

Product name	GLICERINA 99.5% SP
GLICERINA 99.5% SP , USP+Ph.Eur. GMO free E422 (HS code 290545)	

1. Product identity

Chemical Characterization	Glycerine (1, 2, 3 – Propantriol)
Synonyms	Glycerol, Glycerol anhydrous
Empirical formula	C ₃ H ₈ O ₃
CAS No.	56-81-5
EINECS-No.	200-289-5
Molar mass / <i>molare Masse</i>	92,1 g/mol
HS code (Harmonized System Code (HS))	290545

2. Designated use

For use as Food additive (E422).

3. Composition

Component	Ratio	Unit	Source	Country of origin of the rawmaterial	Country of processing
Glycerine	99,5	%	Vegetable oil	Europe	Germany
Water	0,5	%			

4. Shelf life and storage, packaging

shelf life	1 year from release Loading tank
storage and handling conditions	Storage temperature: 35 - 52 °C Nitrogen overlay : necessary when stored over a month Agitator/Circulation : recommended Storage tank stainless steel
Packaging / <i>Verpackung:</i>	tank vehicle - for food transport only. Transport is carried out in clean containers suitable for food transport, avoiding contaminants or other negative influences. IBC –Transport is carried out in clean containers suitable for food transport, avoiding contaminants or other negative influences
Production process	Crude glycerine originates from biodiesel production, which is won by transesterification of not genetically modified vegetable oils.

5. Certifications / Quality Grade

Certifications	Yes	No	remark
ISO 9001 certification	☒	☐	
Kosher certification	☒	☐	
Halal certification	☒	☐	
Energy management (ISO 50001)	☒	☐	
Quality Grade / Registration	Yes	No	remark
Registration according to Regulation (EC) No. 852/2004 on the hygiene of foodstuffs.	☒	☐	
European Pharmacopoeia (EP / Ph. Eur.) Grade	☒	☐	
United States Pharmacopeia (USP) Grade	☒	☐	
British Pharmacopeia (BP) Grade	☐	☒	
Chinese Pharmacopoeia Grade	☐	☒	
E 422 corresponding to EC directive EU 231/2012.	☒	☐	
REACH registration The exemption refers to glycerol which is obtained from natural sources. A registration is not necessary [commission regulation (EC) no. 987/2008 of 8 October 2008, amending regulation (EC) no. 1907/2006 as regards annex IV and V.]	☐	☒	
Safety Data Sheet / Sicherheitsdatenblatt	☒	☐	
FDA Registration (Registration Number: 16162598458)	☒	☐	

6. Statements on special diets

	Yes	No
suitable for gluten-free diet	☒	☐
suitable for lactose-free diet	☒	☐
suitable for vegetarian diet	☒	☐
suitable for vegan diet	☒	☐
suitable for Muslim diet	☒	☐
suitable for Jewish diet	☒	☐

7. Allergens

Contains no Allergens, according to Annex II of the Food Information Regulation VO (EU) No. 1169/2011 as amended from time to time

Product Information Sheet

Allergens (European legislation VO (EU) no. 1129/2011)	Contains	Cross-Contamination (Risk)
gluten containing grain	No	No
shellfish and obtained products	No	No
eggs and obtained products	No	No
peanuts and obtained products	No	No
soybeans and obtained products	No	No
milk and obtained products	No	No
celery and obtained products	No	No
mustard and obtained products	No	No
sesame seeds and obtained products	No	No
sulphur dioxide and sulphite in concentrations higher than 10 mg/kg or 10 mg/l as SO ₂	No	No
lupins and obtained products	No	No
molluscs and obtained products	No	No
edible nuts, such as - almonds (<i>Prunus dulcis</i>), - hazel-nuts (<i>Corylus avellana</i>), - walnuts (<i>Juglans regia</i>), - cashew nuts (<i>Anacardium occidentale</i>), - pecans (<i>Carya illinoiesis</i>), - brazil nuts (<i>Bertholletia excelsa</i>), - macadamia nuts, and - queenslands nuts (<i>Macadamia ternifolia</i>) and obtained products. / (<i>Macadamia ternifolia</i>)	No	No

Contains no ingredients subject to declaration according to the ALBA list (LeDa list) version 2.0/2011

8. Requirements

No.	Parameter	Dim	European Pharmacopoeia (EP) Grade		United States Pharmacopeia (USP) Grade		E422 VO (EU) no. 231/2012	Glycerine F 208 RS		Analysis		Interval
			Specification	Method	Specification	Method		Specification	Method	internal	accred. lab	
1	Characters	--	viscous, colourless, clear, very hygroscopic	Ph. Eur.*	--	--	clear, colourless, hygroscopic, syrupy liquid with only a slight, characteristic odour, which is neither strong nor unpleasant	meets test	Ph. Eur.*	X		**
2	glycerine content (calculated on the anhydrous basis)	%	98,0 - 101,0	Ph. Eur.*	99,0 - 101,0	USP*	≥ 98,0	99,5 - 101,0	Ph. Eur.* / USP*	X		**
3	Identification	--	A / B / C meets test	Ph. Eur.*	A / B / C meets test	USP*	B) specific gravity (25/25°C) C) refractive index (20/20°C)	meets test	Ph. Eur.* / USP*	X		**
4	Appearance of solution	--	clear, colourless	Ph. Eur.*	--	--	--	meets test	Ph. Eur.*	X		**
5	Color	--	--	--	conforms	USP*	--	--	--	X		**
6	Color (APHA)	--	--	--	--	--	--	≤ 10	ISO 2211	X		**
7	Acidity or alkalinity	ml 0,1N NaOH	≤ 0,2	Ph. Eur.*	--	--	--	≤ 0,2	Ph. Eur.*	X		**
8	Fatty acids and esters	ml 0,1N HCl	--	--	≤ 1,0	USP*	--	≤ 1,0	USP*	X		**

Product Information Sheet

9	Fatty acids and esters (calc. as butyric acid)	%	--	--	--	--	≤ 0,1	≤ 0,1	USP*	X		**
10	Ester content	ml 0,1N HCl	≥ 8,0	Ph. Eur.*	--	--	--	≥ 8,0	Ph. Eur.*	X		**
11	Halogenated compounds (Ph. Eur.*) / Limit of chlorinated compounds (USP*)	ppm % of Cl ppm	≤ 35	Ph. Eur.*	≤ 0,003	USP*	≤ 30	≤ 0,003	USP*	X		**
12	Aldehydes		≤ 10	Ph. Eur.*	--	--	--	< 10	Ph. Eur.*	X		**
13	Sugars	--	conforms	Ph. Eur.*	--	--	--	negativ	Ph. Eur.*	X		**
14	Chloride(s)	ppm	≤ 10	Ph. Eur.*	≤ 10	USP*	--	≤ 10	Ph. Eur.* / USP*	X		**
15	Sulfate	ppm	--	--	≤ 20	USP*	--	< 5	acc. DIN EN 14538	X		**
16	Relative density (Ph. Eur.*) d 20/20°C / Specific gravity (USP*) d 25/25°C / Relative density d 25/25°C (E422)	--	1,258 - 1,268	Ph. Eur.*	≥ 1,249	USP*	≥ 1,257	≥ 1,262 / ≥ 1,249 / ≥ 1,257	Ph. Eur.* / USP*	X		**
17	Refractive index n20D	--	1,470 - 1,475	Ph. Eur.*	--	--	1,471 - 1,474	1,471 - 1,474	Ph. Eur.*	X		**
18	Residue on ignition	ml	--	--	≤ 5	USP*	--	< 1	USP*	X		**
19	Sulfated ash	% (m/m)	≤ 0,01	Ph. Eur.*	≤ 0,01	USP*	≤ 0,01	< 0,005	Ph. Eur.*	X		**
20	Water	%	≤ 2,0	Ph. Eur.*	≤ 5,0	USP*	≤ 5,0	< 0,5	Ph. Eur.* / USP*	X		**
21	Impurity A and related substances: - Σ impurities with retention time > retention time of glycerol - each impurity with retention time < retention time of glycerol	% (m/m)	≤ 0,5 ≤ 0,1 ≤ 0,1	Ph. Eur.*	--	--	--	≤ 0,5 ≤ 0,1 ≤ 0,1	Ph. Eur.*	X		**
22	-Limit of diethylene glycol and Diethylene glycol (Impurity A) ethylene glycol: - DEG (diethylene glycol) - EG (ethylene glycol)	%	--	--	≤ 0,10 ≤ 0,10	USP*	--	≤ 0,10 ≤ 0,10	USP*	X		**
23	Related compounds: - total impurities - any individual impurity	%	--	--	≤ 1,0 ≤ 0,1 each	USP*	--	≤ 1,0 ≤ 0,1 each	USP*	X		**
24	organic volatile compounds (VOC) - residual solvents	--	--	--	meets test	USP*	--	meets test	Ph. Eur.* / USP*	X		**
25	butantriolo	%	--	--	--	--	≤ 0,2	< 0,1	Ph. Eur.*	X		**
26	Acrolein	mg/kg	--	--	--	--	≤ 3	≤ 3	WEX 1842 (VES-D) SF0XJ (GC-MS) (VEB)		X	2x / year
27	3-Monochloropropan-1,2-diol (3-MCPD)	mg/kg	--	--	--	--	≤ 0,1	< 0,1	VEB - IHM (AA01279) (Prep. NaBr/GC-MS) / VES-D - IKB.00.14.34.G C (Prep. NaBr/GC-MS)	X (VEB)	X (VES-D)	**
28	arsenic (As)	mg/kg	--	--	--	--	≤ 0,1	≤ 0,1	ISO 17294-2		X	2x / year
29	lead (Pb)	mg/kg	--	--	--	--	≤ 0,1	≤ 0,1	ISO 17294-2		X	2x / year
30	mercury (Hg)	mg/kg	--	--	--	--	≤ 0,1	≤ 0,1	ISO 16772		X	2x / year
31	cadmium(Cd)	mg/kg	--	--	--	--	≤ 0,1	≤ 0,1	ISO 17294-2		X	2x / year

Microbiological requirements												
1	Total viable count	cfu/g	--	--	--	--	--	≤ 100	ISO 4833 - 1		X	2x / year
2	Yeast & Moulds	cfu/g	--	--	--	--	--	≤ 10	ISO 215271:2008		X	2x / year
3	Coliforms	cfu/g	--	--	--	--	--	< 30	ISO 4832:2006		X	2x / year
4	Escherichia coli	in 25 g	--	--	--	--	--	Not detected	ISO 16649-3:2015		X	2x / year

Product Information Sheet

5	Anaerobe sulfite reducing	cfu/g	--	--	--	--	--	≤ 30	ISO 15213:2003		X	2x / year
6	Bacillus cereus	cfu/g	--	--	--	--	--	≤ 10	ISO 7932:2004/A md 1:2020		X	2x / year
7	Staphylococcus aureus	in 1 g	--	--	--	--	--	Not detected	ISO 6888-3:2003		X	2x / year
8	Salmonella ssp	in 25 g	--	--	--	--	--	Not detected	ISO 6579-1:2017		X	2x / year
9	TAMC (total aerobic microbial count)	cfu/g	< 10	Ph. Eur.*	--	--	--	--	--		X	2x / year
10	Gallensalzresistente Bakterien	cfu/g	< 10	Ph. Eur.*	--	--	--	--	--		X	2x / year
11	Staphylococcus aureus	in 1 g	negativ	Ph. Eur.*	--	--	--	--	--		X	2x / year

* current version, ** according to current test plan

9. Nutritional data

Nutrient	Value per 100g	Unit
energy	1824.8	kJ
	435.9	kcal
protein	< 0.07	g
Carbohydrates (multivalent alcohol; 1,2,3-Propanetriol; glycerol)	99.95	g
- thereof sugar	< 0.01	g
Fat	<0.07	g
- thereof saturated fatty acids	< 0.07	g
monounsaturated fatty acids	< 0.01	g
polyunsaturated fatty acids	< 0.01	g
fibre (ash)	< 0.01	g
sodium	< 0.01	g
equivalent as salt	< 0.01	g

10. Statements on quality management

	Yes	No	comments
HACCP concept	☒	☐	According to legal requirements (Regulation (EC) No. 852/2004 on food hygiene)
- Number and description of CCP's	☐	☒	No CCP's identified
- foreign bodies treatment	☒	☐	is documented in our HACCP-handling instruction and analysed in the risk analysis
Traceability	☒	☐	according to European legislation VO (EU) no. 178/2002
Food Fraud	☒	☐	

Food defence	☒	☐	
--------------	-------------------------------------	--------------------------	--

11. Environmental Toxins

The manufacturer declare that the above mentioned product is regularly analyzed twice a year by an accredited external laboratory. No exceedances of the corresponding limit values (lower detection limit) for the following substances were found: - Polycyclic aromatic hydrocarbons (PAH).

- Dioxin-like PCBs
- Polychlorinated biphenyls (PCBs)
- Pesticides

12. Statements on GMO

The products listed above meet the requirements of Regulation (EC) No. 1829/2003 of September 22, 2003 on genetically modified food and feed, as well as the requirements of Regulation (EC) No. 1830/2003 of September 22, 2003 on traceability and Labeling of genetically modified organisms and on the traceability of food and feed produced from genetically modified organisms.

This includes the following content:

- The products do not consist of genetically modified organisms.
- The products do not contain any genetically modified organisms.
- The products are not created entirely or partially from or through genetically modified organisms.
- Carriers, nutrient media, auxiliary substances and other additives, if used, do not contain any genetically modified organisms and are not produced from or by genetically modified organisms.

13. Further details

No.	Statement	Yes	No
1	The above product is free of ethylene oxide and 1,4- dioxane. *	☒	☐
2	Use of catalysts in the manufacturing of the above product	☐	☒
3	The above product is free of any kind of hormones. *	☒	☐
4	The above product is free of Nitrosamines. *	☒	☐
5	The above product does not contain microplastics. *	☒	☐
6	We do not use nanomaterials in the production of glycerin and do not add nanomaterials to the product. *	☐	☒
7	The above product is free of Palm Oil. *	☒	☐
8	We certify that our product, listed above, is not exposed to ionising or radioactive radiation within our production process.	☒	☐

Product Information Sheet

9	The above product is free from residual solvents. It complies with ICH guideline Q3C (R8) on impurities. The potential impurities from the product above are regularly monitored analytically (impurity A on CoA). They are below the detection limit. *	☒	☐
10	Mineral Oil (MOSH and MOAH) We declare that in the process it is not used any raw material or other ingredients that are based on Mineral Oil Saturated Hydrocarbons (MOSH) or Mineral Oil Aromatic Hydrocarbons (MOAH). *		
11	the manufacturer srl declares that GLYCERINE is analysed regularly twice a year by an accredited external laboratory. No exceeding of any appropriate limit for PFAS (Per-and Polyfluoroalkyl Substances) have been found.		

*Please be advised this declaration is not based on specific analysis of the GLICERINA 99.5% SP raw materials and it is based on production process knowledge and the information obtained from our suppliers.

San Giovanni Lupatoto, 22/10/2025