

## 1 Identification

- **Product identifier**
- **Trade name:** Avicel PH105 (Microcrystalline Cellulose 105)
- **Article number:** 100274
- **CAS Number:**  
9004-34-6
- **EC number:**  
232-674-9
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture** Pharmaceutical intermediate
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Fagron Services B.V.  
Molenwerk 13, UITGEEEST, 1911DB  
Netherlands  
Phone: +31251361400
- **Supplier**  
Bella Corp Trading Pty Ltd  
6/34 Dominions Road, Ashmore QLD 4214, Australia  
Telephone: 07 5597 4169  
Email: bellacorp@bellacorp.com.au
- **Emergency telephone number:**  
In case of emergency, please call your local poisons:  
Emergency Australia: 13 11 26 (NSW Poisons Information Centre)  
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**  
The substance 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.

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· vPvB: Not applicable.

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### **3 Composition and Information on Ingredients**

- **Chemical characterisation: Substances**
- **CAS No. Description**  
CAS: 9004-34-6 Avicel PH105 (Microcrystalline Cellulose 105)
- **Identification number(s)**
- **EC number: 232-674-9**

### **4 First Aid Measures**

- **General information:** No special measures required.
- **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:**  
Rinse out mouth and then drink plenty of water.  
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.  
Water
- **Special hazards arising from the substance or mixture**  
In case of fire, the following can be released:  
Carbon monoxide (CO)
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.

### **6 Accidental Release Measures**

- **Personal precautions, protective equipment and emergency procedures**  
Avoid formation of dust.  
Product forms slippery surface when combined with water.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**  
Pick up mechanically.  
Dispose of the material collected according to regulations.

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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**

Prevent formation of dust.

Ensure good ventilation/exhaustion at the workplace.

· **Information about fire - and explosion protection:**

Dust can combine with air to form an explosive mixture.

Keep ignition sources away - Do not smoke.

· **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 in dry conditions.

Store receptacle in a well-ventilated area.

Protect from exposure to the light.

Protect from humidity and water.

· **Maximum storage temperature:** 35°C

· **Minimum storage temperature:** 15°C

· **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: 9004-34-6 Avicel PH105 (Microcrystalline Cellulose 105)**

WES	Long-term value: 10 mg/m <sup>3</sup> inhalable dust
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· **Additional information:** The lists valid during the making were used as basis.

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

· **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.

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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**

· **General Information**

· **Appearance:**

· **Form:** Powder

· **Colour:** Whitish

· **Odour:** Odourless

· **Odour threshold:** Not determined.

· **pH-value:** 5–7.5

· **Change in condition**

· **Melting point/freezing point:** Undetermined.

· **Initial boiling point and boiling range:** Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gas):** Product is not flammable.

· **Auto-ignition temperature:** 340°C

· **Decomposition temperature:** >260°C

· **Ignition temperature:** Not determined.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

· **Lower:** Not determined.

· **Upper:** Not determined.

· **Vapour pressure:** Not applicable.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not applicable.

· **Evaporation rate** Not applicable.

· **Solubility in / Miscibility with**

· **water:** Insoluble.

Not miscible or difficult to mix.

· **Partition coefficient: n-octanol/water:** Not determined.

· **Viscosity:**

· **Dynamic:** Not applicable.

· **Kinematic:** Not applicable.

· **Other information**

No further relevant information available.

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## 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:

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50/4 h	5.05 mg/l (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.
- **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.
- **Additional ecological information:**
- **General notes:**  
Not known to be hazardous to water.  
Not hazardous for water.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

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Trade name: Microcrystalline Cellulose 102

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### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 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.
· 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** Substance is listed.
- **Standard for the Uniform Scheduling of Medicines and Poisons** Substance is not listed.
- **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

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# Safety Data Sheet

according to WHS Regulations

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Printing date 25.06.2024  
Revision: 25.06.2024  
Version number 1.1

Trade name: Microcrystalline Cellulose 102

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· **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

· **\* Data compared to the previous version altered.**

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