. Strongly avoid discharge to soil, sewage system or water courses. Waste code: 20 03 01 Unsorted (mixed) municipal waste

CONTAMINATED PACKAGING

Contaminated packaging should be transferred for utilization or liquidation as an unused product by a company authorized to collect waste.

Waste code: 20 01 39 * Municipal waste sorted and collected separately - plastics

SECTION 14. Transport information

The mixture is not dangerous according to the regulations in force in the field of transport of dangerous goods: road (A.D.R.), sea (IMDG Code) and air (IATA).

SECTION 15. Regulatory information

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

Seveso category: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006: None

Substances in Candidate List (Art. 59 REACH): None

Substances subject to authorization (Annex XIV REACH): None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None

Substances subject to the Rotterdam Convention: None

Substances subject to the Stockholm Convention: None

Healthcare controls. PL: None

15.2. Chemical Safety Assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information

Full text of hazard (H) statements mentioned in section 2-3 of the Safety Data Sheet

Org. Perox. B	Organic peroxide, Category B
Skin Sens. 1	Skin sensitization, Category 1
Eye Irrit. 2	Eye irritation, Category 2
Aquatic Acute 1	Toxic to the aquatic environment, Category 1
H241	Heating may cause a fire or explosion.
H317	May cause an allergic skin reaction
H319	Causes eye irritation
H400	Very toxic to aquatic organisms.

LEGEND:

ATE	Acute Toxicity Estimate
ADR	European Agreement concerning the carriage of Dangerous goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CE50:	Effective concentration (required to induce a 50% effect)
CE No.:	Identifier in ESIS (European archive of existing substances)
CLP	EC Regulation 1272/2008
CAS No.	Chemical Abstract Service Number
CMR	Carcinogenic, Mutagenic or Toxic for Reproduction
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNEL	Derived No Effect Level

ECHA	European Chemicals Agency
EC No.	The EC number, i.e. EINECS, ELINCS or NLP, is the official number of the substance within the European Union
EINECS	European Inventory of Existing Chemical Substances
EmS:	Emergency Schedule
GHS	Globally Harmonized System of classification and labeling of chemicals
IATA	International Air Transport Association
IATA DGR	International Air Transport Association Dangerous Goods Regulation
ICAO-TI	International Civil Aviation Organization - Technical Instructions
IC50:	Immobilization Concentration 50%
IMDG	International Maritime Code for dangerous goods
IMO:	International Maritime Organization
IMSBC	International Maritime Solid Bulk Cargoes Code
INDEX No.	Identifier in Annex VI of CLP
Cow	Octanol/water partition coefficient
LC50	Lethal Concentration 50%
LD50	Lethal Dose 50%
LoW	List of Waste (see http://ec.europa.eu/environment/waste/framework/list.htm)
MSDS	Material Safety Data Sheet
OEL	Occupational Exposure Level
OSHA	Occupational Safety and Health Administration
PBT	Persistent Bioaccumulative and Toxic as REACH Regulation
PEC	Predicted Environmental Concentration
PEL	Predicted Exposure Level
PNEC	Predicted No Effect Concentration
PPE	Personal Protective Equipment
REACH	EC Regulation 1907/2006
RID	Regulation concerning the International transport of dangerous goods by train
SDS	Safety Data Sheet
STOT	Specific Target Organ Toxicity
(STOT) RE	Specific Target Organ Toxicity - Repeated Exposure
(STOT) SE	Specific Target Organ Toxicity - Single Exposure
SVHC	Substances of Very High Concern
TLV	Threshold Limit Value
TLV CEILING	Concentration that should not be exceeded during any time of occupational exposure
TWA STEL	Short-term exposure limit
TWA	Time-weighted average exposure limit
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative as for REACH Regulation

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
 4. Rozporządzenie (UE) 2015/830 Parlamentu Europejskiego
 5. Regulation (EC) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EC) 618/2012 (III Atp. CLP) of the European Parliament
 7. Rozporządzenie (UE) 487/2013 Parlamentu Europejskiego (IV Atp. CLP)
 8. Rozporządzenie (UE) 944/2013 Parlamentu Europejskiego (V Atp. CLP)
 9. Rozporządzenie (UE) 605/2014 Parlamentu Europejskiego (VI Atp. CLP)
 10. Rozporządzenie (UE) 2015/1221 Parlamentu Europejskiego (VII Atp. CLP)
 11. Rozporządzenie (UE) 2016/918 Parlamentu Europejskiego (VIII Atp. CLP)
 12. Rozporządzenie (UE) 2016/1179 (IX Atp. CLP)
 13. Rozporządzenie (UE) 2017/776 (X Atp. CLP)
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - IFA GESTIS website
 - ECHA website

Note for users:

The information contained in this Safety Data Sheet corresponds to our level of knowledge at the time of publication. Users should verify if the provided information is correct and full in relation to the specific designation of the product.

This document cannot be identified with the guarantee for any specific product property.

Due to the fact that the application takes place without the possibility of control from the producer's side; therefore user is obliged to comply at his own responsibility with the laws and regulations regarding the occupational health and safety. The producer is relieved from any liability arising from improper uses.

Provide proper training for staff who is appointed to handling the chemical products.

Changes to previous review:

Revision	Date	Change reference	Implemented by	Change description
1	2021-05-27	N/A	Andrzej Cegliński	First Issue of Document