

PRODUCT SPECIFICATION – PHARMA INGREDIENTS

GLYCERINE VEGETABLE (E422) PHARM. KOSHER

ConnectingChemistry



1. PRODUCT IDENTIFICATION

Product name	GLYCERINE VEGETABLE (E422) PHARM. KOSHER		
Product number	12856	Date of issue: 11/09/2019	Replaces: 20/11/2018
Origin	Vegetable		
Manufacturer	Several (Cremer Oleo, Cargill, Wilmar, Oleon & Glencore)		
Country	Several		
Certification manufacturer	ISO 9001		

1.1 Composition

Single ingredient	
Chemical name	Glycerine, glycerol
Chemical formula	C ₃ H ₈ O ₃
Molecular weight	92,0938

1.2 Legislative information

CAS-N°	56-81-5
INTRASTAT CODE	290545
EINECS	200-289-5
Legal declaration	E422

2. PRODUCT INFORMATION

	Unit	Specification	Method
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2.1 Physical and Chemical properties

Appearance		Clear liquid	
Colour		Colourless	
Odour/taste		Odourless	
Assay	wt%	min. 99,5	Ph.Eur.
Water	wt%	max. 0,5	E422, Ph.Eur.; KF
Colour	APHA	max. 10	Ph.Eur.; ISO2211
Refractive index (20°C)	D 20	1,470 – 1,475	E422, Ph.Eur.
Rel. Density (20°C)	kg/l	Min. 1,26	USP
Impurity A	%	max. 0,1	
Other imp. R (t)	%	max. 0,1	
Sum of imp. R (t)	%	max. 0,5	



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2.2 Microbiological data

TVC	cfu/g	max. 10	
Yeast	cfu/g	max. 10	
Moulds	cfu/g	max. 10	
Enterobacteriaceae	cfu/g	max. 10	
Feecal Streptococcus	cfu/g	max. 1	
E-Coli	cfu/g	max. 1	
Salmonella spp.		Absent/25 g	

2.3 Contaminants (EC-Regulation 1881/2006)

2.3.1 Chemical contaminants

Acidity or alkalinity	ml NaOH 0.1 M	max. 0,2	Ph.Eur.
Aldehydes	mg/kg	max. 10	Ph.Eur.
Sulphated ash	%	max. 0,01	E422, Ph.Eur.
Chloride (Cl)	ppm	max. 10	Ph.Eur.
Esters	ml HCl 0.1 M	min. 8	Ph.Eur.
Halogenated compounds	ppm	max. 35	E422, Ph.Eur.
Heavy metals (as Pb)	ppm	max. 5	E422, Ph.Eur.
Sugar		Negative	
Butanetriols	%	max. 0,2	
Fatty acids&esters as butaric acid	%	max. 0,1	
Arsenic	mg/kg	max. 3	
Cadmium	mg/kg	max. 1	
Lead	mg/kg	max. 2	
Mercury	mg/kg	max. 1	

2.3.2 Physical contaminants

Foreign body control	Y	Filter	
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2.4 Nutritional Information (Directive 90/496/EC, amended by 2003/120/EC and 2008/100/EC)

2.4.1 Nutritional Values

Energy	kJ/100g	1800	
Energy	kcal/100g	430	
Protein	g/100g	0	

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Carbohydrate :	g/100g	100	
Of which Sugars	g/100g	0	
Polyols	g/100g	100	
Starches	g/100g	0	
Others	g/100g	0	
Fat :	g/100g	0	
Of which Saturated	g/100g	0	
Mono-unsaturated	g/100g	0	
Poly-unsaturated	g/100g	0	
Transfatty acids	g/100g	0	
Cholesterol	mg/100g	0	
Water	g/100g	max. 0,5	
Organic acid	g/100g	-	

2.4.2 Minerals

Sodium	mg/100g	-	
Calcium	mg/100g	-	
Zinc	mg/100g	-	
Copper	mg/100g	-	
Phosphorus	mg/100g	-	
Others:	mg/100g	-	

3. STATEMENTS

3.1.1 Allergens food (Directives 2000/13/EC, 2003/89/CE 2007/68/EC)

	Y / N	Direct Contamination	Cross-Contamination (Risk)
Barley	N	N	N
Beef	N	N	N
Cacao	N	N	N
Carrot	N	N	N
Celery and celery products	N	N	N
Cereals containing gluten and products produced with these (wheat, rye, oats, spelt, barley)	N	N	N
Chicken	N	N	N
Coriander	N	N	N



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Crustaceans and Shellfish	N	N	N
Eggs and egg products	N	N	N
Fish and fish products	N	N	N
Glutamate	N	N	N
Lupin and products thereof	N	N	N
Milk and milk products (incl. Lactose)	N	N	N
Molluscs and products thereof	N	N	N
Mustard and mustard products	N	N	N
Nuts and nut products (almonds, hazelnuts, walnuts)	N	N	N
Peanuts and peanut products	N	N	N
Pork	N	N	N
Sesame and sesame products	N	N	N
Soybean and soybean products	N	N	N
Sulphite (E221 - E228)	N	N	N
Sulphur dioxide (> 10 mg/kg)	N	N	N

3.1.2 Allergens cosmetic products (Regulation (EC) N° 1223/2009 on cosmetic products)

Allergens of the 26 allergenic substances which must be labeled on the packaging of cosmetics if added, as such, at concentrations exceeding 0.01 w/w, are not contained in the product.

3.2 Suitability for other diets

Coeliacs	Y	Lactose intolerant	Y
Halal	Y (not certified)	Vegans	Y
Kosher	Y	Vegetarian	Y

3.3 GMO Declaration, acc. Regulations 298/2008/EC and 1830/2003/EC

GLYCERINE VEGETABLE (E422) PHARM. KOSHER does not contain genetically modified organisms and is not produced using raw materials of a genetically modified origin. At no stage during production does the product come into contact with genetically modified organisms.

GLYCERINE VEGETABLE (E422) PHARM. KOSHER is falling under the scope of the EC Regulation n° 1829/2003 on genetically modified food and feed and the EC Regulation n° 1830/2003 on the traceability and labeling of genetically modified organisms and the traceability of products derived from them and to modification of Directive 2001/18/EC.

3.4 Irradiation, acc. Directive 1999/2/EC and 1999/3/EC

This product was not subject to any kind of irradiation treatment

3.5 BSE/TSE Declaration

The used ingredients for GLYCERINE VEGETABLE (E422) PHARM. KOSHER are not of animal origin. The processing equipment and the packing material which is used to manufacture, pack or fill the products into the packing units do not come into contact with any meat or meat-by product.



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3.6 Residual Solvents, complies with

For the manufacturing of the product, no solvents are used. This product is in compliance with the Guideline CPMP/ICH/283/95 and chapter <467> of the current edition of the USP-NF for residual solvents.

3.7 Regulatory information

The product complies with:

Ph. Eur., USP, FCC, JP, E422
EC Regulation 231/2012/EC on food additives listed in Annexes II and III (GLYCERINE VEGETABLE).
EC Regulation n° 1881/2006 setting maximum levels for certain contaminants in foodstuffs.

The production plant complies with:

EC Regulation n° 852/2004 on hygienic requirements for the manufacturing of raw materials in the food industry.

3.8 Animal testing

See Regulation (EC) N° 1223/2009 on cosmetic products

The product was not tested on animals on behalf of Brenntag.

4. PACKAGING

Packaging description	Bulk / cans / drums/ IBC
Packaging net content	-/ 25/ 262/500,1100,1250kg
Different packagings on request	Yes
Paletisation	

5. STORAGE CONDITIONS

Storage conditions	Must be kept in a cool, dry and well ventilated environment, in closed original packaging
Shelf life (recommended re-analysis)	12 months after production, under the above mentioned conditions

6. DISCLAIMER

The content of the Product Specification Sheet is completed to the best of our knowledge. This document does not dismiss the user of his legal obligation with respect to food safety.



COMPANY INFORMATION DISTRIBUTOR		
name	BRENNTAG N.V.	BRENNTAG Nederland B.V.
address	Nijverheidslaan 38 8540 Deerlijk	Donker Duyvisweg 44 3316 BM Dordrecht
country	Belgium	The Netherlands
phone number	+32 (0)56 77 69 44	+31 (0)78 65 44 944
fax number	+32 (0)56 77 57 11	+31 (0)78 65 44 919
website	www.brenntag.be	www.brenntag.nl
e-mail	info@brenntag.be	info@brenntag.nl
activities	Distribution and export of chemicals and raw materials	
VAT number	BE0405317567	NL001375945B01
recall procedure available	Yes	
emergency number (24/365)	+32 (0)56 77 69 44	+31 (0)78 6544 944
QUALITY SYSTEMS		
ISO 9001	Yes	Yes
ISO 14001	Yes	Yes
ISO 22000	Yes	Yes
FSSC 22000	Yes	Yes
GMP+ -feed	Yes	Yes
OHSAS18001	-	Yes
ESAD	Yes	Yes
other	-	AEO