

EN

**ANNEX**

**UNION LIST OF NOVEL FOODS**

**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 under which the novel food may be used		Additional specific labelling requirements	Other requirements
<i>Adansonia digitata</i> (Baobab) dried fruit pulp	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be "Baobab fruit pulp"	
<i>Ajuga reptans</i> extract	<b>Specified food category</b>	<b>Maximum levels</b>		
	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	<b>Specified food category</b>	<b>Maximum levels</b>		
	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			
Algal oil from the microalgae <i>Ulkenia</i> sp.	<b>Specified food category</b>	<b>Maximum levels of DHA</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Oil from the micro-algae <i>Ulkenia</i> sp."	
	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		

<i>Allanblackia</i> seed oil	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be " <i>Allanblackia</i> seed oil'
	Yellow fat spreads and cream based spreads		
<i>Aloe macroclada</i> Baker leaf extract	<b>Specified food category</b>	<b>Maximum levels</b>	
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of the similar gel derived <i>from Aloe vera</i> (L.) Burm.	
Antartic Krill oil from <i>Euphasia superba</i>	<b>Specified food category</b>	<b>Maximum levels of combined DHA and EPA</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Lipid extract from the crustacean Antarctic Krill ( <i>Euphausia superba</i> )"
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g	
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g	
	Non-alcoholic beverages	80 mg/100 ml	
	Milk-based drinks Dairy analogue drinks		
	Spreadable fat and dressings	600 mg/100 g	
	Cooking fats	360 mg/100 ml	
	Breakfast cereals	500 mg/100 g	
	Bakery products (bread and rolls)	200 mg/100 g	
	Nutrition bars/cereal bars	500 mg/100 g	
Food Supplements as defined in Directive 2002/46/EC	3000 mg/day for the general population 450 mg/day for pregnant and		
			All food products containing DHA- and EPA-rich oil from Antarctic Krill should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC)

		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 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			
<b>Antartic Krill oil</b>	<b>Specified food category</b>	<b>Maximum levels of combined</b>	The designation of the novel food on the	All food products

<b>rich in phospholipids from <i>Euphasia superba</i></b>		<b>DHA and EPA</b>	labelling of the foodstuffs containing it shall be "Lipid extract from the crustacean Antarctic Krill ( <i>Euphausia superba</i> )"	containing DHA- and EPA-rich oil from Antarctic Krill should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC)
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g		
	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 (bread and rolls)	200 mg/100 g		
	Nutrition bars/cereal bars	500 mg/100 g		
	Food Supplements as defined in Directive 2002/46/EC	3000 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 as defined in Regulation (EU) No 609/2013	250 mg/meal			

	and meal replacements for weight control			
	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			
<b>Arachidonic acid-rich oil from the fungus <i>Mortierella alpina</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Oil from <i>Mortierella alpina</i> " or " <i>Mortierella alpina</i> oil"	
	Infant formula—and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013		
	Foods for special medical purposes for premature infants as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013		
<b>Argan oil from <i>Argania spinose</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it	
	As seasonings	Not specified		

	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of a vegetable oils	shall be "Argan oil" and if used as seasoning "Vegetable oil only for seasoning" shall be mentioned on the label	
<b>Astaxanthin from <i>Haematococcus pluvialis</i> algae</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel on the labelling of the Food stuff containing it shall be "Astaxanthin"	
	Food Supplements as defined in Directive 2002/46/EC	2.4 mg/day		
<b>Basil seeds (<i>Ocimum basilicum</i>)</b>	<b>Specified food category</b>	<b>Maximum levels</b>		The final product is sold in transparent containers so that Basil seed is visible to consumers
	Beverages based on fruit juice and fruit juice blends	3 g/200 mL for addition of whole basil seeds ( <i>Ocimum basilicum</i> )		
<b>Fermented black bean extract</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Fermented black bean (Soya) extract" or "Fermented Soya extract"	
	Food Supplements as defined in Directive 2002/46/EC	4.5 g/day		
<b>Bovine lactoferrin</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Lactoferrin from cows' milk"	
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 (ready to drink)	100 mg/100 ml		
	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 Regulation (EU) No 609/2013	Depending on the needs of the individual up to 3 g/day		
	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	2000 mg/100 g		
	Ice cream	130 mg/100 g		
	Cakes and pastries	1000 mg/100 g		
	Candies	750 mg/100 g		
	Chewing gum	3000 mg/100 g		
<b><i>Buglossoides arvensis</i> seed oil</b>	<b>Specified food category</b>	<b>Maximum levels of stearidonic acid (STA)</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Refined <i>Buglossoides</i> oil'	
	Dairy products and analogues	250 mg/100 g		
		75 mg/100 g for drinks		
	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 2002/46/EC, excluding food supplements for infants and young children	500 mg/day			



	Foods for special medical purposes as defined in Regulation (EU) No 609/2013, excluding foods for special medical purposes intended for infants and young children	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		
<b>Chewing gum base (monomethoxypolyethylene glycol)</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food 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 base (including CAS No: 1246080-53-4)"	
	Chewing gum	8%		
<b>Chewing gum base (Methyl vinyl ether-maleic anhydride copolymer)</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food 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)"	
	Chewing gum	2%		
<b>Chia oil from <i>Salvia hispanica</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Chia oil ( <i>Salvia hispanica</i> )"	
	Fats and oils	10%		
	Pure chia oil	2 g/day		
	Food Supplements as defined in Directive 2002/46/EC	2 g/day		

<b>Chia seeds (<i>Salvia hispanica</i>)</b>	<b>Specified food category</b>	<b>Maximum levels</b>	<p>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "Chia (<i>Salvia hispanica</i>) seeds"</p> <p>2. Additional labelling of pre-packaged Chia (<i>Salvia hispanica</i>) seed is required to inform the consumer that the daily intake is no more than 15 g.</p>	Fruit juice and fruit juice blends: The final product is sold in transparent containers so that Chia seed is visible to consumers
	Bread products	5% (whole or ground chia seeds)		
	Baked products	10% whole chia seeds		
	Breakfast cereals	10% whole chia seeds		
	Fruit, nut and seed mixes	10% whole chia seeds		
	Beverages based on fruit juice and fruit juice blends	15 g/450 ml for addition of whole, mashed or ground chia seeds		
	Pre-packaged Chia seed as such	15 g/day whole chia seeds		
<b>Chitin-glucan from <i>Aspergillus niger</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Chitin-glucan from <i>Aspergillus niger</i> "	
	Food Supplements as defined in Directive 2002/46/EC	5 g/day		
<b>Chitin-glucan complex from <i>Fomes fomentarius</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Chitin-glucan from <i>Fomes fomentarius</i> "	
	Food Supplements as defined in Directive 2002/46/EC	5 g/day		
<b>Chitosan extract from fungi (<i>Agaricus bisporus</i>; <i>Aspergillus niger</i>)</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Chitosan extract from <i>Agaricus bisporus</i> " or "Chitosan extract from <i>Aspergillus niger</i> "	
	Food Supplements as defined in Directive 2002/46/EC	In line with normal use in food supplements of chitosan from crustaceans		
<b>Chromium Picolinate</b>	<b>Specified food category</b>	<b>Maximum levels of total chromium</b>	The designation of the novel food on the labelling of the foodstuffs containing it	

	<p>Foods covered by Regulation (EU) No 609/2013</p> <p>Milk-based drinks and similar products intended for young children</p> <p>Meal replacement for weight control</p> <p>Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen</p> <p>Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014</p>	250 µg/day	shall be "Chromium Picolinate"	
<b>Citicoline</b>	<b>Specified food category</b>	<b>Maximum levels</b>	<ol style="list-style-type: none"> <li>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "Citicoline"</li> <li>2. The labelling of foods containing citicoline shall bear a statement that the product is not intended to be consumed by children</li> </ol>	
	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	250 mg per serving and a maximum daily consumption level of 1000 mg		
<b><i>Clostridium butyricum</i> (CBM 588)</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be " <i>Clostridium butyricum</i> MIYAIRI 588 (CBM 588)" or " <i>Clostridium</i>	
	Food Supplements as defined in Directive 2002/46/EC	$1,35 \times 10^8$ CFU/day		

			<i>butyricum</i> (CBM 588)"	
<b>Extract of defatted cocoa powder</b>	<b>Specified food category</b>	<b>Maximum levels</b>	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	
	Nutrition bars	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)		
	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			
<b>Specified food category</b>	<b>Maximum levels</b>		Consumers shall be instructed not to consume more than 600 mg of cocoa flavanols per day	
Low fat cocoa extract	Foods including food supplements as defined in Directive 2002/46/EC	730 mg per serving and around 1.2 g/day		
<b>Coriander seed oil from <i>Coriandrum sativum</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Coriander seed oil"	
	Food Supplements as defined in Directive 2002/46/EC	600 mg/day		
<b><math>\alpha</math>-cyclodextrin</b>	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be "Alpha-cyclodextrin' or " $\alpha$ -cyclodextrin"	

<b><math>\gamma</math>-Cyclodextrin</b>	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be "Gamma-Cyclodextrin" or " $\gamma$ -Cyclodextrin"
<b>Dextran preparation produced by <i>Leuconostoc mesenteroides</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Dextran"
	Bakery products	5%	
<b>Diacylglycerol oil of plant origin</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Diacylglycerol oil of plant origin (at least 80 % diacylglycerols)"
	Cooking oils		
	Fat spreads		
	Salad dressings		
	Mayonnaise		
	Meal replacement for weight control (as drinks)		
	Bakery products		
	Yoghurt type products		
<b>Dihydrocapsiate (DHC)</b>	<b>Specified food category</b>		<b>Maximum levels</b>
	Cereal bars	9 mg/100 g	
	Biscuits, cookies and crackers	9 mg/100 g	
	Rice based snacks	12 mg/100 g	
	Carbonated drinks, dilutable drinks, fruit juice based drinks	1.5 mg/100 ml	
	Vegetable drinks	2 mg/100 ml	
	Coffee based drinks, tea based	1.5 mg/100 ml	

	drinks		
	Flavoured water - still	1 mg/100 ml	
	Precooked oatmeal cereal	2.5 mg/100 g	
	Other cereals	4.5 mg/100 g	
	Ice cream, dairy desserts	4 mg/100 g	
	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	
	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/100ml	
<b>Dried extract of</b>	Food Supplements as defined		

<i>Lippia citriodora</i> from cell cultures	in Directive 2002/46/EC			
<i>Echinacea angustifolia</i> extract	<b>Specified food category</b>	<b>Maximum levels</b>		
	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 <i>Echinacea angustifolia</i>		
<i>Echium plantagineum</i> oil	<b>Specified food category</b>	<b>Maximum levels of stearidonic acid (STA)</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Refined echium oil"	
	Milk-based products and drinkable yoghurt products delivered in a single dose	250 mg/100 g; 75 mg/100 g for drinks		
	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			
<b>Epigallocatechin</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The labelling shall bear a statements that	

<b>gallate as a purified extract from green tea leaves (<i>Camellia sinensis</i>)</b>	Food Supplements as defined in Directive 2002/46/EC	150 mg of extract in one portion of food or food supplement	consumers should not consume more than 300 mg of extract per day
	Foods fortified in accordance with Regulation (EC) No 1925/2006		
<b>L-ergothioneine</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "L-ergothioneine"
	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	
<b>Ferric Sodium EDTA</b>	<b>Specified food category</b>	<b>Maximum levels (anhydrous EDTA)</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Ferric Sodium EDTA"
	Food supplements as defined in Directive 2002/46/EC	Children: 18 mg/day Adults: 75 mg/day	
	Foods covered by Regulation (EU) No 609/2013		
	Foods fortified in accordance with Regulation (EC) No 1925/2006	12 mg/100 g	
<b>Ferrous ammonium phosphate</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Ferrous ammonium phosphate"
	Foods including food supplements as defined in Directive 2002/46/EC	To be used in compliance with Directive 2002/46/EC, Regulation (EU) No 609/2013 and/or Regulation (EC) No 1925/2006	
	Foods covered by Regulation (EU) No 609/2013		



	Milk-based drinks and similar products intended for young children			
	Meal replacement for weight control			
	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			
<b>Fish peptides from <i>Sardinops sagax</i></b>	<b>Specified food category</b>	<b>Maximum levels fish peptide product</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Fish ( <i>Sardinops sagax</i> ) peptides"	
	Foods based on yoghurt, yoghurt drinks, fermented milk products, and powdered milk	0.48 g/100 g (ready to eat/drink)		
	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)		
<b>Flavonoids from</b>	<b>Specified food category</b>	<b>Maximum levels of flavonoid</b>	1. The designation of the novel food on	Beverages

<i>Glycyrrhiza glabra</i>	Beverages based on milk	120 mg/day	<p>the labelling of the foodstuffs containing it shall be "Flavonoids from <i>Glycyrrhiza glabra L.</i>"</p> <p>2. The labelling of the foods where the product was added as a novel food ingredient shall bear a statement that:</p> <p>(a) the product should not be consumed by pregnant and breast feeding women, children and young adolescents; and</p> <p>(b) people taking prescription drugs should only consume the product under medical supervision;</p> <p>(c) a maximum of 120 mg of Glavonoid per day should be consumed.</p> <p>3. The amount of Glavonoid in the final food shall be indicated on the labelling of the food containing it.</p>	containing Glavonoid shall be presented to the final consumer as single portions.
	Beverages based on yoghurt			
	Beverages based on fruit or vegetables			
	Food Supplements as defined in Directive 2002/46/EC	120 mg/portion of daily consumption		
	Total diet replacement for weight control as defined in Regulation (EU) No 609/2013	120 mg/day		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	120 mg/day		
<b>2'-O-fucosyllactose</b>	<b>Specified food category</b>	<b>Maximum levels</b>	<p>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "2'-O-fucosyllactose".</p> <p>2. The labelling of food supplements containing 2'-O-fucosyllactose shall bear a statement that the supplements should not be used if other foods with added 2'-O-fucosyllactose are consumed the same day.</p> <p>3. The labelling of food supplements</p>	
	Unflavoured pasteurised and sterilised (including UHT) milk-based products	1.2 g/l		
	Unflavoured fermented milk-based products	1.2 g/l beverages		
		19.2 g/kg products other than beverages		
	Flavoured fermented milk-based products including heat-treated products	1.2 g/l beverages		
19.2 g/kg products other than beverages				

Dairy analogues, including beverage whiteners	1.2 g/l beverages
	12 g/kg for products other than beverages
	400 g/kg for whitener
Cereal bars	12 g/kg
Table-top sweeteners	200 g/kg
Infant formula as defined in Regulation (EU) No 609/2013	1.2 g/l alone or in combination with 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
Follow-on formula as defined in Regulation (EU) No 609/2013	1.2 g/l alone or in combination with 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
Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013	12 g/kg for products other than beverages
	1.2 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	1.2 g/l for milk-based drinks and similar products added

containing 2'-O-fucosyllactose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added 2'-O-fucosyllactose are consumed the same day.

children	alone or in combination with lacto- <i>N</i> -neotetraose, at concentrations 0.6 g/l, 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 well as mixes and instant	9.6 g/l - the maximum level refers to the products ready to use		

	mixes of these products			
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	3.0 g/day for general population 1.2 g/day for young children		
<b>Galacto-oligosaccharide (GOS)</b>	<b>Specified food category</b>	<b>Maximum levels</b>		
	General foodstuffs as well as infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	At the same levels as the comparator on the EU market before 15 May 1997		
<b>Glucosamine HCl from <i>Aspergillus niger</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of glucosamine from shell fish		
	Foods covered by Regulation (EU) No 609/2013			
	Milk-based drinks and similar products intended for young children			
	Meal replacement for weight control			
	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			
<b>Glucosamine sulphate KCl from <i>Aspergillus niger</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of glucosamine from shell fish		
<b>Glucosamine sulphate NaCl from <i>Aspergillus niger</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>		
	Food Supplements as defined in Directive 2002/46/EC	In line with normal food use of glucosamine from shell fish		
<b>Guar Gum</b>	<b>Specified food category</b>	<b>Maximum levels</b>	<ol style="list-style-type: none"> <li>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "Guar Gum".</li> <li>2. A specific mention of the possible risks of digestive discomfort linked to the exposure of children aged under 8 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’.</li> <li>3. 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</li> </ol>	
	Fresh dairy products such as yogurts, fermented milks, fresh cheeses and other dairy-based desserts.	1.5 g/100 g		
	Fruit or vegetable-based liquid foodstuffs (of the "smoothie" variety)	1.8 g/100 g		
	Fruit or vegetable-based compotes	3.25 g/100 g		
	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		

			the dairy product before consumption, in order to take into account the potential risk of gastro-intestinal obstruction.	
<b>Heat-treated milk products fermented with <i>Bacteroides xylanisolvens</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>		
	Fermented milk products (in liquid, semi-liquid and spray-dried powder forms)			
<b>Ice Structuring Protein type III HPLC 12</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Ice Structuring Protein"	
	Edible ices	0.01%		
<b>Isomalto-oligosaccharide</b>	<b>Specified food category</b>	<b>Maximum levels</b>	<ol style="list-style-type: none"> <li>The designation of the novel food on the labelling of the foodstuffs containing it shall be "Isomaltooligosaccharide".</li> <li>Foods containing the novel ingredient must be labelled as "a source of glucose".</li> </ol>	
	Energy-Reduced Soft Drinks	6.5%		
	Energy Drinks	5.0%		
	Foods intended to meet the expenditure of intense muscular efforts, especially for sportsmen (including isotonic drinks)	6.5%		
	Fruit Juices	5%		
	Processed Vegetables and Vegetable Juices	5%		
	Other Soft Drinks	5%		
	Cereals Bars	10%		
	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%		
<b>Isomaltulose</b>	Not specified		<ol style="list-style-type: none"> <li>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "Isomaltulose".</li> <li>2. The designation of the novel food on the labelling shall be accompanied by indication that the "Isomaltulose is a source of glucose and fructose".</li> </ol>	
	<b>Specified food category</b>	<b>Maximum levels</b>		
<b>Lactitol</b>	Food Supplements as defined in Directive 2002/46/EC (capsules or tablets) intended for the adult population	20 g/day	The designation of the novel food on the labelling of the food supplements containing it shall be "Lactitol"	
	<b>Specified food category</b>	<b>Maximum levels</b>		
<b>Lacto-N-neotetraose</b>	Unflavoured pasteurised and sterilised (including UHT) milk-based products	0.6 g/l	<ol style="list-style-type: none"> <li>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "Lacto-N-neotetraose".</li> <li>2. The labelling of food supplements containing lacto-N-neotetraose shall bear a statement that the supplements should not be used if other foods with added lacto-N-neotetraose are consumed the same day.</li> <li>3. The labelling of food supplements containing lacto-N-neotetraose intended for young children shall bear a statement that the supplements</li> </ol>	
	Unflavoured fermented milk-based products	0.6 g/l for beverages 9.6 g/kg for products other than beverages		
	Flavoured fermented milk-based products including heat-treated products	0.6 g/l for beverages 9.6 g/kg for products other than beverages		
	Dairy analogues, including beverage whiteners	0.6 g/l for beverages 6 g/kg for products other than beverages		



	200 g/kg for whitener	should not be used if breast milk or other foods with added lacto-N-neotetraose are consumed the same day.
Cereal bars	6 g/kg	
Table-top sweeteners	100 g/kg	
Infant formula as defined in Regulation (EU) No 609/2013	0.6 g/l in combination with 1.2 g/l of 2'- <i>O</i> -fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer	
Follow-on formula as defined in Regulation (EU) No 609/2013	0.6 g/l in combination with 1.2 g/l of 2'- <i>O</i> -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'- <i>O</i> -fucosyllactose, at concentrations 1.2 g/l, 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 as defined in Regulation (UE) No 609/2013	2.4 g/l for drinks 20 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	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		
<b>Lucerne leaf extract from <i>Medicago sativa</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Lucerne ( <i>Medicago sativa</i> ) protein" or "Alfalfa ( <i>Medicago sativa</i> ) protein".	
	Food supplements as defined in Directive 2002/46/EC	10 g/day		
<b>Lycopene</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Lycopene"	
	Fruit/vegetable juice-based drinks (including concentrates)	2.5 mg/100 g		
	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/100g		
	Soups other than tomato soups	1 mg/100g		
	Bread (including crispy breads)	3 mg/100g		
	Foods for special medical	In accordance with the		

	purposes as defined in Regulation (EU) No 609/2013	particular nutritional requirements of the persons for whom the products are intended	
	Food supplements as defined in Directive 2002/46/EC	15 mg/day	
<b>Lycopene from <i>Blakeslea trispora</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Lycopene"
	Fruit/vegetable juice-based drinks (including concentrates)	2.5 mg/100 g	
	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/100g	
	Soups other than tomato soups	1 mg/100g	
	Bread (including crispy breads)	3 mg/100g	
	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		
<b>Lycopene from tomatoes</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Lycopene"	
	Fruit/vegetable juice-based drinks (including concentrates)	2.5 mg/100 g		
	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/100g		
	Soups other than tomato soups	1 mg/100g		
	Bread (including crispy breads)	3 mg/100g		
	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	15 mg per/day		

	in Directive 2002/46/EC			
<b>Lycopene oleoresin from tomatoes</b>	<b>Specified food category</b>	<b>Maximum levels of lycopene</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Lycopene oleoresin from tomatoes"	
	Fruit/vegetable juice-based drinks (including concentrates)	2.5 mg/100 g		
	Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen	2.5 mg/100 g		
	Total diet replacement for weight control covered by 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/100g		
	Soups other than tomato soups	1 mg/100g		
	Bread (including crispy breads)	3 mg/100g		
	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		
<b>Magnesium citrate malate</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Magnesium citrate malate"	
	Food Supplements as defined in Directive 2002/46/EC	375 mg per/day		

<b>Magnolia Bark Extract</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Magnolia Bark Extract"	
	Mints (confectionary products)	0.2% for breath freshening purposes. Based on a 0.2% maximum incorporation level and a maximum gum/mint size of 1.5g each, each gum or mint serving will contain no more than 3 mg of magnolia bark extract.		
<b>Maize-germ oil high in unsaponifiable matter</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Maize-germ oil high in unsaponifiable matter"	
	Food Supplements as defined in Directive 2002/46/EC	2 g/day		
	Chewing gum	2%		
<b>Methylcellulose</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Methylcellulose"	Methylcellulose is not to be used in foods specially prepared for young children
	Edible ices	2%		
	Flavoured drinks			
	Flavoured or unflavoured fermented milk products			
	Cold desserts (dairy, fat, fruit, cereal, egg-based products)			
	Fruit preparations (pulp, purees or compotes)			
Soups and broths				
<b>(6S)-5-methyltetrahydrofolic acid, glucosamine</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "(6S)-5-methyltetrahydrofolic acid, glucosamine salt" or "5MTHF-	

salt			glucosamine"	
	Food Supplements as defined in Directive 2002/46/EC as a source of folate			
Monomethylsilanetriol (Organic Silicon)	<b>Specified food category</b>	<b>Maximum levels of silicon</b>	The designation of the novel food on the labelling of the food supplements containing it shall be "Organic silicon (monomethylsilanetriol)"	
	Food Supplements as defined in Directive 2002/46/EC (in liquid form)	10.40 mg/day for adult population		
Mycelial extract from Shiitake mushroom ( <i>Lentinula edodes</i> )	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "extract from the mushroom <i>Lentinula edodes</i> " or "extract from Shiitake mushroom"	
	Bread products	2 ml/100 g		
	Soft drinks	0.5 ml/100 ml		
	Ready prepared meals	2.5 ml per meal		
	Foods based on yoghurt	1.5 ml/100 ml		
	Food supplements as defined in Directive 2002/46/EC	2.5 ml per day dose		
Noni fruit juice ( <i>Morinda citrifolia</i> )	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Noni juice" or "Juice of <i>Morinda citrifolia</i> "	
	Pasteurised fruit juice and fruit nectar drinks	30 ml with one serving (up to 100 % noni juice) or 20 ml twice a day, not more than 40 ml per day		
Noni fruit juice powder ( <i>Morinda citrifolia</i> )	Food supplements as defined in Directive 2002/46/EC	6.6 g/day (equivalent to 30 ml of noni juice)	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Noni juice powder" or "Juice powder of <i>Morinda citrifolia</i> "	
Noni fruit puree and concentrate	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it	
		<b>Fruit puree</b>		



<i>(Morinda citrifolia)</i>	Candy/confectionery	45 g/100 g	shall be: For fruit puree: " <i>Morinda citrifolia</i> fruit puree" or "Noni fruit puree" For fruit concentrate: " <i>Morinda citrifolia</i> fruit concentrate" or "Noni fruit concentrate"
	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	
		<b>Fruit concentrate</b>	
	Candy/Confectionery	10 g/100 g	
	Cereal bars	12 g/100 g	
Powdered nutritional drink mixes (dry weight)	12 g/100 g		

	Carbonated beverages	3 g/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/100g		
	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		
<b>Noni leaves</b> <i>(Morinda citrifolia)</i>	<b>Specified food category</b>	<b>Maximum levels</b>	<ol style="list-style-type: none"> <li>The designation of the novel food on the labelling of the foodstuffs containing it shall be "Noni leaves" or "leaves of <i>Morinda citrifolia</i>".</li> <li>Instructions shall be given to the consumer that a cup of infusion should not be prepared with more than 1 g of dried and roasted leaves of <i>Morinda citrifolia</i>.</li> </ol>	
	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 <i>Morinda citrifolia</i>		
<b>Noni fruit powder</b> <i>(Morinda citrifolia)</i>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Morinda citrifolia fruit powder" or "Noni fruit powder"	
	Food Supplements as defined in Directive 2002/46/EC	2.4 g per/day		

<b><i>Odontella aurita</i> microalgae</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be " <i>Odontella aurita</i> microalgae"	
	Flavoured pasta	1.5%		
	Fish soups	1%		
	Marine terrines	0.5%		
	Broth preparations	1%		
	Crackers	1.5%		
	Frozen breaded fish	1.5%		
<b>Oil enriched with phytosterols/phytostanols</b>	<b>Specified food category</b>	<b>Maximum levels of phytosterols/phytostanols</b>	In accordance with Annex III.5 to Regulation (EU) No 1169/2011	
	<p>Spreadable fats as defined in Council Regulation (EC) No 2991/94 Annex, points B and C, excluding cooking and frying fats and spreads based on butter or other animal fat</p> <p>Milk based products, such as products based on semi-skimmed 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 <math>\leq</math> 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</p>	<p>1. The products containing the 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.</p> <p>2. The amount of phytosterols/phytostanols added to a container of beverages shall not exceed 3 g.</p> <p>3. Spicy sauces and salad dressings including</p>		

	vegetable fat or protein.	mayonnaise shall be packed as single portions.		
	Soya drinks			
	Spicy sauces and salad dressings including mayonnaise.			
<b>Oil extracted from squid (<i>Cephalopod</i> sp.)</b>	<b>Specified food category</b>	<b>Maximum levels of DHA and EPA combined</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Squid oil".	
	Dairy products except milk-based beverages	200 mg/100 g or for cheese products 600mg/100g		
	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	3000 mg/day for general population 450 mg/day for pregnant and lactating women		
	Foods for special medical purposes as defined in	In accordance with the particular nutritional		

	Regulation (EU) No 609/2013	requirements of the persons for whom the products intended		
	Total diet replacement for weight control defined in Regulation (EU) No 609/2013 and meal replacements for weight control	200 mg/meal		
<b>Pasteurised fruit-based preparations produced using high-pressure pasteurisation</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The wording "pasteurised by high-pressure treatment" shall be displayed next to the fruit preparations in question as such and in any product in which it is used"	
	Types of fruit: apple, apricot, banana, blackberry, blueberry, cherry, coconut, fig, grape, grapefruit, mandarine, mango, melon, peach, pear, pineapple, prune, raspberry, rhubarb, strawberry			
<b>Phosphated maize starch</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Phosphated maize starch"	
	Baked bakery products	15%		
	Pasta			
	Breakfast cereals			
Cereal bars				
<b>Phosphatidylserine from fish phospholipids</b>	<b>Specified food category</b>	<b>Maximum levels of phosphatidylserine</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be accompanied by indication that the novel food is "derived from fish lecithin"	
	Beverages based on yoghurt	50 mg/100mL		
	Powders based on milk powders	3500 mg/100g (equivalent to 40mg/100mL ready to drink)		
	Foods based on yoghurt	80 mg/100g		
	Cereal bars	350 mg/100g		

	Chocolate based confectionary	200 mg/100g		
	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		
<b>Phosphatidylserine from soya phospholipids</b>	<b>Specified food category</b>	<b>Maximum levels of phosphatidylserine</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Soya phosphatidylserine"	
	Beverages based on yoghurt	50 mg/100 ml		
	Powders based on milk powder	3.5 g/100 g (equivalent to 40 mg/100 ml ready to drink)		
	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		
<b>Phospholipids product containing phosphatidylserine and phosphatidic acid</b>	<b>Specified food category</b>	<b>Maximum levels of phosphatidylserine + phosphatidic acid</b>	The designation of the novel food on the labelling of the foodstuffs containing shall be "Soy phosphatidylserine and phosphatidic acid"	The product is not intended to be marketed to pregnant or breast-feeding women
	Breakfast cereals	80 mg + 80 mg/100 g		
	Cereal bars	350 mg + 350 mg/100 g		
	Foods based on yogurt	80 mg + 80 mg/100 g		
	Soy-based yogurt-like products	80 mg + 80 mg/100 g		
	Yogurt based-drinks	50 mg + 50 mg/100 g		

	Soy-based yogurt-like drinks	50 mg + 50 mg/100 g		
	Powders based on milk powder	3.5 g + 3.5 g/100g (equivalent to 40 mg + 40 mg/100ml ready-to drink)		
	Food Supplements as defined in Directive 2002/46/EC	800 mg/day		
	Foods for special medical purposes as defined in Regulation (EU) No 609/2013	In compliance with Regulation (EU) No 609/2013		
<b>Phospholipides from egg yolk</b>	<b>Specified food category</b>	<b>Maximum levels</b>		
	Not specified			
<b>Phytosterols/phytostanols</b>	<b>Specified food category</b>	<b>Maximum levels</b>	In accordance with Annex III.5 of Regulation (EU) No 1169/2011	
	Rice drinks	1. They 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 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 and spicy sauces shall be packed as		
	Rye bread with flour containing $\geq 50\%$ rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) and $\leq 30\%$ wheat; and with $\leq 4\%$ added sugar but no fat added.			
	Spicy sauces			
	Soya drink			
Milk type products, such as semi-skimmed 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.	single portions		
	Products based on fermented milk, such as yoghurt and cheese type products (fat content $\leq 12$ g 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.			
	Yellow fat spreads as defined by Council Regulation (EC) No 2991/94(1), excluding cooking and frying fats and spreads based on butter or other animal fat.			
<b>Plum kernel oil</b>	<b>Specified food category</b>	<b>Maximum levels</b>		
	For frying and as seasoning	In line with normal food use of vegetable oils		
<b>Potato proteins (coagulated) and hydrolysates</b>	Not specified		The designation of the novel food on the labelling of the foodstuffs containing it shall be "Potato protein"	
<b>Prolyl oligopeptidase (Enzyme)</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Prolyl oligopeptidase"	
	Food Supplements as defined in Directive 2002/46/EC	120 PPU/day (2.7 g of enzyme preparation/day) $(2 \times 10^6)$		



<b>preparation)</b>		PPI/day) for general adult population PPU – Prolyl Peptidase Units or Proline Protease Units PPI – Protease Picomole International		
<b>Protein extract from pig kidneys</b>	<b>Specified food category</b>	<b>Maximum levels</b>		
	Food Supplements as defined in Directive 2002/46/EC Food for special medical purposes as defined in Regulation (EU) No 609/2013	3 capsules/day; equalizing 12.6 mg pig kidney extract a day		
<b>Rapeseed oil high in unsaponifiable matter</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Rapeseed oil extract"	
	Food Supplements as defined in Directive 2002/46/EC	1.5 g per portion recommended for daily consumption		
<b>Rapeseed Protein</b>	As a vegetable protein source in foods except in infant formula and follow-on formula		<ol style="list-style-type: none"> <li>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "Rapeseed protein".</li> <li>2. Any foodstuff containing "rapeseed protein" shall bear a statement that this ingredient may cause allergic reaction to consumers who are allergic to mustard and products thereof. Where relevant, this statement shall appear in close proximity to the list of ingredients.</li> </ol>	
<b>Trans-resveratrol</b>	<b>Specified food category</b>	<b>Maximum levels</b>	1. The designation of the novel food on	

	Food Supplements as defined in Directive 2002/46/EC (capsule or tablet form)	150 mg/day for adult population	<p>the labelling of the food supplements containing it shall be "<i>Trans-resveratrol</i>".</p> <p>2. The labelling of food supplements containing trans-resveratrol shall bear a statement that people using medicines should only consume the product under medical supervision.</p>	
<b>Trans-resveratrol (microbial source)</b>	<b>Specified food category</b>	<b>Maximum levels</b>	<p>1. The designation of the novel food on the labelling of the food supplements containing it shall be "<i>Trans-resveratrol</i>".</p> <p>2. The labelling of food supplements containing trans-resveratrol shall bear a statement that people using medicines should only consume the product under medical supervision.</p>	
	Food supplements as defined in Directive 2002/46/EC	At comparable inclusion levels to resveratrol extracted from Japanese knotweed ( <i>Fallopia japonica</i> )		
<b>Rooster comb extract</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Rooster comb extract" or "Cockerel comb extract"	
	Milk-based drinks	40 mg/100g or mg/100mL		
	Milk based fermented drinks	80 mg/100g or mg/100mL		
	Yoghurt-type products	65 mg/100g or mg/100mL		
	<i>Fromage frais</i>	110 mg/100g or mg/100mL		
<b>Sacha Inchi oil from <i>Plukenetia volubilis</i></b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Sacha inchi oil ( <i>Plukenetia volubilis</i> )"	
	As for linseed oil	In line with normal food use of linseed oil		
<b>Salatrim</b>	<b>Specified food category</b>	<b>Maximum levels</b>	1. The designation of the novel food on	

	Bakery products and confectionary		<p>the labelling of the foodstuffs containing it shall be "reduced energy fat (salatrim)".</p> <ol style="list-style-type: none"> <li>There shall be a statement that excessive consumption may lead to gastro-intestinal disturbance.</li> <li>There shall be a statement that the products are not intended for use by children.</li> </ol>	
<b><i>Schizochytrium sp.</i></b> <b>oil rich in DHA and EPA</b>	<b>Specified food category</b>	<b>Maximum levels of DHA and EPA combined:</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "DHA and EPA-rich oil from the microalgae <i>Schizochytrium sp.</i> "	All food products containing DHA-rich oil from <i>Schizochytrium sp.</i> should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC)
	Food Supplements as defined in Directive 2002/46/EC	3000 mg/day for adult population excluding pregnant and lactating women		
		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 for infants and young children as defined in	200 mg/100 g			

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			
Bakery Products, Breads and Rolls, Sweet Biscuits	200 mg/100 g		
Breakfast Cereals	500 mg/100 g		
Cooking Fats	360 mg/100 g		
Dairy Analogues except drinks	600 mg/100 g for cheese; 200 mg/100 g for soy and imitation milk products (excluding drinks)		
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)		
Non-alcoholic Beverages (including dairy analogue and	80 mg/100 g		

	milk-based drinks)			
	Cereal/Nutrition Bars	500 mg/100 g		
	Spreadable Fats and Dressings	600 mg/100 g		
<b><i>Schizochytrium</i> sp. (ATCC PTA-9695) oil</b>	<b>Specified food category</b>	<b>Maximum levels of DHA</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Oil from the micro-algae <i>Schizochytrium</i> sp. (ATCC PTA-9695)"	
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g		
	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		
	Food Supplements as defined in Directive 2002/46/EC	250 mg DHA/day for general population		
		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 In accordance with the particular nutritional requirements of the persons for whom the products are intended		
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		
	Bakery products (breads and rolls), sweet biscuits	200 mg/100 g 500 mg/100 g	
	Cooking fats	360 mg/100 g 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	
<b>Schizochytrium sp. oil</b>	<b>Specified food category</b>	<b>Maximum levels of DHA</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Oil from the microalgae Schizochytrium sp."
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g	
	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	
	Foods for special medical	In accordance with the	

purposes as defined in Regulation (EU) No 609/2013	particular nutritional requirements of the persons for whom the products are intended	
Bakery products (breads and bread rolls), sweet biscuits	200 mg/100 g	
Cereal bars	500 mg/100 g	
Food Supplements as defined in Directive 2002/46/EC	250 mg DHA/day for general population 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	
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	200 mg/100 g	
Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission		

	Implementing Regulation (EU) No 828/2014-			
	Cooking fats	360 mg/100 g		
	Non-alcoholic beverages (including dairy analogue and milk-based drinks)	80 mg/100 ml		
<b>Fermented soybean extract</b>	<b>Specified food category</b>	<b>Maximum levels</b>	<ol style="list-style-type: none"> <li>The designation of the novel food on the labelling of the foodstuffs containing it shall be "Fermented soybean extract".</li> <li>The labelling of food supplements containing fermented soybean extract shall bear a statement that persons taking medication should only consume the product under medical supervision.</li> </ol>	
	Food Supplements as defined in Directive 2002/46/EC (capsules, tablets or powder form) intended for the adult population, excluding pregnant and lactating women	100 mg/day		
<b>Sucromalt</b>	<b>Specified food category</b>	<b>Maximum levels</b>	<ol style="list-style-type: none"> <li>The designation of the novel food on the labelling of the foodstuffs containing it shall be "Sucromalt".</li> <li>The designation of the novel food on the labelling shall be accompanied by indication that the product is a source of glucose and fructose.</li> </ol>	
	Not specified			
<b>Sugar cane fibre</b>	<b>Specified food category</b>	<b>Maximum levels</b>		
	Bread	8 %		
	Bakery goods	5 %		
	Meat and muscle products	3 %		
	Seasonings and spices	3 %		



	Grated cheeses	2 %		
	Special diet foods	5 %		
	Sauces	2 %		
	Beverages	5 %		
<b>Sunflower oil extract</b>	<b>Specified food category</b>	<b>Maximum levels</b>		
	Food Supplements as defined in Directive 2002/46/EC	1.1 g/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Sunflower oil extract"	
<b>Dried <i>Tetraselmis chuii</i> microalgae</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Dried microalgae <i>Tetraselmis chuii</i> " or "Dried microalgae <i>T. chuii</i> "	
	Sauces	20% or 250mg/day		
	Special salts	1%		
	Condiment	250 mg/day		
<b><i>Therapon barcool</i> / Scortum</b>	Intended use identical to that of the salmon, namely the preparation of culinary fish products and dishes, including cooked, raw, smoked and baked fish products			
<b>D-Tagatose</b>	<b>Specified food category</b>	<b>Maximum levels</b>	1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "D-Tagatose". 2. The labelling of any product where the level of D-Tagatose exceeds 15 g per serving and all beverages containing greater than 1% D-Tagatose (as consumed) shall bear a statement "excessive consumption may produce laxative effects".	
	Not specified			
<b>Taxifolin-rich</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the	

<b>extract</b>	Food Supplements as defined in Directive 2002/46/EC intended for the general population, excluding infants, young children, children and adolescents younger than 14 years	100 mg/day	labelling of the foodstuffs containing it shall be "taxifolin-rich extract".	
<b>Trehalose</b>	<b>Specified food category</b>	<b>Maximum levels</b>	<ol style="list-style-type: none"> <li>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "Trehalose" and shall be displayed on the labelling of the product as such or in the list of ingredients of foodstuffs containing it.</li> <li>2. The designation of the novel food on the labelling shall be accompanied by indication that the "Trehalose is a source of glucose".</li> </ol>	
	Not specified			
<b>UV-treated mushrooms with increased levels of Vitamin D<sub>2</sub></b>	<ol style="list-style-type: none"> <li>1. The EU market approval applies to commercially grown <i>Agaricus bisporus</i></li> <li>2. UV light treatment is applied to harvested mushrooms yielding a Vitamin D content of <math>\leq 10 \mu\text{g}/100\text{g}</math> fresh weight</li> </ol>		<ol style="list-style-type: none"> <li>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "UV-treated mushrooms (<i>Agaricus bisporus</i>) with increased levels of Vitamin D<sub>2</sub>".</li> <li>2. The designation of the novel food on the labelling 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 vitamin D<sub>2</sub> levels".</li> </ol>	
<b>UV-treated baker's</b>	<b>Specified food category</b>	<b>Maximum levels of vitamin</b>	The designation of the novel food on the	

yeast ( <i>Saccharomyces cerevisiae</i> )		<b>D2</b>	labelling of the foodstuffs containing it shall be "Vitamin D yeast" or "Vitamin D <sub>2</sub> yeast"
	Yeast-leavened breads and rolls	5 µg of vitamin D <sub>2</sub> /100 g	
	Yeast-leavened fine bakery wares	5 µg of vitamin D <sub>2</sub> /100 g	
	Food Supplements as defined in Directive 2002/46/EC	5 µg of vitamin D <sub>2</sub> /day	
<b>UV-treated bread</b>	<b>Specified food category</b>	<b>Maximum levels of vitamin D2</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be accompanied by "contains vitamin D produced by UV-treatment"
	Yeast leavened bread and rolls (without toppings)	3 µg vitamin D <sub>2</sub> /100 g	
<b>UV-treated milk</b>	<b>Specified food category</b>	<b>Maximum levels of vitamin D2</b>	<ol style="list-style-type: none"> <li>1. The designation of the novel food on the labelling of the foodstuffs containing it shall be "UV-treated".</li> <li>2. Where UV-treated milk contains an amount of vitamin D that is considered significant in accordance with Point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council, the designation for the labelling shall be accompanied by "contains vitamin D produced by UV-treatment" or "milk containing vitamin D resulting from UV-treatment".</li> </ol>
	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	
	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	
<b>Vitamin K<sub>2</sub> (menaquinone)</b>	To be used in compliance with Directive 2002/46/EC, Regulation (EU) No 609/2013 and/or Regulation (EC) No 1925/2006		The designation of the novel food on the labelling of the foodstuffs containing it shall be "Menaquinone" or "Vitamin K" or "vitamin K <sub>2</sub> "

<b>Wheat bran extract</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Wheat bran extract"	The "Wheat Bran Extract" may not be introduced onto the market as a food supplement or food supplement ingredient. Nor may it be added to infant formula.
	Beer and substitutes	0.4 g/100g		
	Ready to eat cereals	9 g/100g		
	Dairy products	2.4 g/100g		
	Fruit and vegetable juices	0.6 g/100g		
	Soft drinks	0.6 g/100g		
	Meat preparations	2 g/100g		
<b>Yeast beta-glucans</b>	<b>Specified food category</b>	<b>Maximum levels of pure beta-glucans from yeast (<i>Saccharomyces cerevisiae</i>)</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Yeast ( <i>Saccharomyces cerevisiae</i> ) beta-glucans"	
	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 and	1.3 g/kg		

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)		
	0.7 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		

<b>Zeaxanthin (synthetic)</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "synthetic zeaxanthin"
	Food Supplements as defined in Directive 2002/46/EC	2 mg/day	
<b>Zinc L-pidolate</b>	<b>Specified food category</b>	<b>Maximum levels</b>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Zinc L-pidolate"
	Foods covered by Regulation (EU) No 609/2013	3g/day	
	Milk based drinks and similar products intended for young children		
	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		

**Table 2: Specifications**

Authorised Novel Food	Specification
<p><b>Baobab (<i>Adansonia digitata</i>) dried fruit pulp</b></p>	<p><b>Description/Definition:</b> The Baobab (<i>Adansonia digitata</i>) 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 µ) and then packaged.</p> <p><b>Typical nutritional components:</b> 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</p> <p><b>Analytical specifications:</b> 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</p>
<p><b><i>Ajuga reptans</i> extract</b></p>	<p><b>Description/Definition:</b> Extracts from <i>Ajuga reptans</i> L. tissue cultures are substantial equivalent to extracts from flowering aerial parts of <i>Ajuga reptans</i> obtained by traditional cultures.</p>
<p><b>L-Alanyl-L-Glutamine</b></p>	<p><b>Description/Definition:</b> L-Alanyl-L-Glutamine is produced by bacterial fermentation which is purified from the growth media to a purity of greater than 98%. The ingredient is secreted by a modified strain of <i>Escherichia coli</i> and isolated from the fermentation broth by conventional techniques without disruption.</p> <p>Appearance: White crystalline powder Purity: &gt; 98% Infrared spectroscopy: Conformity with ref. standard State of solution: Colourless and clear Assay (dry basis): 98.0-102.0%b</p>

	<p>Related substances: ≤ 0.2%</p> <p>Residue on ignition: ≤ 0.10%</p> <p>Loss on drying: ≤ 0.5%</p> <p>Optical rotation: +9.0 - +11.0°</p> <p>pH (1%; H<sub>2</sub>O): 5.0 - 6.0</p> <p>Ammonium (NH<sub>4</sub>): ≤ 0.020%</p> <p>Chloride (Cl): ≤ 0.020%</p> <p>Sulphate (SO<sub>4</sub>): ≤ 0.020% <i>Escherichia coli</i> : Negative/g</p>
<p><b>Algal oil from the microalgae</b> <i>Ulkenia sp.</i></p>	<p><b>Description/Definition:</b> Oil from the micro-algae <i>Ulkenia sp.</i> 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 % DHA content: ≥ 32.0 %</p>
<p><i>Allanblackia seed oil</i></p>	<p><b>Description/Definition:</b> <i>Allanblackia</i> seed oil is obtained from the seeds of the allanblackia species: <i>A. floribunda</i> (synonymous with <i>A. parviflora</i>) and <i>A. stuhlmannii</i>.</p> <p><b>Composition of fatty acids:</b> Lauric acid (C12:0): &lt; 1% Myristic acid (C14:0): &lt; 1% Palmitic acid (C16:0): &lt; 2% Palmitoleic acid (C16:1): &lt; 1% Stearic acid (C18:0): 45-58% Oleic acid (C18:1): 40-51% Linoleic acid (C18:2): &lt; 1% γ-Linolenic acid (C18:3): &lt; 1% Arachidic acid (C20:0): &lt; 1% Free fatty acids: max 0.1%</p>



	<p><b>Characteristics:</b>  Trans fatty acids: max 0.5%  Peroxide value: max 0.8 meq/kg  Iodine value: &lt; 46 g/100 g  Unsaponifiable matter: max 1.0%  Saponification value: 185-198 mg KOH/g</p>
<b><i>Aloe macroclada</i> Baker leaf extract</b>	<p>Ash: 25%  Dietary fibres: 28.6%  Fat: 2.7%  Moisture: 4.7%  Polysaccharides: 9.5%  Protein: 1.63%  Glucose: 8.9%</p>
<b>Antartic Krill (<i>Euphasia superba</i>) oil</b>	<p><b>Description/Definition:</b>  To produce lipid extract from Antarctic Krill (<i>Euphasia superba</i>) 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.</p> <p>Saponification value: ≤ 230 mg KOH/g  Peroxide value (PV): ≤ 3 meq O<sub>2</sub> /kg oil  Moisture and volatiles: ≤ 3%  Phospholipids: ≤ 50%  Trans-fatty acids: ≤ 1%  EPA (eicosapentaenoic acid): ≥ 9%  DHA (docosahexaenoic acid): ≥ 5%</p>
<b>Antartic Krill (<i>Euphasia superba</i>) oil rich in phospholipids</b>	<p><b>Description/Definition:</b>  Oil rich in phospholipids is produced from Antarctic krill (<i>Euphasia superba</i>) by repeated solvent washings with an approved solvents (under Directive 2009/32/EC) to increase phospholipid content of the oil. Solvents are removed from the final product by evaporation.</p> <p>Saponification value: ≤ 230 mg KOH/g  Peroxide value (PV): ≤ 3 meq O<sub>2</sub> /kg oil  Moisture and volatiles: ≤ 3%</p>

	Phospholipids: $\geq 60\%$ Trans-fatty acids: $\leq 1\%$ EPA (eicosapentaenoic acid): $\geq 9\%$ DHA (docosahexaenoic acid): $\geq 5\%$
<b>Arachidonic acid-rich oil from the fungus <i>Mortierella alpina</i></b>	<p><b>Description/Definition:</b>          The clear yellow arachidonic acid-rich oil is obtained by fermentation of the fungus <i>Mortierella alpina</i> using a suitable liquid. The oil is then extracted from the biomass and purified.</p> <p>Arachidonic acid: <math>&gt; 40\%</math> by weight of the total fatty acid content          Free fatty acids: <math>\leq 0.45\%</math> of the total fatty acid content          Trans fatty acids: <math>\leq 0.5\%</math> of the total fatty acid content          Unsaponifiable matter: <math>\leq 1.5\%</math>          Peroxide value: <math>\leq 5</math> meq/kg          Anisidin value: <math>\leq 20</math>          Acid value: <math>\leq 1.0</math> KOH/g</p>
<b>Argan oil (<i>Argania spinosa</i>)</b>	<p><b>Description/Definition:</b>          Argan oil is the oil obtained by cold pressing of the almond like kernels of the fruits of <i>Argania spinosa</i> (L.) Skeels. Kernels may be roasted prior to pressing, but with no direct contact with a flame.</p> <p><b>Composition:</b>          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: 130-230 mg/100 g          Total tocopherols: 16-90 mg/100g          Oleic acidity: 0.2-1.5%          Peroxide value: <math>&lt;10</math> meq O<sub>2</sub>/kg</p>
<b>Astaxanthin (from <i>Haematococcus pluvialis</i> algae)</b>	<p><b>Description/Definition:</b>          Astaxanthin is a carotenoid produced by <i>Haematococcus pluvialis</i> algae. Production methods for the growth of the algae are variable; using closed systems exposed to sunlight or strictly controlled illuminated light alternatively open ponds may be used. The algal cells are</p>

	<p>harvested and dried; the oleoresin is extracted using either super critical CO2 or a solvent, ethyl acetate. The Astaxanthin is diluted and standardized to 2.5%, 5%, 7%, 10%, 15% or 20% using olive oil, safflower oil, Sunflower oil or MCT (Medium Chain Triglycerides).</p> <p><b>Composition of the Oleoresin:</b>  Fat 42.2- 99%  Protein 0.3-4.4%  Carbohydrate 0-52.8%  Fibre &lt;1%  Ash 0-4.2%  Specification of Carotenoids w/w%  Total Astaxanthins: 2.9-11.1%  9-Z astaxanthin: 0.3-9.0  13-Z astaxanthin: 0.2-5.7  Astaxanthin monoesters: 79.8-91.5%  Astaxanthin diesters: 0.16-4.0%  B-Carotene: 0.01-0.3%  Lutein: 0-1.8%  Canthaxanthin: 0-1.30%</p> <p><b>Microbiological criteria:</b>  Total aerobic bacteria: &lt;3000 CFU/g  Yeast and Moulds: &lt;100 CFU/g  Coliforms: &lt;10 CFU/g  <i>E. coli</i>: Negative  <i>Salmonella</i>: Negative  <i>Staphylococcus</i>: Negative</p>
<p><b>Basil seed (<i>Ocimum basilicum</i>)</b></p>	<p><b>Description/Definition:</b>  Basil (<i>Ocimum basilicum</i> L.) belongs to the family "<i>Lamiaceae</i>" within the order "Lamiales". Post-harvest the seeds are cleaned mechanically. 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 juices and fruit juice blends containing Basil seeds (<i>Ocimum basilicum</i> L.) includes seed pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place. During production, pasteurization steps and microbiological analyses of samples of basil seeds, the fruit juice and the final product shall ensure highest level</p>

	<p>of confidence in the safety of the production process and the final product.</p> <p>Dry Matter: 94.1%</p> <p>Protein: 20.7%</p> <p>Fat: 24.4%</p> <p>Carbohydrate: 1.7%</p> <p>Crude Fibre*: 40.5% Dietary Fibre**</p> <p>(* ) Crude fibre is the part of dietary fibre mainly consisting of indigestible cellulose, pentosans and lignin</p> <p>(**) Method: AOAC 958.29</p> <p>Ash: 6.78%</p>
<b>Fermented black bean extract</b>	<p><b>Description/Definition:</b></p> <p>Fermented black bean extract (Touchi extract) is a fine light-brown protein-rich powder obtained by water extraction of small soybeans (<i>Glycine max (L.) Merr.</i>) fermented with <i>Aspergillus oryzae</i>. The extract contains an <math>\alpha</math>-glucosidase inhibitor.</p> <p><b>Characteristics:</b></p> <p>Fat: <math>\leq 1\%</math></p> <p>Protein: <math>\geq 55\%</math></p> <p>Water: <math>\leq 7\%</math></p> <p>Ash: <math>\leq 10\%</math></p> <p>Carbohydrate: <math>\geq 20\%</math></p> <p><math>\alpha</math>-glucosidase inhibitory activity: IC50 min 0.025 mg/ml</p> <p>Soy isoflavone: <math>\leq 0.3</math> g/100 g</p>
<b>Bovine lactoferrin</b>	<p><b>Description/Definition:</b></p> <p>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.</p> <p>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.</p> <p><b>Physical-Chemical properties of Bovine lactoferrin:</b></p> <p>Moisture: <math>&lt; 4.5\%</math></p> <p>Ash: <math>&lt; 1.5\%</math></p> <p>Arsenic: <math>&lt; 2</math> mg/kg</p>

	<p>Iron: &lt; 350 mg/kg  Protein: &gt; 93%  of which bovine lactoferrin: &gt; 90%  of which other proteins: &lt; 5%  pH (2% solution, 20 °C): 5.2-7.2  Solubility (2% solution, 20 °C): complete</p>
<b><i>Buglossoides arvensis</i> seed oil</b>	<p><b>Description/Definition:</b>  Refined <i>Buglossoides</i> oil is extracted from the seeds of <i>Buglossoides arvensis</i> (L.) I.M.Johnst  Alpha-linolenic acid: ≥ 35% w/w of total fatty acids  Stearidonic acid: ≥ 15% w/w of total fatty acids  Linoleic acid: ≥ 8% w/w of total fatty acids  Trans fatty acids: ≤ 2% w/w of total fatty acids  Acid value: ≤ 0.6 mg KOH/g  Peroxide value: ≤ 5 meq /kg  Unsaponifiable content: ≤ 2%  Protein content (total nitrogen): ≤ 10 µg/ml  Pyrrolizidine alkaloids: Not detectable with a detection limit of 4 µg/kg</p>
<b>Chewing gum base (monomethoxypolyethylene glycol)</b>	<p><b>Description/Definition:</b>  The novel food ingredient is a synthetic polymer (Patent number WO2006016179). It consists of branched polymers of monomethoxypolyethylene glycol (MPEG) grafted onto polyisoprene-graft-maleic anhydride (PIP-g-MA), and unreacted MPEG (less than 35 % by weight).  White to off-white colour.  CAS No.: 1246080-53-4  <b>Characteristics:</b>  Moisture: &lt; 5%  Aluminium: &lt; 3 mg/kg  Lithium: &lt; 0.5 mg/kg  Nickel: &lt; 0.5 mg/kg  Residual anhydride: &lt; 15 µmol/g  Polydispersity index: &lt; 1.4</p>

	<p>Isoprene: &lt; 0.05 mg/kg  Ethylene oxide: &lt; 0.2 mg/kg  Free maleic anhydride: &lt; 0.1%  Total oligomers (less than 1 000 Dalton): ≤ 50 mg/kg  Ethylene glycol: &lt; 200 mg/kg  Diethylene glycol: &lt; 30 mg/kg  Monoethylene glycol methyl ether: &lt; 3 mg/kg  Diethylene glycol methyl ether: &lt; 4 mg/kg  Triethylene glycol methyl ether: &lt; 7 mg/kg  1,4-Dioxane: &lt; 2 mg/kg  Formaldehyde: &lt; 10 mg/kg</p>
<p><b>Chewing gum base (Methyl vinyl ether-maleic anhydride copolymer)</b></p>	<p><b>Description/Definition:</b>  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</p> <p><b>Purity:</b>  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</p> <p><b>Microbiological criteria:</b>  Total aerobic plate count: ≤ 500 CFU/g  Mould/yeast: ≤ 500 CFU/g  <i>Escherichia coli</i>: Negative to test  <i>Salmonella</i> spp.: Negative to test  <i>Staphylococcus aureus</i>: Negative to test  <i>Pseudomonas aeruginosa</i>: Negative to test</p>

<p><b>Chia oil (<i>Salvia hispanica</i>)</b></p>	<p><b>Description/Definition:</b> Chia oil is produced from Chia (<i>Salvia hispanica</i> 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<sub>2</sub>.</p> <p><b>Production process:</b> 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.</p> <p>Acidity expressed as oleic acid: ≤ 2% Peroxide value: ≤ 10 meq/kg Insoluble impurities: ≤ 0.05% Alpha linolenic acid: ≥ 60 % Linoleic acid: 15-20%</p>
<p><b>Chia seeds (<i>Salvia hispanica</i>)</b></p>	<p><b>Description/Definition:</b> Chia (<i>Salvia hispanica</i> L.) is a summer annual herbaceous plant belonging to the <i>Labiatae</i> family. Post-harvest the seeds are cleaned mechanically. Flowers, leaves and other parts of the plant are removed.</p> <p>Dry matter: 90-97% Protein: 15-26% Fat: 18-39% Carbohydrate (*): 18-43% Crude Fibre (**): 18-43% Ash: 3-7%</p> <p>(*): Carbohydrates include the fibre value (EU: CH are available carbohydrates = sugar + starch) (**) Crude fibre is the part of fibre made mainly of indigestible cellulose, pentosans and lignin</p> <p><b>Production process:</b> Production process of fruit juices and fruit juice blends containing Chia seeds includes seed pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place.</p>
<p><b>Chitin-glucan from <i>Aspergillus niger</i></b></p>	<p><b>Description/Definition:</b> Chitin-glucan is obtained from the mycelium of <i>Aspergillus niger</i>; it is a slightly yellow, odourless, free-flowing powder. It has a dry matter content of 90% or more.</p>

	<p>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).</p> <p>Loss on drying: ≤ 10%          Chitin-glucan: ≥ 90%          Ratio of chitin to glucan: 30:70 to 60:40          Ash: ≤ 3%          Lipids: ≤ 1%          Proteins: ≤ 6 %</p>
<p><b>Chitin-glucan complex from <i>Fomes fomentarius</i></b></p>	<p><b>Description/Definition:</b>          Chitin-glucan complex is obtained from the cell walls of the fruit bodies of the fungus <i>Fomes fomentarius</i>. It consists primarily of two polysaccharides:</p> <ul style="list-style-type: none"> <li>• Chitin, composed of repeating units of N-acetyl-D-glucosamine (CAS No: 1398-61-4);</li> <li>• Beta-(1,3)(1,6)-D-glucan, composed of repeating units of D-glucose (CAS No: 9041-22-9).</li> </ul> <p>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.</p> <p>Appearance: Powder, odourless, flavourless, brown</p> <p>Moisture: ≤ 15%          Ash: ≤ 3%          Chitin-glucan: ≥ 90%          Ratio of chitin to glucan: 70:20          Total carbohydrates, excluding glucans: ≤ 0.1%          proteins: ≤ 6%          lipids: ≤ 1%          Melanins: ≤ 8.3%          Additives: None          pH: 6.7-7.5          Lead (ppm): ≤ 1.00          Cadmium (ppm): ≤ 1.00          Mercury (ppm): ≤ 0.03          Arsenic (ppm): ≤ 0.20</p>



	<p>Total mesophilic bacteria: ≤ 1 000/g  Yeast and moulds: ≤ 1 000/g  Coliforms at 30 °C: ≤ 1 000/g  <i>E. coli</i>: ≤ 10/g  <i>Salmonella</i> and other pathogenic bacteria: Absent/25 g</p>
<p><b>Chitosan extract from fungi</b>  (<i>Agaricus bisporus</i>; <i>Aspergillus niger</i>)</p>	<p><b>Description/Definition:</b>  The chitosan extract (containing mainly poly(D-glucosamine)) is obtained from stems of <i>Agaricus bisporus</i> or from the mycelium of <i>Aspergillus niger</i>.  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 drying.  Synonym: Poly(D-glucosamine)  Chitosan CAS number: 9012-76-4  Chitosan formulae: (C<sub>6</sub>H<sub>11</sub>NO<sub>4</sub>)<sub>n</sub>  Chitosan content (% w/dry weight): 85  Glucan content (% w/dry weight): ≤ 15  Loss on drying (% w/dry weight): ≤ 10  Viscosity 1% in acetic acid 1%: 1-15  Degree of acetylation (in % mol/wet weight): 0-30  Viscosity (1% in acetic acid 1%) (mPa.s): 1-14 for chitosan from <i>Aspergillus niger</i>; 12-25 for chitin from <i>Agaricus bisporus</i>  Ash (% w/dry weight): ≤ 3  Proteins (% w/dry weight): ≤ 2  Total heavy metals (ppm): ≤ 20  Mercury (ppm): ≤ 0.1  Lead (ppm): ≤ 1  Arsenic (ppm): ≤ 1  Cadmium (ppm): ≤ 0.5  Aerobic count (cfu/g): ≤ 1000  Yeast and mould count (cfu/g): ≤ 1000  <i>Escherichia coli</i> (cfu/g): ≤ 10  <i>Entrebacteriacare</i> (cfu/g): ≤ 10  <i>Salmonella</i>: absence/25g</p>

	<p><i>Listeria monocytogenes</i>: absence/25g  Particle size: &gt; 100 nm  Taped density (g/cm<sup>3</sup>): 0.7-1  Appearance: fine free-flowing powder  Aspect: Off- white to slightly brownish  Odour: odourless  Fat binding capacity 800x (w/wet weight): pass</p>
<b>Chromium picolinate</b>	<p><b>Description/ Definition:</b>  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.: 14639-25-9  Chemical formula: Cr(C<sub>6</sub>H<sub>4</sub>NO<sub>2</sub>)<sub>3</sub>  Chemical characteristics:  Chromium Picolinate: ≥ 95%  Chromium (III): 12-13%  Chromium (VI): not detected  Water: ≤ 4%</p>
<b>Citicoline</b>	<p><b>Description/ Definition:</b>  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: C<sub>14</sub>H<sub>26</sub>N<sub>4</sub>O<sub>11</sub>P<sub>2</sub>  Molecular weight: 488.32 g/mol  CAS No.: 987-78-0  pH (sample solution of 1%): 2.5-3.5  <b>Purity:</b>  Assay value: ≥ 98% of dry matter  Loss on drying (100 °C for 4 hours): ≤ 5.0%  Ammonium: ≤ 0.05%  Total heavy metals (as Pb): ≤ 10 ppm</p>

	<p>Arsenic: Not more than 2 ppm  Free phosphoric acids: ≤ 0.1%  5'-Cytidylic acid: ≤ 1.0%</p> <p><b>Microbiological criteria:</b>  Total plate count: ≤ 1 000 cfu/g  Yeast and moulds: ≤ 100 cfu/g  <i>Escherichia coli</i>: Absent in 1 g</p>
<b><i>Clostridium butyricum</i> (CBM 588)</b>	<p><b>Description/Definition:</b>  <i>Clostridium butyricum</i> (CBM 588) is a Gram-positive, spore-forming, obligate anaerobic, non-pathogenic, non-genetically modified bacterium.</p> <p><b>Microbiological criteria:</b>  Total viable aerobic count: ≤ 10<sup>3</sup> CFU/g  <i>Escherichia coli</i>: Not detected in 1 g  Staphylococcus aureus: Not detected in 1 g  Pseudomonas aeruginosa: Not detected in 1 g  Yeast and moulds: ≤ 10<sup>2</sup> CFU/g</p>
<b>Extract of defatted cocoa powder</b>	<p>Appearance: Dark brown powder free of visible impurities  Cocoa (<i>Theobroma cacao</i> L.) Extract  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/cm<sup>3</sup>  pH: 5.0 - 6.5  Residual solvent: Max 500 ppm</p>
<b>Low fat cocoa extract</b>	<p>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%</p>

	<p>Cocoa flavanols: Min. 300 mg/g  (-) Epicatechin: Min. 45 mg/g  Loss on drying: Max. 5%</p>
<b>Coriander seed oil</b>	<p><b>Description/Definition:</b>  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  Composition of fatty acids:  Palmitic acid (C16:0): 2-5%  Stearic acid (C18:0): &lt; 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%  <math>\alpha</math>-Linolenic acid (C18:3): &lt; 1.0%  Trans fatty acids: <math>\leq</math> 1%  CAS No.: 8008-52-4</p> <p><b>Purity:</b>  Refractive index (20°C): 1.466-1.474  Acid value: <math>\leq</math> 0.6 mg KOH/g  Peroxide value: <math>\leq</math> 5 meq/kg  Iodine value: 88-102 units  Saponification value: 186-198 mg KOH/g  Unsaponifiable matter: <math>\leq</math> 15 g/kg</p>
<b><math>\alpha</math>-cyclodextrin</b>	<p><b>Description/Definition:</b>  A non-reducing cyclic saccharide consisting of six <math>\alpha</math>-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 <math>\alpha</math>-cyclodextrin may be carried out using one of the following procedures: precipitation of a complex of <math>\alpha</math>-cyclodextrin with 1-decanol, dissolution in water at elevated temperature and re-precipitation, steam-stripping of the complexant, and crystallisation of <math>\alpha</math>-cyclodextrin from the solution; or chromatography with ion-exchange or gel filtration followed by crystallisation of <math>\alpha</math>-cyclodextrin from the purified mother liquor; or membrane separation methods such as ultra-filtration and reverse osmosis: Description: Virtually odorless, white or almost white crystalline solid.</p>

Synonyms:  $\alpha$ -cyclodextrin,  $\alpha$ -dextrin, cyclohexaamylose, cyclomaltohexaose,  $\alpha$ -cycloamylose

Chemical name: Cyclohexaamylose

CAS 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  $\alpha$ -cyclodextrin in a chromatogram of reference  $\alpha$ -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:**

Residual complexant:  $\leq 20$  mg/kg

(1-decanol)

Reducing substances:  $\leq 0.5\%$  (as glucose)

Sulfated ash:  $\leq 0.1\%$

Lead:  $\leq 0.5$  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 mark with purified deionised water. Filter through a 0.45-micrometer filter

Reference solution: Weigh accurately about 100 mg of  $\alpha$ -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-NH<sub>2</sub> (10  $\mu$ m) (*Macherey & Nagel Co. Düren, Germany*) or similar

Length: 250 mm

Diameter: 4 mm

Temperature: 40 °C

	<p>Mobile phase: acetonitrile/water (67/33, v/v)  Flow rate: 2.0 ml/min  Injection volume: 10 µl  Procedure: 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 × (AS/AR) (WR/WS)  where  As and AR are the areas of the peaks due to α-cyclodextrin for the sample solution and reference solution, respectively. Ws and WR are the weights (mg) of the test sample and reference α-cyclodextrin, respectively, after correcting for water content.</p>
<p><b>γ-cyclodextrin</b></p>	<p><b>Description/Definition:</b>  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<sub>6</sub>H<sub>10</sub>O<sub>5</sub>)<sub>8</sub>  Assay: ≥ 98% (dry basis)</p> <p><b>Identification:</b>  Melting range: Decomposes above 285 °C  Solubility: Freely soluble in water; very slightly soluble in ethanol  Specific rotation: [α]<sub>D</sub> 25: between + 174° and + 180° (1 % solution)</p> <p><b>Purity:</b>  Purity: Water: ≤ 11%  Residual complexant (8-cyclohexadecen-1-one (CHDC)): ≤ 4 mg/kg  Residual solvent (n-decane): ≤ 6mg/kg  Reducing substances: ≤ 0.5% (as glucose)  Sulphated ash: ≤ 0.1%</p>

<p><b>Dextran preparation produced by <i>Leuconostoc mesenteroides</i></b></p>	<p><b>1. Powdered form:</b>  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%</p> <p><b>2. Liquid form:</b>  Carbohydrates: 12% with: (Dextran: 6.9%, Mannitol: 1.1%, Fructose: 1.9%, Leucrose: 2.2 %)  Protein: 2%  Lipid: 0.1%  Lactic acid: 2%  Ethanol: 0.5%  Ash: 3.4%  Moisture: 80%</p>
<p><b>Diacylglycerol oil of plant origin</b></p>	<p><b>Description/Definition:</b>  Manufactured from glycerol and fatty acids derived from edible vegetable oils, in particular from soybean oil (<i>Glycine max</i>) or rapeseed oil (<i>Brassica campestris</i>, <i>Brassica napus</i>) using a specific enzyme.</p> <p><b>Acylglycerol Distribution:</b>  Diacylglycerols (DAG): <math>\geq 80\%</math>  1,3-Diacylglycerols (1,3-DAG): <math>\geq 50\%</math>  Triacylglycerols (TAG): <math>\leq 20\%</math>  Monoacylglycerols (MAG): <math>\leq 5\%</math></p> <p><b>Fatty Acid Composition (MAG, DAG, TAG):</b>  Oleic acid (C18:1): 20-65%  Linoleic acid (C18:2): 15-65%  Linolenic acid (C18:3): <math>\leq 15\%</math>  Saturated fatty acids: <math>\leq 10\%</math></p> <p><b>Others:</b></p>

	<p>Acid value: <math>\leq 0.5</math> mg KOH/g  Moisture and volatile: <math>\leq 0.1\%</math>  Peroxide value: <math>\leq 1</math> meq/kg  Unsaponifiables: <math>\leq 2\%</math>  Trans fatty acids <math>\leq 1\%</math>  MAG = monoacylglycerols, DAG = diacylglycerols, TAG = triacylglycerols</p>
<b>Dihydrocapsiate (DHC)</b>	<p><b>Description/Definition:</b>  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: <math>C_{18}H_{28}O_4</math>  CAS No: 205687-03-2</p> <p><b>Physical-chemical properties:</b>  Dihydrocapsiate: <math>&gt; 94\%</math>  8-Methylnonanoic acid: <math>&lt; 6\%</math>  Vanillyl alcohol: <math>&lt; 1\%</math>  Other synthesis related substances: <math>&lt; 2\%</math></p>
<b>Dried extract of <i>Lippia citriodora</i> from cell cultures</b>	<b>Cell cultures:</b> HTN@Vb
<b><i>Echinacea angustifolia</i> extract</b>	Extract of the roots of <i>Echinacea angustifolia</i> obtained from tissue culture plant are substantial equivalent to a commercially available extract from root of <i>Echinacea angustifolia</i> obtained in ethanol-water titrated to 4% echinacoside.
<b><i>Echium plantagineum</i> oil</b>	<p><b>Description/Definition:</b>  Echium oil is the pale yellow product obtained by refining oil extracted from the seeds of <i>Echium plantagineum</i> L. Stearidonic acid: <math>\geq 10\%</math> w/w of total fatty acids  Trans fatty acids: <math>\leq 2\%</math> (w/w of total fatty acids)  Acid value: <math>\leq 0,6</math> mg KOH/g  Peroxide value: <math>\leq 5</math> meq <math>O_2</math>/kg  Unsaponifiable content: <math>\leq 2\%</math>  Protein content (total nitrogen): <math>\leq 20</math> <math>\mu</math>g/mL</p>



	Pyrrolizidine alkaloids: Not detectable with a detection limit 4 µg/kg		
<b>Epigallocatechin gallate as a purified extract from green tea leaves (<i>Camellia sinensis</i>)</b>	<p><b>Description/Definition:</b>  A highly purified extract from the leaves of green tea (<i>Camellia sinensis</i> (L.) Kuntze) in the form of a fine, off-white to pale pink powder. It is composed of a minimum of 90% epigallo-caechin 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  Molecular mass: 458.4g/mol  Loss on drying: max 5%  Heavy metals: max 10ppm  Arsenic: max 3ppm  Lead: max 5 ppm  Assay:  Min. 94% EGCG (on dry material)  max. 0.1% caffeine  Solubility: EGCG is fairly soluble in water, ethanol, methanol and acetone</p>		
	<b>L-ergothioneine</b>	<p><b>Definition</b>  Chemical name (IUPAC): (2S)-3-(2-thioxo-2,3-dihydro-1H-imidazol-4-yl)-2-(trimethylammonio)-Propanoate  Chemical formula: C<sub>9</sub>H<sub>15</sub>N<sub>3</sub>O<sub>2</sub>S  Molecular mass: 229.3 Da  CAS No.: 497-30-3</p>	
<b>Parameter</b>		<b>Specification</b>	<b>Method</b>
Appearance	White powder	Visual	
Optical rotation	[α] <sub>D</sub> ≥ (+) 122° (c = 1, H <sub>2</sub> O) <sup>a)</sup>	Polarimetry	
Chemical purity	≥99.5%	HPLC [Eur. Ph. 2.2.29]	

	≥99%	1H-NMR
Identification	Compliant with the structure	1H-NMR
	C: 47.14 ± 0.4%	
	H: 6.59 ± 0.4%	
	N: 18.32 ± 0.4%	Elemental analysis
Total residual solvents (methanol, ethyl acetate, isopropanol, ethanol)	[Eur. Ph. 01/2008:50400] < 1000 ppm	Gas chromatography [Eur. Ph. 01/2008:20424]
Loss on drying	Internal standard < 0.5%	[Eur. Ph. 01/2008:20232]
Impurities	< 0.8%	HPLC/GPC or 1H-NMR
<b>Heavy metals<sup>b) c)</sup></b>		
Lead	< 3 ppm	ICP/AES
Cadmium	< 1 ppm	(Pb, Cd)
Mercury	< 0.1 ppm	Atomic fluorescence (Hg)
<b>Microbiological specifications<sup>b)</sup></b>		
Total viable aerobic count (TVAC)	≤ 1 x 10 <sup>3</sup> CFU/g	[Eur. Ph. 01/2011:50104]
Total yeast and mould count (TYMC)	≤ 1 x 10 <sup>2</sup> CFU/g	
<i>Escherichia coli</i>	Absent 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 <sub>2</sub> O)		
b) Analyses conducted on each batch		
c) Maximum levels in accordance with Regulation (EC) No 1881/2006		

<p><b>Ferric Sodium EDTA</b></p>	<p><b>Description/Definition:</b>          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: <math>C_{10}H_{12}FeN_2NaO_8 \cdot 3H_2O</math>          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: <math>\leq 0.1</math> %          Nitrilo-triacetic acid: <math>\leq 0.1</math> %</p>
<p><b>Ferrous ammonium phosphate</b></p>	<p><b>Description/Definition:</b>          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: <math>FeNH_4PO_4</math>          Chemical characteristics:          pH of 5 % suspension in water: 6.8-7.8          Iron (total): <math>\geq 28\%</math>          Iron (II): 22-30% (w/w)          Iron (III): <math>\leq 7\%</math> (w/w)          Ammonia: 5-9 % (w/w)          Water: <math>\leq 3\%</math></p>
<p><b>Fish peptides from <i>Sardinops sagax</i></b></p>	<p><b>Description/Definition:</b>          The novel food ingredient is a peptide mixture, which is obtained by an alkaline protease-catalysed hydrolysis of fish (<i>Sardinops sagax</i>) muscle, subsequent isolation of the peptide fraction by column chromatography, concentration under vacuum and spray drying.          Yellowish white powder          Peptides<sup>(1)</sup> (short chain peptides, dipeptides and tripeptides with a molecular weight of less than 2 kDa): <math>\geq 85</math> g/100 g          Val-Tyr (dipeptide): 0.1-0.16 g/100 g</p>

	Ash: ≤ 10 g/100 g Moisture: ≤ 8 g/100 g <sup>(1)</sup> Kjeldahl method
<b>Flavonoids from <i>Glycyrrhiza glabra</i></b>	<p><b>Description/Definition:</b>          Glavonoid is an extract derived from the roots or rootstock of <i>Glycyrrhiza glabra</i> L. by extraction 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.</p> <p>Moisture: &lt; 0.5%          Ash: &lt; 0.1%          Peroxide value: &lt; 0.5 meq/kg          Glabridin: 2.5-3.5% of fat          Glycyrrhizinic acid: &lt; 0.005%          Fat including polyphenol-type substances: ≥ 99%          Protein: &lt; 0.1%          Carbohydrates: not detectable</p>

<b>2'-O-fucosyllactose</b>	<p><b>Description/Definition:</b>  2'-O-fucosyllactose is a white to off-white powder and the liquid concentrate (45% ± 5% w/v) aqueous solution is a colourless to slight yellow clear aqueous solution. The 2'-O-fucosyllactose is produced by a specific authorised synthetic (synth.) or microbiological (microb.) process.</p> <p>Source (microb.) : genetically modified strain of <i>Escherichia coli</i> BL21</p> <p>Chemical name : <math>\alpha</math>-1-Fucopyranosyl-(1→2)-<math>\beta</math>-d-galactopyranosyl-(1→4)-d-glucopyranose</p> <p>Chemical formula: C<sub>18</sub>H<sub>32</sub>O<sub>15</sub></p> <p>CAS No: 41263-94-9</p> <p>Molecular weight: 488.44 g/mol</p> <p><b>Purity:</b>  Assay (water free): ≥ 94 % (synth.), ≥90 % (microb.)  D-Lactose: ≤ 3.0 w/w % (synth.), ≤5.0 % (microb.)  L-fucose: ≤ 1.0 w/w % (synth.), ≤3.0 % (microb.)  Difucosyl-d-lactose isomers: ≤ 1.0 w/w % (synth.), ≤3.0 % singly (microb.)  2'-Fucosyl-d-lactulose: ≤ 1.0 w/w % (synth.), .), ≤5.0 % singly (microb.)  pH (20 °C, 5 % solution): 3.2-7.0  Water (%): ≤ 9.0% (synth. and microb. powder)  Ash, sulphated: ≤ 1.5% (synth.), total Ash: ≤0.5. % (microb. powder and liquid)  Acetic acid: ≤ 1.0% (synth.)  Residual solvents (synth.) (methanol, 2-propanol, methyl acetate, acetone): ≤50 mg/kg singly, ≤200 mg/kg in combination)  Residual proteins: ≤ 0.01% (synth.), (0.001% microb. powder and liquid)  Palladium: ≤ 0.1 mg/kg (synth.)  Nickel: ≤ 3.0 mg/kg (synth.)  Lead: 0.02 mg/kg (microb. powder and liquid)  Arsenic: 0.02 mg/kg (microb. powder and liquid)  Cadmium: 0.01 mg/kg (microb. powder and liquid)  Mercury: 0.5 mg/kg (microb. powder and liquid)  Aflatoxin M<sub>1</sub>: 0.025 µg/kg (microb. powder and liquid)  Microbiological criteria:  Aerobic mesophilic bacteria total count: ≤ 500 CFU/g (synth.)</p>
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	<p>Total plate count: <math>\leq 10^4</math> CFU/g (microb. powder), <math>\leq 5000</math> CFU/g (microb. liquid)  Yeasts and Moulds: <math>\leq 10</math> CFU/g (synth.), <math>\leq 10</math> CFU/g (microb. powder and liquid),  Enterobacteriaceae: absent in 11 g (microb. powder and liquid)  Salmonella: negative/100 g (microb. powder), negative/200 ml (microb. liquid)  Chronobacter: negative/100 g (microb. powder), negative/200 ml (microb. liquid)  Residual endotoxins: <math>\leq 10</math> EU/mg (synth. and microb. powder), <math>\leq 10</math> EU/ml (microb. liquid)</p>
<b>Galacto-oligosaccharide (GOS)</b>	<p>GOS: min 46% Dry Matter (DM)  Lactose: max 40% DM  Glucose: max 27% DM  Galactose: min 0.8% DM  Ash: max 4% DM  Protein: max 5% DM</p>
<b>Glucosamine HCl from <i>Aspergillus niger</i></b>	<p>White crystalline odourless powder  Molecular formula: <math>C_6H_{13}NO_5 \cdot HCl</math>  Relative molecular mass: 215.63 g/mole  D-Glucosamine HCl 98.0-102.0% of reference standard (HPLC)  Specific rotation <math>+70.0^\circ - +73.0^\circ</math></p>
<b>Glucosamine sulphate KCl from <i>Aspergillus niger</i></b>	<p>White crystalline odourless powder  Molecular formula: <math>(C_6H_{14}NO_5)_2SO_4 \cdot 2KCl</math>  Relative molecular mass: 605.52 g/mole  D-Glucosamine Sulfate 2KCl 98.0-102.0% of reference standard (HPLC)  Specific Rotation <math>+50.0^\circ</math> to <math>+52.0^\circ</math></p>
<b>Glucosamine sulphate NaCl from <i>Aspergillus niger</i></b>	<p>White crystalline odourless powder  Molecular formula: <math>C_6H_{14}NO_5)_2SO_4 \cdot 2NaCl</math>  Relative molecular mass: 573.31 g/mole  D-Glucosamine HCl: 98-102% of reference standard (HPLC)  Specific Optical Rotation: <math>+52^\circ - +54^\circ</math></p>

**Guar Gum****Description/Definition:**

Native guar gum is the ground endosperm of seeds from natural strains of guar *Cyamopsis tetragonolobus* L. Taub. (*Leguminosae* family). It consists of a high molecular weight polysaccharide, primarily composed of galactopyranose and mannopyranose units combined 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 Directive No 2008/84/ EC laying down specific purity criteria on food additives other than colours and sweeteners & by Regulation (EC) No. 258/2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, or by any possible subsequent instruments concerning the same subject and laying down new purity criteria.

**Physico-chemical properties:****Powder**

Shelf-life: 2 years

Color: White

Odour: Light

Average diameter of particles: 60-70µm

Moisture: Max 15%

Viscosity \* at 1 hour -

Viscosity\* at 2 hours: Min 3600 mPa.s

Viscosity\* at 24 hours: Min 4000 mPa.s

Solubility: Soluble in hot and cold water

pH for 10g/ L, at 25 °C - 6-7.5

**Flakes**

Useful life: 1 year

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

Odour: Light

	<p>Average diameter of particles: 1-10 mm</p> <p>Moisture: Max 15%</p> <p>Viscosity * at 1 hour: Min 3000 mPa.s</p> <p>Viscosity* at 2 hours —</p> <p>Viscosity* at 24 hours —</p> <p>Solubility - Soluble in hot and cold water</p> <p>pH for 10g/ L, at 25 °C - 5-7.5</p> <p>* The measurements of viscosity are carried out under the following conditions: 1%, 25°C, 20 rpm</p>
<p><b>Heat-treated milk products fermented with <i>Bacteroides xylanisolvens</i></b></p>	<p><b>Description/Definition:</b></p> <p>Heat-treated fermented milk products are produced with <i>Bacteroides xylanisolvens</i> (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 <i>Bacteroides xylanisolvens</i> (DSM 23964). The resulting fermented milk product is homogenised and then heat-treated to inactivate <i>Bacteroides xylanisolvens</i> (DSM 23964). The final product does not contain viable cells of <i>Bacteroides xylanisolvens</i> (DSM 23964)<sup>1</sup>.</p> <p><sup>1</sup> Modified DIN EN ISO 21528-2.</p>
<p><b>Ice Structuring Protein type III HPLC 12</b></p>	<p><b>Description/Definition:</b></p> <p>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 (<i>Saccharomyces cerevisiae</i>) 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.</p> <p>Assay: ≥ 5 g/l active ISP</p> <p>pH: 2.5-3.5</p> <p>Ash: ≤ 2%</p> <p>DNA: Not detectable</p>



<p><b>Isomaltooligosaccharide</b></p>	<p><b>Powder:</b>  Solubility (water) (%): &gt; 99  Glucose (% dry basis): ≤ 5  Isomaltose + DP3 to DP9 (% dry basis): ≥ 90  Moisture (%): ≤ 4  Sulfated ash(g/100g): ≤ 0.3  Heavy metals:  Lead (mg/kg): ≤ 0.5  Arsenic (mg/kg): ≤ 0.5</p> <p><b>Syrup:</b>  Dried solids (g/100 g): &gt; 75  Glucose (% dry basis): ≤ 5  Isomaltose + DP3 to DP9 (% dry basis): ≥ 90  pH: 4 - 6  Sulfated ash(g/100g): ≤ 0.3  Heavy metals:  Lead (mg/kg): ≤ 0.5  Arsenic (mg/kg): ≤ 0.5</p>
<p><b>Isomaltulose</b></p>	<p><b>Description/Definition:</b>  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 taste</p> <p>Chemical name: 6-O-<math>\alpha</math>-D-glucopyranosyl-D-fructofuranose, monohydrate  CAS No.: 13718-94-0  Chemical formula: C<sub>12</sub>H<sub>22</sub>O<sub>11</sub> · H<sub>2</sub>O  Formula weight: 360.3 (monohydrate)  Assay: ≥ 98% on the dry basis  Loss on drying: ≤ 6.5% (60 °C, 5 hours)  Lead: ≤ 0.1 mg/kg</p> <p>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'</p>

<sup>(1)</sup> 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.

<b>Lactitol</b>	<p><b>Description/Definition:</b>            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: C<sub>12</sub>H<sub>24</sub>O<sub>11</sub>            Molecular weight: 344.31 g/mol            CAS No: 585-86-4            Solubility (in water): Very soluble in water            Specific rotation [α] D<sub>20</sub> = + 13° to + 16°            Assay: ≥ 95% d.b (d.b - expressed on the dry weight basis)            Water: ≤ 10.5%            Other polyols: ≤ 2.5% d.b            Reducing sugars: ≤ 0.2% d.b            Chlorides: ≤ 100 mg/kg d.b            Sulphates: ≤ 200 mg/kg d.b            Sulphated ash: ≤ 0.1% d.b            Nickel: ≤ 2 mg/kg d.b            Arsenic: ≤ 3 mg/kg d.b            Lead: ≤ 1 mg/kg d.b</p>
<b>Lacto-N-neotetraose</b>	<p><b>Description/Definition:</b>            Lacto-N-neotetraose is a white to off-white powder. Produced by a specific authorised synthetic or microbiological proces.            Chemical name : β-d-Galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-d-glucopyranosyl-(1→3)-β-d-galactopyranosyl-(1→4)-d-glucopyranose            Chemical formula: C<sub>26</sub>H<sub>45</sub>NO<sub>21</sub>            CAS No: 13007-32-4            Molecular weight: 707.63 g/mol  <b>Purity:</b>            Assay (water free): ≥ 92%</p>

	<p>D-Lactose: ≤ 3.0 w/w %  Lacto-N-triose II: ≤ 3.0 w/w %  Lacto-N-neotetraose fructose isomer: ≤ 1.0 w/w %  para-lacto-N-neohexaose: ≤ 3.0 w/w %  pH (20 °C, 5 % solution): 4.0-7.0  Water (%): ≤ 9.0%  Ash, sulphated: ≤ 0.4%  Acetic acid: ≤ 0.3%  Residual solvents (methanol, 2-propanol, methyl acetate, acetone): ≤ 50 mg/kg singly for 2-propanol, methyl acetate, acetone. ≤ 100 mg/kg for methanol. ≤200 mg/kg in combination  Residual proteins: ≤ 0.01%  Palladium: ≤ 0.1 mg/kg  Nickel: ≤ 3.0 mg/kg  <b>Microbiological criteria:</b>  Aerobic mesophilic bacteria total count: ≤ 500 CFU/g  Yeasts: ≤ 10 CFU/g  Moulds: ≤ 10 CFU/g  Residual endotoxins: ≤ 10 EU/mg</p>
<p><b>Lucerne leaf extract from</b>  <i>Medicago sativa</i></p>	<p><b>Description/Definition:</b>  The Lucerne (<i>Medicago sativa</i> 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.</p> <p><b>Composition:</b>  Protein: 45-60%  Fat: 9-11%  Free carbohydrates (soluble fibre): 1-2%  Polysaccharides (insoluble fibre): 11-15%  including cellulose: 2-3%</p>

	Minerals: 8-13% Saponins: ≤ 1.4% Isoflavones: ≤ 350 mg/kg Coumestrol: ≤ 100 mg/kg Phytates: ≤ 200 mg/kg L-canavanine: ≤ 4.5 mg/kg
<b>Lycopene</b>	<p><b>Description/Definition:</b>  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.</p> <p>Chemical name: Lycopene  CAS No.: 502-65-8 (<i>all-trans</i> lycopene)  Chemical formula: C<sub>40</sub>H<sub>56</sub>  Formula weight: 536.85</p>
<b>Lycopene from <i>Blakeslea trispora</i></b>	<p><b>Description/Definition:</b>  The purified lycopene from <i>Blakeslea trispora</i> 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.</p> <p>Chemical name: Lycopene  CAS No.: 502-65-8 (all trans lycopene)  Chemical formula: C<sub>40</sub>H<sub>56</sub>  Formula weight: 536.85</p>
<b>Lycopene from tomatoes</b>	<p><b>Description/Definition:</b>  The purified lycopene from tomatoes (<i>Lycopersicon esculantum</i> 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.</p> <p>Chemical name: Lycopene  CAS No.: 502-65-8 (all trans lycopene)  Chemical formula: C<sub>40</sub>H<sub>56</sub></p>

	Formula weight: 536.85
<b>Lycopene oleoresin from tomatoes</b>	<p><b>Description/Definition:</b> Lycopene oleoresin from tomatoes is obtained by solvent extraction of ripe tomatoes (<i>Lycopersicon esculentum Mill.</i>) with subsequent removal of the solvent. It is a red to dark brown viscous, clear liquid.</p> <p>Total lycopene: 5-15% Thereof trans-lycopene: 90-95% Total carotenoids (calculated as lycopene): 6.5-16.5% Other carotenoids: 1.75% (Phytoene/phytofluene/<math>\beta</math>-carotene): (0.5 to 0.75/0.4 to 0.65/0.2 to 0.35%) Total tocopherols: 1.5-3.0% Unsaponifiable matter: 13-20% Total fatty acids: 60-75% Water (Karl Fischer): <math>\leq</math> 0.5%</p>
<b>Magnesium citrate malate</b>	<p><b>Description/Definition:</b> Magnesium Citrate Malate with a 1:2 mixture of tri-magnesium di-citrate and magnesium malate for adults Magnesium citrate malate is a white to yellowish-white, amorphous powder. Chemical formula: <math>Mg_5(C_6H_5O_7)_2(C_4H_4O_5)_2</math> 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): <math>\leq</math> 15% Colour (solid): White to yellowish-white Colour (20% aqueous solution): Colourless to yellowish Appearance (20% aqueous solution): Clear solution pH (20% aqueous solution): Approx. 6.0 Impurities:</p>

	Chloride: ≤ 0.05% Sulphate: ≤ 0.05% Arsenic: ≤ 3 ppm Lead: ≤ 2 ppm Cadmium: ≤ 1 ppm Mercury: ≤ 0.1 ppm
<b>Magnolia Bark Extract</b>	<p><b>Description/Definition:</b></p> <p>Magnolia bark extract is obtained from the bark of the plant <i>Magnolia officinalis</i> 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.</p> <p>Magnolia bark extract is mainly composed of two phenolic compounds, magnolol and honokiol.</p> <p>Appearance: Light brownish powder</p> <p>Magnolol: ≥ 92.5%          Honokiol: ≥ 0.5%          Magnolol &amp; Honokiol: ≥ 94%          Total Eudesmol: ≤ 2%          Moisture: 0.50%          Arsenic (ppm): ≤ 0.5          Lead (ppm): ≤ 0.5          Total Heavy Metals (ppm): ≤ 10          Methyl eugenol (ppm): ≤ 10          Turbocurarine (ppm): ≤ 2          Total Alkaloid (ppm): ≤ 100</p>
<b>Maize-germ oil high in unsaponifiable matter</b>	<p><b>Description/Definition:</b></p> <p>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’).</p> <p>Unsaponifiable matter: &gt; 9 g/100 g          Tocopherols: ≥ 1.3 g/100 g          α-tocopherol (%): 10-25%          β-tocopherol (%): &lt; 3%</p>

	<p> <math>\gamma</math>-tocopherol (%): 68-89%  <math>\delta</math>-tocopherol (%): &lt; 7%  Sterols, triterpenic alcohols, methylsterols: &gt; 6.5 g/100 g  Fatty acids in triglycerides:  palmitic acid: 10-20%  stearic acid: &lt; 3.3%  oleic acid: 20-42.2%  linoleic acid: 34-65.6%  linolenic acid: &lt; 2%  Acid value: <math>\leq</math> 6 mg KOH/g  Peroxide value: <math>\leq</math> 10 mEq O<sub>2</sub>/kg  Iron (Fe): &lt; 1 500 <math>\mu</math>g/kg  Copper (Cu): &lt; 100 <math>\mu</math>g/kg  Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene: &lt; 2 <math>\mu</math>g/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' </p>
<p><b>Methylcellulose</b></p>	<p> <b>Description/Definition:</b>  Methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups. Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder  Chemical name: Methyl ether of cellulose  Chemical formula: The polymers contain substituted anhydroglucose units with the following general formula:  C<sub>6</sub>H<sub>7</sub>O<sub>2</sub>(OR<sub>1</sub>)(OR<sub>2</sub>)(OR<sub>3</sub>) where R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub> each may be one of the following:  -H  -CH<sub>3</sub> or  -CH<sub>2</sub>CH<sub>3</sub>  Molecular weight: Macromolecules: from about 20000 (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 (-OCH<sub>3</sub>) and not more than 5 % of hydroxyethoxyl groups (-OCH<sub>2</sub>CH<sub>2</sub>OH)  Solubility: Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform.  Soluble in glacial acetic acid. </p>

	<p>Loss on drying: ≤ 10% (105 °C, 3 hours)  Sulphated Ash: ≤ 1.5% determined at 800 ± 25°C  pH: ≥ 5.0 and not more than 8.0 (1% colloidal solution)  Arsenic: ≤ 3 mg/kg  Lead: ≤ 2 mg/kg  Mercury: ≤ 1 mg/kg  Cadmium: ≤ 1 mg/kg</p>
<b>(6S)-5-methyltetrahydrofolic acid, glucosamine salt</b>	<p><b>Description/Definition:</b>  Chemical name: N-[4-[[[(6S)-2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridiny]methyl]amino]benzoyl]-L-glutamic acid, glucosamine salt  Chemical formula: C<sub>32</sub>H<sub>51</sub>N<sub>9</sub>O<sub>16</sub>  Molecular weight: 817.80 g/mol (anhydrous)  CAS No.: 1181972-37-1  Appearance: Creamy to light-brown powder</p> <p><b>Purity:</b>  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: ≤ 8.0 %  Lead: ≤ 2.0 ppm  Cadmium: ≤ 1.0 ppm  Mercury: ≤ 0.1 ppm  Arsenic: ≤ 2.0 ppm  Boron: ≤ 10 ppm</p> <p><b>Microbiological criteria:</b>  Total aerobic microbial count: ≤ 100 cfu/g  Total combined yeast and moulds: ≤ 100 cfu/g  <i>Escherichia coli</i>: Absent in 10g</p>
<b>Monomethylsilanetriol (Organic Silicon)</b>	<p><b>Description/Definition:</b>  Chemical name: Silanetriol, 1-methyl-</p>



	<p>Chemical formula: CH<sub>6</sub>O<sub>3</sub>Si  Molecular weight: 94.14 g/mol  CAS No: 2445-53-6</p> <p>Organic Silicon (monomethylsilanetriol) preparation (aqueous solution):  Acidity (pH): 6.4-6.8  Silicon: 100-150 mg Si/l  Lead: ≤ 1 µg/l  Mercury: ≤ 1 µg/l  Cadmium: ≤ 1 µg/l  Arsenic: ≤ 3 µg/l  Methanol: ≤ 5 mg/kg (residual presence)</p>
<p><b>Mycelial extract from Shiitake mushroom (<i>Lentinula edodes</i>)</b></p>	<p><b>Description/Definition:</b>  The novel food ingredient is a sterile aqueous extract obtained from the mycelium of <i>Lentinula edodes</i> 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<sup>5</sup> Daltons, a degree of branching of 2/5 and a triple helical tertiary structure.  Composition of the mycelial extract from <i>Lentinula edodes</i>:  Moisture: 98%  Dry matter: 2%  Free glucose: &lt; 20 mg/ml  Total protein (1): &lt; 0.1 mg/ml  N-containing constituents (2): &lt; 10 mg/ml  Lentinan: 0.8 – 1.2 mg/ml  <sup>(1)</sup> Bradford method  <sup>(2)</sup> Kjeldahl method</p>
<p><b>Noni fruit juice (<i>Morinda citrifolia</i>)</b></p>	<p><b>Description/Definition:</b>  Noni fruits (fruits of <i>Morinda citrifolia</i> L.) are pressed. The obtained juice is pasteurised. An optional fermentation step before or after the pressing may occur.  Rubiadin: ≤ 10 µg/kg  Lucidin: ≤ 10 µg/kg</p>

<p><b>Noni fruit juice powder</b> (<i>Morinda citrifolia</i>)</p>	<p><b>Description/Definition:</b></p> <p>Seeds and skin of the sun-dried fruits of <i>Morinda citrifolia</i> are separated. The obtained pulp is filtered to separate juice from the flesh. Desiccation of the produced juice occurs in one or two ways:</p> <p>Either by atomisation using maize maltodextrins, this mixture is obtained by keeping the rates of inflow of the juice and maltodextrins constant</p> <p>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).</p>
<p><b>Noni fruit puree and concentrate</b> (<i>Morinda citrifolia</i>)</p>	<p><b>Description/Definition:</b></p> <p>The fruits of <i>Morinda citrifolia</i> 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. <i>Morinda citrifolia</i> concentrate is prepared from <i>M. citrifolia</i> 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.</p> <p><b>Composition:</b></p> <p><b>Puree:</b></p> <p>Moisture: 89-93%</p> <p>Protein: &lt; 0.6 g/100 g</p> <p>Fat: ≤ 0.4 g/100 g</p> <p>Ash: &lt; 1 g/100 g</p> <p>Total carbohydrates: 5-10 g/100 g</p> <p>Fructose: 0.5-3.82 g/100 g</p> <p>Glucose: 0.5-3.14 g/100 g</p> <p>Dietary fibre: &lt; 0.5-3 g/100 g</p> <p>5,15-dimethylmorindol (1): 0.19-0.254 µg/mL</p> <p>Lucidin (1) : Not detectable</p> <p>Alizarin (1): Not detectable</p> <p>Rubiadin (1): Not detectable</p> <p><b>Concentrate:</b></p> <p>Moisture: 48-53%</p>

	<p>Protein: 3-3.5 g/100 g          Fat: &lt; 0.04 g/100 g          Ash: 4.5-5 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 g/100 g          5,15-dimethylmorindol (1): ≤ 0.254 µg/mL          (1) <i>By an HPLC-UV method developed and validated for the analysis of anthraquinones in Morinda citrifolia puree and concentrate.</i>  <i>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).</i></p>
<b>Noni leaves (<i>Morinda citrifolia</i>)</b>	<p><b>Description/Definition:</b>          After cutting, the leaves of <i>Morinda citrifolia</i> 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.</p> <p><b>Composition:</b>          Moisture: &lt; 5.2%          Protein: 17 - 20%          Carbohydrate: 55-65%          Ash: 10-13%          Fat: 4-9%          Oxalic acid: &lt; 0.14%          Tannic acid: &lt; 2.7%          5,15-dimethylmorindol: &lt; 47 mg/kg          Rubiadin: non detectable, ≤ 10 µg/kg          Lucidin: non detectable, ≤ 10 µg/kg</p>
<b>Noni fruit powder (<i>Morinda citrifolia</i>)</b>	<p><b>Description/Definition:</b>          Noni fruit powder is made from pulped noni pulped noni (<i>Morinda citrifolia L.</i>) 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.</p> <p><b>Composition:</b>          Moisture: 5.3-9%          Protein: 3.8-4.8 g/100 g</p>

	<p>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  Dietary fibre: 15.4-24.5 g/100 g  5,15-dimethylmorindol (1): <math>\leq 2.0 \mu\text{g/mL}</math>  (1) <i>By an HPLC-UV method developed and validated for the analysis of anthraquinones in Morinda citrifolia. 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).</i></p>
<b><i>Odontella aurita</i> microalgae</b>	<p>Silicon: 3.3%  Crystalline silica: max 0.1-0.3% as impurity</p>
<b>Oil enriched with phytosterols/phytostanols</b>	<p><b>Description/Definition:</b>  Oil enriched with phytosterols/phytostanols is composed of an oil fraction and a phytosterol fraction.</p> <p><b>Acylglycerol Distribution:</b>  Free fatty acids (expressed as oleic acid): <math>\leq 2\%</math>  Monoacylglycerols (MAG): <math>\leq 10\%</math>  Diacylglycerols (DAG): <math>\leq 25\%</math>  Triacylglycerols (TAG): Making up the balance</p> <p><b>Phytosterol fraction:</b>  <math>\beta</math>-sitosterol: <math>\leq 80\%</math>  <math>\beta</math>-sitostanol: <math>\leq 15\%</math>  campesterol: <math>\leq 40\%</math>  campestanol: <math>\leq 5\%</math>  stigmasterol: <math>\leq 30\%</math>  brassicasterol <math>\leq 3\%</math>  other sterols/stanols: <math>\leq 3\%</math></p> <p><b>Others:</b>  Moisture and volatile: <math>\leq 0.5\%</math>  Peroxide value: <math>&lt; 5 \text{ meq/kg}</math>  Trans fatty acids: <math>\leq 1\%</math></p>

	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%.		
<b>Oil extracted from squid (Cephalopod sp.)</b>	Acid value: $\leq 0.5$ KOH/g oil Peroxide value: $\leq 5$ meq O <sub>2</sub> /kg oil p-Aniside value: $\leq 20$ Cold test at 0oC: $\leq 3$ hours Moisture: $\leq 0.1\%$ (w/w) Unsaponifiable matter: $\leq 5\%$ Trans fatty acids: $\leq 1\%$ Docosahexaeonic acid: $\geq 20\%$ Eicosapentaenoic acid: $\geq 10\%$		
<b>Pasteurised fruit-based preparations produced using high-pressure pasteurisation</b>	<b>Parameter</b>	<b>Target</b>	<b>Comments</b>
	Fruit storage before high-pressure treatment	Minimum 15 days at $-20$ °C	Fruit harvested and stored in conjunction with good/hygienic agricultural and manufacturing practices
	Fruit added	40 % to 60 % of thawed fruit	Fruit homogenised and added to other ingredients
	pH	3.2 to 4.2	
	° Brix	7 to 42	Assured by added sugars
	aw	$< 0.95$	Assured by added sugars
	Final storage	60 days maximum at $+ 5$ °C maximum	Equivalent to storage regimen for conventionally processed product
<b>Phosphated maize starch</b>	<b>Description/Definition:</b> 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		

	<p>Chemical formula: <math>(C_6H_{10}O_5)_n [(C_6H_9O_5)_2PO_2H]_x [(C_6H_9O_5)PO_3H_2]_y</math>  n = number of glucose units; x, y = degrees of substitution</p> <p>The chemical characteristics of phosphated distarch phosphate:</p> <p>Loss on drying: 10-14%</p> <p>pH: 4.5-7.5</p> <p>Dietary fibre: <math>\geq 70\%</math></p> <p>Starch : 7-14%</p> <p>Protein: <math>\leq 0.8\%</math></p> <p>Lipids: <math>\leq 0.8\%</math></p> <p>Residual bound phosphorus: <math>\leq 0.4\%</math> (as phosphorus) ‘high amylose maize’ as source</p>
<p><b>Phosphatidylserine from Fish Phospholipids</b></p>	<p><b>Description/Definition:</b></p> <p>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.</p> <p>Moisture: &lt; 5%</p> <p>Phospholipids: <math>\geq 75\%</math></p> <p>Phosphatidylserine: <math>\geq 35\%</math></p> <p>Glycerides: &lt; 4%</p> <p>Free L-serine: &lt; 1%</p> <p>Tocopherols: &lt; 0.5%</p> <p>Peroxide value: &lt; 5 meq O<sub>2</sub>/kg</p>
<p><b>Phosphatidylserine from soya phospholipids</b></p>	<p><b>Description/Definition:</b></p> <p>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.</p> <p><b>Characteristics of Phosphatidylserine from soya phospholipids</b></p> <p><b>Powder form:</b></p> <p>Moisture: &lt; 2%</p>

	<p>Phospholipids: <math>\geq 85\%</math>  Phosphatidylserine: <math>\geq 61\%</math>  Glycerides: <math>&lt; 2\%</math>  free L-serine: <math>&lt; 1\%</math>  Tocopherols: <math>&lt; 0.3\%</math>  Phytosterols: <math>&lt; 0.2\%</math></p> <p><b>Liquid form:</b>  Moisture: <math>&lt; 2\%</math>  Phospholipids: <math>\geq 25\%</math>  Phosphatidylserine: <math>\geq 20\%</math>  Glycerides: not applicable  free L-serine: <math>&lt; 1\%</math>  Tocopherols: <math>&lt; 0.3\%</math>  Phytosterols: <math>&lt; 0.2\%</math></p>
<b>Phospholipid product containing phosphatidylserine and phosphatidic acid</b>	<p><b>Description/Definition:</b>  The product is manufactured through enzymatic conversion of soy lecithin. The phospholipid product is a highly concentrated, yellow-brown powder form of phosphatidylserine and phosphatidic acid at an equal level.</p> <p>Moisture: <math>\leq 2\%</math>  Total phospholipids: <math>\geq 70\%</math>  Phosphatidylserine: <math>\geq 20\%</math>  Phosphatidic acid: <math>\geq 20\%</math>  Glycerines : <math>\leq 1\%</math>  Free L-serine: <math>\leq 1\%</math>  Tocopherols: <math>\leq 0.3\%</math>  Phytosterols: <math>\leq 2\%</math>  Silicon dioxide is used with a maximum content of 1%</p>
<b>Phospholipides from egg yolk</b>	85% and 100% pure Phospholipides from egg yolk
<b>Phytosterols/phytostanols</b>	<p><b>Description/Definition:</b>  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.</p>

	<p><b>Composition</b> (with GC-FID or equivalent method):</p> <p>β-sitosterol: &lt; 81%</p> <p>β-sitostanol: &lt; 35% (&lt; 35% for Milk type products, such as semi-skimmed and skimmed milk type products, where the milk fat has been partly or fully replaced by vegetable fat)</p> <p>campesterol: &lt; 40%</p> <p>campestanol: &lt; 15% (&lt; 15% for Milk type products, such as semi-skimmed and skimmed milk type products, where the milk fat has been partly or fully replaced by vegetable fat)</p> <p>stigmasterol: &lt; 30%</p> <p>brassicasterol: &lt; 3%</p> <p>other sterols/stanols: &lt; 3%</p> <p><b>Contamination/Purity</b> (GC-FID or equivalent method):</p> <p>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.</p>
<b>Plum kernel oil</b>	<p><b>Description/Definition:</b></p> <p>Plum kernel oil is a vegetable oil obtained by cold pressing of plum (<i>Prunus domestica</i>) kernels.</p> <p><b>Composition:</b></p> <p>Oleic acid (C18:1): 68%</p> <p>Linoleic acid (C18:2): 23%</p> <p>γ-Tocopherol: 80% of total tocopherols</p> <p>β-Sitosterol: 80-90% of total sterols</p> <p>Triolein: 40-55% of triglycerides</p> <p>Cyanhydric acid: maximum 5 mg/kg oil</p>
<b>Potato proteins (coagulated) and hydrolysates</b>	<p>Dry substance: ≥ 800 mg/g</p> <p>Protein (N*6,25): ≥ 600 mg/g (dry substance)</p> <p>Ash: ≤ 400 mg/g (dry substance)</p> <p>Glycoalkaloid (total): ≤ 150 mg/kg</p> <p>Lysinoalanine (total): ≤ 500 mg/kg</p> <p>Lysinoalanine (free): ≤ 10 mg/kg</p>
<b>Prolyl oligopeptidase (enzyme preparation)</b>	<p><b>Specification of the enzyme:</b></p> <p>Systematic name: Prolyl oligopeptidase</p>



Synonyms: Prolyl endopeptidase, proline-specific endopeptidase, endoprollylpeptidase

Molecular weight: 66 kDa

Enzyme Commission number: EC 3.4.21.26

CAS number: 72162-84-6

Source: A genetically modified strain of *Aspergillus niger* (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:

Total heavy metals (as lead): ≤ 10 mg/kg

Lead: ≤ 1.0 mg/kg

Arsenic: ≤ 1.0 mg/kg

Cadmium: ≤ 0.5 mg/kg

Mercury: ≤ 0.1 mg/kg

Microbiological specifications:

Total aerobic plate count: ≤ 10<sup>3</sup> CFU/g

Total yeasts and moulds: ≤ 10<sup>2</sup> CFU/g

Sulphite reducing anaerobes: ≤ 30 CFU/g

*Enterobacteriaceae*: < 10 CFU/g

*Salmonella*: Absent in 25 g

*Escherichia coli*: Absent in 25 g

*Staphylococcus aureus*: Absent in 10 g

*Pseudomonas aeruginosa*: Absent in 10 g

	<p><i>Listeria monocytogenes</i>: Absent in 25 g</p> <p>Antimicrobial activity: Absent</p> <p>Mycotoxins: Below limits of detection: Aflatoxin B1, B2, G1, G2 (&lt; 0.25 µg/kg), total Aflatoxins (&lt; 2.0 µg/kg), Ochratoxin A (&lt; 0.20 µg/kg), T-2 Toxin (&lt; 5 µg/kg), Zearalenone (&lt; 2.5 µg/kg), Fumonisin B1 and B2 (&lt; 2.5 µg/kg)</p> <p>(1) PPU – Prolyl Peptidase Units or Proline Protease Units</p> <p>(2) PPI – Protease Picomole International</p>
<p><b>Protein extract from pig kidneys</b></p>	<p><b>Description/Definition:</b></p> <p>The protein extract is obtained from homogenised pig kidneys through a combination of salt precipitation and high speed centrifugation. The obtained precipitate contains essentially proteins with 7% of the enzyme 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.</p> <p>Basic Product:</p> <p>Specification: pig kidney protein excerpt with natural content of DiAminOxidase (DAO):</p> <p>Physical condition: liquid</p> <p>Colour: brownish</p> <p>Appearance: slightly turbid solution</p> <p>pH value: 6.4-6.8</p> <p>Enzymatic activity: &gt; 2677 kHDU DAO/ml (DAO REA (DAO Radioextractionassay))</p> <p>Brachyspira spp.: negative (Real Time PCR)</p> <p>Listeria monocytogenes: negative (Real Time PCR)</p> <p>Staphylococcus aureus: &lt; 100 cfu/g</p> <p>Influenza A: negative (RevT. Real Time PCR)</p> <p>Escherichia coli: &lt; 10 cfu/g</p> <p>Total aerobic microbiological count: &lt; 10<sup>5</sup> cfu/g</p> <p>Total combined yeasts / moulds count: &lt; 10<sup>5</sup> cfu/g</p> <p>Salmonella: absent/10g</p> <p>Bile salt resistant enterobacteriaceae: &lt; 10<sup>4</sup> cfu/g</p> <p>Final product:</p>

	<p>Specification pig kidney protein excerpt with natural content of DAO (E.C. 1.4.3.22) in an enteric coated formulation:</p> <p>Physical condition: solid</p> <p>Colour: yellow gray</p> <p>Appearance: micropellets</p> <p>Enzymatic activity: 110-220 kHDU DAO/g pellet (DAO REA (DAO Radioextractionassay))</p> <p>Acid stability 15 min 0.1M HCl followed by 60 min Borat pH=9.0: &gt; 68 kHDU DAO/g pellet (DAO REA (DAO Radioextractionassay))</p> <p>Humidity: &lt; 10%</p> <p>Staphylococcus aureus: &lt; 100 cfu/g</p> <p>Escherichia coli: &lt; 10 cfu/g</p> <p>Total aerobic microbiological count: &lt; 10<sup>4</sup>cfu/g</p> <p>Total combined yeasts / moulds count: &lt; 10<sup>3</sup> cfu/g</p> <p>Salmonella: absent/10g</p> <p>Bile salt resistant enterobacteriaceae: &lt; 10<sup>2</sup> cfu/g</p>
<p><b>Rapeseed oil high in unsaponifiable matter</b></p>	<p><b>Description/Definition:</b></p> <p>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 a minor reduction of triglycerides containing monounsaturated and polyunsaturated fatty acids.</p> <p>Unsaponifiable matter: &gt; 7 g/100 g</p> <p>Tocopherols: &gt; 0.8 g/100 g</p> <p>α-tocopherol (%): 30-50%</p> <p>γ-tocopherol (%): 50-70%</p> <p>δ-tocopherol (%): &lt; 6%</p> <p>Sterols, triterpenic alcohols, methylsterols: &gt; 5 g/100 g</p> <p><b>Fatty acids in triglycerides:</b></p> <p>palmitic acid: 3-8%</p> <p>stearic acid: 0.8-2.5%</p> <p>oleic acid: 50-70%</p> <p>linoleic acid: 15-28%</p> <p>linolenic acid: 6-14%</p>

	<p>erucic acid: &lt; 2%</p> <p>Acid value: ≤ 6 mg KOH/g</p> <p>Peroxide value: ≤ 10 mEq O<sub>2</sub>/kg</p> <p>Iron (Fe): &lt; 1 000 µg/kg</p> <p>Copper (Cu): &lt; 100 µg/kg</p> <p>Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene: &lt; 2 µg/kg</p> <p>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.</p>
<p><b>Rapeseed Protein</b></p>	<p><b>Definition:</b></p> <p>Rapeseed protein is an aqueous protein-rich extract from rapeseed press cake originating from non-genetically modified <i>Brassica napus</i> L. and <i>Brassica rapa</i> L.</p> <p><b>Description:</b></p> <p>White to off-white, spray dried powder</p> <p>Total protein: ≥ 90%</p> <p>Soluble protein: ≥ 85%</p> <p>Moisture: ≤ 7%</p> <p>Carbohydrates: ≤ 7%</p> <p>Fat: ≤ 2%</p> <p>Ash: ≤ 4%</p> <p>Fibre: ≤ 0.5%</p> <p>Total glucosinolates: ≤ 1 mmol/l</p> <p><b>Purity:</b></p> <p>Total phytate: ≤ 1.5%</p> <p>Lead: ≤ 0.5 mg/kg</p> <p><b>Microbiological criteria:</b></p> <p>Yeast and mould count: ≤ 100 cfu/g</p> <p>Aerobic bacteria count: ≤ 10 000 cfu/g</p> <p>Total coliform count: ≤ 10 cfu/g</p> <p><i>Escherichia coli</i>: Absent in 10 g</p> <p><i>Salmonella</i> spp.: Absent in 25 g</p>

<p><b>Trans-resveratrol</b></p>	<p><b>Description/Definition:</b>  <i>Trans</i>-resveratrol is off-white to beige crystals.  Chemical name: 5-[(E)-2-(4-hydroxyphenyl)ethenyl]benzene-1,3-diol  Chemical formula: C<sub>14</sub>H<sub>12</sub>O<sub>3</sub>  Molecular weight: 228.25 Da  CAS No: 501-36-0  Description: <i>Trans</i>-resveratrol is off-white to beige crystals.</p> <p><b>Purity:</b>  <i>Trans</i>-resveratrol: ≥ 98%- 99% (Includes range for positive SEO)  Total by-products (related substances): ≤ 0.5%  Any single related substance: ≤ 0.1%  Lead: ≤ 1ppm  Mercury: ≤ 0.1ppm  Arsenic: ≤ 1ppm  Sulphated ash: ≤ 0.1%  Diisopropylamine: ≤ 50 mg/kg  Loss on drying: ≤ 0.5%</p>
<p><b>Trans-Resverastrol (microbial source)</b></p>	<p>Source: A genetically modified strain of <i>Saccharomyces cerevisiae</i>  Appearance: Off-white to slight yellow powder  Particle size: 100% less than 62.23 µm  <i>Trans</i>-resveratrol content: Min. 98% w/w (dry weight basis)  Ash: Max. 0.5% w/w  Moisture: Max. 3% w/w</p>
<p><b>Rooster comb extract</b></p>	<p><b>Description/ Definition:</b> Rooster comb extract is obtained from <i>Gallus gallus</i> 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%  Dermatan sulphate (chondroitin sulphate B): ≤ 25%</p>

	<p>pH: 5.0-8.5</p> <p><b>Purity:</b>  Chlorides: ≤ 1%  Nitrogen: ≤ 8%  Loss on drying: (105 °C for 6 hours): ≤ 10%  Mercury: ≤ 0,1 mg/kg  Arsenic: ≤ 1 mg/kg  Cadmium: ≤ 1 mg/kg  Chromium: ≤ 10 mg/kg  Lead: ≤ 0.5 mg/kg</p> <p><b>Microbiological criteria:</b>  Total viable aerobic count: ≤ 10<sup>2</sup> cfu/g  Escherichia coli: Absent in 1 g  Salmonella spp.: Absent in 1 g  Staphylococcus aureus: Absent in 1 g  Pseudomonas aeruginosa: Absent in 1g</p>
<p><b>Sacha Inchi oil from <i>Plukenetia volubilis</i></b></p>	<p><b>Description/Definition:</b>  Sacha inchi oil is a 100% cold pressed vegetable oil obtained from the seeds of <i>Plukenetia volubilis</i> L. It is a transparent, fluid (liquid) and shiny oil at room temperature. It has a fruity, light green vegetable taste, without undesirable flavours.</p> <p>Aspect limpidity, shine colour: Fluid at room temperature clean, shiny yellow gold  Odour and taste: Fruity, vegetable without non acceptable taste or odour</p> <p>Water and Volatiles: &lt; 0.2 g/100 g  Impurities insoluble in hexane: &lt; 0.05 g/100 g  Oleic acidity: &lt; 2 g/100 g  Peroxide value: &lt; 15 meq O<sub>2</sub>/kg  Trans fatty acids: &lt; 1 g/100 g  Total unsaturated fatty acids: &gt; 90%  Omega 3 alpha linolenic acid (ALA): &gt; 45%  Saturated fatty acids: &lt; 10%  No trans fatty acids (&lt; 0.5%)</p>

	<p>No erucic acid (&lt; 0.2%)  More than 50 % of tri-linolenin and di-linolenin-triglycerides  Phytosterols composition and level  No cholesterol (&lt; 5 mg/100 g)</p>
<b>Salatrim</b>	<p><b>Description/Definition:</b>  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 at room temperature. Free of particulate matter and of foreign or rancid odour.  Glycerol ester distribution:  Triacylglycerols: &gt; 87%  Diacylglycerols: ≤ 10%  Monoacylglycerols: ≤ 2%  Fatty acid composition:  MOLE % LCFA (long chain fatty acids): 33-70%  MOLE % SCFA (short chain fatty acids): 30-67%  Saturated long chain fatty acids: &lt; 70% by weight  Trans fatty acids: ≤ 1%  Free fatty acids as oleic acid: ≤ 0.5%  Triacylglycerol profile:  Triesters (short/long of 0.5 to 2.0): ≥ 90%  Triesters (short/long = 0): ≤ 10%  Unsaponifiable material: ≤ 1%  Moisture: ≤ 0.3%  Ash: ≤ 0.1%  Colour: ≤ 3.5 Red (Lovibond)  Peroxide value: ≤ 2.0 Meq/Kg</p>
<b><i>Schizochytrium</i> sp. oil rich in DHA and EPA</b>	<p><b>Description/Definition:</b>  DHA/EPA rich <i>Schizochytrium</i> algal oil' is the winterized, deodorized oil derived from cultivated microalgae <i>Schizochytrium</i> sp.  Docosahexaenoic acid (DHA) ≥ 24% w/w</p>

	<p>Eicosapentaenoic acid (EPA) <math>\geq</math> 12% w/w  ratio of DHA to EPA is 2:1  Acid value: <math>\leq</math> 0.5 mg KOH/g  Peroxide value: <math>\leq</math> 5.0 meq/kg oil  Moisture and volatiles: <math>\leq</math> 0.05%  Unsaponifiabiles: <math>\leq</math> 4.5%  Trans-fatty acids: <math>\leq</math> 1%  DHA content: <math>\geq</math> 22.5%  EPA content: <math>\geq</math> 10%</p>
<b><i>Schizochytrium</i> sp. (ATCC PTA-9695) oil</b>	<p>Free fatty acids: <math>\leq</math> 0.4%  Peroxide value: <math>\leq</math> 5.0 meq/kg oil  Unsaponifiabiles: <math>\leq</math> 3.5%  DHA content: <math>\geq</math> 35%  Docosapentaenoic acid (DPA) n-6: <math>\leq</math> 6%  Trans-fatty acids: <math>\leq</math> 2.0%</p>
<b><i>Schizochytrium</i> sp. oil</b>	<p>Acid value: <math>\leq</math> 0.5 mg KOH/g  Peroxide value (PV): <math>\leq</math> 5.0 meq/kg oil  Moisture and volatiles: <math>\leq</math> 0.05%  Unsaponifiabiles: <math>\leq</math> 4.5%  Trans-fatty acids: <math>\leq</math> 1%  DHA content: <math>\geq</math> 32.0%</p>
<b>Fermented soybean extract</b>	<p><b>Description/Definition:</b>  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 K2 is removed during the manufacturing process.  Fermented soybean extract contains nattokinase isolated from natto, a foodstuff produced by the fermentation of non-genetically modified soybeans (<i>Glycine max</i> (L.)) with a selected strain of <i>Bacillus subtilis</i> var. natto.  Nattokinase activity: 20 000 -28 000 FU(1)/g (2)  Identity: Confirmable  Condition: No offensive taste or smell</p>



	<p>Loss on drying: ≤ 10%</p> <p>Vitamin K2: ≤ 0.1 mg/kg</p> <p>Heavy metals: ≤ 20 mg/kg</p> <p>Lead: ≤ 5 mg/kg</p> <p>Arsenic: ≤ 3 mg/kg</p> <p>Total viable aerobic count: ≤ 1 000 CFU (3)/g</p> <p>Yeast and mould: ≤ 100 CFU/g</p> <p>Coliforms: ≤ 30 CFU/g</p> <p>Spore-forming bacteria: ≤ 10 CFU/g</p> <p><i>Escherichia coli</i>: Absence/25 g</p> <p><i>Salmonella</i> sp.: Absence/25 g</p> <p><i>Listeria</i>: Absence/25 g</p> <p>(1) FU: Fibrin degradation unit</p> <p>(2) Assay method as described by Takaoka et al. (2010).</p> <p>(3) CFU: Colony forming unit</p>
<p><b>Sucromalt</b></p>	<p><b>Description/Definition:</b></p> <p>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 <i>Leuconostoc citreum</i> or by means of a recombinant strain of the production organism <i>Bacillus licheniformis</i>. The resulting oligosaccharides are characterised by the presence of <math>\alpha</math>-(1→6) and <math>\alpha</math>-(1→3) glycosidic compounds. The overall product is syrup, in addition to these oligosaccharides, contains mainly fructose but also the disaccharide leucrose and other disaccharides.</p> <p>Total solids: 75-80%</p> <p>Moisture: 20-25%</p> <p>Sulphatase: Max 0.05%</p> <p>pH: 3.5-6.0</p> <p>Conductivity &lt; 200 (30%)</p> <p>Nitrogen &lt; 10 ppm</p> <p>Fructose: 35-45% d.w.</p> <p>Leucrose: 7-15% d.w.</p> <p>Other disaccharides: Max 3%</p>

	Higher saccharides: 40-60% d.w
<b>Sugar Cane Fibre</b>	<p><b>Description/Definition:</b>  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.</p> <p>Moisture : <math>\leq 7.0\%</math>  Ash: <math>\leq 0.3\%</math>  Total Dietary Fibre (AOAC) dry basis (all insoluble): <math>\geq 95\%</math>  of which: Hemicellulose (20-25%) and cellulose (70-75%)  Silica (ppm): <math>\leq 200</math>  Protein: 0%  Fat: Trace  pH: 4-7  Mercury (ppm): <math>\leq 0.1</math>  Lead (ppm): <math>\leq 1</math>  Arsenic (ppm): <math>\leq 1</math>  Cadmium (ppm): <math>\leq 0.1</math>  Yeast and moulds (cfu/g): <math>\leq 1000</math>  <i>Salmonella</i>: absence  <i>Listeria monocytogenes</i>: absence</p>
<b>Sunflower oil extract</b>	<p><b>Description/Definition:</b>  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, <i>Helianthus Annuus</i> L).</p> <p><b>Composition:</b>  Oleic acid (C18:1): 20%  Linoleic acid (C18:2): 70%  Unsaponifiable matter: 8%</p>

	<p>Phytosterols: 5.5%</p> <p>Tocopherols: 1.1%</p>
<b>Dried <i>Tetraselmis chuii</i> microalgae</b>	<p><b>Description/Definition:</b></p> <p>The dried product is obtained from the marine microalgae <i>Tetraselmis chuii</i>, belonging to the <i>Chlorodendraceae</i> family, cultivated in sterile sea water in closed photobioreactors insulated from the outside air.</p> <p>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%</p> <p>Humidity: ≤ 7%</p> <p>Proteins: 35-40%</p> <p>Ashes: 14-16%</p> <p>Carbohydrates: 30-32%</p> <p>Fibre: 2-3%</p> <p>Fat: 5-8%</p> <p>Saturated fatty acids: 29-31% of total fatty acids</p> <p>Monounsaturated fatty acids: 21-24% of total fatty acids</p> <p>Polyunsaturated fatty acids: 44-49% of total fatty acids</p> <p>Iodine: ≤ 15 mg/kg</p>
<b><i>Therapon barcoo</i>/Scortum</b>	<p><b>Description/Definition:</b></p> <p>Scortum/Therapon barcoo is a species of fish in the family Therapontidae. It is an endemic fresh water species from Australia. It is now reared in fish farms.</p> <p>Taxonomic Identification: Class: Actinopterygii &gt; order: Perciformes &gt; family: Therapontidae &gt; genus: Therapon or Scortum Barcoo</p> <p>Composition of fish flesh:</p> <p>Protein (%): 18-25</p> <p>Moisture (%): 65-75</p> <p>Ash (%): 0,5-2</p> <p>Energy (KJ/Kg): 6000-11500</p> <p>Carbohydrates: 0</p> <p>Fat (%): 5-15</p> <p>Fatty acids (mg FA/g fillet):</p>

	14:00: 0.5-6.1 15:00: 0.0-0.4 16:00: 8.8-36.4 16:1(n-7): 0.8-13.1 18:00: 2.2-7.8 18:1(n-9): 10.6-65.3 18:1(n-7): 0.4-2.7 18:2(n-6): 2.1-42.1 18:3(n-6): 0.0-2.3 18:3(n-3): 0.0-27.3 18:4(n-3): 0.0-3.0 20:00: 0.1-0.8 20:2(n-6): 0.2-0.5 20:4(n-6): 0.0-0.3 20:5(n-3): 0.1-5.2 22:5(n-3): 0.0-2.4 22:6(n-3): 0.6-11.3 Σ HUFA n-3: 1.2-20.0 Σ HUFA n-6: 0.3-2.0 HUFA n-3/n-6: 1.5-15.0 Total omega 3 acids: 1.6-40.0 Total omega 6 acids: 2.6-10.0
<b>D-Tagatose</b>	Appearance: White or almost white crystals Chemical name: D-tagatose Synonym: D- <i>lyxo</i> -Hexulose CAS number: 87-81-0 Chemical formula: C <sub>6</sub> H <sub>12</sub> O <sub>6</sub> Formula weight: 180.16

	<p>Assay: <math>\geq 98\%</math> on a dry weight basis  Loss on drying: <math>\leq 0.5\%</math> (102°C, 2 hours)  Lead: <math>\leq 1</math> mg/kg*  Specific Rotation: <math>[\alpha]_{20D}</math>: -4 to -5.6° (1% aqueous solution)<sup>1</sup>  Melting range: 133-137 C1</p> <p>* 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'<sup>1</sup>.</p> <p><sup>1</sup> 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</p>
<p><b>Taxifolin-rich extract</b></p>	<p><b>Description:</b> Taxifolin-rich extract from the wood of Dahurian Larch (<i>Larix gmelinii</i> (Rupr.) Rupr) is a white to pale-yellow powder that crystallizes from hot aqueous solutions.</p> <p><b>Definition:</b></p> <p>Chemical name: [(2R,3R)-2-(3,4 dihydroxyphenyl)-3,5,7-trihydroxy-2,3-dihydrochromen-4-one, also called (+) trans (2R,3R)-dihydroquercetin]</p> <p>Chemical formula: C<sub>15</sub>H<sub>12</sub>O<sub>7</sub></p> <p>Molecular mass: 304.25 Da</p> <p>CAS No: 480-18-2</p> <p><b>Specifications:</b></p> <p><u>Physical parameter</u></p> <p>Moisture: <math>\leq 10\%</math></p> <p><u>Compound analysis</u></p> <p>Taxifolin (m/m): <math>\geq 90.0\%</math> of the dry weight</p> <p><u>Heavy Metals, Pesticide</u></p> <p>Lead: <math>\leq 0.5</math> mg/kg</p> <p>Arsenic: <math>\leq 0.02</math> mg/kg</p> <p>Cadmium: <math>\leq 0.5</math> mg/kg</p> <p>Mercury: <math>\leq 0.1</math> mg/kg</p> <p>Dichlorodiphenyldichloroethane (DDT): <math>\leq 0.05</math> mg/kg</p>

	<p><u>Residual solvents</u> Ethanol: &lt; 5,000 mg/kg</p> <p><u>Microbial Parameters</u> Total Plate Count (TPC): ≤ 10<sup>4</sup> CFU/g Enterobacteria: ≤ 100/g Yeast and Mould : ≤ 100 CFU/g <i>Escherichia coli</i>: Negative/1 g <i>Salmonella</i> spp.: Negative/10 g <i>Staphylococcus aureus</i>: Negative/1 g <i>Pseudomonas</i> spp.: Negative/1 g</p> <p><b>Usual range of components of the Taxifolin-rich extract (as per dry substance)</b></p> <table border="1"> <thead> <tr> <th><u>Extract component</u></th> <th><u>Content, usual observed range (%)</u></th> </tr> </thead> <tbody> <tr> <td>Taxifolin</td> <td>90 – 93</td> </tr> <tr> <td>Aromadendrin</td> <td>2.5 – 3.5</td> </tr> <tr> <td>Eriodictyol</td> <td>0.1 – 0.3</td> </tr> <tr> <td>Quercetin</td> <td>0.3 – 0.5</td> </tr> <tr> <td>Naringenin</td> <td>0.2 – 0.3</td> </tr> <tr> <td>Kaempferol</td> <td>0.01 – 0.1</td> </tr> <tr> <td>Pinocembrin</td> <td>0.05 – 0.12</td> </tr> <tr> <td>Unidentified flavonoids</td> <td>1 - 3</td> </tr> <tr> <td>Water*</td> <td>1.5</td> </tr> </tbody> </table> <p>*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 %.</p>	<u>Extract component</u>	<u>Content, usual observed range (%)</u>	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
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Unidentified flavonoids	1 - 3																				
Water*	1.5																				
<b>Trehalose</b>	<p><b>Description/Definition:</b> A non-reducing disaccharide that consists of two glucose moieties linked by an α-1,1-glucosidic bond. It is obtained from liquefied starch by a multistep enzymatic process. The commercial product is the dihydrate. Virtually odourless, white or almost white crystals with a sweet taste</p>																				

Synonyms:  $\alpha,\alpha$ -trehalose

Chemical name:  $\alpha$ -D-glucopyranosyl- $\alpha$ -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:  $\geq 98\%$  on the dry basis

**Characteristics:**

Identification:

Solubility: Freely soluble in water, very slightly soluble in ethanol

Specific rotation:  $[\alpha]_D^{20} + 199^\circ$  (5 % aqueous solution)

Melting point:  $97^\circ\text{C}$  (dihydrate)

Purity:

Loss on drying:  $\leq 1.5\%$  ( $60^\circ\text{C}$ , 5h)

Total ash:  $\leq 0.05\%$

Lead:  $\leq 1$  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'

**Method of assay:**

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

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 mm

— diameter: 10 mm

— temperature:  $50^\circ\text{C}$

	<p>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 = <math>100 \times (R_U/R_S) (W_S/W_U)</math>  where  <math>R_S</math> = peak area of trehalose in the standard preparation  <math>R_U</math> = peak area of trehalose in the sample preparation  <math>W_S</math> = weight in mg of trehalose in the standard preparation  <math>W_U</math> = weight of dry sample in mg</p>
<p><b>UV treated mushrooms with increased levels of Vitamin D<sub>2</sub></b></p>	<p><b>Description/Definition:</b>  Commercially grown <i>Agaricus bisporus</i> to which UV light treatment is applied to harvested mushrooms yielding a Vitamin D content of ≤10 µg/100g fresh weight</p> <p><b>Vitamin D<sub>2</sub>:</b>  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</p> <p><b>Contents:</b>  Vitamin D in the final product: 5-10 µg/100g fresh weight at the expiration of shelf life</p>
<p><b>UV-treated baker's yeast (<i>Saccharomyces cerevisiae</i>)</b></p>	<p><b>Description/Definition:</b>  Baker's yeast (<i>Saccharomyces cerevisiae</i>) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D<sub>2</sub> (ergocalciferol). Vitamin D<sub>2</sub> content in the yeast concentrate varies between 1 800 000-3 500 000 IU vitamin D/100 g (450-875 µg/g).  Tan-coloured, free-flowing granules</p> <p><b>Vitamin D<sub>2</sub>:</b>  Chemical name: (5Z,7E,22E)-3S-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol  Synonym: Ergocalciferol  CAS No.: 50-14-6</p>



	<p>Molecular weight: 396.65 g/mol</p> <p><b>Microbiological criteria for the yeast concentrate:</b></p> <p>Coliforms: ≤ 1000/g</p> <p><i>Escherichia coli</i>: ≤ 10/g</p> <p><i>Salmonella</i> spp.: Absent in 25g</p>
<b>UV-treated bread</b>	<p><b>Description/Definition:</b></p> <p>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 D<sub>2</sub> (ergocalciferol).</p> <p>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/cm<sup>2</sup>.</p> <p><b>Vitamin D<sub>2</sub>:</b></p> <p>Chemical name : (5Z,7E,22E)-3S-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol</p> <p>Synonym: Ergocalciferol</p> <p>CAS No: 50-14-6</p> <p>Molecular weight: 396.65 g/mol</p> <p>Contents:</p> <p>Vitamin D<sub>2</sub> (ergocalciferol) in the final product: 0.75-3 µg/100 g <sup>(1)</sup></p> <p>Yeast in dough: 1-5 g/100 g <sup>(2)</sup></p> <p><sup>(1)</sup> EN 12821, 2009, European Standard.</p> <p><sup>(2)</sup> Recipe calculation.</p>
<b>UV-treated milk</b>	<p><b>Description/Definition:</b></p> <p>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 D<sub>3</sub> (cholecalciferol) concentrations by conversion of 7-dehydrocholesterol to vitamin D<sub>3</sub>. UV radiation: A process of radiation in ultraviolet light within the wavelength of 200-310 nm with energy input of 1 045 J/l</p> <p><b>Vitamin D<sub>3</sub>:</b></p> <p>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]ethylidene]-4-methylidenecyclohexan-1-ol</p> <p>Synonym: Cholecalciferol</p> <p>CAS No: 67-97-0</p>

	<p>Molecular weight: 384.6377 g/mol</p> <p>Contents:</p> <p>Vitamin D<sub>3</sub> in the final product:</p> <p>Whole milk <sup>(1)</sup>: 0.5-3.2 µg/100 g <sup>(2)</sup></p> <p>Semi-skimmed milk(1): 0.1–1.5 µg/100 g <sup>(2)</sup></p> <p><sup>(1)</sup> 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).</p> <p><sup>(2)</sup> HPLC</p>
<p><b>Vitamin K<sub>2</sub> (menaquinone)</b></p>	<p>This novel food is produced by a specific authorised synthetic or microbiological process</p> <p><u>Specification of the synthetic source</u></p> <p>Chemical Name: (all-E)-2-(3,7,11,15,19,23,27-Heptamethyl-2,6,10,14,18,22,26-octacosaeptaenyl)-3-methyl-1,4-naphthalenedione</p> <p>CAS Number: 2124-57-4</p> <p>Molecular formula: C<sub>46</sub>H<sub>64</sub>O<sub>2</sub></p> <p>Molecular weight: 649 g/mol</p> <p>Appearance: Yellow powder</p> <p>Purity: Max 6% cis-isomer, max 2% other impurities</p> <p>Content: 98-102% Menaquinone-7 (including at least 92% all-trans Menaquinone-7)</p> <p><u>Specifications of the microbial process</u></p> <p>Source: <i>Bacillus subtilis</i> spp. natto</p> <p>Vitamin K<sub>2</sub> (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. It is presented in an oil suspension that primarily contains MK-7, and MK-6 to a smaller extent</p>

<p><b>Wheat bran extract</b></p>	<p><b>Description/Definition:</b>  White crystalline powder obtained by enzymatic extraction from <i>Triticum aestivum</i> 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 % of dry matter  Ash: Max 2% of dry matter</p> <p><b>Microbiological parameters:</b>  Mesophilic bacteria – total count: Max 10 000/g  Yeasts: Max 100/g  Fungi: Max 100/g  <i>Salmonella</i>: Absent in 25g  <i>Bacillus cereus</i>: Max 1000/g  <i>Clostridium perfringens</i>: Max 1000/g</p>
<p><b>Yeast beta-glucans</b></p>	<p><b>Description/Definition:</b>  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)-β-D-glucans.  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 <i>Saccharomyces cerevisiae</i>.  The tertiary structure of the glucan cell wall of <i>Saccharomyces cerevisiae</i> 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 a soluble and insoluble form and insoluble in water, but dispersible in many liquid matrices.</p> <p><b>Chemical characteristics yeast (<i>Saccharomyces cerevisiae</i>) beta-glucans:</b></p> <p><b>Soluble form:</b>  Total carbohydrates: &gt; 75%  Beta-glucans (1.3/1.6): &gt; 75%</p>

Ash: < 4%

Moisture: < 8%

Protein: < 3.5%

Fat: < 10%

**Insoluble form:**

Total carbohydrates: > 70%

Beta-glucans (1.3/1.6): > 70%

Ash: ≤ 12%

Moisture: < 8%

Protein: < 10%

Fat: < 20%

**Insoluble in water, but dispersible in many liquid matrices:**

(1,3)-(1,6)-β-D-Glucans: > 80%

Ash: < 2%

Moisture: < 6%

Protein: < 4%

Total fat: < 3%

**Microbiological data:**

Total plate count: < 1000 CFU/g

Enterobacteriaceae: < 100 CFU/g

Total coliforms: < 10 CFU/g

Yeast: < 25 CFU/g

Mould: < 25 CFU/g

*Salmonella* ssp.: Absent in 25 g

*Escherichia coli*: Absent in 1 g

*Bacillus cereus*: < 100 CFU/g

*Staphylococcus aureus*: Absent in 1 g

**Heavy metals:**

Lead: < 0.2 mg/g

	<p>Arsenic: &lt; 0.2 mg/g  Mercury: &lt; 0.1 mg/g  Cadmium: &lt; 0.1 mg/g</p>
<b>Zeaxanthin (synthetic)</b>	<p><b>Description/Definition:</b>  Zeaxanthin is a naturally occurring xanthophyll pigment, it is an oxygenated carotenoid. Synthetic zeaxanthin is presented either as a spray-dried powder of gelatin or starch base ('beadlets') with added <math>\alpha</math>-tocopherol and ascorbyl palmitate or as a corn oil suspension with added <math>\alpha</math>-tocopherol.</p> <p>Production process: Synthetic zeaxanthin is produced by a multi-step chemical synthesis from smaller molecules. Orange-red crystalline powder with little or no odour</p> <p>Chemical formula: <math>C_{40}H_{56}O_2</math>  CAS No: 144-68-3  Molecular weight: 568.9 daltons</p> <p><b>Physical-chemical properties:</b>  Loss on drying: &lt; 0.2%  All-trans zeaxanthin: &gt; 96%  Cis-zeaxanthin: &lt; 2%  Other carotenoids: &lt; 1.5%  Triphenylphosphine oxid (CAS No 791-28-6): &lt; 50 mg/kg</p>
<b>Zinc L-pidolate</b>	<p><b>Description/Definition:</b>  Zinc L-pidolate is a white to creamy white powder, with characteristic odor.</p> <p>International non-proprietary name (INN): L-pyroglutamic acid, Zinc salt</p> <p>Synonyms: Zinc 5-oxoproline, Zinc pyroglutamate, Zinc pyrrolidone carboxylate, Zinc PCA, L-Zinc pidolate</p> <p>CAS No.: 15454-75-8  Molecular formula: <math>(C_5 H_6 NO_3)_2 Zn</math>  Relative anhydrous molecular mass: 321.4  Appearance: White to slightly white powder  pH (10% aqueous sol.): 5.0 - 6.0  Specific rotation: - 22.8° to - 19.6°  Water: <math>\leq</math> 10.0%  Glutamic acid: &lt;2.0%</p>

Lead:  $\leq 3$  ppm  
Arsenic:  $\leq 2$  ppm  
Cadmium:  $\leq 1$  ppm  
Mercury:  $\leq 0.1$  ppm  
Zinc L-pidolate (purity):  $\geq 98.0\%$   
Total viable mesophilic count:  $\leq 10^3$  U.F.C/g  
Yeasts and moulds:  $\leq 10^2$  U.F.C/g  
Pathogen: Absence