

## 1 Identification

- **Product identifier**
- **Trade name: Bifonazole**  
**Bifonazolum**
- **Article number:** 102605
- **CAS Number:**  
60628-96-8
- **EC number:**  
262-336-6
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Pharma Active ingredients
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Services B.V.  
Molenwerk 13, UITGEEST, 1911DB  
Netherlands  
Phone: +31251361400
  
- Supplier  
Azelis Australia  
Suite 217  
117 Old Pittwater Road  
Brookvale  
NSW 2100  
Australia  
Phone: +61 0299392188  
Fax: +61 0299392799  
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:  
+44 1235 239670 | USA: +1 202 464 2554 | CANADA - +1 800 579 7421 (Toll Free)| ASIA - +65  
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**  
Acute Tox. 4 H302 Harmful if swallowed.  
Repr. 2 H361 Suspected of damaging fertility or the unborn child.

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- **Label elements**
- **GHS label elements**  
The substance is classified and labelled according to the Globally Harmonised System (GHS).  
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**Trade name: Bifonazole  
Bifonazolium**

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· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Warning

· **Hazard statements**

Harmful if swallowed.  
Suspected of damaging fertility or the unborn child.

· **Precautionary statements**

Wear protective gloves/protective clothing/eye protection/face protection.  
IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.  
Rinse mouth.  
IF exposed or concerned: Get medical advice/attention.  
Store locked up.  
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition and Information on Ingredients

· **Chemical characterisation: Substances**

· **CAS No. Description**

CAS: 60628-96-8 Bifonazole  
Bifonazolium

· **Identification number(s)**

· **EC number:** 262-336-6

### 4 First Aid Measures

· **Description of first aid measures**

· **General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.  
In case of irregular breathing or respiratory arrest provide artificial respiration.

· **After inhalation:**

Supply fresh air and to be sure call for a doctor.  
In case of unconsciousness place patient stably in side position for transportation.

· **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:** Do not induce vomiting; call for medical help immediately.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed**

No further relevant information available.

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**Bifonazolum**

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- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

## 5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Use fire extinguishing methods suitable to surrounding conditions.  
Water  
Fire-extinguishing powder  
Foam  
Carbon dioxide
- **Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.  
In case of fire, the following can be released:  
Carbon monoxide (CO)  
Nitrogen oxides (NO<sub>x</sub>)
- **Advice for firefighters**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.

## 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.  
Avoid formation of dust.  
Ensure adequate ventilation
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Ensure adequate ventilation.  
Dispose of the material collected according to regulations.  
Dispose contaminated material as waste according to item 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**  
Prevent formation of dust.  
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store receptacle in a well ventilated area.

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**Bifonazolum**

- Store in dry conditions.  
· **Specific end use(s)** No further relevant information available.

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## 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** 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.
- **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

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
  - **Form:** Crystalline powder
  - **Colour:** Whitish
  - **Odour:** Characteristic
  - **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**
  - **Melting point/freezing point:** 147–151°C
  - **Initial boiling point and boiling range:** Undetermined.
- **Flash point:** Not applicable.

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**Bifonazolum**

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· <b>Flammability (solid, gas):</b>	Product is not flammable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Not determined.
· <b>Explosive properties:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapour pressure:</b>	Not applicable.
· <b>Density at 20°C:</b>	0.3 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with water:</b>	Not determined.
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not applicable.
<b>Kinematic:</b>	Not applicable.
· <b>Other information</b>	No further relevant information available.

## 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **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:**  
Carbon monoxide and carbon dioxide  
Nitrogen oxides (NO<sub>x</sub>)  
Poisonous gases/vapours

## 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity**

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

Oral   LD50   1434 mg/kg (rat)
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· **Additional toxicological information:**

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
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**Bifonazolum**

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## 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.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Assessment by list): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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.

## 14 Transport information

· <b>UN-Number</b>	
· <b>ADG, IMDG, IATA</b>	not regulated
· <b>UN proper shipping name</b>	
· <b>ADG, IMDG, IATA</b>	not regulated
· <b>Transport hazard class(es)</b>	
· <b>ADG, ADN, IMDG, IATA</b>	
· <b>Class</b>	not regulated
· <b>Packing group</b>	
· <b>ADG, IMDG, IATA</b>	not regulated
· <b>Environmental hazards:</b>	Not applicable.
· <b>Special precautions for user</b>	Not applicable.
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	not regulated

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## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Australian Inventory of Industrial Chemicals** Substance is not listed.
- **Standard for the Uniform Scheduling of Medicines and Poisons S2, S4**
- **Australia: Priority Existing Chemicals** Substance is not listed.
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **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  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Acute Tox. 4: Acute toxicity – Category 4  
Repr. 2: Reproductive toxicity – Category 2

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