

## Product specification

**Name of product:** Glycerin 99,5 % Pharma

**Description:** Glycerin 99,5 % obtained from vegetable sources

Product's quality corresponds to European Pharmacopoeia 10 ed.. It is allowed to use in food, pharmaceutical, cosmetic and food industry. The product is listed in the following regulations or adheres to such regulations respectively the COMMISSION REGULATION (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council, as food additive E422.

### Typical parameters:

Parameter	Unit	Quality	Method
Appearance of solution in water			Ph. Eur. 10
Sulphated ash	%	0,00 – 0,01	Ph. Eur. 10
Glycerol contents	%	98,0 – 101,0	Ph. Eur. 10
Colour APHA/HAZEN		0 – 10	EN ISO 6271-2
Index of refraction by 20°C		1,470 – 1,475	Ph. Eur. 10
Identity test		Correspond	Ph. Eur. 10, A+B
Sugar		Correspond	Ph. Eur. 10
Impurity an related substances		max. 0,1	Ph. Eur. 10
Content of any other impurities with a retention time less than the retention time of glycerol	% (m/m)	max. 0,1	Ph. Eur. 10
Content of impurities with a retention times greater than the retention time of glycerol	% (m/m)	max. 0,5	Ph. Eur. 10
Aldehydes	ppm	max. 10	Ph. Eur. 10
Acidity or alkalinity	ml 0,1 M NaOH	max. 0,2	Ph. Eur. 10
Halogenate compounds	ppm	max. 35	Ph. Eur. 10
Esters	ml 0,1 M HCl	min. 8,0	Ph. Eur. 10
Chlorides	ppm	max. 10	Ph. Eur. 10
Water content	%	0,0 – 0,5	Ph. Eur. 10
Heavy metals	ppm	max. 5	Ph. Eur. 10
Diethylene glycol content	% (m/m)	max. 0,1	Ph. Eur. 10
Appearance		color APHA less than 10	Ph. Eur. 10
Density at 20°C	g/cm <sup>3</sup>	min. 1,262	Ph. Eur. 10

Microbiology	Value	Complies
Salmonella (cfu/25g)	Negative	Yes
Escherichia coli (cfu/g)	<10 <sup>2</sup>	Yes

### Oleochem, a.s.

Žukovova 49/30, Střekov

400 03 Ústí nad Labem

The firm is registered in Ústí nad Labem court in section B, file 2646

Vat exempt no. CZ28361806

ID 28361806

[www.oleochem.cz](http://www.oleochem.cz)

**Allergen info:**

Allergen	Present in product? (Yes / No)	Cross contamination possible? (Yes / No)
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof	No	No
Crustaceans and products thereof	No	No
Eggs and products thereof	No	No
Fish and products thereof	No	No
Peanuts and products thereof	No	No
Soybeans and products thereof	No	No
Milk and products thereof (including lactose)	No	No
Nuts (i.e. Almond, Hazelnuts, Walnut, Cashew, Pecan nut, Brazil nut, Pistachio nut, Macadamia nut and Queensland nut, and products thereof)	No	No
Celery and products thereof	No	No
Mustard and products thereof	No	No
Sesame seeds and products thereof	No	No
Sulphur dioxide and sulphides at concentrations of more than 10 mg/kg or 10 mg/litre, expressed as SO <sub>2</sub>	No	No
Lupin and products thereof	No	No
Molluscs and products thereof	No	No

**Nutritional data:**

Nutrients	Values
Energy (kJ/100g)	1800
Fat (g/100g)	0
Saturated fatty acids (g/100g)	0
Carbohydrates (g/100g)	0
Sugars (g/100g)	0
Protein (g/100g)	0
Salt (g/100g)	0

**Genetical Modified Organisms (GMO):** the material does not require labelling as a genetically modified product, as per EU Regulations 1829/2003 and 1830/2003.

**The material do not contain allergens and is according REGULATION (EC) No 1223/2009.**

**Storage, handling, shelf life:** store in cool, dry warehouse, in original containers, away from contamination. Shelf life is packaging in bulk: one year, packaging in drums: one year, packaging in IBC: two years, (in original packing, closed, without air and light acces, quality and product composition like Czech pharmacopoeia) after the date of production, if stored under the right conditions.

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