

1 Identification

- **Product identifier**
- **Trade name:** Velrybka
- **Article number:** 605122
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture**
Laboratory chemicals
Pharmaceutical intermediate
Additive for cosmetic or pharmaceutical preparations
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Services B.V.
Molenwerk 13, UITGEEEST, 1911DB
Netherlands
Phone: +31251361400

- Supplier
Azelis Australia
Suite 217
117 Old Pittwater Road
Brookvale
NSW 2100
Australia
Phone: +61 0299392188
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e-mail: info@azelis.com.au
- **Further information obtainable from:** info@fagron.com.au
- **Emergency telephone number:**
In case of emergency, please call your local poisons:
Emergency Australia: 13 11 26
Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE:
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3158 1074 | MOROCCO - +44 1235 239671 | REST OF THE WORLD - +44 1865 407333
(English only)

2 Hazard(s) Identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonised System (GHS).

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 1314-13-2	zinc oxide	50–≤100%
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- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures


- **Suitable extinguishing agents:**
Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture**
No further relevant information available.
- **Protective equipment:** Wear self-contained respiratory protective device.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to section 13.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.

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personalizing
medicine

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- **Further information about storage conditions:**
Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.

- **Ingredients with limit values that require monitoring at the workplace:**

CAS: 1314-13-2 zinc oxide

WES	Short-term value: 10** mg/m ³ Long-term value: 10* 5** mg/m ³ *dust **fume
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- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:** Wash hands before breaks and at the end of work.
- **Respiratory protection:**
Filter P1
Suitable respiratory protective device recommended.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Safety glasses
- **Body protection:** Protective work clothing

9 Physical and Chemical Properties

- **General Information**

- **Appearance:**

- **Form:** Solid
- **Colour:** Yellowish
- **Odour:** Characteristic
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** 100°C

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· Flash point:	>150°C
· Flammability (solid, gas):	Not determined.
· Auto-ignition temperature:	296°C
· Decomposition temperature:	Not determined.
· Ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
· Lower:	Not determined.
· Upper:	Not determined.
· Vapour pressure at 20°C:	23 hPa
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
· water:	Soluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
· Dynamic:	Not applicable.
· Kinematic:	Not applicable.
· Solvent content:	
· Water:	50.0 %
· Other information	No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

CAS: 1314-13-2 zinc oxide		
Oral	LD50	>5000 mg/kg (rat)

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological Information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number	
· ADG, IMDG, IATA	not regulated
· UN proper shipping name	
· ADG, IMDG, IATA	not regulated
· Transport hazard class(es)	
· ADG, ADN, IMDG, IATA	
· Class	not regulated
· Packing group	
· ADG, IMDG, IATA	not regulated
· Environmental hazards:	Not applicable.
· Special precautions for user	Not applicable.

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| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

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

· Australian Inventory of Industrial Chemicals	
CAS: 1314-13-2	zinc oxide
CAS: 8001-69-2	Lebertran (Typ A) lecoris aselli oleum A Cod-liver oil
CAS: 7732-18-5	Water, distilled, conductivity or of similar purity
CAS: 8012-89-3	Beeswax white - Cera alba Beeswax,yellow - Cera flava
CAS: 8027-33-6	Woolwax alcohols Alcholes adipis lanae
CAS: 7695-91-2	Tocopherol (Vit.E) acetate (D-alfa) Vitamin E Acetate

- Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

- Australia: Priority Existing Chemicals

None of the ingredients is listed.

- Directive 2012/18/EU

- Named dangerous substances - ANNEX I None of the ingredients is listed.
- Seveso category E1 Hazardous to the Aquatic Environment
- Qualifying quantity (tonnes) for the application of lower-tier requirements 100 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t

- National regulations:

- Other regulations, limitations and prohibitive regulations
Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)
- Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- Department issuing SDS: Product Safety Department

- Contact:

- Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent

Safety Data Sheet

according to WHS Regulations

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LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

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