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Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2470. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (Text with EEA relevance)

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[F1ANNEX

UNION LIST OF NOVEL FOODS

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2018/1023 of 23 July 2018 correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods (Text with EEA relevance)

Content of the list

1. The Union list shall consist of Tables 1 and 2.

2. Table 1 includes the authorised novel foods and contains the following information:

Column 1 : Authorised novel food

Column 2 : Conditions under which the novel food may be used. This column is

further subdivided into two: Specified food category and Maximum

levels

Column 3 : Additional specific labelling requirements

Column 4 : Other requirements

3. Table 2 includes the specifications on novel foods and contains the following

information:

Column 1 : Authorised novel food

Column 2 : Specifications

TABLE 1: AUTHORISED NOVEL FOODS

Authorised novel food	Conditions unde novel food may		Additional Other specific requirements labelling requirements		
neuraminic acid Infa foll forr defi Reg	Infant and follow-on formulae as defined by Regulation (EU) No 609/2013 ^a	Maximum levels 0,05 g/L of reconstituted formula	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'N-acetyl-D-neuraminic acid' Food supplements containing N-acetyl-D-neuraminic acid shall bear a statement that the food supplement should not be given to infants,		
	Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013	0,05 g/kg for solid foods			

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Foods for special medical purposes for infants and young children as defined by Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the infants and young children for whom the products are intended but in any case not higher than the maximum levels specified for the category mentioned in the table corresponding to the products.	
Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013	0,2 g/L (drinks) 1,7 g/kg (bars)	
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 ^b	1,25 g/kg	
Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,05 g/L	
Unflavoured fermented milk- based products, heat treated after fermentation, flavoured fermented	0,05 g/L (beverages) 0,4 g/kg (solids)	

young children and children under 10 years of age where they consume breast milk or other foods with added *N*-acetyl-D-neuraminic acid within the same twenty four hour period.

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Ajuga reptans extract from cell cultures	Specified food category	Maximum levels		
Adansonia digitata (Baobab) dried fruit pulp	Not specified	Manimum	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Baobab fruit pulp'	
	Food Supplements as defined in Directive 2002/46/EC°	300 mg/day for general population older than 10 years 55 mg/day for infants 130 mg/day for young children 250 mg/day for children between 3 to 10 years of age		
	Speciality coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions	0,2 g/kg		
	Fruit and vegetable-based drinks Flavoured drinks	0,05 g/L		
	Table top sweeteners	8,3 g/kg		
	including beverage whiteners Cereal bars	(beverages) 0,25 g/kg (solids) 0,5 g/kg		
	milk products including heat-treated products Dairy analogues,	0,05 g/L		

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	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of a similar extract of the flowering aerial parts of <i>Ajuga reptans</i>		
L-Alanyl-L- Glutamine	Specified food category	Maximum levels		
	Food Supplements as defined in Directive 2002/46/EC			
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013 excluding foods for infants and young children			
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen			
Algal oil from the microalgae	Specified food category	Maximum levels of DHA	The designation of the novel food	
Ulkenia sp.	Bakery products (breads, rolls and sweet biscuits)	200 mg/100 g	on the labelling of the foodstuffs containing it shall be 'Oil	
	Cereal bars	500 mg/100 g	from the micro-	
	Non-alcoholic beverages (including milk based beverages)	60 mg/100 ml	algae Ulkenia sp.'	
Allanblackia seed oil	Specified food category	Maximum levels	The designation of the novel food	
	Yellow fat spreads and cream based spreads	20 g/100 g	on the labelling of the foodstuffs containing it shall be 'Allanblackia seed oil'	

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Aloe macroclada Baker leaf	Specified food category	Maximum levels		
extract	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of the similar gel derived from Aloe vera (L.) Burm.		
Antarctic Krill oil from Euphausia superba	Specified food category	Maximum levels of combined DHA and EPA	The designation of the novel food on the labelling of the foodstuffs	
-	Dairy products except milk- based drinks	200 mg/100 g or for cheese products 600 mg/100 g	containing it shall be 'Lipid extract from the crustacean	
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g	Antarctic Krill (Euphausia superba)'	
	Non-alcoholic beverages Milk-based drinks Dairy analogue drinks	80 mg/100 ml		
	Spreadable fat and dressings	600 mg/100 g		
	Cooking fats	360 mg/100 ml	-	
	Breakfast cereals	500 mg/100 g	-	
	Bakery products (breads, rolls and sweet biscuits)	200 mg/100 g		
	Nutrition bars/ cereal bars	500 mg/100 g		
	Food Supplements as defined in Directive 2002/46/EC	3 000 mg/day for the general population 450 mg/day for pregnant and lactating women		
	Foods for special medical purposes as defined in	In accordance with the particular nutritional		

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	Regulation (EU) No 609/2013	requirements of the persons for whom the products are intended		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal		
	Processed cereal-based food and baby food intended for infants and young children covered by Regulation (EU) No 609/2013	200 mg/100 ml		
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen			
	Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014			
Antarctic Krill oil rich in phospholipids from <i>Euphausia</i>	Specified food category	Maximum levels of combined DHA and EPA	The designation of the novel food on the labelling of the foodstuffs	
superba	Dairy products except milk- based drinks	200 mg/100 g or for cheese products 600 mg/100 g	containing it shall be 'Lipid extract from the crustacean Antarctic Krill	

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Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g
Non-alcoholic beverages Milk-based drinks Dairy analogue drinks	80 mg/100 ml
Spreadable fat and dressings	600 mg/100 g
Cooking fats	360 mg/100 ml
Breakfast cereals	500 mg/100 g
Bakery products (breads, rolls and sweet biscuits)	200 mg/100 g
Nutrition bars/ cereal bars	500 mg/100 g
Food Supplements as defined in Directive 2002/46/EC	3 000 mg/day for the general population 450 mg/day for pregnant and lactating women
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal
Processed cereal-based food and baby food intended	200 mg/100 ml

(Euphausia superba)'

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	for infants and young children covered by Regulation (EU) No 609/2013 Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU)			
Augahidania	No 828/2014 Specified food	Maximum	The designation	
Arachidonic acid-rich oil	category	levels	The designation of the novel food	
from the fungus Mortierella alpina	Infant formula and follow- on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013	on the labelling of the foodstuffs containing it shall be 'Oil from Mortierella alpina' or 'Mortierella	
	Foods for special medical purposes for premature infants as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013	alpina oil'	
Argan oil from	Specified food category	Maximum levels	The designation	
Argania spinosa	As seasonings	Not specified	of the novel food on the labelling	
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of vegetable oils	of the foodstuffs containing it shall be 'Argan oil' and if used as seasoning 'Vegetable oil only for seasoning' shall	

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			be mentioned on the label	
Astaxanthin- rich oleoresin from <i>Haematococcus</i> <i>pluvialis</i> algae	Specified food category	Maximum levels	The designation of the novel food	
	Food Supplements as defined in Directive 2002/46/EC	40-80 mg/day of oleoresin, resulting in ≤ 8 mg astaxanthin per day	on the labelling of the foodstuffs containing it shall be 'Astaxanthin'	
Basil seeds (Ocimum	Specified food category	Maximum levels		
basilicum)	Fruit juice and fruit/vegetable blend beverages	3 g/200 ml for addition of whole basil seeds (<i>Ocimum</i> basilicum)		
Fermented black bean	Specified food category	Maximum levels	The designation of the novel food	
extract	Food Supplements as defined in Directive 2002/46/EC	4,5 g/day	on the labelling of the foodstuffs containing it shall be 'Fermented black bean (Soya) extract'' or 'Fermented Soya extract'	
Bovine lactoferrin	Specified food category	Maximum levels	The designation of the novel food	
lactoleriii	Infant formula and follow- on formula as defined in Regulation (EU) No 609/2013 (ready to drink)	100 mg/100 ml	on the labelling of the foodstuffs containing it shall be 'Lactoferrin from cows' milk'	
	Foods on dairy basis intended for young children (ready to eat/drink)	200 mg/100 g		
	Processed cereal food (solid)	670 mg/100 g		
	Foods for special medical purposes as defined in	Depending on the needs of the individual up to 3 g/day		

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	Regulation (EU) No 609/2013			
	Beverages based on milk	200 mg/100 g		
	Powdered drink mixes based on milk (ready to drink)	330 mg/100 g		
	Beverages based on fermented milk (including yoghurt drinks)	50 mg/100 g		
	Non-alcoholic drinks	120 mg/100 g		
	Products based on yoghurt	80 mg/100 g		
	Products based on cheese	2 000 mg/100 g		
	Ice cream	130 mg/100 g		
	Cakes and pastries	1 000 mg/100 g		
	Candies	750 mg/100 g		
	Chewing gum	3 000 mg/100 g		
Buglossoides arvensis seed oil	Specified food category	Maximum levels of stearidonic acid (STA)	The designation of the novel food on the labelling of the foodstuffs	
	Dairy products	250 mg/100 g	containing it	
	and analogues	75 mg/100 g for drinks	shall be 'Refined Buglossoides oil'	
	Cheese and cheese products	750 mg/100 g		
	Butter and other fat and oil emulsions including spreads (not for cooking or frying purposes)	750 mg/100 g		
	Breakfast cereals	625 mg/100 g		
	Food supplements as defined in Directive	500 mg/day		

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	2002/46/EC, excluding food supplements for infants and young children	In accordance		
	special medical purposes as defined in Regulation (EU) No 609/2013, excluding foods for special medical purposes intended for infants and young children	with the particular nutritional requirements of the persons for whom the products are intended		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal		
Calanus finmarchicus oil	Specified food category Food supplements as defined in Directive 2002/46/EC	Maximum levels 2,3 g/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'oil from <i>Calanus finmarchicus</i> (crustacean)'	
Chewing gum base	Specified food category	Maximum levels	The designation of the novel food	
(monomethoxypo	Vathyleg gum	8 %	on the labelling of the foodstuffs containing it shall be 'Gum base (including 1,3-butadiene, 2-methyl-homopolymer, maleated, esters with polyethylene glycol mono-Me ether)' or 'Gum	

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			base (including CAS No: 1246080-53-4)'
Chewing gum base	Specified food category	Maximum levels	The designation of the novel food
(Methyl vinyl ether-maleic anhydride copolymer)	Chewing gum	2 %	on the labelling of the foodstuffs containing it shall be 'Gum base (including methyl vinyl ether-maleic anhydride copolymer)' or 'Gum base (including CAS No 9011-16-9)'
Chia oil from Salvia hispanica	Specified food category	Maximum levels	The designation of the novel food
	Fats and oils	10 %	on the labelling
	Pure chia oil	2 g/day	of the foodstuffs containing it
	Food Supplements as defined in Directive 2002/46/EC	2 g/day	shall be 'Chia oil (Salvia hispanica)'
Chia seeds (Salvia	Specified food category	Maximum levels	1. The designation
hispanica)	Bread products	5 % (whole or ground chia seeds)	of the novel food
	Baked products	10 % whole chia seeds	on the labelling of the
	Breakfast cereals	10 % whole chia seeds	foodstuffs containing it shall
	Fruit, nut and seed mixes	10 % whole chia seeds	be 'Chia
	Fruit juice and fruit/vegetable blend beverages	15 g/day for addition of whole, mashed or ground chia seeds	seeds (Salvia hispanica)' 2. Pre- packaged Chia
	Pre-packaged Chia seed as such	15 g/day whole chia seeds	(Salvia hispanica) seeds shall carry

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	Fruit spreads	1 % whole chia seeds	additional labelling to
	Yoghurt	1,3 g whole chia seeds per 100 g of yoghurt or 4,3 g whole chia seeds per 330 g of yoghurt (portion)	inform the consumer that the daily intake is no
	Sterilised ready to eat meals based on cereal grains, pseudocereals grains and/or pulses	5 % whole chia seeds	more than 15 g.
Chitin- glucan from Aspergillus niger	Food Supplements as defined in Directive 2002/46/EC	Maximum levels 5 g/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chitinglucan from Aspergillus niger'
Chitin-glucan complex from Fomes fomentarius	Food Supplements as defined in Directive 2002/46/EC	Maximum levels 5 g/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chitin-glucan from Fomes fomentarius'
Chitosan extract from fungi (Agaricus bisporus; Aspergillus niger)	Specified food category Food Supplements as defined in Directive 2002/46/EC	Maximum levels In line with normal use in food supplements of chitosan from crustaceans	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chitosan extract from Agaricus bisporus' or 'Chitosan extract from Aspergillus niger'
Chondroitin sulphate	Specified food category	Maximum levels	The designation of the novel food on the labelling

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	Food supplements as defined in Directive 2002/46/EC for adult population, excluding pregnant and lactating women	1 200 mg/day	of the foodstuffs containing it shall be 'Chondroitin sulphate derived from microbial fermentation and sulphation'	
Chromium Picolinate	Specified food category	Maximum levels of total chromium	The designation of the novel food on the labelling	
	Foods covered by Regulation (EU) No 609/2013	250 μg/day	of the foodstuffs containing it shall be 'Chromium Picolinate'	
	Foods fortified in accordance with Regulation (EC) No 1925/2006 ^d			
Cistus incanus	Specified food category	Maximum levels	The designation	
L. Pandalis herb	Herbal infusions	Intended daily intake: 3 g herbs/day (2 cups/day)	of the novel food on the labelling of the foodstuffs containing it shall be 'Cistus incanus L. Pandalis herb'	
Citicoline	Specified food category	Maximum levels	1. The designat	ion
Food Supplements as defined in Directive 2002/46/EC Foods for special medica purposes as defined in	Supplements as defined in Directive	500 mg/day	of the novel food on the labelling of the foodstuff containing it shall be 'Citicoling of foods containing citicoling shall bear a	
	special medical purposes as defined in Regulation (EU)	250 mg per serving and a maximum daily consumption level of 1 000 mg		ng ne'

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			statementhat the product is not intended to be consume by children	ed
Clostridium butyricum	Specified food category Food Supplements as defined in Directive 2002/46/EC	Maximum levels 1,35 × 10 ⁸ CFU/ day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Clostridium butyricum MIYAIRI 588 (CBM 588)' or 'Clostridium butyricum (CBM 588)'	
Extract of defatted cocoa powder	Nutrition bars Milk based beverages Any other foods (including food supplements as defined in Directive 2002/46/ EC) which have become established vehicles for functional ingredients and which are typically positioned for consumption by health conscious adults	Maximum levels 1 g/day and 300 mg polyphenols corresponding to not more than 550 mg of extract of defatted cocoa powder in one portion of food (or food supplement)	Consumers shall be instructed not to consume more than 600 mg polyphenols corresponding to 1,1 g of extract of defatted cocoa powder per day	
Low fat cocoa extract	Specified food category Foods including food supplements	Maximum levels 730 mg per serving and around 1,2 g/day	Consumers shall be instructed not to consume more than 600 mg of	

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	as defined in Directive 2002/46/EC		cocoa flavanols per day	
Coriander seed oil from	Specified food category	Maximum levels	The designation of the novel food	
Coriandrum sativum	Food Supplements as defined in Directive 2002/46/EC	600 mg/day	on the labelling of the foodstuffs containing it shall be 'Coriander seed oil'	
Crataegus pinnatifida	Specified food category	Maximum levels	The designation of the novel food	
dried fruit	Herbal infusions	In line with	on the labelling	
	Jams and jellies in accordance with Directive 2001/113/EC ^e	normal food use of <i>Crataegus</i> <i>laevigata</i>	of the foodstuffs containing it shall be 'Crataegus pinnatifida dried	
	Compotes		fruit'	
α-cyclodextrin	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Alphacyclodextrin' or '\alpha-cyclodextrin'	
γ-cyclodextrin	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Gamma-Cyclodextrin' or 'γ-Cyclodextrin'	
Dextran	Specified food	Maximum levels	The designation	
preparation produced by Leuconostoc mesenteroides	Bakery products	5 %	of the novel food on the labelling of the foodstuffs containing it shall be 'Dextran'	
Diacylglycerol oil of plant	Specified food category	Maximum levels	The designation of the novel food	
origin	Cooking oils		on the labelling	
	Fat spreads		of the foodstuffs containing	

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	Salad dressings		it shall be			
	Mayonnaise		'Diacylgl			
	Meal replacement for weight control (as drinks)		origin (at least 80 %	n (at		
	Bakery products					
	Yoghurt type products					
Dihydrocapsiate (DHC)	Specified food category	Maximum levels		The designati	on	
	Cereal bars	9 mg/100 g		of the		
	Biscuits, cookies and crackers	9 mg/100 g		novel food on the		
	Rice based snacks	12 mg/100 g		labelling of the	£ _a	
	Carbonated drinks, dilutable drinks, fruit juice based beverages	1,5 mg/100 ml	foodstuffs containing it shall be 'Dihydrocapsiate'	containin it shall be	containing it shall be	ining II
	Vegetable drinks	2 mg/100 ml		Food	amanta	
	Coffee based drinks, tea based drinks	1,5 mg/100 ml		supplem containir synthetic dihydroc	ng	
	Flavoured water — still	1 mg/100 ml		will be labelled as 'not		
	Precooked oatmeal cereal	2,5 mg/100 g		intended for		
	Other cereals	4,5 mg/100 g		children up to		
	Ice cream, dairy desserts	4 mg/100 g		4.5 years'		
	Pudding mixes (ready to eat)	2 mg/100 g				
	Products based on yoghurt	2 mg/100 g				
	Chocolate confectionery	7,5 mg/100 g				
	Hard candy	27 mg/100 g				
	Sugar-free gum	115 mg/100 g				
	Whitener/ creamer	40 mg/100 g				

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	Sweeteners	200 mg/100 g		
	Soup (ready to eat)	1,1 mg/100 g		
	Salad dressing	16 mg/100 g		
	Vegetable protein	5 mg/100 g		
	Ready to eat meals	3 mg/meal		
	Meal replacements for weight control	3 mg/meal		
	Meal replacement for weight control (as drinks)	1 mg/100 ml		
	Food Supplements as defined in Directive 2002/46/EC	3 mg/single intake 9 mg/day		
	Non-alcoholic powdered drink mixes	14,5 mg/kg equivalent to 1,5 mg/100 ml		
Dried extract of Lippia citriodora	Specified food category	Maximum levels	The designation of the novel food	
from cell cultures	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of a similar extract from the leaves of <i>Lippia citriodora</i>	on the labelling of the foodstuffs containing it shall be 'dried extract of <i>Lippia citriodora</i> from cell cultures HTN®Vb'	
Echinacea angustifolia	Specified food category	Maximum levels		
extract from cell cultures	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of a similar extract from the root of Echinacea angustifolia		
Echinacea purpurea	Specified food category	Maximum levels	The designation of the novel food on the labelling	

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extract from cell cultures	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of a similar extract from florets within the flower head of <i>Echinacea purpurea</i>	of the foodstuffs containing it shall be 'dried extract of <i>Echinacea purpurea</i> from cell cultures HTN®Vb'	
Echium plantagineum oil	Specified food category	Maximum levels of stearidonic acid (STA)	The designation of the novel food on the labelling of the foodstuffs	
	Milk-based products and drinkable yoghurt products delivered in a single dose	250 mg/100 g; 75 mg/100 g for drinks	containing it shall be 'Refined echium oil'	
	Cheese preparations	750 mg/100 g		
	Spreadable fat and dressings	750 mg/100 g		
	Breakfast cereals	625 mg/100 g		
	Food supplements as defined in Directive 2002/46/EC	500 mg/day		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal		

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Epigallocatechin	Specified food category	Maximum levels	The labelling	
gallate as a purified extract from green tea leaves (<i>Camellia</i> sinensis)	Foods including food supplements as defined in Directive 2002/46/EC	150 mg of extract in one portion of food or food supplement	shall bear a statement that consumers should not consume more than 300 mg of extract per day	
L-ergothioneine	Specified food category	Maximum levels	The designation of the novel food	
	Food supplements as defined in Directive 2002/46/EC	30 mg/day for general population (excluding pregnant and lactating women) 20 mg/day for children older than 3 years	on the labelling of the foodstuffs containing it shall be 'L- ergothioneine'	
Ferric Sodium EDTA	Specified food category	Maximum levels (expressed as anhydrous EDTA)	The designation of the novel food on the labelling of the foodstuffs containing it	
	Food supplements as defined in Directive 2002/46/EC	18 mg/day for children 75 mg/day for adults	shall be 'Ferric Sodium EDTA'	
	Foods covered by Regulation (EU) No 609/2013	12 mg/100 g		
	Foods fortified in accordance with Regulation (EC) No 1925/2006			
Ferrous ammonium phosphate	Specified food category	Maximum levels	The designation of the novel food	
	Food supplements as defined in Directive 2002/46/EC	To be used in compliance with Directive 2002/46/EC, Regulation	on the labelling of the foodstuffs containing it shall be 'Ferrous ammonium	
	Foods covered by Regulation	(EU) No 609/2013 and/or	phosphate'	

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	(EU) No 609/2013 Foods fortified in accordance with Regulation (EC) No 1925/2006	Regulation (EC) No 1925/2006			
Fish peptides from Sardinops sagax	Specified food category	Maximum levels fish peptide product	The design of the not on the lale of the foot	vel food belling	
o y fe p	Foods based on yoghurt, yoghurt drinks, fermented milk products, and powdered milk	0,48 g/100 g (ready to eat/ drink)	containing it shall be 'Fish (Sardinops sagax) peptides'		
	Flavoured water, and vegetable- based drinks	0,3 g/100 g (ready to drink)			
	Breakfast cereals	2 g/100 g			
	Soups, stews and soup powders	0,3 g/100 g (ready to eat)			
Flavonoids from Glycyrrhiza glabra	Specified food category	Maximum levels of flavonoids from Glycyrrhiza glabra	1.	The designat of the novel food on the	Beverages containing flavonoids shall be presented to the final consumer as
	Beverages based on milk	120 mg/day		labelling single portions of the foodstuffs	
	Beverages based on yoghurt			containii it shall	
	Beverages based on fruit or vegetables		be 'Flavonoid from Glycyrrhize glabra L.' 2. The labelling of the		
So as in	Food Supplements as defined in Directive 2002/46/EC	120 mg/day			
	Total diet replacement for weight control as defined in Regulation (EU)	120 mg/day		foods where the product was added	

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Foods for	120 mg/day		as a novel	
special medical			food	
purposes as				-4
defined in			ingredie	nt
Regulation (EU)			shall	
No 609/2013			bear a	
			statemen	t
			that:	
			(a)	the
				product
				should
				not
				be
				consumed
				by
				pregnant
				and
				breast
				feeding
				women,
				children
				and
				young
				adolescents;
				and
			(b)	people
				taking
				prescription
				drugs
				should
				only
				consume
				the
				product
				under
				medical
				supervision;
			(c)	a
				maximum
				of
				120
				mg
				of
				flavonoids
				per
				day
				should
				be
				consumed.
		3.	The	
			amount	
			of	
			flavonoi	ds
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			in the final food shall be indicated on the labelling of the food containing it.
Fucoidan	Specified food	Maximum	The designation
extract from the	category	levels	of the novel food
seaweed Fucus vesiculosus	Foods including food	250 mg/day	on the labelling of the foodstuffs
	supplements		containing
	as defined		it shall be
	in Directive 2002/46/EC		'Fucoidan extract from
	for the general		seaweed Fucus
	population		vesiculosus'.
Fucoidan	Specified food category	Maximum levels	The designation
extract from the seaweed	Foods	250 mg/day	of the novel food on the labelling
Undaria	including food	230 mg, day	of the foodstuffs
pinnatifida	supplements		containing it shall be
	as defined in Directive		'Fucoidan
	2002/46/EC		extract from
	for the general		seaweed Undaria
	population	16 .	pinnatifida'
2'- Fucosyllactose	Specified food category	Maximum levels	1. The designation
1 deosy naecose	Unflavoured	1,2 g/l	of the
	pasteurised		novel
	and sterilised (including UHT)		food on the
	milk-based		labelling
	products		of the
	Unflavoured	1,2 g/l beverages	foodstuffs containing
	fermented milk- based products	19,2 g/kg	it shall
	vascu products	products other	be '2'- fucosyllactose'.
		than beverages	2. The
	Flavoured fermented milk-	1,2 g/l beverages	labelling
	based products	19,2 g/kg	of food supplements
	including heat-	products other than beverages	containing
	treated products	man ocyclages	2'-
			fucosyllactose

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Dairy analogues, including	1,2 g/l beverages	shall bear a
beverage whiteners	12 g/kg for products other than beverages	statement that the supplements
	400 g/kg for whitener	should not be used if
Cereal bars	12 g/kg	other
Table-top sweeteners	200 g/kg	foods with added
Infant formula as defined in Regulation (EU) No 609/2013	1,2 g/l alone or in combination with up to 0,6 g/l of lacto- <i>N</i> -neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	fucosyllactose are consumed the same day. 3. The labelling of food supplements containing
Follow-on formula as defined in Regulation (EU) No 609/2013	1,2 g/l alone or in combination with up to 0,6 g/l of lacto- <i>N</i> -neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	fucosyllactose intended for young children shall bear a statement that the supplements should not be
Processed cereal-based food and baby	12 g/kg for products other than beverages	used if breast milk or
food for infants and young children as defined in Regulation (EU) No 609/2013	1,2 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer	other foods with added 2'- fucosyllactose are consumed
Milk-based drinks and similar products intended for young children	1,2 g/l for milk- based drinks and similar products added alone or in combination	the same day.

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	with up to 0,6 g/l lacto-N-neotetraose, at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	4,8 g/l for drinks 40 g/kg for bars
Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	60 g/kg
Flavoured drinks	1,2 g/l
Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as	9,6 g/l — the maximum level refers to the products ready to use

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	well as mixes and instant mixes of these products	
	Food supplements as defined in Directive	3,0 g/day for general population
	2002/46/EC, excluding food supplements for infants	1,2 g/day for young children
Galacto- oligosaccharide	Specified food category	Maximum levels (expressed as ratio kg galacto- oligosaccharide/ kg final food)
	Food Supplements as defined in Directive 2002/46/EC	0,333
	Milk	0,02
	Milk drinks	0,03
	Meal replacement for weight control (as drinks)	0,02
	Dairy analogue drinks	0,02
	Yoghurt	0,033
	Dairy based deserts	0,043
	Frozen dairy deserts	0,043
	Fruit drinks and energy drinks	0,021
	Infant meal replacement drinks	0,012
	Baby juice	0,025
	Baby yogurt drink	0,024

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	Baby desert	0,027	
	Baby snack	0,143	
	Baby cereals	0,027	
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	0,013	
	Juice	0,021	
	Fruit pie fillings	0,059	
	Fruit preparations	0,125	
	Bars	0,125	
	Cereals	0,125	
	Infant formula and follow- on formula as defined in Regulation (EU) No 609/2013	0,008	
	110 000/2019		
Glucosamine HCl	Specified food category	Maximum levels	
	Specified food		
	Specified food category Food Supplements as defined in Directive	In line with normal food use of glucosamine	
	Specified food category Food Supplements as defined in Directive 2002/46/EC Foods covered by Regulation (EU) No	In line with normal food use of glucosamine	
	Specified food category Food Supplements as defined in Directive 2002/46/EC Foods covered by Regulation (EU) No 609/2013 Meal replacement for	In line with normal food use of glucosamine	

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Glucosamine	reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 Specified food	Maximum			
sulphate KCl	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of glucosamine from shell fish			
Glucosamine sulphate NaCl	Specified food category	Maximum levels			
suipilate MaCi	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of glucosamine from shell fish			
Guar Gum	Specified food category	Maximum levels	1.	The	on
	Fresh dairy products such as yogurts, fermented milks, fresh cheeses and other dairy-based desserts.	1,5 g/100 g		designation of the novel food on the labelling of the foodstuffs	ŝ
	Fruit or vegetable-based liquid foodstuffs (of the 'smoothie' variety) 1,8 g/100 g 1,8 g/100 g 2.	2.	containing it shall be 'Guar Gum'. A specific	15	
	Fruit or vegetable-based compotes	3,25 g/100 g	mention of the possible risks of digestive discomfe linked to the		
	Cereals accompanied by a dairy product, in packaging containing two compartments	10 g/100 g in the cereals None in the accompanying dairy product 1 g/100 g in the product when ready to eat		digestive discomfort linked to the exposure of children aged	ort

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3.	to guar gum must be visible on the label of any foodstuffs containing it. For example, 'Excessive consumption of these products may cause digestive discomfort, especially for children under 8 years of age'. In the case of products with two compartments containing dairy and cereal products respectively, the instructions for use must clearly specify the need to mix the cereal and the dairy product before consumption,
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			in order to take into account the potential risk of gastro- intestinal obstruction.
Heat-treated milk products fermented with Bacteroides xylanisolvens	Fermented milk products (in liquid, semi-liquid and spraydried powder forms)	Maximum levels	
Hydroxytyrosol	Fish and vegetable oils, (except olive oils and olive pomace oils as defined in Part VIII of Annex VII of Regulation (EU) No 1308/2013 ^f), placed as such on the market	Maximum levels 0,215 g/kg	The designation of the novel food on the labelling of the food products containing it shall be 'hydroxytyrosol'. The labelling of the food products containing hydroxytyrosol shall bear the following
	Spreadable fats as defined in Part VII of Annex VII of Regulation (EU) No 1308/2013, placed as such on the market	0,175 g/kg	statements: (a) This food product should not be consumed by children under the age of three years, pregnant women, and lactating women;

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			(b) This food product should not be used for cooking baking or frying'	
Ice Structuring Protein type III HPLC 12	Specified food category Edible ices	Maximum levels 0,01 %	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Ice Structuring Protein'	
Aqueous extracts of dried leaves of Ilex guayusa	Specified food category Herbal infusions Food Supplements as defined in Directive 2002/46/EC	Maximum levels In line with normal use in herbal infusions and food supplements of a similar aqueous extract of dried leaves of Ilex paraguariensis	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Extracts of dried leaves of <i>Ilex guayusa</i> '	
Isomalto- oligosaccharide	Specified food category Energy-Reduced Soft Drinks Energy Drinks Foods intended to meet the expenditure of intense muscular efforts, especially for sportsmen (including isotonic drinks) Fruit Juices Processed Vegetables and Vegetable Juices	Maximum levels 6,5 % 5,0 % 6,5 % 5 % 5 % 5 %	1. The designat of the novel food on the labelling of the foodstuf containing it shall be 'Isomalt' 2. Foods containing the novel ingredie must be labelled as 'a	fs ng ooligosaccharide'. ng

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	Other Soft Drinks	5 %		source of
	Cereals Bars	10 %		glucose'.
	Cookies, Biscuits	20 %		
	Breakfast Cereal Bars	25 %		
	Hard Candies	97 %		
	Soft Candies/ Chocolate Bars	25 %		
	Meal replacement for weight control (as bars or milk based)	20 %		
Isomaltulose	Not specified		2.	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Isomaltulose'. The designation of the novel food on the labelling shall be accompanied by indication that the 'Isomaltulose is a source of glucose and fructose'.

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Lactitol	Specified food category	Maximum levels	The designation of the novel food	
	Food Supplements as defined in Directive 2002/46/EC (capsules or tablets) intended for the adult population	20 g/day	on the labelling of the food supplements containing it shall be 'Lactitol'	
Lacto-N- neotetraose	Specified food category	Maximum levels	1. The designat	ion
neotetraose	Unflavoured pasteurised and sterilised (including UHT) milk-based products	0,6 g/l	of the novel food on the labelling of the foodstuff containing it shall be 'lacto-N-neotetrao' The labelling of food suppleme containing lacto-N-neotetrao shall bear a statement that the suppleme should	
	Unflavoured fermented milk-based products	0,6 g/l for beverages 9,6 g/kg for products other than beverages		ng
	Flavoured fermented milk-based products including heat-treated products Dairy analogues, including	0,6 g/l for beverages 9,6 g/kg for products other than beverages 0,6 g/l for beverages		ents ng
	beverage whiteners	6 g/kg for products other than beverages 200 g/kg for whitener		
	Cereal bars	6 g/kg	not be used if	
	Table-top sweeteners	100 g/kg	other foods with added lacto-N-neotetrac are consume the same day.	
	Infant formula as defined in Regulation (EU) No 609/2013	0,6 g/l in combination with up to 1,2 g/l of 2'-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted		

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	as instructed by the manufacturer	3.
Follow-on formula as defined in Regulation (EU) No 609/2013	0,6 g/l in combination with up to 1,2 g/l of 2'-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	
Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	6 g/kg for products other than beverages 0,6 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer	
Milk-based drinks and similar products intended for young children	0,6 g/l for milk- based drinks and similar products added alone or in combination with 2'- fucosyllactose, at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended	
Total diet replacement for weight control	2,4 g/l for drinks 20 g/kg for bars	

The labelling of food supplements containing lacto-Nneotetraose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added lacto-Nneotetraose are consumed the same day.

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	as defined in Regulation (EU) No 609/2013 Bread and pasta products bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	30 g/kg		
	Flavoured drinks	0,6 g/l		
	Coffee, tea (excluding black tea), herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	4,8 g/l — the maximum level refers to the products ready to use		
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	1,5 g/day for general population 0,6 g/day for young children		
Lucerne leaf extract from	Specified food category	Maximum levels	The designation of the novel food	
Medicago sativa	Food supplements as defined in Directive 2002/46/EC	10 g/day	on the labelling of the foodstuffs containing it shall be 'Lucerne (Medicago sativa) protein' or 'Alfalfa	

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			(Medicago sativa) protein'.	
Lycopene	Specified food category	Maximum levels	The designation of the novel food	
	Fruit/vegetable juice-based drinks (including concentrates)	2,5 mg/100 g	on the labelling of the foodstuffs containing it shall be	
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g	'Lycopene'	
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	8 mg/meal		
	Breakfast cereals	5 mg/100 g		
	Fats and dressings	10 mg/100 g		
	Soups other than tomato soups	1 mg/100 g		
	Bread (including crispy breads)	3 mg/100 g		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
	Food supplements as defined in Directive 2002/46/EC	15 mg/day		
Lycopene from Blakeslea trispora	Specified food category	Maximum levels	The designation of the novel food on the labelling	

Lycopene from tomatoes

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Fruit/vegetable juice-based drinks (including concentrates)	2,5 mg/100 g	on the labelling of the foodstuffs containing it shall be 'Lycopene'	
Specified food category	Maximum levels	The designation of the novel food	
Food supplements as defined in Directive 2002/46/EC	15 mg/day		
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
Bread (including crispy breads)	3 mg/100 g		
Soups other than tomato soups	1 mg/100 g		
Fats and dressings	10 mg/100 g		
Breakfast cereals	5 mg/100 g		
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	8 mg/meal		
Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g		
Fruit/vegetable juice-based drinks (including concentrates)	2,5 mg/100 g	of the foodstuffs containing it shall be 'Lycopene'	

Lycopene oleoresin from tomatoes

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Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2,5 mg/100 g		
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	8 mg/meal		
Breakfast cereals	5 mg/100 g		
Fats and dressings	10 mg/100 g		
Soups other than tomato soups	1 mg/100 g		
Bread (including crispy breads)	3 mg/100 g		
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
Food supplements as defined in Directive 2002/46/EC	15 mg/day		
Specified food category	Maximum levels of lycopene	The designation of the novel food on the labelling	
Fruit/vegetable juice-based drinks (including concentrates)	2,5 mg/100 g	of the foodstuffs containing it shall be 'Lycopene	
Drinks intended to meet the expenditure of intense muscular	2,5 mg/100 g	oleoresin from tomatoes'	

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	effort especially for sportsmen Total diet replacement for weight control covered by Regulation (EU)	8 mg/meal		
	No 609/2013 and meal replacements for weight control			
	Breakfast cereals	5 mg/100 g		
	Fats and dressings	10 mg/100 g		
	Soups other than tomato soups	1 mg/100 g		
	Bread (including crispy breads)	3 mg/100 g		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended		
Magnesium citrate malate	Specified food category	Maximum levels	The designation of the novel food	
Citi ate maiate	Food Supplements as defined in Directive 2002/46/EC		on the labelling of the foodstuffs containing it shall be 'Magnesium citrate malate'	
Magnolia Bark Extract	Specified food category	Maximum levels	The designation of the novel food	
	Mints (confectionary products)	0,2 % for breath freshening purposes. Based	on the labelling of the foodstuffs containing it shall be	
	Chewing gum	on a 0,2 % maximum incorporation level and a maximum gum/ mint size of 1,5 g each, each gum or mint serving	'Magnolia Bark Extract'	

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		will contain no more than 3 mg of magnolia bark extract.		
Maize-germ oil high in	Specified food category	Maximum levels	The designation of the novel food	
unsaponifiable matter	Food Supplements as defined in Directive 2002/46/EC	2 g/day	on the labelling of the foodstuffs containing it shall be 'Maize- germ oil extract'	
	Chewing gum	2 %		
Methylcellulose	Specified food category	Maximum levels	The designation of the novel food	Methylcellulose is not to be
	Edible ices	2 %	on the labelling of the foodstuffs	used in foods specially
	Flavoured drinks		containing	prepared for
	Flavoured or unflavoured fermented milk products		it shall be 'Methylcellulose'	young children
	Cold desserts (dairy, fat, fruit, cereal, egg-based products)			
	Fruit preparations (pulps, purees or compotes)			
	Soups and broths			
(6S)-5- methyltetrahydro acid, glucosamine salt	Specified food of 644egory	Maximum levels	The designation of the novel food on the labelling of the foodstuffs containing it shall be '(6S)-5-methyltetrahydrof acid, glucosamine salt' or '5MTHF-glucosamine'	olic
	Food Supplements as defined in Directive 2002/46/EC as a source of folate			

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Monomethylsilar (Organic Silicon)	Food Supplements as defined in Directive 2002/46/EC for adult population (in liquid form)	Maximum levels of silicon 10,40 mg/day	The designation of the novel food on the labelling of the food supplements containing it shall be 'Organic silicon (monomethylsilan	etriol)'
Mycelial extract from Shiitake	Specified food category	Maximum levels	The designation of the novel food	
mushroom (<i>Lentinula</i>	Bread products	2 ml/100 g	on the labelling of the foodstuffs	
edodes)	Soft drinks	0,5 ml/100 ml	containing	
	Ready prepared meals	2,5 ml per meal	it shall be 'extract from the mushroom	
	Foods based on yoghurt	1,5 ml/100 ml	Lentinula edodes' or	
	Food supplements as defined in Directive 2002/46/EC	2,5 ml per day dose	'extract from Shiitake mushroom'	
Noni fruit	Specified food	Maximum	The designation	
Noni fruit juice (Morinda citrifolia)		Maximum levels 30 ml with one serving (up to 100 % noni juice) or 20 ml twice a day, not more than 40 ml per day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice' or 'Juice of Morinda citrifolia'	
juice (Morinda	Specified food category Pasteurised fruit and fruit nectar	levels 30 ml with one serving (up to 100 % noni juice) or 20 ml twice a day, not more than 40 ml per	of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice' or 'Juice of <i>Morinda</i>	
Noni fruit juice powder (Morinda citrifolia) Noni fruit puree	Specified food category Pasteurised fruit and fruit nectar based drinks Food supplements as defined in Directive 2002/46/EC	levels 30 ml with one serving (up to 100 % noni juice) or 20 ml twice a day, not more than 40 ml per day 6,6 g/day (equivalent to 30 ml of noni juice)	of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice' or 'Juice of Morinda citrifolia' The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice powder' or 'Juice powder of Morinda citrifolia' The designation	
Noni fruit juice powder (Morinda citrifolia)	Specified food category Pasteurised fruit and fruit nectar based drinks Food supplements as defined in Directive 2002/46/EC	levels 30 ml with one serving (up to 100 % noni juice) or 20 ml twice a day, not more than 40 ml per day 6,6 g/day (equivalent to 30 ml of noni juice)	of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice' or 'Juice of Morinda citrifolia' The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice powder' or 'Juice powder of Morinda citrifolia'	

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Candy/ confectionery	45 g/100 g
Cereal bars	53 g/100 g
Powdered nutritional drink mixes (dry weight)	53 g/100 g
Carbonated beverages	11 g/100 g
Ice cream & sorbet	31 g/100 g
Yoghurt	12 g/100 g
Biscuits	53 g/100 g
Buns, cakes and pastries	53 g/100 g
Breakfast cereals (wholegrain)	88 g/100 g
Jams and jellies in accordance with Directive 2001/113/EC	133 g/100 g Based on pre- processing quantity to produce final 100 g product
Sweet spreads, fillings and icings	31 g/100 g
Savoury sauces, pickles, gravies and condiments	88 g/100 g
Food Supplements as defined in Directive 2002/46/EC	26 g/day
	Fruit concentrate
Candy/ Confectionery	10 g/100 g
Cereal bars	12 g/100 g
Powdered nutritional drink mixes (dry weight)	12 g/100 g

containing it shall be:
For fruit puree: 'Morinda citrifolia fruit puree' or 'Noni fruit puree' For fruit concentrate: 'Morinda citrifolia fruit concentrate' or 'Noni fruit concentrate'

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	Carbonated	3 g/100 g]		
	beverages	<i>5 g</i> , 100 g			
	Ice cream & sorbet	7 g/100 g			
	Yoghurt	3 g/100 g			
	Biscuits	12 g/100 g			
	Buns, cakes and pastries	12 g/100 g			
	Breakfast cereals (wholegrain)	20 g/100 g			
	Jams and jellies in accordance with Directive 2001/113/EC	30 g/100 g			
	Sweet spreads, fillings and icings	7 g/100 g			
	Savoury sauces, pickles, gravies and condiments	20 g/100 g			
	Food Supplements as defined in Directive 2002/46/EC	6 g/day			
Noni leaves (Morinda	Specified food category	Maximum levels	1.	The designat	ion
citrifolia)	For the preparation of infusions	A cup of infusion to be consumed shall not be prepared with more than 1 g of dried and roasted leaves of Morinda citrifolia	2.	of the novel food on the labelling of the foodstuf containing it shall be 'Noni leaves' or 'leaves of Morinda citrifolia Instructionshall be given	fs ng

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	Succification of	Marinum	to the consumer that a cup of infusion should not be prepared with more than 1 g of dried and roasted leaves of Morinda citrifolia.
Noni fruit powder (<i>Morinda</i> citrifolia)	Food Supplements as defined in Directive 2002/46/EC	Maximum levels 2,4 g per/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Morinda citrifolia fruit powder' or 'Noni fruit powder'
Odontella aurita microalgae	Specified food category Flavoured pasta Fish soups Marine terrines Broth preparations Crackers Frozen breaded fish	Maximum levels 1,5 % 1 % 0,5 % 1 % 1,5 % 1,5 %	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Odontella aurita microalgae'
Oil enriched with phytosterols/ phytostanols	Specified food category Spreadable fats as defined in Annex VII, Part VII and	Maximum levels of phytosterols/ phytostanols 1. The products containing the	

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Appendix II, points B and C of Regulation (EU) No 1308/2013, and excluding cooking and frying fats and spreads based on butter or other animal fat Milk based products, such as products based on semiskimmed and skimmed milk products, possibly with the addition of fruits and/or cereals, products based on fermented milk such as yoghurt and cheese based products (fat content ≤ 12 g per 100 g), where possibly the milk fat has been reduced and the fat or protein has been partly or fully replaced by vegetable fat or protein Soya drinks Salad dressings, mayonnaise and spicy sauces	2.	novel food ingredient shall be presented in such a manner that they can be easily divided into portions that contain either a maximum of 3 g (in case of one portion per day) or a maximum of 1 g (in case of three portions per day) of added phytosterols/ phytostanols. The amount of phytosterols/ phytostanols added to a container of beverages shall not
	3.	exceed 3 g. Salad dressings, mayonnaise

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		and spicy sauces shall be packed as single portions		
Oil extracted from squids	Specified food category	Maximum levels of DHA and EPA combined	The designation of the novel food on the labelling of the foodstuffs	
	Dairy products except milk- based beverages	200 mg/100 g or for cheese products 600 mg/100 g	containing it shall be 'Squid oil'.	
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g		
	Spreadable fat and dressings	600 mg/100 g		
	Breakfast cereals	500 mg/100 g		
	Bakery products (breads and bread rolls)	200 mg/100 g		
	Cereal bars	500 mg/100 g		
	Non-alcoholic beverages (including milk- based beverages)	60 mg/100 ml		
	Food Supplements as defined in Directive 2002/46/EC	3 000 mg/day for general population 450 mg/day for pregnant and lactating women		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products intended		

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	Total diet replacement for weight control defined in Regulation (EU) No 609/2013 and meal replacements for weight control	200 mg/meal		
Pasteurised fruit-based	Specified food category	Maximum levels	The wording 'pasteurised by	
preparations produced using high-pressure treatment	Types of fruit: apple, apricot, banana, blackberry, blueberry, cherry, coconut, fig, grape, grapefruit, mandarin, mango, melon, peach, pear, pineapple, prune, raspberry, rhubarb,		high-pressure treatment' shall be displayed next to the name of the fruit preparations as such and in any product in which it is used	
	strawberry			
Phosphated maize starch	-	Maximum levels	The designation of the novel food	
Phosphated maize starch	strawberry Specified food		of the novel food on the labelling of the foodstuffs	
	Specified food category Baked bakery	levels	of the novel food on the labelling of the foodstuffs containing it shall be	
	Specified food category Baked bakery products	levels	of the novel food on the labelling of the foodstuffs containing it shall be 'Phosphated	
maize starch	Strawberry Specified food category Baked bakery products Pasta Breakfast cereals Cereal bars	levels 15 %	of the novel food on the labelling of the foodstuffs containing it shall be 'Phosphated maize starch'	
	Strawberry Specified food category Baked bakery products Pasta Breakfast cereals Cereal bars	levels 15 % Maximum levels of	of the novel food on the labelling of the foodstuffs containing it shall be 'Phosphated maize starch' The designation of the novel food	
Phosphatidylseri from fish	Specified food category Baked bakery products Pasta Breakfast cereals Cereal bars nespecified food	levels 15 % Maximum	of the novel food on the labelling of the foodstuffs containing it shall be 'Phosphated maize starch' The designation of the novel food of the foodstuffs containing it	
Phosphatidylseri from fish	Specified food category Baked bakery products Pasta Breakfast cereals Cereal bars n Specified food category Beverages based	levels 15 % Maximum levels of phosphatidylseria	of the novel food on the labelling of the foodstuffs containing it shall be 'Phosphated maize starch' The designation of the novel food of the foodstuffs	e'
Phosphatidylseri from fish	Strawberry Specified food category Baked bakery products Pasta Breakfast cereals Cereal bars nSpecified food category Beverages based on yoghurt Powders based	Maximum levels of phosphatidylserii 50 mg/100 ml 3 500 mg/100 g (equivalent to 40 mg/100 ml ready	of the novel food on the labelling of the foodstuffs containing it shall be 'Phosphated maize starch' The designation of the novel food of the foodstuffs containing it shall be 'Fish	è'

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	Chocolate based confectionary	200 mg/100 g		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In compliance with Regulation (EU) No 609/2013		
	Food supplements as defined in Directive 2002/46/EC	300 mg/day		
Phosphatidylseri from soya phospholipids	nSpecified food category	Maximum levels of phosphatidylseria	The designation of the novel food 16 % the labelling	
	Beverages based on yoghurt	50 mg/100 ml	of the foodstuffs containing it shall be 'Soya	
	Powders based on milk powder	3,5 g/100 g (equivalent to 40 mg/100 ml ready to drink)	phosphatidylsering	è'
	Foods based on yoghurt	80 mg/100 g		
	Cereal bars	350 mg/100 g		
	Chocolate based confectionary	200 mg/100 g		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In compliance with Regulation (EU) No 609/2013		
Phospholipid product containing	Specified food category	Maximum levels of phosphatidylseria	The designation of the novel food **The food the labelling **The labelling **T	The product is not intended to be marketed
equal	Breakfast cereals	80 mg/100 g	of the foodstuffs	to pregnant or
amounts of phosphatidylsering and phosphatidic acid	Cereal bars	350 mg/100 g	containing shall be 'Soy	breast-feeding women
	Foods based on yogurt	80 mg/100 g	phosphatidylsering and phosphatidic acid'	2
	Soy-based yogurt-like products	80 mg/100 g	uotu .	
	Yogurt based- drinks	50 mg/100 g		

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	Soy-based yogurt-like drinks Powders based on milk powder Food Supplements as defined in Directive 2002/46/EC	50 mg/100 g 3,5 g/100 g (equivalent to 40 mg/100 ml ready-to drink) 800 mg/day		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In compliance with Regulation (EU) No 609/2013		
Phospholipides from egg yolk	Specified food category	Maximum levels		
Phytoglycogen	Not specified Not specified Maximum		The designation	
i ny togry cogen	category	levels	of the novel food	
	Processed foods	25 %	on the labelling of the foodstuffs containing it shall be	
			'Phytoglycogen'	
Phytosterols/ phytostanols	Specified food category	Maximum levels	In accordance with Annex III.5	
Phytosterols/ phytostanols		levels	In accordance with Annex III.5 of Regulation	
	category Rice drinks Rye bread with flour containing ≥ 50 % rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) and ≤ 30 % wheat; and with ≤ 4 % added sugar but no fat added.		In accordance with Annex III.5 of Regulation (EU) No 1169/2011 d	
	category Rice drinks Rye bread with flour containing ≥ 50 % rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) and ≤ 30 % wheat; and with ≤ 4 % added sugar but	levels 1. They shall be presente in such a manner that they can be easily divided into portions	In accordance with Annex III.5 of Regulation (EU) No 1169/2011 d	

ANNEX

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Milk type products, such as semiskimmed and skimmed milk type products, possibly with the addition of fruits and/or cereals, where possibly the milk fat has been reduced, or where milk fat and/or protein has been partly or fully replaced by vegetable fat and/or protein.

Products based on fermented milk such as yoghurt and cheese type products (fat content < 12 % per 100 g), where possibly the milk fat has been reduced, or where milk fat and/or protein has been partly or fully replaced by vegetable fat and/or protein

Spreadable fats as defined in Annex VII, Part VII and Appendix II, points B and C of Regulation (EU) No 1308/2013, and excluding cooking and frying fats and spreads based on butter or other animal fat.

(in case of 1 portion/day) or a maximum of 1 g (in case of 3 portions/day) of added phytosterols/phytostanols.

The amount of phytosterols/ phytostanols added to a container of beverages shall not exceed 3 g. Salad dressings, mayonnaise and spicy sauces shall be packed as single portions

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Plum kernel oil Potato proteins	Food Supplements as defined in Directive 2002/46/EC Specified food category For frying and as seasoning	Maximum levels In line with normal food use of vegetable oils	The designation	
(coagulated) and hydrolysates thereof	Not specified		of the novel food on the labelling of the foodstuffs containing it shall be 'Potato protein'	
Prolyl oligopeptidase (enzyme preparation)	Food Supplements as defined in Directive 2002/46/EC for general adult population	Maximum levels 120 PPU/day (2,7 g of enzyme preparation/day) (2 × 10 ⁶ PPI/ day) PPU – Prolyl Peptidase Units or Proline Protease Units PPI – Protease Picomole International	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Prolyl oligopeptidase'	
Protein extract from pig kidneys	Specified food category Food Supplements as defined in Directive 2002/46/EC Food for special medical purposes as defined in Regulation (EU) No 609/2013	Maximum levels 3 capsules/day; equalizing 12,6 mg pig kidney extract a day Diamine oxidase (DAO) content: 0,9 mg/day (3 capsules with a content of DAO of 0,3 mg/capsule)		
Rapeseed oil high in unsaponifiable matter	Specified food category Food Supplements as defined	Maximum levels 1,5 g per portion recommended	The designation of the novel food on the labelling of the foodstuffs containing	

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	in Directive 2002/46/EC	for daily consumption	it shall be 'Rapeseed oi extract'	1
Rapeseed Protein	As a vegetable protein source in foods except in infant formula and follow-on formula		of to now food on a label of the food condition it slips be 'Rai pro condition food condition fo	ignation he vel d the elling he dstuffs staining hall spessed tein'. y dstuff staining pessed tein' ll r a sement t s redient y se ergic ction ssumers o ergic stard ducts reof. sere evant, sement ll pear elose ximity

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				list of ingredients.
Trans- resveratrol		1.	The designation	
resveration	Food Supplements as defined in Directive 2002/46/EC for adult population (capsule or tablet form)	150 mg/day	2.	of the novel food on the labelling of the food supplements containing it shall be 'Trans-resveratrol'. The labelling of food supplements containing trans-resveratrol shall bear a statement that people using medicines should only consume the product under medical supervision.
Trans-	Specified food	Maximum	1.	The
resveratrol	category	levels	-	designation
(microbial source)	Food supplements	In line with normal use		of the novel
Source	as defined	in food		food
	in Directive	supplements		on the
	2002/46/EC	of resveratrol		labelling
		extracted from Japanese		of the food
		knotweed		supplements
		(Fallopia		containing
		japonica)		it shall be

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Rooster comb	Specified food	Maximum	resveratrol'. The labelling of food supplements containing transresveratrol shall bear a statement that people using medicines should only consume the product under medical supervision.
extract	category Milk-based	levels 40 mg/100 g or	The designation of the novel food on the labelling
	drinks	mg/100 ml	of the foodstuffs containing it
	Milk based fermented drinks	80 mg/100 g or mg/100 ml	shall be 'Rooster comb extract' or
	Yoghurt-type products	65 mg/100 g or mg/100 ml	'Cockerel comb extract'
	Fromage frais	110 mg/100 g or mg/100 ml	
Sacha inchi oil from <i>Plukenetia</i>	Specified food category	Maximum levels	The designation of the novel food
volubilis	As for linseed oil	In line with normal food use of linseed oil	on the labelling of the foodstuffs containing it shall be 'Sacha inchi oil (Plukenetia volubilis)'
Salatrims	Specified food category	Maximum levels	1. The designation
	Bakery products and confectionary		of the novel food on the

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			labelling of the foodstuffs containing it shall be 'reduced energy fat (salatrims)'. 2. There shall be a statement that excessive consumption may lead to gastro- intestinal disturbance. 3. There shall be a statement that the products are not intended for use by children.
Schizochytrium sp. oil rich in DHA and EPA	Specified food category	Maximum levels of DHA and EPA combined:	The designation of the novel food on the labelling of the foodstuffs
	Food Supplements as defined in Directive 2002/46/EC for adult population excluding pregnant and lactating women	3 000 mg/day	containing it shall be 'DHA and EPA-rich oil from the microalgae Schizochytrium sp.'
	Food Supplements as defined in Directive 2002/46/EC for	450 mg/day	

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pregnant and lactating women	
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal
Milk-based drinks and similar products intended for young children	200 mg/100 g
Processed cereal based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen	
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing	

Schizochytrium sp. (ATCC PTA-9695) oil Status: Point in time view as at 13/08/2018.

Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g	microalgae Schizochytrium sp. (ATCC PTA-9695)'	
Dairy products except milk- based drinks	200 mg/100 g or for cheese products 600 mg/100 g	on the labelling of the foodstuffs containing it shall be 'Oil from the	
Specified food category	Maximum levels of DHA	The designation of the novel food	
Spreadable Fats and Dressings	600 mg/100 g		
Cereal/Nutrition Bars	500 mg/100 g		
Non-alcoholic Beverages (including dairy analogue and milk-based drinks)	80 mg/100 g		
Dairy Products except milk- based drinks	600 mg/100 g for cheese; 200 mg/100 g for milk products (including milk, fromage frais and yoghurt products; excluding drinks)		
Dairy Analogues except drinks	600 mg/100 g for cheese; 200 mg/100 g for soy and imitation milk products (excluding drinks)		
Cooking Fats	360 mg/100 g		
Breakfast Cereals	500 mg/100 g		
Bakery Products (Breads, Rolls and Sweet Biscuits)	200 mg/100 g		
Regulation (EU) No 828/2014			

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	I
Spreadable fats and dressings	600 mg/100 g
Breakfast cereals	500 mg/100 g
Food Supplements as defined	250 mg DHA/ day for general population
in Directive 2002/46/EC	450 mg DHA/ day for pregnant and lactating women
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal
Milk-based drinks and similar products intended for young children	200 mg/100 g
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen	
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the

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		products are intended		
	Bakery products (breads,rolls, and, sweet biscuits)	200 mg/100 g		
	Cereal bars	500 mg/100 g		
	Cooking fats	360 mg/100 g		
	Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 ml		
	Infant formula and follow- on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013		
	Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013	200 mg/100 g		
Schizochytrium sp. oil	Specified food category	Maximum levels of DHA	The designation of the novel food	
	Dairy products except milk- based drinks	200 mg/100 g or for cheese products 600 mg/100 g	on the labelling of the foodstuffs containing it shall be 'Oil from the	
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g	microalgae Schizochytrium sp.'	
	Spreadable fats and dressings	600 mg/100 g		
	Breakfast cereals	500 mg/100 g		
	Food Supplements as defined in Directive 2002/46/EC	250 mg DHA/ day for general population		

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1	
	450 mg DHA/ day for pregnant and lactating women
Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal
Milk-based drinks and similar products intended for young children	200 mg/100 g
Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013	
Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen	
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	
Foods for special medical purposes as defined in	In accordance with the particular nutritional requirements

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	Regulation (EU) No 609/2013 Bakery products (breads, rolls and sweet biscuits)	of the persons for whom the products are intended 200 mg/100 g		
	Cereal bars	500 mg/100 g		
	Cooking fats	360 mg/100 g		
	Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 ml		
Schizochytrium sp. (T18) oil	Specified food category	Maximum levels of DHA	The designation of the novel food	
sp. (110) on	Dairy products except milk- based drinks	200 mg/100 g or for cheese products 600 mg/100 g	on the labelling of the foodstuffs containing it shall be	
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g	'Oil from the microalgae <i>Schizochytrium</i> sp.'	
	Spreadable fats and dressings	600 mg/100 g		
	Breakfast cereals	500 mg/100 g		
	Food Supplements as defined	250 mg DHA/ day for general population		
	in Directive 2002/46/EC	450 mg DHA/ day for pregnant and lactating women		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control	250 mg/meal		
	Milk-based drinks and	200 mg/100 g		

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similar products intended for young children Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen	
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014	
Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In accordance with the particular nutritional requirements of the persons for whom the products are intended
Bakery products (breads, rolls and, sweet biscuits)	200 mg/100 g
Cereal bars	500 mg/100 g
Cooking fats	360 mg/100 g
Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 ml
Infant formula and follow- on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013

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Fermented	Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013 Specified food	200 mg/100 g Maximum	1. The
soybean extract	Food Supplements as defined in Directive 2002/46/EC (capsules, tablets or powder form) intended for the adult population, excluding pregnant and lactating women	levels 100 mg/day	designation of the novel food on the labelling of the foodstuffs containing it shall be 'Fermented soybean extract'. 2. The labelling of food supplements containing fermented soybean extract shall bear a statement that persons taking medication should only consume the product under medical
Spermidine- rich wheat germ extract	Specified food category	Maximum levels	supervision. The designation of the novel food on the labelling of the food

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(Triticum aestivum)	Food Supplements as defined in Directive 2002/46/EC intended for the adult population, excluding pregnant and lactating women	Equivalent of max. 6 mg/day spermidine	suppleme containin it shall be 'spermidi rich whea extract'	g ine-	
Sucromalt	Specified food category Not specified	Maximum levels	2.	The designat of the novel food on the labelling of the foodstuf containing it shall be 'Sucrom The designat of the novel food on the labelling shall be accompably indication that the product is a source of glucose and fructose.	fs ng alt'. ion
Sugar cane fibre	Specified food category	Maximum levels			
	Bread	8 %			
	Bakery goods	5 %			
	Meat and muscle products	3 %			

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			_	
	Seasonings and spices	3 %		
	Grated cheeses	2 %		
	Special diet foods	5 %		
	Sauces	2 %		
	Beverages	5 %		
Sunflower oil extract	Specified food category	Maximum levels	The designation of the novel food	
	Food Supplements as defined in Directive 2002/46/EC	1,1 g/day	on the labelling of the foodstuffs containing it shall be 'Sunflower oil extract'	
Dried Tetraselmis	Specified food category	Maximum levels	The designation of the novel food	
<i>chuii</i> microalgae	Sauces	20 % or 250mg/ day	on the labelling of the foodstuffs	
	Special salts	1 %	containing it shall be 'Dried	
	Condiment	250 mg/day	microalgae	
	Food Supplements as defined in Directive 2002/46/EC	250 mg/day	Tetraselmis chuii' or 'Dried microalgae T. chuii' Food supplements containing dried microalgae Tetraselmis chuii shall bear the following statement: 'Contains negligible amounts of iodine'	
Therapon barcoo/Scortum	Intended use identical salmon, namely the culinary fish production including cooked, baked fish productions.	ne preparation of ucts and dishes, raw, smoked and		
D-Tagatose	Specified food category	Maximum levels	1. The	
	Not specified	ecres	designat of the novel food	1011

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			on the labelling of the foodstuft containing it shall be 'D-Tagatose The labelling of any product where the level of D-Tagatose exceeds 15 g per serving and all beverage containing greater than 1 % D-Tagatose (as consume shall bear a statemer 'excessive consump may produce laxative effects'.	fs ag as a set of the
Taxifolin-rich	Specified food	Maximum levels	The designation	
extract	Food Supplements as defined in Directive 2002/46/EC intended for the general population, excluding infants, young children,	100 mg/day	of the novel food on the labelling of the foodstuffs containing it shall be 'taxifolin-rich extract'.	

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Trehalose	children and adolescents younger than 14 years Specified food	Maximum	1.	The	
	category	levels		designat	ion
	Not specified			of the	
	1			novel	
				food	
				on the	
				labelling	
				of the foodstuf	fa
				containii	
				it shall	15
				be	
				'Trehalo	se'
				and	
				shall be	•
				displaye	d
				on the labelling	
				of the	
				product	
				as such	
				or in	
				the	
				list of	
				ingredie	nts
				of facility	Ç _a
				foodstuf containii	
				it.	18
			2.	The	
				designat	ion
				of the	
				novel	
				food	
				on the	
				labelling shall be	
				accompa	nied
				by	
				indicatio	n
				that the	
				'Trehalo	se
				is a	
				source	
				of	
				glucose'	-

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UV-treated mushrooms (Agaricus	Specified food category	Maximum levels of vitamin D ₂		
bisporus)	Mushrooms (Agaricus bisporus)	10 μg of vitamin D ₂ /100 g fresh weight	2.	The designation on the label of the novel food as such or of the foodstuffs containing it shall be 'UV-treated mushrooms (Agaricus bisporus)'. The designation on the label of the novel food as such or of the foodstuffs containing it shall be accompanied by indication that a 'controlled light treatment was used to increase vitamin D levels' or 'UV treatment was used to increase

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			vitamin D ₂ levels'.	
UV-treated baker's yeast (Saccharomyces cerevisiae)	Specified food category	Maximum levels of vitamin D ₂	The designation of the novel food on the labelling	
	Yeast-leavened breads and rolls	5 μg of vitamin D ₂ /100 g	of the foodstuffs containing it shall be 'Vitamin	
	Yeast-leavened fine bakery wares	5 μg of vitamin D ₂ /100 g	D yeast' or 'Vitamin D ₂ yeast'	
	Food Supplements as defined in Directive 2002/46/EC	5 μg of vitamin D ₂ /day		
UV-treated bread	Specified food category	Maximum levels of vitamin D ₂	The designation on the label of the novel	
	Yeast leavened bread and rolls (without toppings)	3 μg vitamin D ₂ /100 g	food shall be accompanied by 'contains vitamin D produced by UV-treatment'	
UV-treated milk	Specified food category	Maximum levels of vitamin D ₃	1. The designation the	ion
	Pasteurised whole milk as defined in Regulation (EU) No 1308/2013 to be consumed as such	5-32 μg/kg for general population excluding infants	label of the novel food shall be 'UV-treated'. Where	
	Pasteurised semi-skimmed milk as defined in Regulation (EU) No 1308/2013 to be consumed as such	1-15 μg/kg for general population excluding infants	UV- treated milk contains an amount of vitamin D that is consider significa in accordar	ed nt

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			with Point 2 of Part A of Annex XIII to Regulating (EU) No 1169/20 of the Europea Parliame and of the Council, the designate for the labelling shall be accompably 'contain vitamin D produced by UV-treatment or 'milk containing vitamin D resulting from UV-treatment or 'milk containing from UV-treat	nent ion anied t'
Vitamin K ₂ (menaquinone)	To be used in com Directive 2002/46 (EU) No 609/2011 Regulation (EC) N	6/EC, Regulation 3 and/or	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Menaquinone' or 'Vitamin K ₂ '	
Wheat bran extract	Specified food category Beer and substitutes	Maximum levels 0,4 g/100 g	The designation of the novel food on the labelling of the foodstuffs containing it	The 'Wheat Bran Extract' may not be introduced onto the market as a food supplement or

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	Ready to eat cereals	9 g/100 g	shall be 'Wheat bran extract'	food supplement ingredient.
	Dairy products	2,4 g/100 g		Nor may it be added to infant
	Fruit and vegetable juices	0,6 g/100 g		formula.
	Soft drinks	0,6 g/100 g		
	Meat preparations	2 g/100 g		
Yeast beta-glucans	Specified food category	Maximum levels of pure beta-glucans from yeast (Saccharomyces cervisiae)	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Yeast (Saccharomyces cerevisiae) betaglucans'	
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	1,275 g/day for children older than 12 years and general adult population 0,675 g/day for children younger than 12 years		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	1,275 g/day		
	Food for special medical purposes as defined in Regulation (EU) No 609/2013, excluding food for special medical purposes intended for infants and young children	1,275 g/day		
	Beverages based on fruit and/ or vegetable juices including concentrate	1,3 g/kg		

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and dehydrated juices	
Fruit-flavoured drinks	0,8 g/kg
Cocoa beverages preparation powder	38,3 g/kg (powder)
Other beverages	0,8 g/kg (ready to drink)
	7 g/kg (powder)
Cereal bars	6 g/kg
Breakfast cereals	15,3 g/kg
Wholegrain and high fibre instant hot breakfast cereals	1,5 g/kg
Cookie-type biscuits	6,7 g/kg
Cracker-type biscuits	6,7 g/kg
Milk based beverages	3,8 g/kg
Fermented milk products	3,8 g/kg
Milk product analogues	3,8 g/kg
Dried milk/milk powder	25,5 g/kg
Soups and soup mixes	0,9 g/kg (ready to eat)
	1,8 g/kg (condensed)
	6,3 g/kg (powder)
Chocolate and confectionery	4 g/kg
Protein bars and powders	19,1 g/kg
Jam, marmalade and other fruit spreads	11,3 g/kg

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Zeaxanthin	Specified food category	Maximum levels	The designation of the novel food	
	Food Supplements as defined in Directive 2002/46/EC	2 mg/day	on the labelling of the foodstuffs containing it shall be 'synthetic zeaxanthin'	
Zinc L-pidolate	Specified food category	Maximum levels	The designation of the novel food	
	Foods covered by Regulation (EU) No 609/2013	3 g/day	on the labelling of the foodstuffs containing it shall be 'Zinc L-	
	Milk based drinks and similar products intended for young children	pidolate'		
	Meal replacement for weight control			
	Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen			
	Food bearing statement on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014			
	Food Supplements as defined in Directive 2002/46/EC			

a Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

ANNEX

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Status: Point in time view as at 13/08/2018.

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2470. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- b Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (OJ L 228, 31.7.2014, p. 5).
- c Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).
- d Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).
- e Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption (OJ L 10, 12.1.2002, p. 67).
- f Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulation (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) 1234/2007 (OJ L 347, 20.12.2013, p. 671).

TABLE 2: SPECIFICATIONS

Authorised	Specifications	
Novel Food		
N-Acetyl-D-	Description:	
neuraminic acid	N-Acetyl-D-neuraminic acid is a white to off-white crystalline powder	
	Definition:	
	Chemical name:	
	IUPAC names:	
	N-Acetyl-D-neuraminic acid (dihydrate)	
	5-Acetamido-3,5-dideoxy-D-glycero-D-galacto-non-2-ulopyranosonic	
	acid (dihydrate)	
	Synonyms:	
	Sialic acid (dihydrate)	
	Chemical formula:	
	$C_{11}H_{19}NO_9$ (acid)	
	$C_{11}H_{23}NO_{11}$ ($C_{11}H_{19}NO_9 * 2H_2O$) (dihydrate)	
	Molecular mass:	
	309,3 Da (acid)	
	345,3 (309,3 + 36,0) (dihydrate)	
	CAS No.:	
	131-48-6 (free acid)	
	50795-27-2 (dihydrate)	
	Specifications:	
	Description: white to off-white crystalline powder	
	pH (20 °C, 5 % solution): 1,7 – 2,5	
	N-Acetyl-D-neuraminic acid (dihydrate): > 97,0 %	
	Water (dihydrate calculates to $10,4\%$): $\leq 12,5\%$ (w/w)	
	Ash, sulphated: $< 0.2 \%$ (w/w)	
	Acetic acid (as free acid and/or sodium acetate): < 0,5 % (w/w)	
	Heavy Metals:	
	Iron: < 20,0 mg/kg	
	Lead: $< 0.1 \text{ mg/kg}$	
	Residual proteins: < 0,01 % (w/w) Residual solvents:	
	2-Propanol: $< 0.1 \% (w/w)$	

- a 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 (OJ L 83, 22.3.2012, p. 1).
- b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Acetone: < 0,1 % (w/w) Ethyl acetate: < 0,1 % (w/w) **Microbiological criteria:** Salmonella: Absence in 25 g

Aerobic mesophilic total count: < 500 CFU/g

Enterobacteriaceae: Absence in 10 g

Cronobacter (Enterobacter) sakazakii: Absence in 10 g

Listeria monocytogenes: Absence in 25 g

Bacillus cereus: < 50 CFU/g

Yeasts: < 10 CFU/g Moulds: < 10 CFU/g

Residual endotoxins: < 10 EU/mg

CFU: Colony Forming Units; EU: Endotoxin Units.

Adansonia digitata (Baobab) dried fruit pulp

Description/Definition:

The Baobab (*Adansonia digitata*) fruits are harvested from trees. The hard shells are cracked open and the pulp is separated from the seeds and the shell. This is milled, separated into coarse and fine lots (particle size 3 to $600 \, \mu$) and then packaged.

Typical nutritional components:

Moisture (loss on drying) (g/100 g): 4,5-13,7

Protein (g/100 g): 1,8-9,3 Fat (g/100 g): 0-1,6

Total carbohydrate (g/100 g): 76,3-89,5 Total sugars (as glucose): 15,2-36,5 Sodium (mg/100 g): 0,1-25,2

Analytical specifications:

Foreign matter: Not more than 0,2 %

Moisture (loss on drying) (g/100 g): 4,5-13,7

Ash (g/100 g): 3,8-6,6

Ajuga reptans extract from cell cultures

Description/Definition:

Hydroalcoholic extract from *Ajuga reptans* L. tissue cultures which is substantially equivalent to extracts from flowering aerial parts of *Ajuga reptans* obtained by traditional cultures.

L-Alanyl-L-Glutamine

Description/Definition:

L-Alanyl-L-Glutamine is produced by fermentation with a genetically modified strain of *Escherichia coli*. During the fermentation process, the ingredient is secreted into the growth medium from which it is subsequently separated and purified to a concentration of > 98 %.

Appearance: White crystalline powder

Purity: > 98 %

Infrared spectroscopy: Conformity with ref. standard

Appearance of solution: Colourless and clear

Assay (dry basis): 98-102 % Related substances (each): ≤ 0.2 % Residue on ignition: ≤ 0.1 % Loss on drying: ≤ 0.5 %

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 (OJ L 83, 22.3.2012, p. 1).

b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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> Optical rotation: $+9.0 - +11.0^{\circ}$ pH (1 %; H₂O): 5,0-6,0 Ammonium (NH₄): $\leq 0.020 \%$ Chloride (Cl): ≤ 0,020 % Sulphate (SO₄): $\leq 0.020 \%$ Microbiological criteria: Escherichia coli: Absence/g

Algal oil from the microalgae Ulkenia sp.

Description/Definition:

Oil from the micro-algae *Ulkenia* sp.

Acid value: $\leq 0.5 \text{ mg KOH/g}$

Peroxide value (PV): ≤ 5.0 meg/kg oil Moisture and volatiles: $\leq 0.05 \%$

Unsaponifiables: $\leq 4.5 \%$ Trans-fatty acids: $\leq 1.0 \%$ DHA content: ≥ 32 %

Allanblackia seed oil

Description/Definition:

Allanblackia seed oil is obtained from the seeds of the allanblackia species: A. floribunda (synonymous with A. parviflora) and A. stuhlmannii.

Composition of fatty acids:

Lauric acid (C12:0): < 1,0 % Myristic acid (C14:0): < 1,0 % Palmitic acid (C16:0): < 2,0 % Palmitoleic acid (C16:1): < 1,0 % Stearic acid (C18:0): 45-58 % Oleic acid (C18:1): 40-51 % Linoleic acid (C18:2): < 1,0 % γ -Linolenic acid (C18:3): < 1,0 % Arachidic acid (C20:0): < 1,0 % Free fatty acids: max 0,1 %

Characteristics:

Trans fatty acids: max 0,5 %

Peroxide value (PV): max 0,8 meg/kg

Iodine value: < 46 g/100 gUnsaponifiable matter: max 1,0 %

Saponification value: 185-198 mg KOH/g

Aloe macroclada Baker leaf extract

Description/Definition:

Powdered gel extract derived from the leaves of Aloe macroclada Baker which is substantially equivalent to the same gel derived from *Aloe vera*

(L.) Burm.f. leaves.

Ash: 25 %

Dietary fibres: 28,6 %

Fat: 2,7 % Moisture: 4,7 % Polysaccharides: 9,5 %

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 (OJ L 83, 22.3.2012, p. 1).

Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Protein: 1,63 % Glucose: 8,9 %

Antarctic Krill oil from Euphausia superba

Description/Definition:

To produce lipid extract from Antarctic Krill (*Euphausia superba*) deep-frozen crushed krill or dried krill meal is subjected to lipid extraction with an approved extraction solvent (under Directive 2009/32/EC). Proteins and krill material are removed from the lipid extract by filtration. The extraction solvents and residual water are removed by evaporation.

Saponification value: $\leq 230 \text{ mg KOH/g}$ Peroxide value (PV): $\leq 3 \text{ meq O }_2/\text{kg oil}$

Oxidative stability: All food products containing Antarctic Krill oil from *Euphausia superba* should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC). Moisture and volatiles: $\leq 3\%$ or 0,6 expressed as water activity at 25 °C

Phospholipids: 35-50 % Trans-fatty acids: ≤ 1 %

EPA (eicosapentaenoic acid): $\geq 9 \%$ DHA (docosahexaenoic acid): $\geq 5 \%$

Antarctic Krill oil rich in phospholipids from *Euphausia superba*

Description/Definition:

Oil rich in phospholipids is produced from Antarctic krill (*Euphausia superba*) by repeated solvent washings with an approved solvent (under Directive 2009/32/EC) to increase phospholipid content of the oil. Solvents are removed from the final product by evaporation.

Saponification value: $\leq 230 \text{ mg KOH/g}$ Peroxide value (PV): $\leq 3 \text{ meq } O_2/\text{kg oil}$

Moisture and volatiles: ≤ 3 % or 0,6 expressed as water activity at 25 °C

Phospholipids: \geq 60 % Trans-fatty acids: \leq 1 %

EPA (eicosapentaenoic acid): \geq 9 % DHA (docosahexaenoic acid): \geq 5 %

Arachidonic acid-rich oil from the fungus *Mortierella alpina*

Description/Definition:

The clear yellow arachidonic acid-rich oil is obtained by fermentation of the non-genetically modified strains IS-4, I49-N18, FJRK-MA01 and CBS 210.32 of the fungus *Mortierella alpina* using a suitable liquid. The oil is then extracted from the biomass and purified.

Arachidonic acid: ≥ 40 % by weight of the total fatty acid content

Free fatty acids: ≤ 0.45 % of the total fatty acid content Trans fatty acids: ≤ 0.5 % of the total fatty acid content

Unsaponifiable matter: ≤ 1.5 %Peroxide value (PV): ≤ 5 meq/kg

Anisidin value: ≤ 20 Acid value: ≤ 1.0 KOH/g Moisture: ≤ 0.5 %

Argan oil from Argania spinosa

Description/Definition:

- a 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 (OJ L 83, 22.3.2012, p. 1).
- b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Argan oil is the oil obtained by cold pressing of the almond like kernels of the fruits of *Argania spinosa* (L.) Skeels. Kernels may be roasted prior to pressing, but with no direct contact with a flame.

Composition:

Palmitic acid (C16:0): 12-15 % Stearic acid (C18:0): 5-7 % Oleic acid (C18:1): 43-50 % Linoleic acid (C18:2): 29-36 % Unsaponifiable matter: 0,3-2 % Total sterols: 100-500 mg/100 g Total tocopherols: 16-90 mg/100 g

Oleic acidity: 0,2-1,5 %

Peroxide value (PV): $\leq 10 \text{ meq } O_2/kg$

Astaxanthinrich oleoresin from *Haematococcus* pluvialis algae

Description/Definition:

Astaxanthin is a carotenoid produced by *Haematococcus pluvialis* algae. Production methods for the growth of the algae are variable; using either closed systems exposed to sunlight or strictly controlled illuminated light; alternatively open ponds may be used. The algal cells are harvested and dried; the oleoresin is extracted using either super critical CO_2 or a solvent (ethyl acetate). The Astaxanthin is diluted and standardized to 2,5 %, 5,0 %, 7,0 %, 10 %, 15 % or 20 % using olive oil, safflower oil, Sunflower oil or MCT (Medium Chain Triglycerides).

Composition of the Oleoresin:

Fat: 42,2- 99 % Protein: 0,3-4,4 % Carbohydrate: 0-52,8 %

Fibre: < 1,0 % Ash: 0,0-4,2 %

Specification of Carotenoids w/w%

Total Astaxanthins: 2,9-11,1 %9-cis-astaxanthin: 0,3-17,3 %

13-cis-astaxanthin: 0,2-7,0 %

Astaxanthin monoesters: 79,8-91,5 % Astaxanthin diesters: 0,16-19,0 %

B-Carotene: 0,01-0,3 %

Lutein: 0-1,8 %

Canthaxanthin: 0-1,30 % Microbiological criteria:

Total aerobic bacteria: < 3 000 CFU/g Yeast and Moulds: < 100 CFU/g

Coliforms: < 10 CFU/g *E. coli*: Negative *Salmonella*: Negative *Staphylococcus*: Negative

Basil seeds (Ocimum basilicum)

Description/Definition:

Basil (*Ocimum basilicum* L.) belongs to the family '*Lamiaceae*' within the order 'Lamiales'. Post-harvest the seeds are cleaned mechanically.

- a 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 (OJ L 83, 22.3.2012, p. 1).
- b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Flowers, leaves and other parts of the plant are removed. Highest level of purity of Basil seeds has to be ensured by filtering (optical, mechanical). Production process of fruit juice and fruit/vegetable blend beverages containing Basil seeds (*Ocimum basilicum* L.) includes seed pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place.

Dry Matter: 94,1 % Protein: 20,7 % Fat: 24,4 %

Carbohydrate: 1,7 %

Dietary Fibre: 40,5 % (Method: AOAC 958,29)

Ash: 6,78 %

Fermented black bean extract

Description/Definition:

Fermented black bean extract (Touchi extract) is a fine light-brown protein-rich powder obtained by water extraction of small soybeans (*Glycine max (L.) Merr.*) fermented with *Aspergillus oryzae*. The extract contains an α -glucosidase inhibitor.

Characteristics:

Fat: $\leq 1.0 \%$

Protein: ≥ 55 %Water: $\leq 7,0$ %

Ash: $\leq 10 \%$

Carbohydrate: ≥ 20 %

 α -glucosidase inhibitory activity: IC50 min 0,025 mg/ml

Soy isoflavone: $\leq 0.3 \text{ g}/100 \text{ g}$

Bovine lactoferrin

Description/Definition:

Bovine lactoferrin is a protein that occurs naturally in cows' milk. It is an iron-binding glycoprotein of approximately 77 kDa and consists of a single polypeptide chain of 689 amino acids.

Production process: Bovine lactoferrin is isolated from skimmed milk or cheese whey via ion exchange and subsequent ultra-filtration steps. Finally, it is dried by freeze drying or spraying and the large particles are sieved out. It is a virtually odourless, light pinkish powder.

Physical-Chemical properties of Bovine lactoferrin:

Moisture: < 4,5 % Ash: < 1,5 %

Arsenic: < 2,0 mg/kg Iron: < 350 mg/kg Protein: > 93 %

of which bovine lactoferrin: > 95 % of which other proteins: < 5,0 % pH (2 % solution, 20 °C): 5,2-7,2 Solubility (2 % solution, 20 °C): complete

Buglossoides arvensis seed oil

Description/Definition:

Refined Buglossoides oil is extracted from the seeds of *Buglossoides* arvensis (L.) I.M.Johnst

Alpha-linolenic acid: $\geq 35 \%$ w/w of total fatty acids

- a 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 (OJ L 83, 22.3.2012, p. 1).
- b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Stearidonic acid: ≥ 15 % w/w of total fatty acids Linoleic acid: $\geq 8,0$ % w/w of total fatty acids Trans fatty acids: $\leq 2,0$ % w/w of total fatty acids

Acid value: $\leq 0.6 \text{ mg KOH/g}$

Peroxide value (PV): ≤ 5,0 meq O₂/kg Unsaponifiable content: < 2,0 %

Protein content (total nitrogen): $\leq 10 \,\mu\text{g/ml}$

Pyrrolizidine alkaloids: Not detectable with a detection limit of 4,0 µg/kg

Calanus finmarchicus oil

Description/Definition:

The novel food is ruby coloured, slightly viscous oil with a slight shellfish odour extracted from the crustacean (marine zooplankton) *Calanus finmarchicus*. The ingredient consists primarily of wax esters (> 85 %) with minor amounts of triglycerides and other neutral lipids.

Specifications:

Water: < 1,0 % Wax esters: > 85 % Total fatty acids: > 46 %

Eicosapentaenoic acid (EPA): > 3,0 % Docosahexaenoic acid (DHA): > 4,0 %

Total fatty alcohols: > 28 % C20:1 n-9 fatty alcohol: > 9,0 % C22:1 n-11 fatty alcohol: > 12 %

Trans fatty acids: < 1,0 % Astaxanthinesters: < 0,1 %

Peroxide value (PV): < 3.0 meq. O_2/kg

Chewing gum base

Description/Definition:The novel food ingredient is a synthetic polymer (Patent

(monomethoxypolyethyde Ne O 2006016179). It consists of branched polymers of monomethoxypolyethylene glycol (MPEG) grafted onto polyisoprene-

monomethoxypolyethylene glycol (MPEG) grafted onto polyisoprenegraft-maleic anhydride (PIP-g-MA), and unreacted MPEG (less than 35

% by weight).

White to off-white colour. CAS No.: 1246080-53-4

Characteristics:

Moisture: < 5,0 %

Aluminium: < 3,0 mg/kg Lithium: < 0,5 mg/kg Nickel: < 0,5 mg/kg

Residual anhydride: < 15 μmol/g

Polydispersity index: < 1,4 Isoprene: < 0,05 mg/kg Ethylene oxide: < 0,2 mg/kg

Free maleic anhydride: < 0,1 %Total oligomeres (less than 1 000 Dalton):

 $\leq 50 \text{ mg/kg}$

Ethylene glycol: < 200 mg/kg Diethylene glycol: < 30 mg/kg

a 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 (OJ L 83, 22.3.2012, p. 1).

b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).

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Monoethylene glycol methyl ether: < 3,0 mg/kg Diethylene glycol methyl ether: < 4,0 mg/kg Triethylene glycol methyl ether: < 7,0 mg/kg

1,4-Dioxane: < 2,0 mg/kg Formaldehyde: < 10 mg/kg

Chewing gum base (Methyl vinyl ether-maleic anhydride copolymer)

Description/Definition:

Methyl vinyl ether-maleic anhydride copolymer is an anhydrous

copolymer of methyl vinyl ether and maleic anhydride.

Free-flowing, white to white-off powder

CAS No: 9011-16-9

Purity:

Assay value: At least 99,5 % in dry matter Specific viscosity (1 % MEK): 2-10 Residual methyl vinyl ether: ≤ 150 ppm Residual maleic anhydride: ≤ 250 ppm

Acetaldehyde: ≤ 500 ppm Methanol: ≤ 500 ppm Dilauroyl peroxide: ≤ 15 ppm Total heavy metals: ≤ 10 ppm **Microbiological criteria:**

Total aerobic plate count: ≤ 500 CFU/g

Mould/yeast: ≤ 500 CFU/g Escherichia coli: Negative to test Salmonella: Negative to test

Staphylococcus aureus: Negative to test Pseudomonas aeruginosa: Negative to test

Chia oil from Salvia hispanica

Description/Definition:

Chia oil is produced from Chia (*Salvia hispanica* L.) seeds (99,9 % pure) by cold pressing. No solvents are used and, once pressed, the oil is held in decantation tanks and a filtration process employed to remove impurities.

It can also be produced by extraction with supercritical CO_2 .

Production process:

Produced by cold pressing. No solvents are used and, once pressed, the oil is held in decantation tanks and a filtration process employed to remove impurities.

Acidity expressed as oleic acid: ≤ 2.0 % Peroxide value (PV): ≤ 10 meq/kg Insoluble impurities: ≤ 0.05 % Alpha linolenic acid: ≥ 60 % Linoleic acid: 15-20 %

Chia seeds (Salvia hispanica)

Description/Definition:

Chia (Salvia hispanica L.) is a summer annual herbaceous plant belonging to the Labiatae family. Post-harvest the seeds are cleaned mechanically. Flowers, leaves and other parts of the plant are removed.

Dry matter: 90-97 % Protein: 15-26 %

- a 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 (OJ L 83, 22.3.2012, p. 1).
- b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Fat: 18-39 %

Carbohydrate (*): 18-43 % Crude Fibre(**): 18-43 %

Ash: 3-7 %

- (*) Carbohydrates include the fibre value
- (**) Crude fibre is the part of fibre made mainly of indigestible cellulose, pentosans and lignin

Production process:

Production process of fruit juices and fruit juice blends beverages, containing Chia seeds, includes seed pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place.

Chitinglucan from Aspergillus niger

Description/Definition:

Chitin-glucan is obtained from the mycelium of *Aspergillus niger*; it is a slightly yellow, odourless, free-flowing powder. It has a dry matter content of 90 % or more.

Chitin-glucan is composed largely of two polysaccharides:

- chitin, composed of repeating units of N-acetyl-D-glucosamine
 - (CAS No: 1398-61-4),
- beta (1, 3)-glucan, composed of repeating units of D-glucose (CAS No: 9041-22-9).

Loss on drying: $\leq 10 \%$ Chitin-glucan: $\geq 90 \%$

Ratio of chitin to glucan: 30:70 to 60:40

Ash: ≤ 3,0 % Lipids: ≤ 1,0 % Proteins: ≤ 6,0 %

Chitin-glucan complex from Fomes fomentarius

Description/Definition:

Chitin-glucan complex is obtained from the cell walls of the fruit bodies of the fungus *Fomes fomentarius*. It consists primarily of two polysaccharides:

- Chitin, composed of repeating units of N-acetyl-D-glucosamine (CAS No: 1398-61-4);
 - Beta-(1,3)(1,6)-D-glucan, composed of repeating units of D-glucose (CAS No: 9041-22-9).

The production process consists of several steps, including: cleaning, reduction in size and grinding, softening in water and heating in an alkaline solution, washing, drying. No hydrolysis is applied during the production process.

Appearance: Powder, odourless, flavourless, brown

Purity:

Moisture: $\leq 15 \%$ Ash: $\leq 3.0 \%$ Chitin-glucan: $\geq 90 \%$

Ratio of chitin to glucan: 70:20

Total carbohydrates, excluding glucans: $\leq 0.1 \%$

- a 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 (OJ L 83, 22.3.2012, p. 1).
- b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Proteins: $\leq 2.0 \%$ Lipids: $\leq 1.0 \%$ Melanins: $\leq 8.3 \%$ Additives: None pH: 6,7-7,5 **Heavy metals:** Lead (ppm): ≤ 1.00

Cadmium (ppm): $\leq 1,00$ Mercury (ppm): $\leq 0,03$

Arsenic (ppm): ≤ 0.20 Microbiological criteria:

Total mesophilic bacteria: $\leq 10^3/g$

Yeast and moulds: $\leq 10^3/g$ Coliforms at 30 °C: $\leq 10^3/g$

 $E. coli: \leq 10/g$

Salmonella and other pathogenic bacteria: Absence/25 g

Chitosan extract from fungi (Agaricus bisporus; Aspergillus niger)

Description/Definition:

The chitosan extract (containing mainly poly(D-glucosamine)) is obtained from stems of *Agaricus bisporus* or from the mycelium of *Aspergillus niger*.

The patented production process consists of several steps, including: extraction and deacetylation (hydrolysis) in alkaline medium, solubilisation in acidic medium, precipitation in alkaline medium, washing and draing

washing and drying.

Synonym: Poly(D-glucosamine) Chitosan CAS number: 9012-76-4 Chitosan formula: (C₆H₁₁NO₄)_n Appearance: fine free-flowing powder Aspect: Off –white to slightly brownish

Odour: Odourless

Purity:

Chitosan content (% w/w dry weight):≥ 85 Glucan content (% w/w dry weight): ≤ 15 Loss on drying (% w/w dry weight): ≤ 10 Viscosity (1 % in 1 % acetic acid): 1-15

Degree of acetylation (in % mol/wet weight): 0-30

Viscosity (1 % in 1 % acetic acid) (mPa.s): 1-14 for chitosan from

Aspergillus niger; 12-25 for chitin from Agaricus bisporus

Ash (% w/w dry weight): ≤ 3.0 Proteins (% w/w dry weight): ≤ 2.0

Particle size: > 100 nm

Tapped density (g/cm^3) : 0,7-1,0

Fat binding capacity $800 \times (\text{w/w} \text{ wet weight})$: pass**Heavy metals:**

Mercury (ppm): ≤ 0.1 Lead (ppm): ≤ 1.0 Arsenic (ppm): ≤ 1.0 Cadmium (ppm): ≤ 0.5

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Microbiological criteria:

Aerobic count (CFU/g): $\leq 10^3$

Yeast and mould count (CFU/g): $\leq 10^3$

Escherichia coli (CFU/g): ≤ 10 Enterobacteriaceae (CFU/g): ≤ 10

Salmonella: Absence/25g

Listeria monocytogenes: Absence/25g

Chondroitin sulphate

Description/Definition:

Chondroitin sulphate (sodium salt) is a biosynthetic product. It is obtained by chemical sulphation of chondroitin derived from

fermentation by the bacterium Escherichia coli O5:K4:H4 strain U1-41

(ATCC 23502).

Chondroitin sulphate (sodium salt) (% dry basis): 95-105

MWw (weight avg.) (kDa): 5-12 MWn (number avg.) (kDa): 4-11

Dispersity $(w_h/w_{0.05})$: ≤ 0.7

Sulphation pattern (ΔDi -6S) (%): ≤ 85

Loss on drying (%) (105 °C to constant weight): $\leq 10,0$

Residue on ignition (% dry basis): 20-30

Protein (% dry basis): ≤ 0.5 Endotoxins (EU/mg): ≤ 100

Total organic impurities (mg/kg): ≤ 50

Chromium Picolinate

Description/Definition:

Chromium picolinate is a reddish free-flowing powder, slightly soluble in

water at pH 7. The salt is also soluble in polar organic solvents. Chemical name: tris(2pyridinecarboxylato-N,O)chromium(III) or 2-

pyridinecarboxylic acid chromium(III) salt

CAS No.: 14639-25-9Chemical formula: Cr(C₆H₄NO₂)₃

Chemical characteristics: Chromium Picolinate: ≥ 95 % Chromium (III): 12-13 % Chromium (VI): not detected

Water: $\leq 4.0 \%$

Cistus incanus L. Pandalis herb

Description:

Cistus incanus L. Pandalis herb; species belonging to the *Cistaceae* family and native to the Mediterranean region, Chalkidiki Peninsula.

Composition:

Moisture: 9–10 g/100 g herbs Protein: 6,1 g/100 g herbs Fat: 1,6 g/100 g herbs

Carbohydrates: 50,1 g/100 g herbs

Fiber: 27,1 g/100 g herbs Minerals: 4,4 g/100 g herbs

Sodium: 0,18 g Potassium: 0,75 g

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Magnesium: 0,24 g Calcium: 1,0 g Iron: 65 mg Vitamin B_1 : 3,0 μ g Vitamin B_2 : 30 μ g Vitamin B_6 : 54 μ g

Vitamin C: 28 mg

Vitamin A: less than 0,1 mg Vitamin E: 40–50 mg

Alpha-Tocopherol: 20–50 mg

Beta and Gamma-Tocopherols: 2–15 mg

Delta-Tocopherol: 0,1–2 mg

Citicoline

Description/Definition:

Citicoline is produced by a microbial process.

Citicoline is composed of cytosine, ribose, pyrophosphate and choline.

White crystalline powder

Chemical name: Choline cytidine 5'-pyrophosphate, Cytidine 5'-

(trihydrogen diphosphate) P'-[2-(trimethylammonio)ethyl]ester inner salt

Chemical formula: C₁₄H₂₆N₄O₁₁P₂ Molecular weight: 488,32 g/mol

CAS No.: 987-78-0

pH (sample solution of 1 %): 2,5-3,5

Purity:

Assay value: \geq 98 % of dry matter

Loss on drying (100 °C for 4 hours): $\leq 5.0 \%$

Ammonium: $\leq 0.05 \%$

Free phosphoric acids: ≤ 0.1 % 5'-Cytidylic acid: ≤ 1.0 % **Microbiological criteria:** Total plate count: $\leq 10^3$ CFU/g Yeast and moulds: $\leq 10^2$ CFU/g

Escherichia coli: Absence in 1 g

Arsenic: Not more than 2 ppm

Clostridium butyricum

Description/Definition:

Clostridium butyricum (CBM-588) is a Gram-positive, spore-forming, obligate anaerobic, non-pathogenic, non-genetically modified bacterium.

Depository number FERM BP-2789

Microbiological criteria:

Total viable aerobic count: $\leq 10^3$ CFU/g

Escherichia coli: Not detected in 1 gStaphylococcus aureus: Not detected

in 1 g

Pseudomonas aeruginosa: Not detected in 1 g

Yeast and moulds: $\leq 10^2 \text{ CFU/g}$

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Extract of defatted cocoa powder	Cocoa (<i>Theobroma cacao</i> L.) Extract Appearance: Dark brown powder free of visible impurities Physical and chemical properties: Polyphenol content: Min 55,0 % GAE Theobromine content: Max 10,0 % Ash content: Max 5,0 % Moisture content: Max 8,0 % Bulk density: 0,40-0,55 g/cm³ pH: 5,0-6,5 Residual solvent: Max 500 ppm
Low fat cocoa extract	Low fat Cocoa (<i>Theobroma cacao</i> L.) extract Appearance: Dark red to purple powder Cocoa extract, concentrate: Min 99 % Silicon dioxide (technological aid): Max 1,0 % Cocoa flavanols: Min. 300 mg/g — Epicatechin: Min. 45 mg/g Loss on drying: Max. 5,0 %
Coriander seed oil from Coriandrum sativum	Description/Definition: Coriander seed oil is an oil containing glycerides of fatty acids that is produced from the seeds of the coriander plant <i>Coriandrum sativum</i> L. Slight yellow colour, bland taste CAS No.: 8008-52-4 Composition of fatty acids: Palmitic acid (C16:0): 2-5 % Stearic acid (C18:0): <1,5 % Petroselinic acid (cis-C18:1(n-12)): 60-75 % Oleic acid (cis-C18:1 (n-9)): 8-15 %Linoleic acid (C18:2): 12-19 % α-Linolenic acid (C18:3): <1,0 % Trans fatty acids: ≤1,0 % Purity: Refractive index (20 °C): 1,466-1,474 Acid value: ≤2,5 mg KOH/g Peroxide value (PV): ≤5,0 meq/kg Iodine value: 88-110 units Saponification value: 186-200 mg KOH/g Unsaponifiable matter: ≤15 g/kg
Crataegus pinnatifida dried fruit	Description/Definition: Dried fruits of <i>Crataegus pinnatifida</i> species belonging to the <i>Rosaceae</i> family and native to north China and Korea. Composition: Dry matter: 80 % Carbohydrates: 55 g/kg fresh weight Fructose: 26,5–29,3 g/100 g Glucose: 25,5–28,1 g/100 g Vitamin C: 29,1 mg/100 g fresh weight

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Sodium: 2,9 g/100 g fresh weight

Compotes are products obtained by thermal processing of the edible part of one or several species of fruits, whole or in pieces, sieved or not, without significant concentration. Sugars, water, cider, spices and lemon juice may be used.

α-cyclodextrin

Description/Definition:

A non-reducing cyclic saccharide consisting of six α -1,4-linked D-glucopyranosyl units produced by the action of cyclodextrin glucosyltransferase (CGTase, EC 2.4.1.19) on hydrolyzed starch. Recovery and purification of α -cyclodextrin may be carried out using one of the following procedures: precipitation of a complex of α -cyclodextrin with 1-decanol, dissolution in water at elevated temperature and reprecipitation, steam-stripping of the complexant, and crystallisation of α -cyclodextrin from the solution; or chromatography with ion-exchange or gel filtration followed by crystallisation of α -cyclodextrin from the purified mother liquor; or membrane separation methods such as ultra-filtration and reverse osmosis: Description: Virtually odourless, white or almost white crystalline solid.

Synonyms: α-cyclodextrin, α-dextrin, cyclohexaamylose,

cyclomaltohexaose, α-cycloamylase

Chemical name: CyclohexaamyloseCAS No.: 10016-20-3

Chemical formula: $(C_6H_{10}O_5)_6$ Formula weight: 972,85 Assay: \geq 98 % (dry basis)

Identification:

Melting range: Decomposes above 278 °C

Solubility: Freely soluble in water; very slightly soluble in ethanol Specific rotation: $[\alpha]_D^{25}$: Between +145° and +151° (1 % solution) Chromatography: The retention time for the major peak in a liquid chromatogram of the sample corresponds to that for α -cyclodextrin in a chromatogram of reference α -cyclodextrin (available from *Consortium für Elektrochemische Industrie GmbH, München, Germany or Wacker Biochem Group, Adrian, MI, USA*) using the conditions described in the METHOD OF ASSAY

Purity:

Water: ≤ 11 % (Karl Fischer Method) Residual complexant: ≤ 20 mg/kg

(1-decanol)

Reducing substances: ≤ 0.5 % (as glucose)

Sulphated ash: $\leq 0.1 \%$ Lead: $\leq 0.5 \text{ mg/kg}$ **Method of assay:**

Determine by liquid chromatography using the following conditions: Sample solution: Weigh accurately about 100 mg of test sample into a 10 ml volumetric flask and add 8 ml of deionised water. Dissolve the sample completely using an ultra-sonification bath (10-15 min) and dilute to the

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mark with purified deionised water. Filter through a 0,45-micrometer filter

Reference solution: Weigh accurately about 100 mg of α -cyclodextrin into a 10 ml volumetric flask and add 8 ml of deionised water. Dissolve the sample completely using an ultra-sonification bath and dilute to the mark with purified deionised water.

Chromatography: Liquid chromatograph equipped with a refractive index detector and an integrating recorder.

Column and packing: Nucleosil-100-NH₂ (10 µm) (Macherey & Nagel

Co. Düren, Germany) or similar

Length: 250 mm Diameter: 4 mm Temperature: 40 °C

Mobile phase: acetonitrile/water (67/33, v/v)

Flow rate: 2,0 ml/min

Injection volume: 10 μ lProcedure: Inject the sample solution into the chromatograph, record the chromatogram, and measure the area of the α -CD peak. Calculate the percentage of α -cyclodextrin in the test sample as follows:

% α -cyclodextrin (dry basis) = $100 \times (A_S/A_R) (W_R/W_S)$

where

 A_S and A_R are the areas of the peaks due to α -cyclodextrin for the sample solution and reference solution, respectively.

 W_S and W_R are the weights (mg) of the test sample and reference α -cyclodextrin, respectively, after correcting for water content.

y-cyclodextrin

Description/Definition:

A non-reducing cyclic saccharide consisting of eight α -1,4-linked D-glucopyranosyl units produced by the action of cyclodextrin glucosyltransferase (CGTase, EC 2.4.1.19) on hydrolysed starch. Recovery and purification of γ -cyclodextrin may be carried out by precipitation of a complex of γ -cyclodextrin with 8-cyclohexadecen-1-one, dissolution of the complex with water and n-decane, steam-stripping of the aqueous phase and recovery of gamma-CD from the solution by crystallisation.

Virtually odourless, white or almost white crystalline solid Synonyms: γ -cyclodextrin, γ -dextrin, cyclooctaamylose,

cyclomaltooctaose, γ-cycloamylase Chemical name: Cyclooctaamylose

CAS number: 17465-86-0 Chemical formula: $(C_6H_{10}O_5)_8$ Assay: $\geq 98\%$ (dry basis)

Identification:

Melting range: Decomposes above 285 °C

Solubility: Freely soluble in water; very slightly soluble in ethanol Specific rotation: $[\alpha]_D^{25}$: between + 174° and + 180° (1 % solution)

Purity:

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Water: ≤ 11 %

Residual complexant (8-cyclohexadecen-1-one (CHDC)): $\leq 4 \text{ mg/kg}$

Residual solvent (n-decane): \leq 6mg/kg Reducing substances: \leq 0.5 % (as glucose)

Sulphated ash: $\leq 0.1 \%$

Dextran preparation produced by Leuconostoc mesenteroides

1. **Powdered form:**

Carbohydrates: 60 % with: (Dextran: 50 %, Mannitol: 0,5 %,

Fructose: 0,3 %, Leucrose: 9,2 %)

Protein: 6,5 % Lipid: 0,5 % Lactic acid: 10 % Ethanol: traces Ash: 13 % Moisture: 10 %

2. Liquid form:

Carbohydrates: 12 % with: (Dextran: 6,9 %, Mannitol: 1,1 %,

Fructose: 1,9 %, Leucrose: 2,2 %)

Protein: 2,0 % Lipid: 0,1 % Lactic acid: 2,0 % Ethanol: 0,5 % Ash: 3,4 % Moisture: 80 %

Diacylglycerol oil of plant origin

Description/Definition:

Manufactured from glycerol and fatty acids derived from edible vegetable oils, in particular from soybean oil (*Glycine max*) or rapeseed oil (*Brassica campestris, Brassica napus*) using a specific enzyme.

Acylglycerol Distribution:

Diacylglycerols (DAG): ≥ 80 % 1,3-Diacylglycerols (1,3-DAG): ≥ 50 %

Triacylglycerols (TAG): ≤ 20 % Monoacylglycerols (MAG): ≤ 5,0 %

Fatty Acid Composition (MAG, DAG, TAG):

Oleic acid (C18:1): 20-65 % Linoleic acid (C18:2): 15-65 % Linolenic acid (C18:3): \leq 15 % Saturated fatty acids: \leq 10 %

Others:

Acid value: ≤ 0.5 mg KOH/g Moisture and volatile: ≤ 0.1 % Peroxide value (PV): ≤ 1.0 meq/kg

Unsaponifiables: ≤ 2,0 % Trans fatty acids≤ 1,0 %

MAG = monoacylglycerols, DAG = diacylglycerols, TAG =

triacylglycerols

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Dihydrocapsiate (DHC)	Description/Definition: Dihydrocapsiate is synthesised by enzyme-catalysed esterification of vanillyl alcohol and 8-methylnonanoic acid. Following the esterification dihydrocapsiate is extracted with n-hexane. Viscous to colourless to yellow liquid Chemical formula: C_{18} H_{28} O_4 CAS $No: 205687-03-2$ $Physical$ -chemical properties: Dihydrocapsiate: > 94 % 8-Methylnonanoic acid: $< 6,0$ % $Vanillyl$ acohol: $< 1,0$ % $Vanillyl$ Va
Dried extract of Lippia citriodora from cell cultures	Description/Definition: Dried extract of <i>Lippia citriodora</i> (Palau) Kunth from cell cultures HTN [®] Vb.
Echinacea angustifolia extract from cell cultures	Description/Definition: Extract of the roots of <i>Echinacea angustifolia</i> obtained from plant tissue culture which is substantially equivalent to a root extract from <i>Echinacea angustifolia</i> obtained in ethanol-water titrated to 4 % echinacoside.
Echinacea purpurea extract from cell cultures	Description/Definition: Dried extract of <i>Echinacea purpurea</i> from cell cultures HTN [®] Vb
Echium plantagineum oil	Description/Definition: Echium oil is the pale yellow product obtained by refining oil extracted from the seeds of <i>Echium plantagineum</i> L. Stearidonic acid: ≥ 10 % w/w of total fatty acids Trans fatty acids: ≤ 2,0 % (w/w of total fatty acids) Acid value: ≤ 0,6 mg KOH/g Peroxide value (PV): ≤ 5,0 meq O_2 /kg Unsaponifiable content: ≤ 2,0 % Protein content (total nitrogen): ≤ 20 μg/ml Pyrrolizidine alkaloids: Not detectable with a detection limit 4,0 μg/kg
Epigallocatechin gallate as a purified extract from green tea leaves (<i>Camellia</i> sinensis)	Description/Definition: A highly purified extract from the leaves of green tea (<i>Camellia sinensis</i> (<i>L.</i>) <i>Kuntze</i>) in the form of a fine, off-white to pale pink powder. It is composed of a minimum of 90 % epigallo-catechin gallate (EGCG), and has a melting point between approx. 210 and 215 °C Appearance: off-white to pale pink powder Chemical name: polyphenol (-) epigallocatechin-3-gallate Synonyms: epigallocatechin gallate (EGCG) CAS No.: 989-51-5 INCI name: epigallocatechin gallate
a Commission Posul	ation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in

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Molecular mass: 458,4 g/mol Loss on drying: max 5,0 %

Heavy metals: Arsenic: max 3,0 ppm Lead: max 5,0 ppm

Assay:

Min. 94 % EGCG (on dry material)

max. 0,1 % caffeine

Solubility: EGCG is fairly soluble in water, ethanol, methanol and

acetone

L-ergothioneine

Definition

Chemical name (IUPAC): (2S)-3-(2-thioxo-2,3-dihydro-1*H*-imidazol-4-

yl)-2-(trimethylammonio)-Propanoate

Chemical formula: C₉H₁₅N₃O₂S Molecular mass: 229,3 Da CAS No.: 497-30-3

Parameter **Specification** Method Appearance White powder Visual Optical rotation $[\alpha]_D \ge (+) 122^\circ$ Polarimetry $(c = 1, H_2O)^{a)}$ Chemical purity \geq 99,5 % HPLC [Eur. Ph. 2,2.29] \geq 99,0 % 1H-NMR Identification Compliant with 1H-NMR the structure Elemental analysis C: $47,14 \pm 0,4 \%$ H: $6.59 \pm 0.4 \%$ N: $18,32 \pm 0,4 \%$ Total residual [Eur. Ph. Gas chromatography solvents 01/2008:50400] [Eur. Ph. 01/2008:20424] (methanol, < 1 000 ppm ethyl acetate, isopropanol, ethanol) Loss on drying Internal standard [Eur. Ph. 01/2008:20232] < 0,5 % **Impurities** < 0,8 % HPLC/GPC or 1H-NMR Heavy metals^{b) c)} Lead < 3.0 ppmICP/AES Cadmium (Pb, Cd) < 1,0 ppmMercury < 0,1 ppm Atomic fluorescence (Hg)

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Microbiological specifications ^{b)}			
Total viable aerobic count (TVAC)	$\leq 1 \times 10^3 \text{ CFU/g}$	[Eur. Ph. 01/2011:50104]	
Total yeast and mould count (TYMC)	$\leq 1 \times 10^2 \text{ CFU/g}$		
Escherichia coli	Absence in 1 g		

Eur. Ph.: European Pharmacopoeia; 1H-NMR: proton nuclear magnetic resonance; HPLC: high-performance liquid chromatography; GPC: gel permeation chromatography; ICP/AES: Inductively coupled plasma atomic emission spectroscopy;

CFU: colony-forming units.

- a) Lit. $[\alpha]_D = (+) 126,6^{\circ} (c = 1, H_2O)$
- b) Analyses conducted on each batch
- c) Maximum levels in accordance with Regulation (EC) No 1881/2006

Ferric Sodium EDTA

Description/Definition:

Ferric Sodium EDTA (ethylenediaminetetraacetic acid) is an odourless free-flowing, yellow to brown powder with a chemical purity of more than 99 % (w/w). It is freely soluble in water.

Chemical formula: C₁₀H₁₂FeN₂NaO₈ * 3H₂O

Chemical characteristics: pH of 1 % solution: 3,5-5,5

Iron: 12,5-13,5 % Sodium: 5,5 % Water: 12,8 %

Organic matter (CHNO): 68,4 %

EDTA: 65,5-70,5 %

Water insoluble matter: $\leq 0.1 \%$ Nitrilo-triacetic acid: $\leq 0.1 \%$

Ferrous ammonium phosphate

Description/Definition:

Ferrous ammonium phosphate is a grey/green fine powder, practically insoluble in water and soluble in dilute mineral acids.

CAS No.: 10101-60-7

Chemical formula: FeNH₄PO₄ Chemical characteristics:

pH of 5 % suspension in water: 6,8-7,8

Iron (total): ≥ 28 % Iron (II): 22-30 % (w/w) Iron (III): ≤ 7,0 % (w/w) Ammonia: 5-9 % (w/w)

Water: $\leq 3.0 \%$

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Fish peptides from Sardinops sagax

Description/Definition:

The novel food ingredient is a peptide mixture, which is obtained by an alkaline protease-catalysed hydrolysis of fish (*Sardinops sagax*) muscle, subsequent isolation of the peptide fraction by column chromatography, concentration under vacuum and spray drying.

Yellowish white powderPeptides (1) (short chain peptides, dipeptides and tripeptides with a molecular weight of less than 2 kDa): \geq 85 g/100 g

Val-Tyr (dipeptide): 0,1-0,16 g/100 g

Ash: $\leq 10 \text{ g}/100 \text{ g}$ Moisture: $\leq 8 \text{ g}/100 \text{ g}$

(1) Kjeldahl method

Flavonoids from Glycyrrhiza glabra

Description/Definition:

Flavonoids derived from the roots or rootstock of *Glycyrrhiza glabra* L. are extracted with ethanol followed by further extraction of this ethanolic extract with medium-chain triglycerides. It is a dark-brown coloured liquid, containing 2,5 % to 3,5 % of glabridin.

Moisture: < 0,5 % Ash: < 0,1 %

Peroxide value (PV): < 0,5 meq/kg

Glabridin: 2,5-3,5 % of fat Glycyrrhizinic acid: < 0,005 %

Fat including polyphenol-type substances: ≥ 99 %

Protein: < 0,1 %

Carbohydrates: not detectable

Fucoidan extract from the seaweed Fucus vesiculosus

Description/Definition:

Fucoidan from the seaweed *Fucus vesiculosus* is extracted using aqueous extraction in acidic solution and filtration processes without the use of organic solvents. The resulting extract is concentrated and dried to yield the fucoidan extract with the following specifications:

Off-white to brown powder

Odour and Taste: Bland odour and taste Moisture: < 10 % (105 °C for 2 hours) pH value: 4,0-7,0 (1 % suspension at 25 °C)

Heavy metals:

Arsenic (inorganic): < 1,0 ppm

Cadmium: < 3,0 ppm Lead: < 2,0 ppm

Mercury: < 1,0 ppmMicrobiological criteria:

Total aerobic microbial count: < 10 000 CFU/g Yeast and mould count: < 100 CFU/g Total enterobacteria count: Absence/g

Escherichia coli: Absence/g Salmonella: Absence/10 g

Staphylococcus aureus: Absence/g

a 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 (OJ L 83, 22.3.2012, p. 1).

b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

Status: Point in time view as at 13/08/2018.

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2470. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Composition of the two permitted types of extracts, based on the level of

fucoidan: Extract 1:

Fucoidan: 75-95 % Alginate: 2,0-5,5 %

Polyphloroglucinol: 0,5-15 %

Mannitol: 1-5 %

Natural salts/Free Minerals: 0,5-2,5 % Other carbohydrates: 0,5-1,0 %

Protein: 2,0-2,5 %

Extract 2:

Fucoidan: 60-65 % Alginate: 3,0-6,0 %

Polyphloroglucinol: 20-30 %

Mannitol: < 1,0 %

Natural salts/Free Minerals: 0,5-2,0 % Other carbohydrates: 0,5-2,0 %

Protein: 2,0-2,5 %

Fucoidan extract from the seaweed Undaria pinnatifida

Description/Definition:

Fucoidan from seaweed *Undaria pinnatifida* is extracted using aqueous extraction in acidic solution and filtration processes without the use of organic solvents. The resulting extract is concentrated and dried to yield the fucoidan extract with the following specifications:

Off-white to brown powder

Odour and Taste: Bland odour and tasteMoisture: < 10 % (105 °C for 2

1ours)

pH value: 4,0-7,0 (1 % suspension at 25 °C)

Heavy metals:

Arsenic (inorganic): < 1,0 ppm

Cadmium: < 3,0 ppm Lead: < 2,0 ppm Mercury: < 1,0 ppm **Microbiology:**

Total aerobic microbial count: < 10 000 CFU/g

Yeast and mould count: < 100 CFU/g Total enterobacteria count: Absence/g

Escherichia coli: Absence/g Salmonella: Absence/10 g

Staphylococcus aureus: Absence/g

Composition of the two permitted types of extracts, based on the level of

fucoidan: Extract 1:

Fucoidan: 75-95 % Alginate: 2,0-6,5 %

Polyphloroglucinol: 0,5-3,0 %

Mannitol: 1-10 %

Natural salts/Free Minerals: 0,5-1,0 %

a 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 (OJ L 83, 22.3.2012, p. 1).

b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Other carbohydrates: 0,5-2,0 %

Protein: 2,0-2,5 %

Extract 2:

Fucoidan: 50-55 % Alginate: 2,0-4,0 %

Polyphloroglucinol: 1,0-3,0 %

Mannitol: 25-35 %

Natural salts/Free Minerals: 8-10 % Other carbohydrates: 0,5-2,0 %

Protein: 1,0-1,5 %

2'-

Fucosyllactose (synthetic)

Definition:

Chemical name: α -L-Fucopyranosyl- $(1\rightarrow 2)$ - β -D-galactopyranosyl-

(1 \rightarrow 4)- D-glucopyranose Chemical formula: $C_{18}H_{32}O_{15}$

CAS No: 41263-94-9

Molecular weight: 488,44 g/mol

Description:

2'-fucosyllactose is a white to off-white powder that is produced by a

chemical synthesis process.

Purity:

2'-Fucosyllactose: \geq 95 % D-Lactose: \leq 1,0 w/w % L-Fucose: \leq 1,0 w/w %

Difucosyl- D-lactose isomers: $\leq 1.0 \text{ w/w }\%$ 2'-Fucosyl- D-lactulose: $\leq 0.6 \text{ w/w }\%$ pH (20 °C, 5 % solution): 3,2-7,0

Water (%): \leq 9,0 % Ash, sulphated: \leq 0,2 % Acetic acid: \leq 0,3 %

Residual solvents (methanol, 2-propanol, methyl acetate, acetone): ≤ 50.0

mg/kg singly, ≤ 200.0 mg/kg in combination

Residual proteins: $\leq 0.01 \%$

Heavy Metals:

Palladium: ≤ 0,1 mg/kg Nickel: ≤ 3,0 mg/kg **Microbiological criteria:**

Aerobic mesophilic bacteria total count: ≤ 500 CFU/g

Yeasts and Moulds: ≤ 10 CFU/g Residual endotoxins: ≤ 10 EU/mg

2'-

Fucosyllactose (microbial source)

Definition:

Chemical name: α -L-Fucopyranosyl- $(1\rightarrow 2)$ - β -D-galactopyranosyl-

(1→4)-D-glucopyranose Chemical formula: C₁₈H₃₂O₁₅ CAS No: 41263-94-9

Molecular weight: 488,44 g/mol

a 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 (OJ L 83, 22.3.2012, p. 1).

b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Source:

Genetically modified strain of *Escherichia coli* K-12

Description:

2'-Fucosyllactose is a white to offwhite powder that is produced by a microbial process.

Purity:

2'-Fucosyllactose: $\geq 90 \%$ D-Lactose: $\leq 3,0 \%$ L-Fucose: $\leq 2,0$

Difucosyl-D-lactose: \leq 2,0 % 2'-Fucosyl-D-lactulose: \leq 1,0 % pH (20 °C, 5 % solution): 3,0-7,5

Water: $\leq 9.0 \%$

Sulphated ash: ≤ 2,0 % Acetic acid: < 1.0 %

Residual proteins: ≤ 0,01 % Microbiological criteria:

Aerobic mesophilic bacteria total

count: ≤ 3 000 CFU/g Yeasts: ≤ 100 CFU/g Moulds: ≤ 100 CFU/g Endotoxins: ≤ 10 EU/mg

Source:

Genetically modified strain of *Escherichia coli* BL21

Description:

2'-Fucosyllactose is a white to off white powder and the liquid concentrate (45 % \pm 5 % w/v) aqueous solution is a colourless to slight yellow clear aqueous solution. 2'-Fucosyllactose is produced by a microbiological process.

Purity:

2'-Fucosyllactose: ≥ 90 %

Lactose: $\leq 5.0 \%$ Fucose: $\leq 3.0 \%$

3-Fucosyllactose: ≤ 5,0 % Fucosylgalactose: ≤ 3,0 % Difucosyllactose: ≤ 5,0 %

Glucose: $\leq 3.0 \%$ Galactose: $\leq 3.0 \%$ Water: $\leq 9.0 \%$ (powder)

Ash, sulphated: $\leq 0.5 \%$ (powder

and liquid)

Residual proteins: ≤ 0,01 % (powder and liquid)**Heavy Metals:** Lead: ≤ 0,02 mg/kg (powder and

liquid);

Arsenic: ≤ 0.2 mg/kg (powder and

liquid)

Cadmium: $\leq 0.1 \text{ mg/kg}$ (powder

and liquid)

Mercury: ≤ 0.5 mg/kg (powder and

liquid)

Microbiological criteria:

Total plate count: $\leq 10^4$ CFU/g (powder), $\leq 5\,000$ CFU/g (liquid) Yeasts and Moulds: ≤ 100 CFU/g (powder); ≤ 50 CFU/g (liquid) Enterobacteriaceae/Coliforms: absence in 11g (powder and liquid) Salmonella: negative/100 g (powder), negative/200 ml (liquid) Cronobacter: negative/100 g (powder), negative/200 ml (liquid)

- a 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 (OJ L 83, 22.3.2012, p. 1).
- **b** Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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	Endotoxins: ≤ 100 EU/g (powder), ≤ 100 EU/ml (liquid) Aflatoxin M1: ≤ 0,025 μg/kg (powder and liquid)		
Galacto- oligosaccharide	Description/Definition: Galacto-oligosaccharide is produced from milk lactose by an enzymatic process using β-galactosidases from Aspergillus oryzae, Bifidobacterium bifidum, Pichia pastoris, Sporobolomyces singularis, Kluyveromyces lactis, Bacillus circulans, and Papiliotrema terrestris. GOS: min 46 % Dry Matter (DM) Lactose: max 40 % DM Glucose: max 27 % DM Galactose: min 0,8 % DM Ash: max 4,0 % DM Protein: max 4,5 % DM Nitrite: max. 2 mg/kg		
Glucosamine HCl from Aspergillus niger and genetically modified strain of E. coli K-12	White crystalline odourless powder Molecular formula: $C_6H_{13}NO_5 \cdot HCl$ Relative molecular mass: 215,63 g/mol D-Glucosamine HCl 98,0-102,0 % of reference standard (HPLC) Specific rotation + $70,0^{\circ}$ - + $73,0^{\circ}$		
Glucosamine sulphate KCl from Aspergillus niger and genetically modified strain of E. coli K-12	White crystalline odourless powder Molecular formula: $(C_6H_{14}NO_5)_2SO_4 \cdot 2KCl$ Relative molecular mass: $605,52$ g/mol D-Glucosamine Sulphate 2KCl 98,0-102,0 % of reference standard (HPLC) Specific Rotation +50,0° to +52,0°		
Glucosamine sulphate NaCl from Aspergillus niger and genetically modified strain of E. coli K-12	White crystalline odourless powder Molecular formula: (C ₆ H ₁₄ NO ₅) ₂ SO ₄ · 2NaCl Relative molecular mass: 573,31 g/mol D-Glucosamine HCl: 98-102 % of reference standard (HPLC) Specific Optical Rotation: +52° - +54°		
Guar Gum a Commission Regu	Description/Definition: Native guar gum is the ground endosperm of seeds from natural strains of guar <i>Cyamopsis tetragonolobus</i> L. Taub. (<i>Leguminosae</i> family). It consists of a high molecular weight polysaccharide, primarily composed of galactopyranose and mannopyranose units combined lation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in		

a 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 (OJ L 83, 22.3.2012, p. 1).

b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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through glycosidic linkages, which may be described chemically as a galactomannan (galactomannan content not less than 75 %).

Appearance: White to yellowish powder

Molecular weight: Between 50 000 – 8 000 000 Daltons

CAS number: 9000-30-0 Einecs Number: 232-536-8

Purity: As specified by Commission Regulation (EU) No 231/2012 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^a & by Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins^b.

Physico-chemical properties:

Powder

Shelf-life: 2 years Colour: White Odour: Light

Average diameter of particles: 60-70µm

Moisture: Max 15 %

Viscosity * at 1 hour —Viscosity * at 2 hours: Min 3 600 mPa.s

Viscosity * at 24 hours: Min 4 000 mPa.s Solubility: Soluble in hot and cold water

pH for 10g/L, at 25 °C - 6-7,5

Flakes

Useful life: 1 year

Colour: White/off white with absence or minimal presence of black spots

Odour: Light

Average diameter of particles: 1-10 mm

Moisture: Max 15 %

Viscosity * at 1 hour: Min 3 000 mPa.s

Viscosity * at 2 hours — Viscosity * at 24 hours —

Solubility — Soluble in hot and cold water

pH for 10g/L, at 25 °C - 5-7,5

(*) The measurements of viscosity are carried out under the following conditions: 1 %, 25 °C, 20 rpm

Heat-treated milk products fermented with Bacteroides xylanisolvens

Description/Definition:

Heat-treated fermented milk products are produced with *Bacteroides xylanisolvens* (DSM 23964) as starter culture.

Semi-skimmed milk (between 1,5 % and 1,8 % fat) or skimmed milk (0,5 % fat or less) is pasteurised or ultra-heat-treated before starting the fermentation with *Bacteroides xylanisolvens* (DSM 23964). The resulting fermented milk product is homogenised and then heat-treated to inactivate *Bacteroides xylanisolvens* (DSM 23964). The final product

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- b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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does not contain viable cells of *Bacteroides xylanisolvens* (DSM 23964) (¹).

(1) Modified DIN EN ISO 21528-2.

Hydroxytyrosol

Description/Definition:

Hydroxytyrosol is a pale yellow viscous liquid obtained by chemical

synthesis

Molecular formula: C₈H₁₀O₃ Molecular weight: 154,6 g/mol

CAS No: 10597-60-1 Moisture ≤ 0,4 %

Odour: Characteristic Taste: Slightly bitter Solubility (water): Miscible with water

pH: 3,5-4,5

Refractive Index: 1,571-1,575

Purity:

Hydroxytyrosol: ≥ 99 % Acetic acid: ≤ 0,4 %

Hydroxytyrosol acetate: ≤ 0,3 %

Sum of homovanillic acid, iso-homovanilic acid, and 3-

methoxy-4hydroxyphenylglycol: ≤ 0,3 %

Heavy Metals

Lead: ≤ 0,03 mg/kg Cadmium: ≤ 0,01 mg/kg Mercury: ≤ 0,01 mg/kg **Residual Solvents**

Ethyl acetate: \leq 25,0 mg/kg Isopropanol: \leq 2,50 mg/kg Methanol: \leq 2,00 mg/kg Tetrahydrofuran: \leq 0,01 mg/kg

Ice Structuring Protein type III HPLC 12

Description/Definition:

The Ice Structuring Protein (ISP) preparation is a light-brown liquid produced by submerged fermentation of a genetically-modified strain of food-grade baker's yeast (*Saccharomyces cerevisiae*) in which a synthetic gene for the ISP has been inserted into the yeast's genome. The protein is expressed and secreted into the growth medium where it is separated from the yeast cells by micro-filtration and concentrated by ultra-filtration. As a result, the yeast cells are not transferred into the ISP preparation as such or under an altered form. The ISP preparation consists of native ISP, glycosylated ISP and proteins and peptides from the yeast and sugars as well as acids and salts commonly found in food. The concentrate is stabilised with 10 mM citric acid buffer.

Assay: ≥ 5 g/l active ISP

pH: 2,5-3,5 Ash: ≤ 2,0 %

DNA: Not detectable

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b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Aqueous extract of dried leaves of *Ilex guayusa*

Description/Definition:

Dark brown liquid. Aqueous extracts of dried leaves of *Ilex*

guayusa. Composition: Protein: < 0,1 g/100 ml Fat: < 0,1 g/100 ml

Carbohydrate: 0,2–0,3 g/100 ml Total sugars: < 0,2 g/100 ml Caffeine: 19,8–57,7 mg/100 ml Theobromine: 0,14–2,0 mg/100 ml Chlorogenic acids: 9,9–72,4 mg/100ml

Isomaltooligosaccharide

Powder:

Solubility (water) (%): > 99 Glucose (% dry basis): ≤ 5.0

Isomaltose + DP3 to DP9 (% dry basis): \geq 90

Moisture (%): ≤ 4.0

Sulphated ash(g/100 g): ≤ 0.3

Heavy metals: Lead (mg/kg): ≤ 0.5 Arsenic (mg/kg): ≤ 0.5

Syrup:

Dried solids (g/100 g): > 75 Glucose (% dry basis): $\le 5,0$

Isomaltose + DP3 to DP9 (% dry basis): \geq 90

pH: 4 - 6

Sulphated ash(g/100 g): ≤ 0.3

Heavy metals: Lead (mg/kg): ≤ 0.5 Arsenic (mg/kg): ≤ 0.5

Isomaltulose

Description/Definition:

A reducing disaccharide that consists of one glucose and one fructose moiety linked by an alpha-1,6-glycosidic bond. It is obtained from sucrose by an enzymatic process. The commercial product is the monohydrate. Appearance: Virtually odourless, white or almost white crystals with a sweet tasteChemical name: 6-O- α -D-glucopyranosyl-D-

fructofuranose, monohydrate

CAS No.: 13718-94-0

Chemical formula: C₁₂H₂₂O₁₁ · H₂O

Structural formula

a 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 (OJ L 83, 22.3.2012, p. 1).

b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Formula weight: 360,3 (monohydrate)

Purity:

Assay: \geq 98 % on the dry basis

Loss on drying: $\leq 6.5 \%$ (60 °C, 5 hours)

Heavy metals: Lead: $\leq 0.1 \text{ mg/kg}$

Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5(1), 'Instrumental methods'

(1) Food and Nutrition Paper 5 Rev. 2 — Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA), 1991, 322 pp., English, ISBN 92-5-102991-1.

Lactitol Description/Definition:

Crystalline powder or colourless solution manufactured via catalytic hydrogenation of lactose. Crystalline products occur in anhydrous, monohydrate and dihydrate forms. Nickel is used as a catalyst.

Chemical name: 4-O-β-D-Galactopyranosyl-D-glucitol

Chemical formula: C₁₂H₂₄O₁₁ Molecular weight: 344,31 g/mol CAS No: 585-86-4**Purity:**

Solubility (in water): Very soluble in water Specific rotation $[\alpha]_D^{20} = +13^\circ$ to $+16^\circ$

Assay: \geq 95 % d.b (d.b — expressed on the dry weight basis)

Water: $\le 10.5 \%$

Other polyols: $\leq 2,5$ % d.b Reducing sugars: $\leq 0,2$ % d.b Chlorides: ≤ 100 mg/kg d.b Sulphates: ≤ 200 mg/kg d.b Sulphated ash: $\leq 0,1$ % d.b Nickel: $\leq 2,0$ mg/kg d.b Arsenic: $\leq 3,0$ mg/kg d.b

- a 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 (OJ L 83, 22.3.2012, p. 1).
- b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Lead: $\leq 1.0 \text{ mg/kg d.b}$

Lacto-N-neotetraose (synthetic)

Definition:

Chemical name: β -D-Galactopyranosyl- $(1\rightarrow 4)$ -2-acetamido-2-deoxy- β -D-glucopyranosyl- $(1\rightarrow 3)$ - β -D-galactopyranosyl- $(1\rightarrow 4)$ - D-

glucopyranose

Chemical formula: C₂₆H₄₅NO₂₁

CAS No: 13007-32-4

Molecular weight: 707,63 g/mol

Description:

Lacto-*N*-neotetraose is a white to off-white powder. Produced by a chemical synthesis process and is isolated by crystallisation.

Purity:

Assay (water free): $\geq 96 \%$

D-Lactose: ≤ 1,0 %

Lacto-N-triose II: $\leq 0.3 \%$

Lacto-N-neotetraose fructose isomer: ≤ 0,6 %

pH (20 °C, 5 % solution): 5,0-7,0

Water: $\leq 9.0 \%$

Ash, sulphated: $\leq 0.4 \%$

Acetic acid: ≤ 0.3 %Residual solvents (methanol, 2-propanol, methyl acetate, acetone): ≤ 50 mg/kg singly, ≤ 200 mg/kg in combination

Residual proteins: ≤ 0,01 % Palladium: ≤ 0,1 mg/kg Nickel: ≤ 3,0 mg/kg Migrabial original aritoria.

Microbiological criteria:

Aerobic mesophilic bacteria total count: ≤ 500 CFU/g

Yeasts: $\leq 10 \text{ CFU/g}$ Moulds: $\leq 10 \text{ CFU/g}$

Residual endotoxins: ≤ 10 EU/mg

Lacto-Nneotetraose (microbial source)

Definition:

Chemical name: β -D-Galactopyranosyl- $(1\rightarrow 4)$ -2-acetamido-2-deoxy- β -D-glucopyranosyl- $(1\rightarrow 3)$ - β -D-galactopyranosyl- $(1\rightarrow 4)$ -D-glucopyranose

Chemical formula: C₂₆H₄₅NO₂₁

CAS No: 13007-32-4

Molecular weight: 707,63 g/mol

Source:

Genetically modified strain of Escherichia coli K-12

Description:

Lacto-*N*-neotetraose is a white to off-white powder that is produced by a microbiological process. Lacto-*N*-neotetraose is isolated by crystallisation.

Purity:

Assay (water free): $\geq 92 \%$ D-Lactose: $\leq 3.0 \%$

Lacto-N-triose II: ≤ 3,0 % para-Lacto-N-neohexaose: ≤ 3,0 %

a 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 (OJ L 83, 22.3.2012, p. 1).

b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).

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Lacto-N-neotetraose fructose isomer: ≤ 1,0 %

pH (20 °C, 5 % solution): 4,0-7,0

Water: $\leq 9.0 \%$

Ash, sulphated: $\leq 0.4 \%$

Residual solvents (methanol): $\leq 100 \text{ mg/kg}$

Residual proteins: ≤ 0.01 %Microbiological criteria: Aerobic mesophilic bacteria total count: ≤ 500 CFU/g

Yeasts: $\leq 10 \text{ CFU/g}$ Moulds: $\leq 10 \text{ CFU/g}$

Residual endotoxins: ≤ 10 EU/mg

Lucerne leaf extract from *Medicago sativa*

Description/Definition:

The Lucerne (*Medicago sativa* L.) is processed within 2 hours after harvest. It is chopped and crushed. By passing through an oleaginous-type press, the Lucerne provides a fibrous residue and press juice (10% of dry matter). The dry matter of this juice contains about 35% of crude protein. The press juice (pH 5,8-6,2) is neutralised. Preheating and vapour injection allows coagulation of proteins associated with carotenoid and chlorophyll pigments. The protein precipitate is separated by centrifugation and thereafter dried. After adding ascorbic acid the Lucerne protein concentrate is granulated and stored in inert gas or in cold storage.

Composition:

Protein: 45-60 % Fat: 9-11 %

Free carbohydrates (soluble fibre): 1-2 % Polysaccharides (insoluble fibre): 11-15 %

including cellulose: 2-3 %

Minerals: 8-13 % Saponins: ≤ 1,4 % Isoflavones: ≤ 350 mg/kg Coumestrol: ≤ 100 mg/kg Phytates: ≤ 200 mg/kg L-canavanine: ≤ 4,5 mg/kg

Lycopene

Description/Definition:

Synthetic lycopene is produced by the Wittig condensation of synthetic intermediates commonly used in the production of other carotenoids used in food. Synthetic lycopene consists of ≥ 96 % lycopene and minor quantities of other related carotenoid components. Lycopene is presented either as a powder in a suitable matrix or an oily dispersion. The colour is dark red or red-violet. Antioxidative protection has to be assured.

Chemical name: Lycopene

CAS No.: 502-65-8 (all-trans lycopene)

Chemical formula: C₄₀H₅₆ Formula weight: 536,85 Da

a 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 (OJ L 83, 22.3.2012, p. 1).

b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).

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Lycopene from *Blakeslea trispora*

Description/Definition:

The purified lycopene from *Blakeslea trispora* consists of ≥ 95 % lycopene and ≤ 5 % other carotenoids. It is presented either as a powder in a suitable matrix or an oily dispersion. The colour is dark red or redviolet. Anti-oxidative protection has to be assured.

Chemical name: Lycopene

CAS No.: 502-65-8 (all trans lycopene)

Chemical formula: C₄₀H₅₆ Formula weight: 536,85 Da

Lycopene from tomatoes

Description/Definition:

The purified lycopene from tomatoes (*Lycopersicon esculantum* L.) consists of ≥ 95 % lycopene and ≤ 5 % other carotenoids. It is presented either as a powder in a suitable matrix or an oily dispersion. The colour is dark red or red-violet. Anti-oxidative protection has to be assured.

Chemical name: Lycopene

CAS No.: 502-65-8 (all trans lycopene)

Chemical formula: C₄₀H₅₆ Formula weight: 536,85 Da

Lycopene oleoresin from tomatoes

Description/Definition:

Lycopene oleoresin from tomatoes is obtained by solvent extraction of ripe tomatoes (*Lycopersicon esculentum Mill.*) with subsequent removal of the solvent. It is a red to dark brown viscous, clear liquid.

Total lycopene: 5-15 %

Thereof trans-lycopene: 90-95 %

Total carotenoids (calculated as lycopene): 6,5-16,5 %

Other carotenoids: 1,75 %

(Phytoene/phytofluene/β-carotene): (0,5-0,75/0,4-0,65/0,2-0,35 %)

Total tocopherols: 1,5-3,0 % Unsaponifiable matter: 13-20 % Total fatty acids: 60-75 % Water (Karl Fischer): ≤ 0,5 %

Magnesium citrate malate

Description/Definition:

Magnesium citrate malate is a white to yellowish-white, amorphous

powder. Chemical formula: $Mg_5(C_6H_5O_7)_2(C_4H_4O_5)_2$

Chemical name: Pentamagnesium di-(2-hydroxybutanedioate)-di-(2-

hydroxypropane-1,2,3-tricarboxylate)

CAS No.: 1259381-40-2

Molecular weight: 763,99 Daltons (anhydrous)

Solubility: Freely soluble in water (about 20 g in 100 ml) Description of the physical state: Amorphous powder

Assay magnesium: 12,0-15,0 %

Loss on drying (120 °C/4 hours): \leq 15 % Colour (solid): White to yellowish-white

Colour (20 % aqueous solution): Colourless to yellowish Appearance (20 % aqueous solution): Clear solution

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pH (20 % aqueous solution): Approx. 6,0

Impurities:

Chloride: $\leq 0.05 \%$ Sulphate: $\leq 0.05 \%$ Arsenic: $\leq 3.0 \text{ ppm}$ Lead: $\leq 2.0 \text{ ppm}$ Cadmium: $\leq 1 \text{ ppm}$ Mercury: $\leq 0.1 \text{ ppm}$

Magnolia Bark Extract

Description/Definition:

Magnolia bark extract is obtained from the bark of the plant *Magnolia officinalis* L. and produced with supercritical carbon dioxide. The bark is washed and oven dried to reduce moisture content before being crushed and extracted with supercritical carbon dioxide. The extract is dissolved in medical-grade ethanol and re-crystallised to yield magnolia bark extract.

Magnolia bark extract is mainly composed of two phenolic compounds, magnolol and honokiol.

Appearance: Light brownish powder

Purity:

Magnolol: \geq 85,2 % Honokiol: \geq 0,5 %

Magnolol & Honokiol: ≥ 94 %

Total Eudesmol: $\leq 2 \%$

Moisture: 0,50 %Heavy metals:

Arsenic (ppm): ≤ 0.5 Lead (ppm): ≤ 0.5

Methyl eugenol (ppm): ≤ 10 Tubocurarine (ppm): ≤ 2.0 Total Alkaloid (ppm): ≤ 100

Maize-germ oil high in unsaponifiable matter

Description/Definition:

Maize-germ oil high in unsaponifiable matter is produced by vacuum distillation and it is different from refined maize-germ oil in the concentration of the unsaponifiable fraction (1,2 g in refined maize-germ oil and 10 g in 'maize-germ oil high in unsaponifiable matter').

Purity:

Unsaponifiable matter: > 9,0 g/100 g

Tocopherols: ≥ 1.3 g/100 g α-tocopherol (%): 10-25 % β-tocopherol (%): < 3.0 % γ-tocopherol (%): 68-89 % δ-tocopherol (%): < 7.0 %

Sterols, triterpenic alcohols, methylsterols: > 6,5 g/100 g

Fatty acids in triglycerides: palmitic acid: 10,0-20,0 % stearic acid: < 3,3 % oleic acid: 20,0-42,2 %

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> linoleic acid: 34,0-65,6 % linolenic acid: < 2,0 % Acid value: $\leq 6.0 \text{ mg KOH/g}$

Peroxide value (PV): $\leq 10 \text{ mEq O}_2/\text{kg}$

Heavy metals:

Iron (Fe): $< 1500 \mu g/kg$ Copper (Cu): $< 100 \mu g/kg$

Impurities:

Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene: < 2 μg/kg Treatment with active carbon is required to ensure that polycyclic aromatic hydrocarbons (PAH) are not enriched in the production of 'maize-germ oil high in unsaponifiable matter'

Methylcellulose

Description/Definition:

Methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups.

Chemical name: Methyl ether of cellulose

Chemical formula: The polymers contain substituted anhydroglucose units with the following general formula:

C6H7O2(OR1)(OR2)(OR3) where R1, R2, R3 each may be one of the following:

Η

CH₃ or

CH₂CH₃

Molecular weight: Macromolecules: from about 20 000 (n about 100) up to about 380 000 g/mol (n about 2 000)

Assay: Content not less than 25 % and not more than 33 % of methoxyl groups (-OCH₃) and not more than 5 % of hydroxyethoxyl groups (-OCH₂CH₂OH)

Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder.

Solubility: Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid.

Purity:

Loss on drying: $\leq 10 \%$ (105 °C, 3 hours)

Sulphated Ash: ≤ 1.5 % determined at 800 ± 25 °C

pH: \geq 5,0 and \leq 8,0 (1 % colloidal solution)

Heavy metals:

Arsenic: $\leq 3.0 \text{ mg/kg}$ Lead: $\leq 2.0 \text{ mg/kg}$ Mercury: $\leq 1.0 \text{ mg/kg}$ Cadmium: $\leq 1.0 \text{ mg/kg}$

(6S)-5-

Description/Definition:

methyltetrahydrofoliamical name: N-[4-[[[(6S)-2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4oxo-6-pteridinyl]methyl]amino]benzoyl]-L-glutamic acid, glucosamine

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glucosamine salt

Chemical formula: C₃₂H₅₁N₉O₁₆

Molecular weight: 817,80 g/mol (anhydrous)

CAS No.: 1181972-37-1

Appearance: Creamy to light-brown powder**Purity:**

Diastereoisomeric purity: At least 99 % of (6S)-5-methyltetrahydrofolic

acid

Glucosamine assay: 34-46 % in dry basis

5-Methyltetrahydrofolic acid assay: 54-59 % in dry basis

Water: $\leq 8,0 \%$ **Heavy metals:** Lead: $\leq 2,0$ ppm Cadmium: $\leq 1,0$ ppm Mercury: $\leq 0,1$ ppm Arsenic: $\leq 2,0$ ppm Boron: ≤ 10 ppm

Microbiological criteria:

Total aerobic microbial count: ≤ 100 CFU/g

Yeasts and moulds: ≤ 100 CFU/g *Escherichia coli*: Absence in 10g

Monomethylsilan Deichription/Definition:

(Organic Silicon)

Chemical name: Silanetriol, 1-methyl-

Chemical formula: CH₆O₃Si Molecular weight: 94,14 g/mol

CAS No: 2445-53-6

Purity:

Organic Silicon (monomethylsilanetriol) preparation (aqueous solution):

Acidity (pH): 6,4-6,8 Silicon: 100-150 mg Si/l

Heavy metals: Lead: $\leq 1,0~\mu g/l$ Mercury: $\leq 1,0~\mu g/l$ Cadmium: $\leq 1,0~\mu g/l$ Arsenic: $\leq 3,0~\mu g/l$

Solvents:

Methanol: ≤ 5.0 mg/kg (residual presence)

Mycelial extract

from Shiitake mushroom (Lentinula edodes)

Description/Definition:

The novel food ingredient is a sterile aqueous extract obtained from the mycelium of *Lentinula edodes* cultivated in a submerged fermentation. It is a light brown, slightly turbid liquid.

Lentinan is a β -(1-3) β -(1-6)-D-glucan which has a molecular weight of approximately 5×10^5 Daltons, a degree of branching of 2/5 and a triple

helical tertiary structure.

Purity/Composition of the mycelial extract from Lentinula edodes:

Moisture: 98 % Dry matter: 2 %

Free glucose: < 20 mg/ml

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Total protein(¹): < 0,1 mg/ml N-containing constituents(²): < 10 mg/ml Lentinan: 0,8 – 1,2 mg/ml\

- (1) Bradford method
- (2) Kjeldahl method

Noni fruit juice (*Morinda citrifolia*)

Description/Definition:

Noni fruits (fruits of *Morinda citrifolia* L.) are pressed. The obtained juice is pasteurised. An optional fermentation step before or after the pressing may occur.

Rubiadin: $\leq 10 \mu g/kg$ Lucidin: $\leq 10 \mu g/kg$

Noni fruit juice powder (Morinda citrifolia)

Description/Definition:

Seeds and skin of the sun-dried fruits of *Morinda citrifolia* are separated. The obtained pulp is filtered to separate juice from the flesh. Desiccation of the produced juice occurs in one or two ways:

Either by atomisation using maize maltodextrins, this mixture is obtained by keeping the rates of inflow of the juice and maltodextrins constant Or by zeodratation or drying and then mixing with an excipient, this process allows the juice to be dried initially and then mixed with maltodextrins (same amount as used in atomisation).

Noni fruit puree and concentrate (Morinda citrifolia)

Description/Definition:

The fruits of *Morinda citrifolia* are harvested by hand. Seeds and skin may be separated mechanically from the pureed fruits. After pasteurisation, the puree is packaged in aseptic containers and stored under cold conditions. *Morinda citrifolia* concentrate is prepared from *M. citrifolia* puree by treatment with pectinolytic enzymes (50–60 °C for 1-2 h). Then the puree is heated to inactivate the pectinases and then immediately cooled. The juice is separated in a decanter centrifuge. Afterwards the juice is collected and pasteurised, prior to being concentrated in a vacuum evaporator from a brix of 6 to 8 to a brix of 49 to 51 in the final concentrate.

Composition:

Puree:

Moisture: 89-93 % Protein: < 0,6 g/100 g Fat: ≤ 0,4 g/100 g Ash: < 1,0 g/100 g

Total carbohydrates: 5-10 g/100 g

Fructose: 0,5-3,82 g/100 g Glucose: 0,5-3,14 g/100 g Dietary fibre: < 0,5-3 g/100 g

5,15-dimethylmorindol (1): $\leq 0,254 \,\mu\text{g/ml}$

Lucidin (1): Not detectable

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Alizarin (1): Not detectable Rubiadin (1): Not detectable

Concentrate: Moisture: 48-53 % Protein: 3-3,5 g/100 g Fat: < 0,04 g/100 g Ash: 4,5-5,0 g/100 g

Total carbohydrates: 37-45 g/100 g

Fructose: 9-11 g/100 g Glucose: 9-11 g/100 g Dietary fibre: 1,5-5,0 g/100 g

5,15-dimethylmorindol (1): \leq 0,254 µg/ml

(1) By an HPLC-UV method developed and validated for the analysis of anthraquinones in Morinda citrifolia puree and concentrate. Limits of detection: 2,5 ng/ml (5,15 dimethylmorindol); 50,0 ng/ml (lucidin); 6,3 ng/ml (alizarin) and 62,5 ng/ml (rubiadin).

Noni leaves (Morinda citrifolia)

Description/Definition:

After cutting, the leaves of *Morinda citrifolia* are subject to drying and roasting steps. The product has a particle size ranging from broken leaves to coarse powder with fines. It is of greenish brown to brown colour.

Purity/Composition:

Moisture: < 5,2 % Protein: 17- 20 % Carbohydrate: 55-65 %

Ash: 10-13 % Fat: 4-9 %

Oxalic acid: < 0,14 % Tannic acid: < 2,7 %

5,15-dimethylmorindol: < 47 mg/kgRubiadin: non detectable, $\le 10 \text{ µg/kg}$ Lucidin: non detectable, $\le 10 \text{ µg/kg}$

Noni fruit powder (Morinda citrifolia)

Description/Definition:

Noni fruit powder is made from pulped noni (*Morinda citrifolia L.*) fruits by freeze-drying. Fruits are pulped and seeds are removed. After freeze-drying during which water is removed from noni fruits, the remaining noni pulp is milled to a powder and encapsulated.

Purity/Composition Moisture: 5,3-9 %

Protein: 3,8-4,8 g/100 g

Fat: 1-2 g/100 g Ash: 4,6-5,7 g/100 g

Total carbohydrates: 80-85 g/100 g Fructose: 20,4-22,5 g/100 g Glucose: 22-25 g/100 g

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	(1) By an Hi analysis	indol (1): $\leq 2,0 \mu g/$ PLC-UV method de of anthraquinones	ml eveloped and validated for the in Morinda citrifolia fruit powder. ml (5,15 dimethylmorindol)	
Odontella aurita microalgae	Silicon: 3,3 % Crystalline silica: max 0,1-0,3 % as impurity			
Oil enriched with phytosterols/phytostanols	Description/Definition: Oil enriched with phytosterols/phytostanols is composed of an oil fraction and a phytosterol fraction. Acylglycerol Distribution: Free fatty acids (expressed as oleic acid): ≤ 2.0 % Monoacylglycerols (MAG): ≤ 10 % Diacylglycerols (DAG): ≤ 25 % Triacylglycerols (TAG): Making up the balance Phytosterol fraction: β-sitosterol: ≤ 80 % β-sitostanol: ≤ 15 % campesterol: ≤ 40 % campesterol: ≤ 30 % brassicasterol ≤ 3.0 % other sterols/stanols: ≤ 3.0 % Others: Moisture and volatile: ≤ 0.5 % Peroxide value (PV): < 5.0 meq/kg Trans fatty acids: ≤ 1 % Contamination/Purity (GC-FID or equivalent method) of phytosterols/phytostanols: Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 %.			
Oil extracted from squids	Acid value: ≤ 0.5 KOH/g oil Peroxide value (PV): ≤ 5 meq O ₂ /kg oil p-Anisidine value: ≤ 20 Cold test at 0 °C: ≤ 3 hours Moisture: ≤ 0.1 % (w/w) Unsaponifiable matter: ≤ 5.0 %Trans fatty acids: ≤ 1.0 % Docosahexaeonic acid: ≥ 20 % Eicosapentaenoic acid: ≥ 10 %			
Pasteurised	Parameter	Target	Comments	
fruit-based preparations produced using	Fruit storage before high-	Minimum 15 days at – 20 °C	Fruit harvested and stored in conjunction with good/hygienic	

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high-pressure treatment

pressure treatment		agricultural and manufacturing practices
Fruit added	40 % to 60 % of thawed fruit	Fruit homogenised and added to other ingredients
рН	3,2 to 4,2	
^o Brix	7 to 42	Assured by added sugars
a_{w}	< 0,95	Assured by added sugars
Final storage	60 days maximum at + 5 °C maximum	Equivalent to storage regimen for conventionally processed product

Phosphated maize starch

Description/Definition:

Phosphated maize starch (phosphated distarch phosphate) is a chemically modified resistant starch derived from high amylose starch by combining chemical treatments to create phosphate cross-links between carbohydrate residues and esterified hydroxyl groups.

The novel food ingredient is a white or nearly white powder.

CAS No: 11120-02-8

Chemical formula: $(C_6H_{10}O_5)_n [(C_6H_9O_5)_2PO_2H]x [(C_6H_9O_5)PO_3H_2]y$

n = number of glucose units; x, y = degrees of substitutionThe chemical characteristics of phosphated distarch phosphate:

Loss on drying: 10-14 %

pH: 4,5-7,5

Dietary fibre: $\geq 70 \%$

Starch: 7-14 % Protein: $\leq 0.8 \%$ Lipids: $\leq 0.8 \%$

Residual bound phosphorus: $\leq 0.4\%$ (as phosphorus) 'high amylose

maize' as source

PhosphatidylserinDescription/Definition:

from fish phospholipids

The novel food ingredient is yellow to brown powder.

Phosphatidylserine is obtained from fish phospholipids by an enzymatic

transphosphorylation with the amino acid L-serine.

Specification of the phosphatidylserine product manufactured from fish phospholipids:

Moisture: < 5,0 % Phospholipids: $\geq 75 \%$ Phosphatidylserine: $\geq 35 \%$ Glycerides: < 4.0 % Free L-serine: < 1,0 %

Tocopherols: $< 0.5 \% (^1)$

Peroxide value (PV): $\leq 5.0 \text{ meq } O_2/kg$

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> Tocopherols may be added as antioxidants according to $\binom{1}{1}$ Commission Regulation (EU) No 1129/2011

PhosphatidylserinDescription/Definition:

from sova phospholipids

The novel food ingredient is off-white to light yellow powder. It is also available in liquid form with a clear brown to orange colour. The liquid form contains medium chain triacylglycerides (MCT) as a carrier. It contains lower levels of Phosphatidylserine due to the fact that it includes significant amounts of oil (MCT).

Phosphatidylserine from soya phospholipids is obtained through enzymatic transphosphatidylation of high-phosphatidylcholine soybean lecithin with the amino acid L-serine. Phosphatidylserine consists of a glycerophosphate skeleton conjugated with two fatty acids and L-serine via a phosphodiester linkage.

Characteristics of Phosphatidylserine from soya phospholipids:

Powder form:

Moisture: < 2,0 % Phospholipids: ≥ 85 % Phosphatidylserine: ≥ 61 % Glycerides: < 2,0 % free L-serine: < 1,0 % Tocopherols: < 0.3 % Phytosterols: < 0,2 %

Liquid form: Moisture: < 2.0 %

Phospholipids: ≥ 25 %Phosphatidylserine: ≥ 20 %

Glycerides: not applicable free L-serine: < 1,0 % Tocopherols: < 0,3 % Phytosterols: < 0,2 %

Phospholipid product

containing equal amounts of

Description/Definition:

The product is manufactured through enzymatic conversion of soy lecithin. The phospholipid product is a highly concentrated, yellowbrown powder form of phosphatidylserine and phosphatidic acid at an equal level.

phosphatidylserins pecification of the product:

and phosphatidic

acid

Moisture: $\leq 2.0 \%$

Total phospholipids: ≥ 70 % Phosphatidylserine: $\geq 20 \%$ Phosphatidic acid: $\geq 20 \%$

Glycerides: ≤ 1,0 % Free L-serine: $\leq 1.0 \%$ Tocopherols: $\leq 0.3 \%$ Phytosterols: $\leq 2.0 \%$

Silicon dioxide is used with a maximum content of 1.0 %

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DI 1 22 23	05.0/ 1.100.0/ PI 1.11.11.0
Phospholipides from egg yolk	85 % and 100 % pure Phospholipides from egg yolk
Phytoglycogen	Description: White to off-white powder which is an odourless, colourless, flavourless polysaccharide derived from non-GM sweet corn using conventional food processing techniques Definition: Glucose polymer $(C_6H_{12}O_6)$ n with linear linkages of $\alpha(1-4)$ glycosidic bonds branched every 8 to 12 glucose units by $\alpha(1-6)$ glycosidic bonds Specifications: Carbohydrates: 97 % Sugars: 0,5 % Fibre: 0,8 % Fat: 0,2 % Protein: 0,6 %
Phytosterols/phytostanols	Description/Definition: Phytosterols and phytostanols are sterols and stanols that are extracted from plants and may be presented as free sterols and stanols or esterified with food grade fatty acids. Composition (with GC-FID or equivalent method): β-sitosterol: < 81 % β-sitostanol: < 35 % campesterol: < 40 % campestanol: < 15 % stigmasterol: < 30 % brassicasterol: < 3,0 % Contamination/Purity (GC-FID or equivalent method): Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient.
Plum kernel oil	Description/Definition: Plum kernel oil is a vegetable oil obtained by cold pressing of plum (<i>Prunus domestica</i>) kernels. Composition: Oleic acid (C18:1): 68 % Linoleic acid (C18:2): 23 % γ-Tocopherol:80 % of total tocopherols β-Sitosterol: 80-90 % of total sterols Triolein: 40-55 % of triglycerides Cyanhydric acid: maximum 5 mg/kg oil
Potato proteins (coagulated) and	Dry substance: $\geq 800 \text{ mg/g}$ Protein (N * 6,25): $\geq 600 \text{ mg/g}$ (dry substance) Ash: $\leq 400 \text{ mg/g}$ (dry substance) Glycoalkaloid (total): $\leq 150 \text{ mg/kg}$

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hydrolysates	Lysinoalanine (total): ≤ 500 mg/kg		
thereof	Lysinoalanine (free): $\leq 10 \text{ mg/kg}$		
Prolyl	Specification of the enzyme:		
oligopeptidase	Systematic name: Prolyl oligopeptidase		
(enzyme	Synonyms: Prolyl endopeptidase, proline-specific endopeptidase,		
preparation)	endoprolylpeptidase		
	Molecular weight: 66 kDa		
	Enzyme Commission number: EC 3.4.21.26		
	CAS number: 72162-84-6		
	Source: A genetically modified strain of <i>Aspergillus niger</i> (GEP-44)		
	Description: Prolyl oligopeptidase is available as an enzyme preparation		
	containing approximately 30 % maltodextrin.		
	Specifications of the enzyme preparation of prolyl oligopeptidase:		
	Activity: $> 580\ 000\ PPI(^1)/g\ (> 34.8\ PPU(^2)/g)$		
	Appearance: Microgranulate		
	Colour: Off-white to orange yellowish. The colour may change from		
	batch to batch		
	Dry Matter: > 94 %		
	Gluten: < 20 ppm		
	Heavy metals:		
	Lead: $\leq 1.0 \text{ mg/kg}$		
	Arsenic: $\leq 1.0 \text{ mg/kg}$		
	Cadmium: $\leq 0.5 \text{ mg/kg}$		
	Mercury: ≤ 0,1 mg/kg		
	Microbiological criteria: Total aerobic plate count: $\leq 10^3$ CFU/g		
	Total yeasts and moulds: $\leq 10^{\circ}$ CFU/g		
	Sulphite reducing anaerobes: $\leq 30 \text{ CFU/g}$		
	Enterobacteriaceae: < 10 CFU/g		
	Salmonella: Absence in 25 g		
	Escherichia coli: Absence in 25 g		
	Staphylococcus aureus: Absence in 10 g		
	Pseudomonas aeruginosa: Absence in 10 g		
	Listeria monocytogenes: Absence in 25 g		
	Antimicrobial activity: AbsentMycotoxins: Below limits of detection:		
	Aflatoxin B1, B2, G1, G2 ($< 0.25 \mu g/kg$), total Aflatoxins ($< 2.0 \mu g/kg$),		
	Ochratoxin A (< 0,20 μg/kg), T-2 Toxin (< 5 μg/kg), Zearalenone (< 2,5		
	μ g/kg), Fumonisin B1 and B2 (< 2,5 μ g/kg)		
	(¹) PPI – Protease Picomole International		
	(2) PPU – Prolyl Peptidase Units or Proline Protease Units		
Protein extract	Description/Definition:		
from pig	The protein extract is obtained from homogenised pig kidneys through		
kidneys	a combination of salt precipitation and high speed centrifugation. The		
	obtained precipitate contains essentially proteins with 7 % of the enzyme		
a Commission Pagulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in			

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diamine oxidase (enzyme nomenclature E.C. 1.4.3.22) and is resuspended in a physiologic buffer system. The obtained pig kidney extract is formulated as encapsulated enteric coated pellets to reach the active sites of digestion.

Basic Product:

Specification: pig kidney protein excerpt with natural content of Diamin

oxidase (DAO):

Physical condition: liquid

Colour: brownish

Appearance: slightly turbid solution

pH value: 6,4-6,8

Enzymatic activity: > 2 677 kHDU DAO/ml (DAO REA (DAO

Radioextractionassay)) **Microbiological criteria:**

Brachyspira spp.: negative (Real Time PCR) Listeria monocytogenes: negative (Real Time PCR)

Staphylococcus aureus: < 100 CFU/g

Influenza A: negative (Reverse Transcription Real Time PCR)

Escherichia coli: < 10 CFU/g

Total aerobic microbiological count: $< 10^5$ CFU/g

Yeasts/moulds count: < 10⁵ CFU/g

Salmonella: Absence/10g

Bile salt resistant enterobacteriaceae: < 10⁴ CFU/g

Final product:

Specification pig kidney protein excerpt with natural content of DAO

(E.C. 1.4.3.22) in an enteric coated formulation:

Physical condition: solid

Colour: yellow grayAppearance: micropellets

Enzymatic activity: 110-220 kHDU DAO/g pellet (DAO REA (DAO

Radioextractionassay))

Acid stability 15 min 0,1M HCl followed by 60 min Borat pH = 9.0: > 68

kHDU DAO/g pellet (DAO REA (DAO Radioextractionassay))

Humidity: < 10 %

Staphylococcus aureus: < 100 CFU/g

Escherichia coli: < 10 CFU/g

Total aerobic microbiological count: < 10⁴ CFU/g Total combined yeasts/moulds count: < 10³ CFU/g

Salmonella: Absence/10g

Bile salt resistant enterobacteriaceae: $< 10^2$ CFU/g

Rapeseed oil high in unsaponifiable matter

Description/Definition:

Rapeseed oil high in unsaponifiable matter' is produced by vacuum distillation and it is different from refined rapeseed oil in the concentration of the unsaponifiable fraction (1 g in refined rapeseed oil and 9 g in 'rapeseed oil high in unsaponifiable matter'). There is

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a minor reduction of triglycerides containing monounsaturated and polyunsaturated fatty acids.

Purity:

Unsaponifiable matter: > 7,0 g/100 g

Tocopherols: > 0,8 g/100 g α-tocopherol (%): 30-50 % γ-tocopherol (%): 50-70 % δ-tocopherol (%): < 6,0 %

Sterols, triterpenic alcohols, methylsterols: > 5,0 g/100 g

Fatty acids in triglycerides:

palmitic acid: 3-8 % stearic acid: 0,8-2,5 % oleic acid: 50-70 % linoleic acid: 15-28 % linolenic acid: 6-14 % erucic acid: < 2,0 %

Acid value: $\leq 6.0 \text{ mg KOH/g}$

Peroxide value (PV): $\leq 10 \text{ mEq O}_2/\text{kgHeavy metals:}$

Iron (Fe): < 1 000 μg/kg Copper (Cu): < 100 μg/kg

Impurities:

Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene: $< 2 \mu g/kg$ Treatment with active carbon is required to ensure that polycyclic aromatic hydrocarbons (PAH) are not enriched in the production of 'rapeseed oil high in unsaponifiable matter.

Rapeseed Protein

Definition:

Rapeseed protein is an aqueous protein-rich extract from rapeseed press cake originating from non-genetically modified *Brassica napus* L. and *Brassica rapa* L.

Description:

White to off-white, spray dried powder

Total protein: $\geq 90 \%$ Soluble protein: $\geq 85 \%$ Moisture: $\leq 7,0 \%$ Carbohydrates: $\leq 7,0 \%$

Fat: ≤ 2,0 % Ash: ≤ 4,0 % Fibre: ≤ 0,5 %

Total glucosinolates: ≤ 1 mmol/kg

Purity:

Total phytate: $\leq 1.5 \%$ Lead: $\leq 0.5 \text{ mg/kg}$

Microbiological criteria:

Yeast and mould count: ≤ 100 CFU/g Aerobic bacteria count: ≤ 10 000 CFU/g Total coliform count: ≤ 10 CFU/g Escherichia coli: Absence in 10 g

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Salmonella: Absence in 25 g

Transresveratrol

Description/Definition:

Synthetic*Trans*-resveratrol is off-white to beige crystals.

Chemical name: 5-[(E)-2-(4-hydroxyphenyl)ethenyl]benzene-1,3-diol

Chemical formula: C₁₄H₁₂O₃ Molecular weight: 228,25 Da

CAS No: 501-36-0

Purity:

Trans-resveratrol: $\geq 98 \%$ -99 %

Total by-products (related substances): $\leq 0.5 \%$

Any single related substance: $\leq 0.1 \%$

Sulphated ash: $\leq 0.1 \%$ Loss on drying: $\leq 0.5 \%$

Heavy metals: Lead: $\leq 1,0$ ppm Mercury: $\leq 0,1$ ppm Arsenic: $\leq 1,0$ ppm Impurities:

Diisopropylamine: $\leq 50 \text{ mg/kg}$

Microbial source: A genetically modified strain of *Saccharomyces*

cerevisiae

Appearance: Off-white to slight yellow powder

Particle size: 100 % less than 62,23 µm

Trans-resveratrol content: Min. 98 % w/w (dry weight basis)

Ash: Max. 0,5 % w/w Moisture: Max. 3 % w/w

Rooster comb extract

Description/Definition:

Rooster comb extract is obtained from *Gallus gallus* by enzymatic hydrolysis of rooster comb and by subsequent filtration, concentration and precipitation steps. The principal constituents of rooster comb extract are the glycosaminoglycans hyaluronic acid, chondroitin sulphate A and dermatan sulphate (chondroitin sulphate B). White or almost white hygroscopic powder.

Hyaluronic acid: 60-80 %

Chondroitin sulphate A: ≤ 5.0 %Dermatan sulphate (chondroitin sulphate

B): ≤ 25 % pH: 5,0-8,5 **Purity:**

Chlorides: $\leq 1.0 \%$ Nitrogen: $\leq 8.0 \%$

Loss on drying: (105 °C for 6 hours): \leq 10 %

Heavy metals:

Mercury: ≤ 0,1 mg/kg Arsenic: ≤ 1,0 mg/kg Cadmium: ≤ 1,0 mg/kg Chromium: ≤ 10 mg/kg

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Lead: $\leq 0.5 \text{ mg/kg}$

Microbiological criteria:

Total viable aerobic count: $\leq 10^2$ CFU/g

Escherichia coli: Absence in 1 g Salmonella: Absence in 1 g

Staphylococcus aureus: Absence in 1 g Pseudomonas aeruginosa: Absence in 1g

Sacha Inchi oil from *Plukenetia* volubilis

Description/Definition:

Sacha inchi oil is a 100 % cold pressed vegetable oil obtained from the seeds of *Plukenetia volubiis* L. It is a transparent, fluid (liquid) and shiny oil at room temperature. It has a fruity, light, green vegetable taste without undesirable flavours.

Aspect, limpidity, shine, colour: Fluid at room temperature, clean, shiny vellow gold

Odour and taste: Fruity, vegetable without non acceptable taste or odour **Purity:**

Water and Volatiles: < 0,2 g/100 g

Impurities insoluble in hexane: < 0,05 g/100 g

Oleic acidity: < 2.0 g/100 g

Peroxide value (PV): $\leq 15 \text{ meq O}_2/\text{kg}$

Trans fatty acids: < 1,0 g/100 g

Total unsaturated fatty acids: > 90 %Omega 3 alpha linolenic acid

(ALA): > 45 %

Saturated fatty acids: < 10 % No trans fatty acids (< 0,5 %) No erucic acid (< 0,2 %)

More than 50 % of tri-linolenin and di-linolenin-triglycerides

Phytosterols composition and level No cholesterol (< 5,0 mg/100 g)

Salatrims

Description/Definition:

Salatrim is the internationally recognised acronym for (short and long chain acyl triglyceride molecules). Salatrim is prepared by non-enzymatic inter-esterification of triacetin, tripropionin, tributyrin, or their mixtures with hydrogenated canola, soybean, cottonseed, or sunflower oil. Description: Clear, slightly amber liquid to a light coloured waxy solid

Description: Clear, slightly amber liquid to a light coloured waxy solid at room temperature. Free of particulate matter and of foreign or rancid odour.

Glycerol ester disribution: Triacylglycerols: > 87 % Diacylglycerols: ≤ 10 % Monoacylglycerols: ≤ 2,0 %

Fatty acid composition:

MOLE % LCFA (long chain fatty acids): 33-70 % MOLE % SCFA (short chain fatty acids): 30-67 % Saturated long chain fatty acids: < 70 % by weight

Trans fatty acids: $\leq 1.0 \%$

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	Free fatty acids as oleic acid: $\leq 0.5 \%$ Triacylglycerol profile: Triesters (short/long of 0.5 to 2.0): $\geq 90 \%$ Triesters (short/long = 0): $\leq 10 \%$ Unsaponifiable material: $\leq 1.0 \%$ Moisture: $\leq 0.3 \%$ Ash: $\leq 0.1 \%$ Colour: $\leq 3.5 \text{ Red (Lovibond)}$ Peroxide value (PV): $\leq 2.0 \text{ Meq/Kg}$
Schizochytrium sp. oil rich in DHA and EPA	Acid value: ≤ 0.5 mg KOH/g Peroxide value (PV): ≤ 5.0 meq/kg oil Oxidative stability: All food products containing <i>Schizochytrium sp.</i> oil rich in DHA and EPA should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC) Moisture and volatiles: ≤ 0.05 % Unsaponifiables: ≤ 4.5 % Trans-fatty acids: ≤ 1 % DHA content: ≥ 22.5 % EPA content: ≥ 10 %
Schizochytrium sp. (ATCC PTA-9695) oil	Peroxide value (PV): ≤ 5.0 meq/kg oil Unsaponifiables: ≤ 3.5 % Trans-fatty acids: ≤ 2.0 % Free fatty acids: ≤ 0.4 % Docosapentaenoic acid (DPA) n-6: ≤ 7.5 % DHA content: ≥ 35 %
Schizochytrium sp. oil	Acid value: ≤ 0,5 mg KOH/g Peroxide value (PV): ≤ 5,0 meq/kg oil Moisture and volatiles: ≤ 0,05 % Unsaponifiables: ≤ 4,5 % Trans-fatty acids: ≤ 1,0 % DHA content: ≥ 32,0 %
Schizochytrium sp. (T18) oil	Acid value: ≤ 0.5 mg KOH/g Peroxide value (PV): ≤ 5.0 meq/kg oil Moisture and volatiles: ≤ 0.05 % Unsaponifiables: ≤ 3.5 % Trans-fatty acids: ≤ 2.0 % Free fatty acids: ≤ 0.4 % DHA content: ≥ 35 %
Fermented soybean extract	Description/Definition: Fermented soybean extract is an odourless milk-white coloured powder. It is comprised of 30 % fermented soybean extract powder and 70 % resistant dextrin (as carrier) from corn-starch, which is added during the processing. Vitamin K ₂ is removed during the manufacturing process.
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Fermented soybean extract contains nattokinase isolated from natto, a foodstuff produced by the fermentation of non-genetically modified soybeans (*Glycine max* (L.)) with a selected strain of *Bacillus subtilis* var. natto.

Nattokinase activity: 20 000 -28 000 Fibrin degradation unit/g(1)

Identity: Confirmable

Condition: No offensive taste or smell

Loss on drying: $\leq 10 \%$ Vitamin K₂: $\leq 0.1 \text{ mg/kg}$

Heavy metals: Lead: ≤ 5,0 mg/kg Arsenic: ≤ 3,0 mg/kg Microbiological criteria:

Total viable aerobic count: $\leq 10^3 \text{ CFU}(^3)/\text{g}$

Yeast and mould: $\leq 10^2 \text{ CFU/g}$

Coliforms: ≤ 30 CFU/g

Spore-forming bacteria: ≤ 10 CFU/g Escherichia coli: Absence/25 g Salmonella: Absence/25 g Listeria: Absence/25 g

(1) Assay method as described by Takaoka et al. (2010).

Spermidinerich wheat germ extract (*Triticum* aestivum)

Description/Definition:

Spermidine-rich wheat germ extract is obtained from non-fermented, non-sprouting wheat germs (*Triticum aestivum*) by the process of solid-liquid extraction targeting specifically, but not exclusively polyamines.

Spermidine: 0,8-2,4 mg/g Spermine: 0,4-1,2 mg/g

Spermidine trichloride < 0,1 μg/gPutrescine: < 0,3 mg/g

Cadaverine: $< 0.1 \mu g/g$

Mycotoxins:

Aflatoxins (total): < 0,4 μg/kg **Microbiological criteria:**

Total aerobic bacteria: < 10 000 CFU/g Yeast and moulds: < 100 CFU/g Escherichia coli: < 10 CFU/g Salmonella: Absence/25g

Listeria monocytogenes: Absence/25g

Sucromalt

Description/Definition:

Sucromalt is a complex mixture of saccharides which is produced from sucrose and a starch hydrolysate by means of an enzymatic reaction. In this process, glucose units are attached to saccharides from the starch hydrolysate by means of an enzyme produced by the bacterium *Leuconostoc citreum* or by means of a recombinant strain of the production organism *Bacillus licheniformis*. The resulting oligosaccharides are characterised by the presence of α -(1 \rightarrow 6) and α -

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 $(1\rightarrow 3)$ glycosidic compounds. The overall product is syrup, in addition to these oligosaccharides, contains mainly fructose but also the disaccharide leucrose and other disaccharides.

Total solids: 75-80 % Moisture: 20-25 % Sulphatase: Max 0,05 %

pH: 3,5-6,0

Conductivity < 200 (30 %)

Nitrogen < 10 ppm Fructose: 35-45 % d.w. Leucrose: 7-15 % d.w.

Other disaccharides: Max 3 % Higher saccharides: 40-60 % d.w

Sugar cane fibre

Description/Definition:

Sugar Cane Fibre is derived from the dry cell wall or fibrous residue remaining after expression or extraction of sugar juice from sugar cane, of the Saccharum genotype. It consists primarily of cellulose and hemicellulose.

The production process consists of several steps, including: chipping, alkaline digestion, removal of lignins and other non-cellulosic components, bleaching of purified fibres, acid washing and neutralization. Moisture: $\leq 7.0 \%$

Ash: $\leq 0.3 \%$

Total Dietary Fibre (AOAC) dry basis (all insoluble): $\geq 95\%$ of which: Hemicellulose (20-25%) and cellulose (70-75%)

Silica (ppm): ≤ 200 Protein: 0,0 % Fat: Trace pH: 4-7 **Heavy metals:**

Mercury (ppm): $\leq 0,1$ Lead (ppm): $\leq 1,0$ Arsenic (ppm): $\leq 1,0$ Cadmium (ppm): $\leq 0,1$ **Microbiological criteria:**

Yeast and moulds (CFU/g): $\leq 1~000$

Salmonella: Absence

Listeria monocytogenes: Absence

Sunflower oil extract

Description/Definition:

The sunflower extract is obtained by a concentration factor of 10 of the unsaponifiable fraction of refined sunflower oil extracted from the seeds of the sunflower, *Helianthus Annuus* L.

Composition:

Oleic acid (C18:1): 20 % Linoleic acid (C18:2): 70 % Unsaponifiable matter: 8,0 %

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Phytosterols: 5,5 % Tocopherols: 1,1 %

Dried Tetraselmis chuii microalgae

Description/Definition:

The dried product is obtained from the marine microalgae *Tetraselmis chuii*, belonging to the *Chlorodendraceae* family, cultivated in sterile sea water in closed photobioreactors insulated from the outside air.**Purity/Composition:**

Identified by means of nuclear marker rDNA 18 S (sequence analysed no less than 1 600 base pairs) in the National Centre for Biotechnology information (NCBI) database: Not less than 99.9 %

Humidity: ≤ 7,0 % Proteins: 35-40 % Ashes: 14-16 %

Carbohydrates: 30-32 %

Fibre: 2-3 % Fat: 5-8 %

Saturated fatty acids: 29-31 % of total fatty acids Monounsaturated fatty acids: 21-24 % of total fatty acids Polyunsaturated fatty acids: 44-49 % of total fatty acids

Iodine: $\leq 15 \text{ mg/kg}$

Therapon barcoo/Scortum

Description/Definition:

Scortum/*Therapon barcoo* is a species of fish in the family Terapontidae. It is an endemic fresh water species from Australia. It is now reared in fish farms.

Taxonomic Identification: Class: Actinopterygii > order: Perciformes > family: Terapontidae > genus: *Therapon* or *Scortum barcoo*

Composition of fish flesh: Protein (%): 18-25 Moisture (%): 65-75 Ash (%): 0,5-2,0

Energy (KJ/Kg): 6000-11500 Carbohydrates (%): 0,0

Fat (%): 5-15

Fatty acids (mg FA/g fillet): Σ PUFA n-3: 1,2-20,0 Σ PUFA n-6: 0,3-2,0 PUFA n-3/n-6: 1,5-15,0 Total omega 3 acids: 1,6-40,0 Total omega 6 acids: 2,6-10,0

D-Tagatose

Description/Definition:

Tagatose is produced by isomerization of galactose by means of chemical or enzymatic conversion, or by epimerization of fructose by means of enzymatic conversion. These are single-step conversions.

Appearance: White or almost white crystals

Chemical name: D-tagatose Synonym: D-lyxo-Hexulose

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CAS number: 87-81-0 Chemical formula: C₆H₁₂O₆ Formula weight: 180,16 (g/mol)

Purity:

Assay: \geq 98 % on a dry weight basis Loss on drying: \leq 0,5 % (102 °C, 2 hours)

Specific Rotation: $[\alpha]_D^{20}$: -4 to -5.6° (1 % agueous solution)(1)

Melting range: 133-137 °C

Heavy metals: Lead: $\leq 1.0 \text{ mg/kg(*)}$

- (*) Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5. 'Instrumental methods'(1).
- (1) Food and nutrition paper 5 Rev 2 Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA) 1991, 307 p.; English ISBN 92-5-102991-1

Taxifolin-rich extract

Description:

Taxifolin-rich extract from the wood of Dahurian Larch (*Larix gmelinii* (Rupr.) Rupr) is a white to pale-yellow powder that crystallizes from hot aqueous solutions.

Definition:

Chemical name: [(2R,3R)-2-(3,4 dihydroxyphenyl)-3,5,7-trihydroxy-2,3-dihydrochromen-4-one, also called (+) trans (2R,3R)- dihydroquercetin]

Chemical formula: C₁₅H₁₂O₇ Molecular mass: 304,25 Da

CAS No: 480-18-2 **Specifications:** *Physical parameter*

Moisture: ≤ 10 %*Compound analysis* Taxifolin (m/m): ≥ 90.0 % of the dry weight

Heavy Metals, Pesticide

Lead: $\leq 0.5 \text{ mg/kg}$ Arsenic: $\leq 0.02 \text{ mg/kg}$ Cadmium: $\leq 0.5 \text{ mg/kg}$ Mercury: $\leq 0.1 \text{ mg/kg}$

Dichlorodiphenyltrichloroethane (DDT): ≤ 0.05 mg/kg

Residual solvents
Ethanol: < 5 000 mg/kg
Microbiological criteria

Total Plate Count (TPC): $\leq 10^4$ CFU/g

Enterobacteria: ≤ 100/g

Yeast and Mould : $\leq 100 \text{ CFU/g}$

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Escherichia coli: Absence/1 g Salmonella: Absence/10 g

Staphylococcus aureus: Absence/1 g

Pseudomonas: Absence/1g

Usual range of components of the Taxifolin-rich extract (as per dry substance)

Extract component	Content, usual observed range (%)
Taxifolin	90 – 93
Aromadendrin	2,5 – 3,5
Eriodictyol	0.1 - 0.3
Quercetin	0,3 – 0,5
Naringenin	0,2 – 0,3
Kaempferol	0,01 – 0,1
Pinocembrin	0,05 - 0,12
Unidentified flavonoids	1 – 3
Water(*)	1,5

(*) Taxifolin in its hydrated form and during the drying process is a crystal. This results on the inclusion of water of crystallisation in a quantity of 1,5 %.

Trehalose

Description/Definition:

A non-reducing disaccharide that consists of two glucose moieties linkes by an α -1,1-glucosidic bond. It is obtained from liquefied starch or from sucrose by a multistep enzymatic process. The commercial product is the dihydrate. Virtually odourless, white or almost white crystals with a sweet taste

Synonyms: α,α-trehalose

Chemical name: α-D-glucopyranosyl-α-D-glucopyranoside, dihydrate

CAS No.: 6138-23-4 (dihydrate)

Chemical formula: $C_{12}H_{22}O_{11} \cdot 2H_2O$ (dihydrate)

Formula weight: 378,33 (dihydrate) Assay: ≥ 98 % on the dry basis

Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5 (1), 'Instrumental methods'

Method of assay:

Principle: trehalose is identified by liquid chromatography and quantified by comparison to a reference standard containing standard trehalose

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b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Preparation of sample solution: weigh accurately about 3 g of dry sample into a 100 ml volumetric flask and add about 80 ml of purified, deionised water. Bring sample to complete dissolution and dilute to mark with purified deionised water. Filter through a 0,45 micron filter

Preparation of standard solution: dissolve accurately weighed quantities of dry standard reference trehalose in water to obtain a solution having known concentration of about 30 mg of trehalose per ml.

Apparatus: liquid chromatography equipped with a refractive index detector and integrating recorder

Conditions:

Column: Shodex Ionpack KS-801 (Showa Denko Co.) or equivalent

length: 300 mmdiameter: 10 mmtemperature: 50 °C

Mobile phase: water flow rate: 0,4 ml/min Injection volume: 8 µl

Procedure: inject separately equal volumes of the sample solution and the

standard solution into the chromatograph.

Record the chromatograms and measure the size of response of the trehalose peak

Calculate the quantity, in mg, of trehalose in 1 ml of the sample solution by the following formula:% trehalose = $100 \times (R_U/R_S) (W_S/W_U)$

where

 $\begin{array}{ll} R_S & = \mbox{ peak area of trehalose in the standard preparation} \\ R_U & = \mbox{ peak area of trehalose in the sample preparation} \\ W_S & = \mbox{ weight in mg of trehalose in the standard preparation} \end{array}$

 W_U = weight of dry sample in mg

Characteristics:

Identification:

Solubility: Freely soluble in water, very slightly soluble in ethanol Specific rotation: $\left[\alpha\right]_{D}^{20} = +179^{\circ}$ (5 % aqueous solution, dihydrate),

+199° (5 % aqueous solution, anhydrous substance)

Melting point: 97 °C (dihydrate)

Purity:

Loss on drying: $\leq 1,5 \%$ (60 °C, 5h)

Total ash: $\leq 0.05 \%$ **Heavy metals:** Lead: $\leq 1.0 \text{ mg/kg}$

UV treated mushrooms (Agaricus bisporus)

Description/Definition:

Commercially grown *Agaricus bisporus* to which UV light treatment is applied to harvested mushrooms.

UV radiation: a process of radiation in ultraviolet light within the wavelength of 200-800 nm.

Vitamin D_2 :

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b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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Chemical name: (3β,5Z,7E,22E)-9,10-secoergosta-5,7,10(19),22-

tetraen-3-ol

Synonym: Ergocalciferol

CAS No: 50-14-6

Molecular weight: 396,65 g/mol

Contents:

Vitamin D_2 in the final product: 5-10 µg/100 g fresh weight at the

expiration of shelf life

UV-treated baker's yeast (Saccharomyces cerevisiae)

Description/Definition:

Baker's yeast ($Saccharomyces\ cerevisiae$) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D_2 (ergocalciferol).

Vitamin D₂ content in the yeast concentrate varies between 1 800 0003

500 000 IU vitamin D/100 g (450-875 μg/g).

Tan-coloured, free-flowing granules

Vitamin D₂:

Chemical name: (5Z,7E,22E)-3S-9,10-secoergosta-5,7,10(19),22-

tetraen-3-ol

Synonym: Ergocalciferol

CAS No.: 50-14-6

Molecular weight: 396,65 g/mol

Microbiological criteria for the yeast concentrate:

Coliforms: $\leq 10^3/g$ Escherichia coli: $\leq 10/g$ Salmonella: Absence in 25g

UV-treated bread

Description/Definition:

UV-treated bread is yeast leavened bread and rolls (without toppings) to which a treatment with ultraviolet radiation is applied after baking in order to convert ergosterol to vitamin D₂ (ergocalciferol).

UV radiation: A process of radiation in ultraviolet light within the wavelength of 240-315 nm for maximum of 5 seconds with energy input of 10-50 mJ/cm².

Vitamin D₂:

Chemical name: (5Z,7E,22E)-3S-9,10-secoergosta-5,7,10(19),22-

tetraen-3-ol

Synonym: Ergocalciferol

CAS No: 50-14-6

Molecular weight: 396,65 g/mol

Contents:

Vitamin D₂ (ergocalciferol) in the final product: $0.75-3 \mu g/100 g(^{1})$

Yeast in dough: 1-5 g/100 g (2)

- (1) EN 12821, 2009, European Standard.
- (2) Recipe calculation.

a 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 (OJ L 83, 22.3.2012, p. 1).

b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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UV-treated milk

Description/Definition:

UV-treated milk is cow's milk (whole and semi-skimmed) to which a treatment with ultraviolet (UV) radiation via turbulent flow is applied after pasteurisation. The treatment of the pasteurised milk with UV radiation results in an increase in the vitamin D₃ (cholecalciferol) concentrations by conversion of 7-dehydrocholesterol to vitamin D₃. UV radiation: A process of radiation in ultraviolet light within the wavelength of 200-310 nm with energy input of 1 045 J/l.

Vitamin D₃:

Chemical name: (1S,3Z)-3-[(2E)-2-[(1R,3aS,7aR)-7a-methyl-1-[(2R)-6-methylheptan-2-yl]-2,3,3a,5,6,7-hexahydro-1H-inden-4-ylidene]-4-methylidenecyclohexan-1-ol

Synonym: Cholecalciferol

CAS No: 67-97-0

Molecular weight: 384,6377 g/mol

Contents:

Vitamin D_3 in the final product: Whole milk(1)0,5-3,2 μ g/100 g(2)

Semi-skimmed milk(1): $0,1-1,5 \mu g/100 g(^2)$

- (1) As defined by Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).
- $(^2)$ HPLC

Vitamin K₂ (menaquinone)

This novel food is produced by a synthetic or microbiological process. Vitamin K_2 (2-methyl-3-all-trans-polyprenyl-1,4-naphthoquinones), or the menaquinone series, is a group of prenylated naphthoquinone derivatives. The number of isoprene residues, where 1 isoprene unit consists of 5 carbons comprising the side chain, is used to characterise the menaquinone homologues containing primarily MK-7 and to a smaller extent MK-6.

Vitamin K_2 (menaquinones) series with menaquinone-7 (MK-7)(n = 6) being $C_{46}H_{64}O_2$, menaquinone-6 (MK-6)(n = 5) being $C_{41}H_{56}O_2$ and menaquinone-4 (MK-4)(n = 3) being $C_{31}H_{40}O_2$.

Chemical Name: (all-E)-2-(3,7,11,15,19,23,27-

Heptamethyl-2,6,10,14,18,22,26-octacosaheptaenyl)-3-methyl-1,4-

naphtalenedione

CAS Number: 2124-57-4 Molecular formula: C₄₆H₆₄O₂ Molecular weight: 649 g/mol

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b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).]

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2-methyl-1,4-naphthoquinone (menadione moiety)

Specification of synthetic Vitamin K_2 (menaquinone-7)

Appearance: Yellow powder

Purity: Max 6,0 % cis-isomer, max 2,0 % other impurities

Content: 97-102 % Menaquinone-7 (including at least 92 % all-trans

Menaquinone-7)

Specifications of microbiologically produced Vitamin K₂ (menaguinone-7)

Source: Bacillus subtilis spp. natto and Bacillus licheniformis

Appearance: Yellow powder or oil suspension

Wheat bran extract

Description/Definition:

White crystalline powder obtained by enzymatic extraction from *Triticum*

aestivum L. bran, rich in arabinoxylan oligosaccharides

Dry matter: Min. 94 %

Arabinoxylan oligosaccharides: Min 70 % of dry matter

Average degree of polymerisation of arabinoxylan oligosaccharides: 3-8 Ferulic acid (bound to arabinoxylan oligosaccharides): 1-3 % of dry

matter

Total poly/oligosaccharides: Min 90 %

Protein: Max 2 % of dry matter Ash: Max 2 % of dry matter **Microbiological parameters:**

Mesophilic bacteria – total count: Max 10 000/g

Yeasts: Max 100/g Fungi: Max 100/g

Salmonella: Absence in 25g Bacillus cereus: Max 1000/g

Clostridium perfringens: Max 1000/g

Yeast betaglucans

Description/Definition:

Beta-glucans are complex, high molecular mass (100–200 kDa) polysaccharides, found in the cell wall of many yeasts and cereals. The chemical name for 'yeast beta-glucans' is (1-3),(1-6)-\(\beta\)-\(\beta\)-B-D-glucans.

- a 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 (OJ L 83, 22.3.2012, p. 1).
- b Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (OJ L 30, 6.2.2015, p. 10).

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Beta-glucans consist of a backbone of β -1-3-linked glucose residues that are branched by β -1-6-linkages, to which chitin and mannoproteins are linked by β -1-4-bonds.

Beta-glucans are isolated from yeast Saccharomyces cerevisiae.

The tertiary structure of the glucan cell wall of *Saccharomyces cerevisiae* consists of chains of β -1,3-linked glucose residues, branched by β -1,6-linkages, forming a backbone to which are linked chitin via β -1,4- bonds, β -1,6-glucans and some mannoproteins.

This novel food is available in three different forms: soluble, insoluble and insoluble in water, but dispersible in many liquid matrices.

Chemical characteristics yeast (Saccharomyces cerevisiae) betaglucans:

Soluble form:

Total carbohydrates: > 75 % Beta-glucans (1,3/1,6): > 75 %

Ash: < 4,0 % Moisture: < 8,0 % Protein: < 3,5 % Fat: < 10 %

Insoluble form:

Total carbohydrates: > 70 % Beta-glucans (1,3/1,6): > 70 %

Ash: ≤ 12 % Moisture: < 8,0 % Protein: < 10 % Fat: < 20 %

Insoluble in water, but dispersible in many liquid matrices:

(1,3)-(1,6)- β -D-Glucans: > 80 %

Ash: < 2,0 % Moisture: < 6,0 % Protein: < 4,0 % Total fat: < 3,0 %

Microbiological data for insoluble in water, but dispersible in many

liquid matrices:

Total plate count: < 1 000 CFU/g Enterobacteriaceae: < 100 CFU/g Total coliforms: < 10 CFU/g

Yeast: < 25 CFU/g Mould: < 25 CFU/g

Salmonella: Absence in 25 g Escherichia coli: Absence in 1 g Bacillus cereus: < 100 CFU/g

Staphylococcus aureus: Absence in 1 g

Heavy metals for insoluble in water, but dispersible in many liquid

matrices:

Lead: < 0,2 mg/g Arsenic: < 0,2 mg/g

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Mercury: < 0,1 mg/g Cadmium: < 0,1 mg/g

Zeaxanthin

Description/Definition:

Zeaxanthin is a naturally occurring xanthophyll pigment, it is an oxygenated carotenoid.

The synthetic zeaxanthin is presented either as a spray-dried powder of gelatin or starch base ('beadlets') with added α -tocopherol and ascorbyl palmitate or as a corn oil suspension with added α -tocopherol. Synthetic zeaxanthin is produced by a multi-step chemical synthesis from smaller molecules.

Orange-red crystalline powder with little or no odour.

Chemical formula: C₄₀H₅₆O₂

CAS No: 144-68-3

Molecular weight: 568,9 daltons **Physical-chemical properties:**

Loss on drying: < 0,2 %

All-trans zeaxanthin: > 96 %

Cis-zeaxanthin: < 2,0 %

Other carotenoids: < 1,5 %

Triphenylphosphine oxid (CAS No 791-28-6): < 50 mg/kg

Zinc L-pidolate

Description/Definition:

Zinc L-pidolate is a white to off-white powder, with characteristic odour. International non-proprietary name (INN): L-pyroglutamic acid, Zinc salt Synonyms: Zinc 5-oxoproline, Zinc pyroglutamate, Zinc pyrrolidone

carboxylate, Zinc PCA, L-Zinc pidolate

CAS No.: 15454-75-8

Molecular formula: (C₅ H₆ NO₃)₂ Zn Relative anhydrous molecular mass: 321,4 Appearance: White to slightly white powder

Purity:

Zinc L-pidolate (purity): $\geq 98 \%$ pH (10 % aqueous sol.): 5,0-6,0 Specific rotation: 19,6°- 22,8°

Water: ≤ 10,0 % Glutamic acid: < 2,0 %

Heavy metals: Lead: ≤ 3,0 ppm Arsenic: ≤ 2,0 ppm Cadmium: ≤ 1,0 ppm Mercury: ≤ 0,1 ppm Microbiological criteria:

Total viable mesophilic count: ≤ 1 000 CFU/g

Yeasts and moulds: $\leq 100 \text{ CFU/g}$

Pathogen: Absence

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