

91205-AVICEL PH-101**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1 Identification of the substance or preparation**

Name: Avicel PH-101

Bulk code: 91205

Internal code: 405333

1.2 Synonyms

E-460 (i)

2. DESCRIPTION

Appearance: Powder.

Colour: White or almost white.

Odour: Odourless.

Origin: Plant (cellulose pulp obtained from trees).

3. COMPOSITION/INFORMATION ON COMPONENTS

CAS: 9004-34-6

EINECS/ELINCS: 23-674-9

Components:

100% microcrystalline cellulose

Method of production: Microcrystalline cellulose is manufactured through controlled hydrolysis with dilute solutions of α -cellulose mineral acid obtained as pulp from trees. After hydrolysis, the hydrocellulose is purified by filtration and the aqueous slurry is dried to form dry, porous particles of various sizes. The solvents used are a hydrochloric acid solution and a dilute ammonia solution.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: The product is practically insoluble in water, acetone, ethanol, toluene, dilute acids and in sodium hydroxide solution (50 g/l).

Hygroscopic.



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5. PROPERTIES/USES

Excipient for pharmaceutical use.

Food use.

The product can be used as a food additive according to the food additive specification (Reg. EU 231/2012).

The product is manufactured in line with the Hazard Analysis and Critical Control Point (HACCP) system and safety procedures in accordance with Commission Regulation (EC) Nos 852/2004, 853/2004, 854/2004, 178/2002; therefore, it is suitable for food application.

6. DOSAGE

No information available.

7. REMARKS

STORAGE:

Store at room temperature, in a cool, dry place, away from sunlight and moisture, in a tightly closed container.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

The product is free from the risk of bovine spongiform encephalopathy (according to EMEA guidelines 410/01 Rev02 and Regulation (EC) No 999/2001 and deferrals, laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies).

GMOs:

The product is not a derivative of genetically modified organisms (GMOs) according to regulations 1829/2003/EC and 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and any amending legislation.



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SVHC:

The product does not contain SVHC substances in an amount greater than 0.1%.

NANOMATERIAL:

The product is not a nanomaterial according to EU Regulation No 1169/2011.

RADIATION:

The product has not undergone irradiation in accordance with Directive 1999/2/EC and Directive 1999/3/EC.

PESTICIDES:

The product is compliant with EC Regulation 396/2005, Ministerial Decree 27/08/2004 and amendments.

RESIDUAL SOLVENTS:

The product is compliant with Directive 2009/32/EC and its amendments, with the ICH Q3C (R7) guideline, with Ph. Eur. general chapter 5.4 and with USP <467> and its amendments. No organic solvents are used.

COLOURANTS/PRESERVATIVES:

The product does not contain colourants or preservatives.

CONTAMINANTS:

The product is compliant with the contaminants (EC Regulation No 1881/2006 and its amendments):

- Dioxin/PCBs
- Mycotoxins

Alkaloids: The product is monitored for contamination with pyrrolizidine alkaloids.

IMPURITIES:

- PAHs: According to EU Regulation 1933/2015 (Benzo(a)pyrene = <10 ppb and PAH 4 = <50 ppb)
- Gelatine: Absent.
- Foreign material/metals: Absent.
- Flavourings: Absent.
- Sweeteners: Absent.
- Added sugar (sucrose, dextrose, glucose): Absent.
- Melamine: Absent.
- Latex: The product does not contain latex, has not been in contact with it, nor is it a derivative thereof.



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ALLERGENS:

- **Food allergens:** The product does not contain nor is it susceptible to cross-contamination with any of the food allergens referred to in Annex II to Regulation (EU) No 1169/2011.

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian use.

NUTRITIONAL COMPOSITION:

Energy value	//
Fat (saturated, monounsaturated, polyunsaturated)	//
Carbohydrates (sugar, polyols, starch)	//
Salt	//
Fibre	//
Protein	//

WADA:

The product does not contain any substances included in the World Anti-Doping Agency's (WADA) Prohibited List (latest edition).

*Products may contain ethanol as a solvent used in some of the chemical syntheses and as a cleaning agent in the manufacturing processes. According to the World Anti-Doping Agency, alcohol is prohibited in competition only, in the following sports: Air Sports (FAI), Archery (WA), Automobile (FIA), Powerboating (UIM). Detection will be performed by breath and/or blood tests. The doping violation threshold is equivalent to a blood alcohol concentration of 0.10 g/l.

CITES:

Not derived from endangered species (see CITES LIST/ www.cites.org)