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# COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470

## of 20 December 2017

## establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods

**(Text with EEA relevance)**

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# COMMISSION IMPLEMENTING REGULATION (EU) 2017/2470

**of 20 December 2017**

**establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods**

**(Text with EEA relevance)**

*Article 1*

**Union list of authorised novel foods**

The Union list of novel foods authorised to be placed on the market within the Union as referred to in Article 6(1) of Regulation (EU) 2015/2283 is hereby established and set out in the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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*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

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**Table 1: Authorised novel foods**

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| ***N*-Acetyl-D-neuraminic acid** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be '*N*-acetyl-D-neuraminic acid'<br>Food supplements containing *N*-acetyl-D-neuraminic acid shall bear a statement that the food supplement should not be given to infants, young children and children under 10 years of age where they consume breast milk or other foods with added *N*-acetyl-D-neuraminic acid within the same twenty four hour period. | | |
| | Infant and follow-on formulae as defined by Regulation (EU) No 609/2013 ([1]) | 0,05 g/L of reconstituted formula | | | |
| | Processed cereal-based foods and baby foods for infants and young children as defined by Regulation (EU) No 609/2013 | 0,05 g/kg for solid foods | | | |
| | Foods for special medical purposes for infants and young children as defined by Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the infants and young children for whom the products are intended but in any case not higher than the maximum levels specified for the category mentioned in the table corresponding to the products. | | | |
| | Total diet replacement foods for weight control as defined by Regulation (EU) No 609/2013 | 0,2 g/L (drinks)<br>1,7 g/kg (bars) | | | |
| | Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 ([2]) | 1,25 g/kg | | | |
| | Unflavoured pasteurised and sterilised (including UHT) milk-based products | 0,05 g/L | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Unflavoured fermented milk-based products, heat treated after fermentation, flavoured fermented milk products including heat-treated products | 0,05 g/L (beverages)<br>0,4 g/kg (solids) | | | |
| | Dairy analogues, including beverage whiteners | 0,05 g/L (beverages)<br>0,25 g/kg (solids) | | | |
| | Cereal bars | 0,5 g/kg | | | |
| | Table top sweeteners | 8,3 g/kg | | | |
| | Fruit and vegetable-based drinks | 0,05 g/L | | | |
| | Flavoured drinks | 0,05 g/L | | | |
| | Speciality coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions | 0,2 g/kg | | | |
| | Food Supplements as defined in Directive 2002/46/EC (3) | 300 mg/day for general population older than 10 years<br>55 mg/day for infants<br>130 mg/day for young children<br>250 mg/day for children between 3 to 10 years of age | | | |
| ***Adansonia digitata*** **(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’ | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| ***Ajuga reptans* extract from cell cultures** | *Specified food category* | *Maximum levels* | | | |
| | 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 *Ajuga reptans* | | | |
| **L-Alanyl-L-Glutamine** | *Specified food category* | *Maximum levels* | | | |
| | Food Supplements as defined in Directive 2002/46/EC | | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 excluding foods for infants and young children | | | | |
| | Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen | | | | |
| **Algal oil from the microalgae *Ulkenia* sp.** | *Specified food category* | *Maximum levels of DHA* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the micro-algae *Ulkenia sp.*' | | |
| | Bakery products (breads, rolls and sweet biscuits) | 200 mg/100 g | | | |
| | Cereal bars | 500 mg/100 g | | | |
| | Non-alcoholic beverages (including milk based beverages) | 60 mg/100 ml | | | |
| ***Allanblackia* seed oil** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be '*Allanblackia* seed oil' | | |
| | Yellow fat spreads and cream based spreads | 20 g/100 g | | | |
| ***Aloe macroclada* Baker leaf extract** | *Specified food category* | *Maximum levels* | | | |
| | Food Supplements as defined in Directive 2002/46/EC | In line with normal use in food supplements of the similar gel derived *from Aloe vera* (L.) Burm. | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Antarctic Krill oil from *Euphausia superba*** | *Specified food category* | *Maximum levels of combined DHA and EPA* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lipid extract from the crustacean Antarctic Krill (*Euphausia superba*)' | | |
| | 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<br>Milk-based drinks<br>Dairy analogue drinks | 80 mg/100 ml | | | |
| | Spreadable fat and dressings | 600 mg/100 g | | | |
| | Cooking fats | 360 mg/100 ml | | | |
| | Breakfast cereals | 500 mg/100 g | | | |
| | Bakery products (breads, rolls and sweet biscuits) | 200 mg/100 g | | | |
| | Nutrition bars/cereal bars | 500 mg/100 g | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 3 000 mg/day for the general population<br>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 | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Processed cereal-based food and baby food intended for infants and young children covered by Regulation (EU) No 609/2013 | 200 mg/100 ml | | | |
| | Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen | | | | |
| | Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 | | | | |
| **Antarctic Krill oil rich in phospholipids from *Euphausia superba*** | *Specified food category* | *Maximum levels of combined DHA and EPA* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lipid extract from the crustacean Antarctic Krill (*Euphausia superba*)' | | |
| | 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<br>Milk-based drinks<br>Dairy analogue drinks | 80 mg/100 ml | | | |
| | Spreadable fat and dressings | 600 mg/100 g | | | |
| | Cooking fats | 360 mg/100 ml | | | |
| | Breakfast cereals | 500 mg/100 g | | | |
| | Bakery products (breads, rolls and sweet biscuits) | 200 mg/100 g | | | |
| | Nutrition bars/cereal bars | 500 mg/100 g | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Food Supplements as defined in Directive 2002/46/EC | 3 000 mg/day for the general population<br>450 mg/day for pregnant and lactating women | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |
| | Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control | 250 mg/meal | | | |
| | Processed cereal-based food and baby food intended 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 | | | | |
| **Arachidonic acid-rich oil from the fungus *Mortierella alpina*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from *Mortierella alpina*' or '*Mortierella alpina* 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 | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Argan oil from *Argania spinosa*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Argan oil' and if used as seasoning 'Vegetable oil only for seasoning' shall be mentioned on the label | | |
| | As seasonings | Not specified | | | |
| | Food Supplements as defined in Directive 2002/46/EC | In line with normal food use of vegetable oils | | | |
| **Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Astaxanthin' | | |
| | Food Supplements as defined in Directive 2002/46/EC | 40-80 mg/day of oleoresin, resulting in ≤ 8 mg astaxanthin per day | | | |
| **Basil seeds (*Ocimum basilicum*)** | *Specified food category* | *Maximum levels* | | | |
| | Fruit juice and fruit/vegetable blend beverages | 3 g/200 ml for addition of whole basil seeds (*Ocimum basilicum*) | | | |
| **Fermented black bean extract** | *Specified food category* | *Maximum levels* | 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 | | | |
| **Bovine lactoferrin** | *Specified food category* | *Maximum levels* | 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 | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | 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 | 2 000 mg/100 g | | | |
| | Ice cream | 130 mg/100 g | | | |
| | Cakes and pastries | 1 000 mg/100 g | | | |
| | Candies | 750 mg/100 g | | | |
| | Chewing gum | 3 000 mg/100 g | | | |
| ***Buglossoides arvensis* seed oil** | *Specified food category* | *Maximum levels of stearidonic acid (STA)* | The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Refined *Buglossoides* 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 | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | 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 | | | |
| ***Calanus finmarchicus* oil** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'oil from *Calanus finmarchicus* (crustacean)' | | |
| | Food supplements as defined in Directive 2002/46/EC | 2,3 g/day | | | |
| **Chewing gum base (monomethoxypolyethylene glycol)** | *Specified food category* | *Maximum levels* | 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 % | | | |
| **Chewing gum base (Methyl vinyl ether-maleic anhydride copolymer)** | *Specified food category* | *Maximum levels* | 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 % | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Chia oil from *Salvia hispanica*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chia oil (*Salvia hispanica*)' | | |
| | Fats and oils | 10 % | | | |
| | Pure chia oil | 2 g/day | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 2 g/day | | | |
| **Chia seeds (*Salvia hispanica*)** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chia seeds (*Salvia hispanica*)'<br>2. Pre-packaged Chia (*Salvia hispanica*) seeds shall carry additional labelling to inform the consumer that the daily intake is no more than 15 g. | | |
| | 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 | | | |
| | Fruit juice and fruit/vegetable blend beverages | 15 g/day for addition of whole, mashed or ground chia seeds | | | |
| | Pre-packaged Chia seed as such | 15 g/day whole chia seeds | | | |
| | Fruit spreads | 1 % whole chia seeds | | | |
| | Yoghurt | 1,3 g whole chia seeds per 100 g of yoghurt or 4,3 g whole chia seeds per 330 g of yoghurt (portion) | | | |
| | Sterilised ready to eat meals based on cereal grains, pseudocereals grains and/or pulses | 5 % whole chia seeds | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Chitin-glucan from *Aspergillus niger*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chitin-glucan from *Aspergillus niger*' | | |
| | Food Supplements as defined in Directive 2002/46/EC | 5 g/day | | | |
| **Chitin-glucan complex from *Fomes fomentarius*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chitin-glucan from *Fomes fomentarius*' | | |
| | Food Supplements as defined in Directive 2002/46/EC | 5 g/day | | | |
| **Chitosan extract from fungi (*Agaricus bisporus*; *Aspergillus niger*)** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chitosan extract from *Agaricus bisporus*' or 'Chitosan extract from *Aspergillus niger*' | | |
| | Food Supplements as defined in Directive 2002/46/EC | In line with normal use in food supplements of chitosan from crustaceans | | | |
| **Chondroitin sulphate** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chondroitin sulphate derived from microbial fermentation and sulphation' | | |
| | Food supplements as defined in Directive 2002/46/EC for adult population, excluding pregnant and lactating women | 1 200 mg/day | | | |
| **Chromium Picolinate** | *Specified food category* | *Maximum levels of total chromium* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Chromium Picolinate' | | |
| | Foods covered by Regulation (EU) No 609/2013 | 250 µg/day | | | |
| | Foods fortified in accordance with Regulation (EC) No 1925/2006 ([4]) | | | | |
| ***Cistus incanus* L. Pandalis herb** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be '*Cistus incanus* L. Pandalis herb' | | |
| | Herbal infusions | Intended daily intake: 3 g herbs/day (2 cups/day) | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Citicoline** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Citicoline'<br>2. The labelling of foods containing citicoline shall bear a statement that the product is not intended to be consumed by children | | |
| | 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 1 000 mg | | | |
| ***Clostridium butyricum*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be '*Clostridium butyricum* MIYAIRI 588 (CBM 588)' or '*Clostridium butyricum* (CBM 588)' | | |
| | Food Supplements as defined in Directive 2002/46/EC | $1{,}35 \times 10^8$ CFU/day | | | |
| **Extract of defatted cocoa powder** | *Specified food category* | *Maximum levels* | 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 | | | | |
| **Low fat cocoa extract** | *Specified food category* | *Maximum levels* | Consumers shall be instructed not to consume more than 600 mg of cocoa flavanols per day | | |
| | Foods including food supplements as defined in Directive 2002/46/EC | 730 mg per serving and around 1,2 g/day | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Coriander seed oil from *Coriandrum sativum*** | *Specified food category* | *Maximum levels* | 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 | | | |
| ***Crataegus pinnatifida* dried fruit** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be '*Crataegus pinnatifida* dried fruit' | | |
| | Herbal infusions | In line with normal food use of *Crataegus laevigata* | | | |
| | Jams and jellies in accordance with Directive 2001/113/EC (5) | | | | |
| | Compotes | | | | |
| **α-cyclodextrin** | Not specified | | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Alpha-cyclodextrin' or 'α-cyclodextrin' | | |
| **γ-cyclodextrin** | Not specified | | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Gamma-Cyclodextrin' or 'γ-Cyclodextrin' | | |
| **Dextran preparation produced by *Leuconostoc mesenteroides*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Dextran' | | |
| | Bakery products | 5 % | | | |
| **Diacylglycerol oil of plant origin** | *Specified food category* | *Maximum levels* | 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 | | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Dihydrocapsiate (DHC)** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Dihydrocapsiate'<br>2. Food supplements containing synthetic dihydrocapsiate will be labelled as 'not intended for children up to 4.5 years' | | |
| | 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 beverages | 1,5 mg/100 ml | | | |
| | Vegetable drinks | 2 mg/100 ml | | | |
| | Coffee based drinks, tea based drinks | 1,5 mg/100 ml | | | |
| | 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 | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | 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<br>9 mg/day | | | |
| | Non-alcoholic powdered drink mixes | 14,5 mg/kg equivalent to 1,5 mg/100 ml | | | |
| ▼M13 **Dried aerial parts of *Hoodia parviflora*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'dried aerial parts of *Hoodia parviflora*' | | Authorised on 3 September 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.<br>Applicant: Desert Labs, Ltd Kibbutz Yotvata, 88820 Israel.<br>During the period of data protection the novel food dried aerial parts of *Hoodia parviflora* is authorised for placing on the |
| | Food Supplements as defined in Directive 2002/46/EC for adult population | 9,4 mg/day | | | |

▼M13

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | | | | | market within the Union only by Desert Labs, Ltd unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Desert Labs, Ltd.<br>End date of the data protection: 3 September 2023. |
| ▼M9<br>**Dried extract of *Lippia citriodora* from cell cultures** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'dried extract of *Lippia citriodora* from cell cultures HTN®Vb' | | |
| | Food Supplements as defined in Directive 2002/46/EC | In line with normal use in food supplements of a similar extract from the leaves of *Lippia citriodora* | | | |
| ***Echinacea angustifolia* extract from cell cultures** | *Specified food category* | *Maximum levels* | | | |
| | Food Supplements as defined in Directive 2002/46/EC | In line with normal use in food supplements of a similar extract from the root of *Echinacea angustifolia* | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| ***Echinacea purpurea* extract from cell cultures** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'dried extract of *Echinacea purpurea* from cell cultures HTN®Vb' | | |
| | Food Supplements as defined in Directive 2002/46/EC | In line with normal use in food supplements of a similar extract from florets within the flower head of *Echinacea purpurea* | | | |
| ***Echium plantagineum* oil** | *Specified food category* | *Maximum levels of stearidonic acid (STA)* | 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 | | | |
| **Epigallocatechin gallate as a purified extract from green tea leaves (*Camellia sinensis*)** | *Specified food category* | *Maximum levels* | The labelling shall bear a statement that consumers should not consume more than 300 mg of extract per day | | |
| | Foods including food supplements as defined in Directive 2002/46/EC | 150 mg of extract in one portion of food or food supplement | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **L-ergothioneine** | *Specified food category* | *Maximum levels* | 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)<br>20 mg/day for children older than 3 years | | | |
| **Ferric Sodium EDTA** | *Specified food category* | *Maximum levels (expressed as anhydrous EDTA)* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Ferric Sodium EDTA' | | |
| | Food supplements as defined in Directive 2002/46/EC | 18 mg/day for children<br>75 mg/day for adults | | | |
| | Foods covered by Regulation (EU) No 609/2013 | 12 mg/100 g | | | |
| | Foods fortified in accordance with Regulation (EC) No 1925/2006 | | | | |
| **Ferrous ammonium phosphate** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Ferrous ammonium phosphate' | | |
| | 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 | | | | |
| | Foods fortified in accordance with Regulation (EC) No 1925/2006 | | | | |
| **Fish peptides from *Sardinops sagax*** | *Specified food category* | *Maximum levels fish peptide product* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Fish (*Sardinops sagax*) 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) | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Breakfast cereals | 2 g/100 g | | | |
| | Soups, stews and soup powders | 0,3 g/100 g (ready to eat) | | | |
| **Flavonoids from *Glycyrrhiza glabra*** | *Specified food category* | *Maximum levels of flavonoids from Glycyrrhiza glabra* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Flavonoids from *Glycyrrhiza glabra L.*'<br>2. The labelling of the foods where the product was added as a novel food ingredient shall bear a statement that:<br>(a) the product should not be consumed by pregnant and breast feeding women, children and young adolescents; and<br>(b) people taking prescription drugs should only consume the product under medical supervision;<br>(c) a maximum of 120 mg of flavonoids per day should be consumed.<br>3. The amount of flavonoids in the final food shall be indicated on the labelling of the food containing it. | Beverages containing flavonoids shall be presented to the final consumer as single portions. | |
| | Beverages based on milk | 120 mg/day | | | |
| | Beverages based on yoghurt | | | | |
| | Beverages based on fruit or vegetables | | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 120 mg/day | | | |
| | 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 | | | |
| **Fucoidan extract from the seaweed *Fucus vesiculosus*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Fucoidan extract from seaweed *Fucus vesiculosus*'. | | |
| | Foods including food supplements as defined in Directive 2002/46/EC for the general population | 250 mg/day | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Fucoidan extract from the seaweed *Undaria pinnatifida*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Fucoidan extract from seaweed Undaria pinnatifida' | | |
| | Foods including food supplements as defined in Directive 2002/46/EC for the general population | 250 mg/day | | | |
| **2′-Fucosyllactose** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be '2′-fucosyllactose'.<br>2. The labelling of food supplements containing 2′-fucosyllactose shall bear a statement that the supplements should not be used if other foods with added 2′-fucosyllactose are consumed the same day.<br>3. The labelling of food supplements containing 2′-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′-fucosyllactose are consumed the same day. | | |
| | 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 up to 0,6 g/l of lacto-*N*-neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Follow-on formula as defined in Regulation (EU) No 609/2013 | 1,2 g/l alone or in combination with up to 0,6 g/l of lacto-*N*-neotetraose at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer | | | |
| | 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 children | 1,2 g/l for milk-based drinks and similar products added alone or in combination with up to 0,6 g/l lacto-*N*-neotetraose, at a ratio of 2:1 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |
| | Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 | 4,8 g/l for drinks | | | |
| | | 40 g/kg for bars | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | 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 mixes of these products | 9,6 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 | 3,0 g/day for general population | | | |
| | | 1,2 g/day for young children | | | |
| **Galacto-oligosaccharide** | *Specified food category* | *Maximum levels (expressed as ratio kg galacto-oligosaccharide/kg final food)* | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 0,333 | | | |
| | Milk | 0,020 | | | |
| | Milk drinks | 0,030 | | | |
| | Meal replacement for weight control (as drinks) | 0,020 | | | |
| | Dairy analogue drinks | 0,020 | | | |
| | Yoghurt | 0,033 | | | |
| | Dairy based deserts | 0,043 | | | |
| | Frozen dairy deserts | 0,043 | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Fruit drinks and energy drinks | 0,021 | | | |
| | Infant meal replacement drinks | 0,012 | | | |
| | Baby juice | 0,025 | | | |
| | Baby yogurt drink | 0,024 | | | |
| | Baby desert | 0,027 | | | |
| | Baby snack | 0,143 | | | |
| | Baby cereals | 0,027 | | | |
| | Drinks intended to meet the expenditure of intense muscular effort especially for sportsmen | 0,013 | | | |
| | Juice | 0,021 | | | |
| | Fruit pie fillings | 0,059 | | | |
| | Fruit preparations | 0,125 | | | |
| | Bars | 0,125 | | | |
| | Cereals | 0,125 | | | |
| | Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 | 0,008 | | | |
| **Glucosamine HCl** | *Specified food category* | *Maximum levels* | | | |
| | 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 | | | | |
| | | | | | |
| | Meal replacement for weight control | | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | 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 | | | | |
| **Glucosamine sulphate KCl** | *Specified food category* | *Maximum levels* | | | |
| | Food Supplements as defined in Directive 2002/46/EC | In line with normal food use of glucosamine from shell fish | | | |
| **Glucosamine sulphate NaCl** | *Specified food category* | *Maximum levels* | | | |
| | Food Supplements as defined in Directive 2002/46/EC | In line with normal food use of glucosamine from shell fish | | | |
| **Guar Gum** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Guar Gum'.<br>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.<br>For example, 'Excessive consumption of these products may cause digestive discomfort, especially for children under 8 years of age'.<br>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 the dairy product before consumption, in order to take into account the potential risk of gastrointestinal obstruction. | | |
| | 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<br>None in the accompanying dairy product<br>1 g/100 g in the product when ready to eat | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Heat-treated milk products fermented with *Bacteroides xylanisolvens*** | *Specified food category* | *Maximum levels* | | | |
| | Fermented milk products (in liquid, semi-liquid and spray-dried powder forms) | | | | |
| **Hydroxytyrosol** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the food products containing it shall be 'hydroxytyrosol'.<br>The labelling of the food products containing hydroxytyrosol shall bear the following statements:<br>(a) This food product should not be consumed by children under the age of three years, pregnant women, and lactating women;<br>(b) This food product should not be used for cooking, baking or frying' | | |
| | Fish and vegetable oils, (except olive oils and olive pomace oils as defined in Part VIII of Annex VII of Regulation (EU) No 1308/2013 ([6])), placed as such on the market | 0,215 g/kg | | | |
| | Spreadable fats as defined in Part VII of Annex VII of Regulation (EU) No 1308/2013, placed as such on the market | 0,175 g/kg | | | |
| **Ice Structuring Protein type III HPLC 12** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Ice Structuring Protein' | | |
| | Edible ices | 0,01 % | | | |
| **Aqueous extracts of dried leaves of *Ilex guayusa*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Extracts of dried leaves of *Ilex guayusa*' | | |
| | Herbal infusions | In line with normal use in herbal infusions and food supplements of a similar aqueous extract of dried leaves of *Ilex paraguariensis* | | | |
| | Food Supplements as defined in Directive 2002/46/EC | | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Isomalto-oligosaccharide** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Isomaltooligosaccharide'.<br>2. Foods containing the novel ingredient must be labelled as 'a source of glucose'. | | |
| | 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 % | | | |
| **Isomaltulose** | Not specified | | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Isomaltulose'.<br>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'. | | |

▼M14

| | | | | | |
|---|---|---|---|---|---|
| **Lactitol** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the food supplements containing it shall be 'Lactitol' | | |
| | Food Supplements as defined in Directive 2002/46/EC (capsules, tablets or powder) intended for the adult population | 20 g/day | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Lacto-*N*-neotetraose** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'lacto-*N*-neotetraose'.<br>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.<br>3. The labelling of food supplements containing lacto-*N*-neotetraose intended for young children shall bear a statement that the supplements should not be used if breast milk or other foods with added lacto-*N*-neotetraose are consumed the same day. | | |
| | Unflavoured pasteurised and sterilised (including UHT) milk-based products | 0,6 g/l | | | |
| | Unflavoured fermented milk-based products | 0,6 g/l for beverages<br>9,6 g/kg for products other than beverages | | | |
| | Flavoured fermented milk-based products including heat-treated products | 0,6 g/l for beverages<br>9,6 g/kg for products other than beverages | | | |
| | Dairy analogues, including beverage whiteners | 0,6 g/l for beverages<br>6 g/kg for products other than beverages<br>200 g/kg for whitener | | | |
| | 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 up to 1,2 g/l of 2′-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer | | | |
| | Follow-on formula as defined in Regulation (EU) No 609/2013 | 0,6 g/l in combination with up to 1,2 g/l of 2′-fucosyllactose at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | 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<br>0,6 g/l for liquid food ready for use, marketed as such or reconstituted as instructed by the manufacturer | | | |
| | Milk-based drinks and similar products intended for young children | 0,6 g/l for milk-based drinks and similar products added alone or in combination with 2′-fucosyllactose, at a ratio of 1:2 in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |
| | Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 | 2,4 g/l for drinks<br>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 | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | 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<br>0,6 g/day for young children | | | |
| **Lucerne leaf extract from *Medicago sativa*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Lucerne (*Medicago sativa*) protein' or 'Alfalfa (*Medicago sativa*) protein'. | | |
| | Food supplements as defined in Directive 2002/46/EC | 10 g/day | | | |
| **Lycopene** | *Specified food category* | *Maximum levels* | 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/100 g | | | |
| | Soups other than tomato soups | 1 mg/100 g | | | |
| | Bread (including crispy breads) | 3 mg/100 g | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |
| | Food supplements as defined in Directive 2002/46/EC | 15 mg/day | | | |
| **Lycopene from *Blakeslea trispora*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling 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/100 g | | | |
| | Soups other than tomato soups | 1 mg/100 g | | | |
| | Bread (including crispy breads) | 3 mg/100 g | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |
| | Food supplements as defined in Directive 2002/46/EC | 15 mg/day | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other require-ments | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Lycopene from tomatoes** | *Specified food category* | *Maximum levels* | 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/100 g | | | |
| | Soups other than tomato soups | 1 mg/100 g | | | |
| | Bread (including crispy breads) | 3 mg/100 g | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |
| | Food supplements as defined in Directive 2002/46/EC | 15 mg/day | | | |
| **Lycopene oleoresin from tomatoes** | *Specified food category* | *Maximum levels of lycopene* | 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 | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | 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/100 g | | | |
| | Soups other than tomato soups | 1 mg/100 g | | | |
| | Bread (including crispy breads) | 3 mg/100 g | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |
| **Magnesium citrate malate** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Magnesium citrate malate' | | |
| | Food Supplements as defined in Directive 2002/46/EC | | | | |
| **Magnolia Bark Extract** | *Specified food category* | *Maximum levels* | 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 1,5 g each, each gum or mint serving will contain no more than 3 mg of magnolia bark extract. | | | |
| | Chewing gum | | | | |
| **Maize-germ oil high in unsaponifiable matter** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Maize-germ oil extract' | | |
| | Food Supplements as defined in Directive 2002/46/EC | 2 g/day | | | |
| | Chewing gum | 2 % | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Methylcellulose** | *Specified food category* | *Maximum levels* | 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 (pulps, purees or compotes) | | | | |
| | Soups and broths | | | | |

▼M11

| | | | | | |
|---|---|---|---|---|---|
| **1-Methylnicotinamide chloride** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be '1- Methylnicotinamide chloride'.<br>Food supplements containing 1-Methylnicotinamide shall bear the following statement:<br>This food supplement should be consumed by adults only excluding pregnant and lactating women | | Authorised on 2 September 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.<br>Applicant: Pharmena SA, Wolczanska 178, 90 530 Lodz, Poland. During the period of data protection the novel food 1-methylnicotinamide chloride is authorised for placing on the market within the Union only by Pharmena S.A. unless a subsequent |
| | Food Supplements as defined in Directive 2002/46/EC for the adult population excluding pregnant and lactating women | 58 mg/day | | | |

▼M11

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | | | | | applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Pharmena S.A.<br>End date of the data protection: 2 September 2023 |
| ▼M9 **(6S)-5-methyltetrahydrofolic acid, glucosamine salt** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be '(6S)-5-methyltetrahydrofolic acid, glucosamine salt' or '5MTHF-glucosamine' | | |
| | Food Supplements as defined in Directive 2002/46/EC as a source of folate | | | | |
| **Monomethylsilanetriol (Organic Silicon)** | *Specified food category* | *Maximum levels of silicon* | 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 for adult population (in liquid form) | 10,40 mg/day | | | |
| **Mycelial extract from Shiitake mushroom (*Lentinula edodes*)** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'extract from the mushroom *Lentinula edodes*' 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 | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other require-ments | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Noni fruit juice (*Morinda citrifolia*)** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Noni juice' or 'Juice of *Morinda citrifolia*' | | |
| | Pasteurised fruit and fruit nectar based drinks | 30 ml with one serving (up to 100 % noni juice)<br>or<br>20 ml twice a day, not more than 40 ml per day | | | |
| **Noni fruit juice powder (*Morinda citrifolia*)** | 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 *Morinda citrifolia*' | | |
| **Noni fruit puree and concentrate (*Morinda citrifolia*)** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be:<br>For fruit puree:<br>'*Morinda citrifolia* fruit puree' or 'Noni fruit puree'<br>For fruit concentrate:<br>'*Morinda citrifolia* fruit concentrate' or 'Noni fruit concentrate' | | |
| | | Fruit puree | | | |
| | Candy/confectionery | 45 g/100 g | | | |
| | Cereal bars | 53 g/100 g | | | |
| | Powdered nutritional drink mixes (dry weight) | 53 g/100 g | | | |
| | Carbonated beverages | 11 g/100 g | | | |
| | Ice cream & sorbet | 31 g/100 g | | | |
| | Yoghurt | 12 g/100 g | | | |
| | Biscuits | 53 g/100 g | | | |
| | Buns, cakes and pastries | 53 g/100 g | | | |
| | Breakfast cereals (wholegrain) | 88 g/100 g | | | |
| | Jams and jellies in accordance with Directive 2001/113/EC | 133 g/100 g<br>Based on pre-processing quantity to produce final 100 g product | | | |
| | Sweet spreads, fillings and icings | 31 g/100 g | | | |

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Savoury sauces, pickles, gravies and condiments | 88 g/100 g | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 26 g/day | | | |
| | | Fruit concentrate | | | |
| | Candy/Confectionery | 10 g/100 g | | | |
| | Cereal bars | 12 g/100 g | | | |
| | Powdered nutritional drink mixes (dry weight) | 12 g/100 g | | | |
| | 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/100 g | | | |
| | Jams and jellies in accordance with Directive 2001/113/EC | 30 g/100 g | | | |
| | Sweet spreads, fillings and icings | 7 g/100 g | | | |
| | Savoury sauces, pickles, gravies and condiments | 20 g/100 g | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 6 g/day | | | |
| **Noni leaves (*Morinda citrifolia*)** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Noni leaves' or 'leaves of *Morinda citrifolia*'.<br>2. 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 Morinda citrifolia. | | |
| | For the preparation of infusions | A cup of infusion to be consumed shall not be prepared with more than 1 g of dried and roasted leaves of *Morinda citrifolia* | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Noni fruit powder (*Morinda citrifolia*)** | *Specified food category* | *Maximum levels* | 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 | | | |
| ***Odontella aurita* microalgae** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be '*Odontella aurita* microalgae' | | |
| | Flavoured pasta | 1,5 % | | | |
| | Fish soups | 1 % | | | |
| | Marine terrines | 0,5 % | | | |
| | Broth preparations | 1 % | | | |
| | Crackers | 1,5 % | | | |
| | Frozen breaded fish | 1,5 % | | | |
| **Oil enriched with phytosterols/phytostanols** | *Specified food category* | *Maximum levels of phytosterols/phytostanols* | In accordance with Annex III.5 to Regulation (EU) No 1169/2011 | | |
| | Spreadable fats as defined in Annex VII, Part VII and Appendix II, points B and C of Regulation (EU) No 1308/2013, and excluding cooking and frying fats and spreads based on butter or other animal fat | 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.<br>2. The amount of phytosterols/phytostanols added to a container of beverages shall not exceed 3 g.<br>3. Salad dressings, mayonnaise and spicy sauces shall be packed as single portions. | | | |
| | 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 ≤ 12 g per 100 g), where possibly the milk fat has been reduced and the fat or protein has been partly or fully replaced by vegetable fat or protein | | | | |
| | Soya drinks | | | | |
| | Salad dressings, mayonnaise and spicy sauces | | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Oil extracted from squids** | *Specified food category* | *Maximum levels of DHA and EPA combined* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Squid oil'. | | |
| | Dairy products except milk-based beverages | 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 | | | |
| | Bakery products (breads and bread rolls) | 200 mg/100 g | | | |
| | Cereal bars | 500 mg/100 g | | | |
| | Non-alcoholic beverages (including milk-based beverages) | 60 mg/100 ml | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 3 000 mg/day for general population<br>450 mg/day for pregnant and lactating women | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products intended | | | |
| | Total diet replacement for weight control defined in Regulation (EU) No 609/2013 and meal replacements for weight control | 200 mg/meal | | | |
| **Pasteurised fruit-based preparations produced using high-pressure treatment** | *Specified food category* | *Maximum levels* | The wording 'pasteurised by high-pressure treatment' shall be displayed next to the name of the fruit preparations as such and in any product in which it is used | | |
| | Types of fruit:<br>apple, apricot, banana, blackberry, blueberry, cherry, coconut, fig, grape, grapefruit, mandarin, mango, melon, peach, pear, pineapple, prune, raspberry, rhubarb, strawberry | | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Phosphated maize starch** | *Specified food category* | *Maximum levels* | 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 | | | | |
| **Phosphatidylserine from fish phospholipids** | *Specified food category* | *Maximum levels of phosphatidylserine* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Fish phosphatidylserine' | | |
| | Beverages based on yoghurt | 50 mg/100 ml | | | |
| | Powders based on milk powders | 3 500 mg/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 | | | |
| | Food supplements as defined in Directive 2002/46/EC | 300 mg/day | | | |
| **Phosphatidylserine from soya phospholipids** | *Specified food category* | *Maximum levels of phosphatidylserine* | 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 | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Chocolate based confectionary | 200 mg/100 g | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In compliance with Regulation (EU) No 609/2013 | | | |
| **Phospholipid product containing equal amounts of phosphatidylserine and phosphatidic acid** | *Specified food category* | *Maximum levels of phosphatidylserine* | 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/100 g | | | |
| | Cereal bars | 350 mg/100 g | | | |
| | Foods based on yogurt | 80 mg/100 g | | | |
| | Soy-based yogurt-like products | 80 mg/100 g | | | |
| | Yogurt based-drinks | 50 mg/100 g | | | |
| | Soy-based yogurt-like drinks | 50 mg/100 g | | | |
| | Powders based on milk powder | 3,5 g/100 g (equivalent to 40 mg/100 ml 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 | | | |
| **Phospholipides from egg yolk** | *Specified food category* | *Maximum levels* | | | |
| | Not specified | | | | |
| **Phytoglycogen** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Phytoglycogen' | | |
| | Processed foods | 25 % | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Phytosterols/phytostanols** | *Specified food category* | *Maximum levels* | 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.<br>The amount of phytosterols/phytostanols added to a container of beverages shall not exceed 3 g.<br>Salad dressings, mayonnaise and spicy sauces shall be packed as single portions | | | |
| | Rye bread with flour containing ≥ 50 % rye (wholemeal rye flour, whole or cracked rye kernels and rye flakes) and ≤ 30 % wheat; and with ≤ 4 % added sugar but no fat added. | | | | |
| | Salad dressings, mayonnaise and 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. | | | | |
| | Products based on fermented milk such as yoghurt and cheese type products (fat content < 12 % per 100 g), where possibly the milk fat has been reduced, or where milk fat and/or protein has been partly or fully replaced by vegetable fat and/or protein | | | | |
| | Spreadable fats as defined in Annex VII, Part VII and Appendix II, points B and C of Regulation (EU) No 1308/2013, and excluding cooking and frying fats and spreads based on butter or other animal fat. | | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 3 g/day | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Plum kernel oil** | *Specified food category* | *Maximum levels* | | | |
| | For frying and as seasoning | In line with normal food use of vegetable oils | | | |
| **Potato proteins (coagulated) and hydrolysates thereof** | Not specified | | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Potato protein' | | |
| **Prolyl oligopeptidase (enzyme preparation)** | *Specified food category* | *Maximum levels* | 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 for general adult population | 120 PPU/day (2,7 g of enzyme preparation/day) ($2 \times 10^6$ PPI/day)<br>PPU – Prolyl Peptidase Units or Proline Protease Units<br>PPI – Protease Picomole International | | | |
| **Protein extract from pig kidneys** | *Specified food category* | *Maximum levels* | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 3 capsules/day; equalizing 12,6 mg pig kidney extract a day<br>Diamine oxidase (DAO) content: 0,9 mg/day (3 capsules with a content of DAO of 0,3 mg/capsule) | | | |
| | Food for special medical purposes as defined in Regulation (EU) No 609/2013 | | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| ▼M10 | | | | | |
| **Pyrroloquinoline quinone disodium salt** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Pyrroloquinoline quinone disodium salt'.<br><br>Food supplements containing Pyrroloquinoline quinone disodium salt shall bear the following statement:<br><br>This food supplement should be consumed by adults only excluding pregnant and lactating women | | Authorised on 2 September 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.<br><br>Applicant: Mitsubishi Gas Chemical Company, Inc., Mitsubishi Building 5-2 Marunouchi 2-chome, Chiyoda-ku, Tokyo 100-8324, Japan. During the period of data protection the novel food Pyrroloquinoline quinone disodium salt is authorised for placing on the market within the Union only by Mitsubishi Gas Chemical Company, Inc., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Mitsubishi Gas Chemical Company, Inc.<br><br>End date of the data protection: 2 september 2023 |
| | Food Supplements as defined in Directive 2002/46/EC intended for the adult population, excluding pregnant and lactating women | 20 mg/day | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Rapeseed oil high in unsaponifiable matter** | *Specified food category* | *Maximum levels* | 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 | | | |
| **Rapeseed Protein** | As a vegetable protein source in foods except in infant formula and follow-on formula | | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Rapeseed protein'.<br>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. | | |
| **Trans-resveratrol** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the food supplements containing it shall be '*Trans*-resveratrol'.<br>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. | | |
| | Food Supplements as defined in Directive 2002/46/EC for adult population (capsule or tablet form) | 150 mg/day | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Trans-resveratrol (microbial source)** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the food supplements containing it shall be '*Trans*-resveratrol'.<br>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. | | |
| | Food supplements as defined in Directive 2002/46/EC | In line with normal use in food supplements of resveratrol extracted from Japanese knotweed (*Fallopia japonica*) | | | |
| **Rooster comb extract** | *Specified food category* | *Maximum levels* | 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/100 g or mg/100 ml | | | |
| | Milk based fermented drinks | 80 mg/100 g or mg/100 ml | | | |
| | Yoghurt-type products | 65 mg/100 g or mg/100 ml | | | |
| | *Fromage frais* | 110 mg/100 g or mg/100 ml | | | |
| **Sacha inchi oil from *Plukenetia volubilis*** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Sacha inchi oil (Plukenetia volubilis)' | | |
| | As for linseed oil | In line with normal food use of linseed oil | | | |
| **Salatrims** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'reduced energy fat (salatrims)'.<br>2. There shall be a statement that excessive consumption may lead to gastro-intestinal disturbance.<br>3. There shall be a statement that the products are not intended for use by children. | | |
| | Bakery products and confectionary | | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| ***Schizochytrium sp.* oil rich in DHA and EPA** | *Specified food category* | *Maximum levels of DHA and EPA combined*: | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'DHA and EPA-rich oil from the microalgae *Schizochytrium* sp.' | | |
| | Food Supplements as defined in Directive 2002/46/EC for adult population excluding pregnant and lactating women | 3 000 mg/day | | | |
| | Food Supplements as defined in Directive 2002/46/EC for pregnant and lactating women | 450 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 | | | |
| | Milk-based drinks and similar products intended for young children | 200 mg/100 g | | | |
| | Processed cereal based food and baby food for infants and young children as defined in Regulation (EU) No 609/2013 | | | | |
| | Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen | | | | |
| | Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 | | | | |
| | Bakery Products (Breads, Rolls and Sweet Biscuits) | 200 mg/100 g | | | |
| | Breakfast Cereals | 500 mg/100 g | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | 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 milk-based drinks) | 80 mg/100 g | | | |
| | Cereal/Nutrition Bars | 500 mg/100 g | | | |
| | Spreadable Fats and Dressings | 600 mg/100 g | | | |
| ***Schizochytrium* sp. (ATCC PTA-9695) oil** | *Specified food category* | *Maximum levels of DHA* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the microalgae *Schizochytrium* 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 fats and dressings | 600 mg/100 g | | | |
| | Breakfast cereals | 500 mg/100 g | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 250 mg DHA/day for general population | | | |
| | | 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 | | | |

▼M9

| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Milk-based drinks and similar products intended for young children | 200 mg/100 g | | | |
| | Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen | | | | |
| | Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 | | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |
| | Bakery products (breads,rolls, and, sweet biscuits) | 200 mg/100 g | | | |
| | Cereal bars | 500 mg/100 g | | | |
| | Cooking fats | 360 mg/100 g | | | |
| | Non-alcoholic beverages (including dairy analogue and milk-based drinks) | 80 mg/100 ml | | | |
| | Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 | In accordance with Regulation (EU) No 609/2013 | | | |
| | Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013 | 200 mg/100 g | | | |
| ***Schizochytrium* sp. oil** | *Specified food category* | *Maximum levels of DHA* | The designation of the novel food 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 | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Spreadable fats and dressings | 600 mg/100 g | | | |
| | Breakfast cereals | 500 mg/100 g | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 250 mg DHA/day for general population | | | |
| | | 450 mg DHA/day for pregnant and lactating women | | | |
| | Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control | 250 mg/meal | | | |
| | Milk-based drinks and similar products intended for young children | 200 mg/100 g | | | |
| | Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013 | | | | |
| | Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen | | | | |
| | Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 | | | | |
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |
| | Bakery products (breads, rolls and sweet biscuits) | 200 mg/100 g | | | |
| | Cereal bars | 500 mg/100 g | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Cooking fats | 360 mg/100 g | | | |
| | Non-alcoholic beverages (including dairy analogue and milk-based drinks) | 80 mg/100 ml | | | |
| ***Schizochytrium* sp. (T18) oil** | *Specified food category* | *Maximum levels of DHA* | The designation of the novel food 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 fats and dressings | 600 mg/100 g | | | |
| | Breakfast cereals | 500 mg/100 g | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 250 mg DHA/day for general population | | | |
| | | 450 mg DHA/day for pregnant and lactating women | | | |
| | Total diet replacement for weight control as defined in Regulation (EU) No 609/2013 and meal replacements for weight control | 250 mg/meal | | | |
| | Milk-based drinks and similar products intended for young children | 200 mg/100 g | | | |
| | Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen | | | | |
| | Foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 | | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Foods for special medical purposes as defined in Regulation (EU) No 609/2013 | In accordance with the particular nutritional requirements of the persons for whom the products are intended | | | |
| | Bakery products (breads, rolls and, sweet biscuits) | 200 mg/100 g | | | |
| | Cereal bars | 500 mg/100 g | | | |
| | Cooking fats | 360 mg/100 g | | | |
| | Non-alcoholic beverages (including dairy analogue and milk-based drinks) | 80 mg/100 ml | | | |
| | Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013 | In accordance with Regulation (EU) No 609/2013 | | | |
| | Processed cereal-based foods and baby foods for infants and young children as defined in Regulation (EU) No 609/2013 | 200 mg/100 g | | | |
| **Fermented soybean extract** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Fermented soybean extract'.<br>2. The labelling of food supplements containing fermented soybean extract shall bear a statement that persons taking medication should only consume the product under medical supervision. | | |
| | 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 | | | |
| **Spermidine-rich wheat germ extract (*Triticum aestivum*)** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the food supplements containing it shall be 'spermidine-rich wheat germ extract' | | |
| | Food Supplements as defined in Directive 2002/46/EC intended for the adult population, excluding pregnant and lactating women | Equivalent of max. 6 mg/day spermidine | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Sucromalt** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Sucromalt'.<br>2. The designation of the novel food on the labelling shall be accompanied by indication that the product is a source of glucose and fructose. | | |
| | Not specified | | | | |
| **Sugar cane fibre** | *Specified food category* | *Maximum levels* | | | |
| | 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 % | | | |
| **Sunflower oil extract** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Sunflower oil extract' | | |
| | Food Supplements as defined in Directive 2002/46/EC | 1,1 g/day | | | |
| **Dried *Tetraselmis chuii* microalgae** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Dried microalgae *Tetraselmis chuii*' or 'Dried microalgae *T. chuii*'<br>Food supplements containing dried microalgae *Tetraselmis chuii* shall bear the following statement: 'Contains negligible amounts of iodine' | | |
| | Sauces | 20 % or 250mg/day | | | |
| | Special salts | 1 % | | | |
| | Condiment | 250 mg/day | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 250 mg/day | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| ***Therapon barcoo*/ Scortum** | 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 | | | | |
| **D-Tagatose** | *Specified food category* | *Maximum levels* | 1. The designation of the novel food on the labelling of the foodstuffs containing it shall be 'D-Tagatose'.<br>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 | | | | |
| **Taxifolin-rich extract** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'taxifolin-rich extract'. | | |
| | 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 | | | |
| **Trehalose** | *Specified food category* | *Maximum levels* | 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.<br>2. The designation of the novel food on the labelling shall be accompanied by indication that the 'Trehalose is a source of glucose'. | | |
| | Not specified | | | | |
| **UV-treated mushrooms (*Agaricus bisporus*)** | *Specified food category* | *Maximum levels of vitamin $D_2$* | | | |
| | Mushrooms (*Agaricus bisporus*) | 10 µg of vitamin $D_2$/100 g fresh weight | 1. The designation on the label of the novel food as such or of the foodstuffs containing it shall be 'UV-treated mushrooms (*Agaricus bisporus*)'. | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | | | 2. The designation on the label of the novel food as such or of the foodstuffs containing it shall be accompanied by indication that a 'controlled light treatment was used to increase vitamin D levels' or 'UV treatment was used to increase vitamin $D_2$ levels'. | | |
| **UV-treated baker's yeast (*Saccharomyces cerevisiae*)** | *Specified food category* | *Maximum levels of vitamin $D_2$* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Vitamin D yeast' or 'Vitamin $D_2$ yeast' | | |
| | Yeast-leavened breads and rolls | 5 µg of vitamin $D_2$/100 g | | | |
| | Yeast-leavened fine bakery wares | 5 µg of vitamin $D_2$/100 g | | | |
| | Food Supplements as defined in Directive 2002/46/EC | 5 µg of vitamin $D_2$/day | | | |
| **UV-treated bread** | *Specified food category* | *Maximum levels of vitamin $D_2$* | The designation on the label of the novel food shall be accompanied by 'contains vitamin D produced by UV-treatment' | | |
| | Yeast leavened bread and rolls (without toppings) | 3 µg vitamin $D_2$/100 g | | | |
| **UV-treated milk** | *Specified food category* | *Maximum levels of vitamin $D_3$* | 1. The designation on the label of the novel food shall be 'UV-treated'.<br>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'. | | |
| | 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 | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Vitamin $K_2$ (menaquinone)** | 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 $K_2$' | | |
| **Wheat bran extract** | *Specified food category* | *Maximum levels* | 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/100 g | | | |
| | Ready to eat cereals | 9 g/100 g | | | |
| | Dairy products | 2,4 g/100 g | | | |
| | Fruit and vegetable juices | 0,6 g/100 g | | | |
| | Soft drinks | 0,6 g/100 g | | | |
| | Meat preparations | 2 g/100 g | | | |
| **Yeast beta-glucans** | *Specified food category* | *Maximum levels of pure beta-glucans from yeast (Saccharomyces cervisiae)* | The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Yeast (*Saccharomyces cerevisiae*) 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<br>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 | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| | Beverages based on fruit and/or vegetable juices including concentrate and dehydrated juices | 1,3 g/kg | | | |
| | Fruit-flavoured drinks | 0,8 g/kg | | | |
| | Cocoa beverages preparation powder | 38,3 g/kg (powder) | | | |
| | Other beverages | 0,8 g/kg (ready to drink) | | | |
| | | 7 g/kg (powder) | | | |
| | Cereal bars | 6 g/kg | | | |
| | Breakfast cereals | 15,3 g/kg | | | |
| | Wholegrain and high fibre instant hot breakfast cereals | 1,5 g/kg | | | |
| | Cookie-type biscuits | 6,7 g/kg | | | |
| | Cracker-type biscuits | 6,7 g/kg | | | |
| | Milk based beverages | 3,8 g/kg | | | |
| | Fermented milk products | 3,8 g/kg | | | |
| | Milk product analogues | 3,8 g/kg | | | |
| | Dried milk/milk powder | 25,5 g/kg | | | |
| | Soups and soup mixes | 0,9 g/kg (ready to eat) | | | |
| | | 1,8 g/kg (condensed) | | | |
| | | 6,3 g/kg (powder) | | | |
| | Chocolate and confectionery | 4 g/kg | | | |
| | Protein bars and powders | 19,1 g/kg | | | |
| | Jam, marmalade and other fruit spreads | 11,3 g/kg | | | |

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| | | | | | |
|---|---|---|---|---|---|
| **Zeaxanthin** | *Specified food category* | *Maximum levels* | The designation of the novel food on the labelling of the foodstuffs containing it shall be ‘Zeaxanthin’. | | |
| | Food Supplements as defined in Directive 2002/46/EC | 2 mg/day | | | |

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| Authorised novel food | Conditions under which the novel food may be used | | Additional specific labelling requirements | Other requirements | ►M13 Data Protection ◄ |
|---|---|---|---|---|---|
| **Zinc L-pidolate** | *Specified food category* | *Maximum levels* | 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 | 3 g/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 | | | | |

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

(2) Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (OJ L 228, 31.7.2014, p. 5).

(3) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

(4) Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

(5) Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption (OJ L 10, 12.1.2002, p. 67).

(6) Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulation (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) 1234/2007 (OJ L 347, 20.12.2013, p. 671).

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**Table 2: Specifications**

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

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| Authorised Novel Food | Specifications |
|---|---|
| | Residual proteins: < 0,01 % (w/w)**Residual solvents:**<br>2-Propanol: < 0,1 % (w/w)<br>Acetone: < 0,1 % (w/w)<br>Ethyl acetate: < 0,1 % (w/w)<br>**Microbiological criteria:**<br>*Salmonella:* Absence in 25 g<br>Aerobic mesophilic total count:< 500 CFU/g<br>Enterobacteriaceae: Absence in 10 g<br>*Cronobacter (Enterobacter) sakazakii:* Absence in 10 g<br>*Listeria monocytogenes:* Absence in 25 g<br>*Bacillus cereus:* < 50 CFU/g<br>Yeasts: < 10 CFU/g<br>Moulds: < 10 CFU/g<br>Residual endotoxins: < 10 EU/mg<br>CFU: Colony Forming Units; EU: Endotoxin Units. |
| ***Adansonia digitata* (Baobab) dried fruit pulp** | **Description/Definition:**<br>The Baobab (*Adansonia digitata*) fruits are harvested from trees. The hard shells are cracked open and the pulp is separated from the seeds and the shell. This is milled, separated into coarse and fine lots (particle size 3 to 600 μ) and then packaged.<br>**Typical nutritional components:**<br>Moisture (loss on drying) (g/100 g): 4,5-13,7<br>Protein (g/100 g): 1,8-9,3<br>Fat (g/100 g): 0-1,6<br>Total carbohydrate (g/100 g): 76,3-89,5<br>Total sugars (as glucose): 15,2-36,5<br>Sodium (mg/100 g): 0,1-25,2<br>**Analytical specifications:**<br>Foreign matter: Not more than 0,2 %<br>Moisture (loss on drying) (g/100 g): 4,5-13,7<br>Ash (g/100 g): 3,8-6,6 |

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| Authorised Novel Food | Specifications |
|---|---|
| ***Ajuga reptans* extract from cell cultures** | **Description/Definition:**<br>Hydroalcoholic extract from *Ajuga reptans* L. tissue cultures which is substantially equivalent to extracts from flowering aerial parts of *Ajuga reptans* obtained by traditional cultures. |
| **L-Alanyl-L-Glutamine** | **Description/Definition:**<br>L-Alanyl-L-Glutamine is produced by fermentation with a genetically modified strain of *Escherichia coli*. During the fermentation process, the ingredient is secreted into the growth medium from which it is subsequently separated and purified to a concentration of > 98 %.<br>Appearance: White crystalline powder<br>Purity: > 98 %<br>Infrared spectroscopy: Conformity with ref. standard<br>Appearance of solution: Colourless and clear<br>Assay (dry basis): 98-102 %<br>Related substances (each): ≤ 0,2 %<br>Residue on ignition: ≤ 0,1 %<br>Loss on drying: ≤ 0,5 %<br>Optical rotation: +9,0 - +11,0$^{o}$<br>pH (1 %; $H_2O$): 5,0-6,0<br>Ammonium ($NH_4$): ≤ 0,020 %<br>Chloride (Cl): ≤ 0,020 %<br>Sulphate ($SO_4$): ≤ 0,020 %<br>**Microbiological criteria:**<br>*Escherichia coli*: Absence/g |
| **Algal oil from the microalgae *Ulkenia* sp.** | **Description/Definition:**<br>Oil from the micro-algae *Ulkenia* sp.<br>Acid value: ≤ 0,5 mg KOH/g<br>Peroxide value (PV): ≤ 5,0 meq/kg oil<br>Moisture and volatiles: ≤ 0,05 %<br>Unsaponifiables: ≤ 4,5 %<br>Trans-fatty acids: ≤ 1,0 %<br>DHA content: ≥ 32 % |

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| Authorised Novel Food | Specifications |
|---|---|
| ***Allanblackia seed oil*** | **Description/Definition:**<br>*Allanblackia* seed oil is obtained from the seeds of the allanblackia species: *A. floribunda* (synonymous with *A. parviflora*) and *A. stuhlmannii.*<br>**Composition of fatty acids:**<br>Lauric acid (C12:0): < 1,0 %<br>Myristic acid (C14:0): < 1,0 %<br>Palmitic acid (C16:0): < 2,0 %<br>Palmitoleic acid (C16:1): < 1,0 %<br>Stearic acid (C18:0): 45-58 %<br>Oleic acid (C18:1): 40-51 %<br>Linoleic acid (C18:2): < 1,0 %<br>γ-Linolenic acid (C18:3): < 1,0 %<br>Arachidic acid (C20:0): < 1,0 %<br>Free fatty acids: max 0,1 %<br>**Characteristics:**<br>Trans fatty acids: max 0,5 %<br>Peroxide value (PV): max 0,8 meq/kg<br>Iodine value: < 46 g/100 g<br>Unsaponifiable matter: max 1,0 %<br>Saponification value: 185-198 mg KOH/g |
| ***Aloe macroclada* Baker leaf extract** | **Description/Definition:**<br>Powdered gel extract derived from the leaves of *Aloe macroclada* Baker which is substantially equivalent to the same gel derived from *Aloe vera* (L.) Burm.f. leaves.<br>Ash: 25 %<br>Dietary fibres: 28,6 %<br>Fat: 2,7 %<br>Moisture: 4,7 %<br>Polysaccharides: 9,5 %<br>Protein: 1,63 %<br>Glucose: 8,9 % |

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| Authorised Novel Food | Specifications |
|---|---|
| **Antarctic Krill oil from *Euphausia superba*** | **Description/Definition:**<br>To produce lipid extract from Antarctic Krill (*Euphausia superba*) deep-frozen crushed krill or dried krill meal is subjected to lipid extraction with an approved extraction solvent (under Directive 2009/32/EC). Proteins and krill material are removed from the lipid extract by filtration. The extraction solvents and residual water are removed by evaporation.<br>Saponification value: ≤ 230 mg KOH/g<br>Peroxide value (PV): ≤ 3 meq $O_2$/kg oil<br>Oxidative stability: All food products containing Antarctic Krill oil from *Euphausia superba* should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC).<br>Moisture and volatiles: ≤ 3 % or 0,6 expressed as water activity at 25 °C<br>Phospholipids: 35-50 %<br>Trans-fatty acids: ≤ 1 %<br>EPA (eicosapentaenoic acid): ≥ 9 %<br>DHA (docosahexaenoic acid): ≥ 5 % |
| **Antarctic Krill oil rich in phospholipids from *Euphausia superba*** | **Description/Definition:**<br>Oil rich in phospholipids is produced from Antarctic krill (*Euphausia superba*) by repeated solvent washings with an approved solvent (under Directive 2009/32/EC) to increase phospholipid content of the oil. Solvents are removed from the final product by evaporation.<br>Saponification value: ≤ 230 mg KOH/g<br>Peroxide value (PV): ≤ 3 meq $O_2$/kg oil<br>Moisture and volatiles: ≤ 3 % or 0,6 expressed as water activity at 25 °C<br>Phospholipids: ≥ 60 %<br>Trans-fatty acids: ≤ 1 %<br>EPA (eicosapentaenoic acid): ≥ 9 %<br>DHA (docosahexaenoic acid): ≥ 5 % |
| **Arachidonic acid-rich oil from the fungus *Mortierella alpina*** | **Description/Definition:**<br>The clear yellow arachidonic acid-rich oil is obtained by fermentation of the non-genetically modified strains IS-4, I49-N18, FJRK-MA01 and CBS 210.32 of the fungus *Mortierella alpina* using a suitable liquid. The oil is then extracted from the biomass and purified.<br>Arachidonic acid: ≥ 40 % by weight of the total fatty acid content<br>Free fatty acids: ≤ 0,45 % of the total fatty acid content<br>Trans fatty acids: ≤ 0,5 % of the total fatty acid content<br>Unsaponifiable matter: ≤ 1,5 % |

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| Authorised Novel Food | Specifications |
|---|---|
| | Peroxide value (PV): ≤ 5 meq/kg<br>Anisidin value: ≤ 20<br>Acid value: ≤ 1,0 KOH/g<br>Moisture: ≤ 0,5 % |
| **Argan oil from *Argania spinosa*** | **Description/Definition:**<br>Argan oil is the oil obtained by cold pressing of the almond like kernels of the fruits of *Argania spinosa* (L.) Skeels. Kernels may be roasted prior to pressing, but with no direct contact with a flame.<br>**Composition:**<br>Palmitic acid (C16:0): 12-15 %<br>Stearic acid (C18:0): 5-7 %<br>Oleic acid (C18:1): 43-50 %<br>Linoleic acid (C18:2): 29-36 %<br>Unsaponifiable matter: 0,3-2 %<br>Total sterols: 100-500 mg/100 g<br>Total tocopherols: 16-90 mg/100 g<br>Oleic acidity: 0,2-1,5 %<br>Peroxide value (PV): < 10 meq $O_2$/kg |
| **Astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae** | **Description/Definition:**<br>Astaxanthin is a carotenoid produced by *Haematococcus pluvialis* algae. Production methods for the growth of the algae are variable; using either closed systems exposed to sunlight or strictly controlled illuminated light; alternatively open ponds may be used. The algal cells are harvested and dried; the oleoresin is extracted using either super critical $CO_2$ or a solvent (ethyl acetate). The Astaxanthin is diluted and standardized to 2,5 %, 5,0 %, 7,0 %, 10 %, 15 % or 20 % using olive oil, safflower oil, Sunflower oil or MCT (Medium Chain Triglycerides).<br>**Composition of the Oleoresin:**<br>Fat: 42,2- 99 %<br>Protein: 0,3-4,4 %<br>Carbohydrate: 0-52,8 %<br>Fibre: < 1,0 %<br>Ash: 0,0-4,2 %<br>Specification of Carotenoids w/w%<br>Total Astaxanthins: 2,9-11,1 % |

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| Authorised Novel Food | Specifications |
|---|---|
| | 9-cis-astaxanthin: 0,3-17,3 %<br>13-cis-astaxanthin: 0,2-7,0 %<br>Astaxanthin monoesters: 79,8-91,5 %<br>Astaxanthin diesters: 0,16-19,0 %<br>B-Carotene: 0,01-0,3 %<br>Lutein: 0-1,8 %<br>Canthaxanthin: 0-1,30 %<br>**Microbiological criteria:**<br>Total aerobic bacteria: < 3 000 CFU/g<br>Yeast and Moulds: < 100 CFU/g<br>Coliforms: < 10 CFU/g<br>*E. coli*: Negative<br>*Salmonella*: Negative<br>*Staphylococcus*: Negative |
| **Basil seeds (*Ocimum basilicum*)** | **Description/Definition:**<br>Basil (*Ocimum basilicum* L.) belongs to the family '*Lamiaceae*' 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 juice and fruit/vegetable blend beverages containing Basil seeds (*Ocimum basilicum* L.) includes seed pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place.<br>Dry Matter: 94,1 %<br>Protein: 20,7 %<br>Fat: 24,4 %<br>Carbohydrate: 1,7 %<br>Dietary Fibre: 40,5 % (Method: AOAC 958,29)<br>Ash: 6,78 % |
| **Fermented black bean extract** | **Description/Definition:**<br>Fermented black bean extract (Touchi extract) is a fine light-brown protein-rich powder obtained by water extraction of small soybeans (*Glycine max (L.) Merr.*) fermented with *Aspergillus oryzae*. The extract contains an α-glucosidase inhibitor.<br>**Characteristics:**<br>Fat: ≤ 1,0 % |

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| | Protein: ≥ 55 %<br>Water: ≤ 7,0 %<br>Ash: ≤ 10 %<br>Carbohydrate: ≥ 20 %<br>α-glucosidase inhibitory activity: IC50 min 0,025 mg/ml<br>Soy isoflavone: ≤ 0,3 g/100 g |
| **Bovine lactoferrin** | **Description/Definition:**<br>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.<br>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.<br>**Physical-Chemical properties of Bovine lactoferrin:**<br>Moisture: < 4,5 %<br>Ash: < 1,5 %<br>Arsenic: < 2,0 mg/kg<br>Iron: < 350 mg/kg<br>Protein: > 93 %<br>of which bovine lactoferrin: > 95 %<br>of which other proteins: < 5,0 %<br>pH (2 % solution, 20 °C): 5,2-7,2<br>Solubility (2 % solution, 20 °C): complete |
| ***Buglossoides arvensis* seed oil** | **Description/Definition:**<br>Refined Buglossoides oil is extracted from the seeds of *Buglossoides arvensis* (L.) I.M.Johnst<br>Alpha-linolenic acid: ≥ 35 % w/w of total fatty acids<br>Stearidonic acid: ≥ 15 % w/w of total fatty acids<br>Linoleic acid: ≥ 8,0 % w/w of total fatty acids<br>Trans fatty acids: ≤ 2,0 % w/w of total fatty acids |

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| Authorised Novel Food | Specifications |
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| | Acid value: ≤ 0,6 mg KOH/g<br>Peroxide value (PV): ≤ 5,0 meq $O_2$/kg<br>Unsaponifiable content: ≤ 2,0 %<br>Protein content (total nitrogen): ≤ 10 µg/ml<br>Pyrrolizidine alkaloids: Not detectable with a detection limit of 4,0 µg/kg |
| ***Calanus finmarchicus* oil** | **Description/Definition:**<br>The novel food is ruby coloured, slightly viscous oil with a slight shellfish odour extracted from the crustacean (marine zooplankton) *Calanus finmarchicus*. The ingredient consists primarily of wax esters (> 85 %) with minor amounts of triglycerides and other neutral lipids.<br>**Specifications:**<br>Water: < 1,0 %<br>Wax esters: > 85 %<br>Total fatty acids: > 46 %<br>Eicosapentaenoic acid (EPA): > 3,0 %<br>Docosahexaenoic acid (DHA): > 4,0 %<br>Total fatty alcohols: > 28 %<br>C20:1 n-9 fatty alcohol: > 9,0 %<br>C22:1 n-11 fatty alcohol: > 12 %<br>Trans fatty acids: < 1,0 %<br>Astaxanthinesters: < 0,1 %<br>Peroxide value (PV): < 3,0 meq. $O_2$/kg |
| **Chewing gum base (monomethoxypolyethylene glycol)** | **Description/Definition:**<br>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).<br>White to off-white colour.<br>CAS No.: 1246080-53-4<br>**Characteristics:**<br>Moisture: < 5,0 % |

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| Authorised Novel Food | Specifications |
|---|---|
| | Aluminium: < 3,0 mg/kg<br>Lithium: < 0,5 mg/kg<br>Nickel: < 0,5 mg/kg<br>Residual anhydride: < 15 μmol/g<br>Polydispersity index: < 1,4<br>Isoprene: < 0,05 mg/kg<br>Ethylene oxide: < 0,2 mg/kg<br>Free maleic anhydride: < 0,1 %<br>Total oligomeres (less than 1 000 Dalton): ≤ 50 mg/kg<br>Ethylene glycol: < 200 mg/kg<br>Diethylene glycol: < 30 mg/kg<br>Monoethylene glycol methyl ether: < 3,0 mg/kg<br>Diethylene glycol methyl ether: < 4,0 mg/kg<br>Triethylene glycol methyl ether: < 7,0 mg/kg<br>1,4-Dioxane: < 2,0 mg/kg<br>Formaldehyde: < 10 mg/kg |
| **Chewing gum base (Methyl vinyl ether-maleic anhydride copolymer)** | **Description/Definition:**<br>Methyl vinyl ether-maleic anhydride copolymer is an anhydrous copolymer of methyl vinyl ether and maleic anhydride.<br>Free-flowing, white to white-off powder<br>CAS No: 9011-16-9<br>**Purity:**<br>Assay value: At least 99,5 % in dry matter<br>Specific viscosity (1 % MEK): 2-10<br>Residual methyl vinyl ether: ≤ 150 ppm<br>Residual maleic anhydride: ≤ 250 ppm<br>Acetaldehyde: ≤ 500 ppm<br>Methanol: ≤ 500 ppm<br>Dilauroyl peroxide: ≤ 15 ppm<br>Total heavy metals: ≤ 10 ppm |

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| Authorised Novel Food | Specifications |
|---|---|
| | **Microbiological criteria:**<br>Total aerobic plate count: ≤ 500 CFU/g<br>Mould/yeast: ≤ 500 CFU/g<br>*Escherichia coli*: Negative to test<br>*Salmonella*: Negative to test<br>*Staphylococcus aureus:* Negative to test<br>*Pseudomonas aeruginosa*: Negative to test |
| **Chia oil from *Salvia hispanica*** | **Description/Definition:**<br>Chia oil is produced from Chia (*Salvia hispanica* L.) seeds (99,9 % pure) by cold pressing. No solvents are used and, once pressed, the oil is held in decantation tanks and a filtration process employed to remove impurities. It can also be produced by extraction with supercritical $CO_2$.<br>**Production process:**<br>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.<br>Acidity expressed as oleic acid: ≤ 2,0 %<br>Peroxide value (PV): ≤ 10 meq/kg<br>Insoluble impurities: ≤ 0,05 %<br>Alpha linolenic acid: ≥ 60 %<br>Linoleic acid: 15-20 % |
| **Chia seeds (*Salvia hispanica*)** | **Description/Definition:**<br>Chia (*Salvia hispanica* L.) is a summer annual herbaceous plant belonging to the *Labiatae* family. Post-harvest the seeds are cleaned mechanically. Flowers, leaves and other parts of the plant are removed.<br>Dry matter: 90-97 %<br>Protein: 15-26 %<br>Fat: 18-39 %<br>Carbohydrate (*): 18-43 %<br>Crude Fibre(**): 18-43 %<br>Ash: 3-7 %<br>(*) Carbohydrates include the fibre value<br>(**) Crude fibre is the part of fibre made mainly of indigestible cellulose, pentosans and lignin |

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| Authorised Novel Food | Specifications |
|---|---|
| | **Production process:**<br>Production process of fruit juices and fruit juice blends beverages, containing Chia seeds, includes seed pre-hydration and pasteurisation steps. Microbiological controls and monitoring systems are in place. |
| **Chitin-glucan from *Aspergillus niger*** | **Description/Definition:**<br>Chitin-glucan is obtained from the mycelium of *Aspergillus niger*; it is a slightly yellow, odourless, free-flowing powder. It has a dry matter content of 90 % or more.<br>Chitin-glucan is composed largely of two polysaccharides:<br>— chitin, composed of repeating units of N-acetyl-D-glucosamine (CAS No: 1398-61-4),<br>— beta (1, 3)-glucan, composed of repeating units of D-glucose (CAS No: 9041-22-9).<br>Loss on drying: ≤ 10 %<br>Chitin-glucan: ≥ 90 %<br>Ratio of chitin to glucan: 30:70 to 60:40<br>Ash: ≤ 3,0 %<br>Lipids: ≤ 1,0 %<br>Proteins: ≤ 6,0 % |
| **Chitin-glucan complex from *Fomes fomentarius*** | **Description/Definition:**<br>Chitin-glucan complex is obtained from the cell walls of the fruit bodies of the fungus *Fomes fomentarius*. It consists primarily of two polysaccharides:<br>— Chitin, composed of repeating units of N-acetyl-D-glucosamine (CAS No: 1398-61-4);<br>— Beta-(1,3)(1,6)-D-glucan, composed of repeating units of D-glucose (CAS No: 9041-22-9).<br>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.<br>Appearance: Powder, odourless, flavourless, brown<br>**Purity:**<br>Moisture: ≤ 15 %<br>Ash: ≤ 3,0 %<br>Chitin-glucan: ≥ 90 %<br>Ratio of chitin to glucan: 70:20<br>Total carbohydrates, excluding glucans: ≤ 0,1 % |

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| Authorised Novel Food | Specifications |
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| | Proteins: ≤ 2,0 %<br>Lipids: ≤ 1,0 %<br>Melanins: ≤ 8,3 %<br>Additives: None<br>pH: 6,7-7,5<br>**Heavy metals:**<br>Lead (ppm): ≤ 1,00<br>Cadmium (ppm): ≤ 1,00<br>Mercury (ppm): ≤ 0,03<br>Arsenic (ppm): ≤ 0,20<br>**Microbiological criteria:**<br>Total mesophilic bacteria: ≤ $10^3$/g<br>Yeast and moulds: ≤ $10^3$/g<br>Coliforms at 30 °C: ≤ $10^3$/g<br>*E. coli*: ≤ 10/g<br>*Salmonella* and other pathogenic bacteria: Absence/25 g |
| **Chitosan extract from fungi (*Agaricus bisporus*; *Aspergillus niger*)** | **Description/Definition:**<br>The chitosan extract (containing mainly poly(D-glucosamine)) is obtained from stems of *Agaricus bisporus* or from the mycelium of *Aspergillus niger*. The patented production process consists of several steps, including: extraction and deacetylation (hydrolysis) in alkaline medium, solubilisation in acidic medium, precipitation in alkaline medium, washing and drying.<br>Synonym: Poly(D-glucosamine)<br>Chitosan CAS number: 9012-76-4<br>Chitosan formula: $(C_6H_{11}NO_4)_n$<br>Appearance: fine free-flowing powder<br>Aspect: Off –white to slightly brownish<br>Odour: Odourless<br>**Purity:**<br>Chitosan content (% w/w dry weight):≥ 85<br>Glucan content (% w/w dry weight): ≤ 15<br>Loss on drying (% w/w dry weight): ≤ 10<br>Viscosity (1 % in 1 % acetic acid): 1-15 |

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|---|---|
| | Degree of acetylation (in % mol/wet weight): 0-30<br>Viscosity (1 % in 1 % acetic acid) (mPa.s): 1-14 for chitosan from Aspergillus niger; 12-25 for chitin from *Agaricus bisporus*<br>Ash (% w/w dry weight): ≤ 3,0<br>Proteins (% w/w dry weight): ≤ 2,0<br>Particle size: > 100 nm<br>Tapped density ($g/cm^3$): 0,7-1,0<br>Fat binding capacity 800 × (w/w wet weight): pass<br>**Heavy metals:**<br>Mercury (ppm): ≤ 0,1<br>Lead (ppm): ≤ 1,0<br>Arsenic (ppm): ≤ 1,0<br>Cadmium (ppm): ≤ 0,5<br>**Microbiological criteria:**<br>Aerobic count (CFU/g): ≤ $10^3$<br>Yeast and mould count (CFU/g): ≤ $10^3$<br>*Escherichia coli* (CFU/g): ≤ 10<br>Enterobacteriaceae (CFU/g): ≤ 10<br>*Salmonella*: Absence/25g<br>*Listeria monocytogenes*: Absence/25g |
| **Chondroitin sulphate** | **Description/Definition:**<br>Chondroitin sulphate (sodium salt) is a biosynthetic product. It is obtained by chemical sulphation of chondroitin derived from fermentation by the bacterium *Escherichia coli* O5:K4:H4 strain U1-41 (ATCC 23502).<br>Chondroitin sulphate (sodium salt) (% dry basis): 95-105<br>MWw (weight avg.) (kDa): 5-12<br>MWn (number avg.) (kDa): 4-11<br>Dispersity ($w_h/w_{0,05}$): ≤ 0,7<br>Sulphation pattern (ΔDi-6S) (%): ≤ 85<br>Loss on drying (%) (105 °C to constant weight): ≤ 10,0<br>Residue on ignition (% dry basis): 20-30<br>Protein (% dry basis): ≤ 0,5<br>Endotoxins (EU/mg): ≤ 100<br>Total organic impurities (mg/kg): ≤ 50 |

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| Authorised Novel Food | Specifications |
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| **Chromium Picolinate** | **Description/Definition:**<br>Chromium picolinate is a reddish free-flowing powder, slightly soluble in water at pH 7. The salt is also soluble in polar organic solvents.<br>Chemical name: tris(2pyridinecarboxylato-N,O)chromium(III) or 2-pyridinecarboxylic acid chromium(III) salt<br>CAS No.: 14639-25-9Chemical formula: $Cr(C_6H_4NO_2)_3$<br>Chemical characteristics:<br>Chromium Picolinate: ≥ 95 %<br>Chromium (III): 12-13 %<br>Chromium (VI): not detected<br>Water: ≤ 4,0 % |
| ***Cistus incanus* L. Pandalis herb** | **Description:**<br>*Cistus incanus* L. Pandalis herb; species belonging to the *Cistaceae* family and native to the Mediterranean region, Chalkidiki Peninsula.<br>**Composition:**<br>Moisture: 9–10 g/100 g herbs<br>Protein: 6,1 g/100 g herbs<br>Fat: 1,6 g/100 g herbs<br>Carbohydrates: 50,1 g/100 g herbs<br>Fiber: 27,1 g/100 g herbs<br>Minerals: 4,4 g/100 g herbs<br>Sodium: 0,18 g<br>Potassium: 0,75 g<br>Magnesium: 0,24 g<br>Calcium: 1,0 g<br>Iron: 65 mg<br>Vitamin $B_1$: 3,0 µg<br>Vitamin $B_2$: 30 µg<br>Vitamin $B_6$: 54 µg<br>Vitamin C: 28 mg<br>Vitamin A: less than 0,1 mg<br>Vitamin E: 40–50 mg |

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| Authorised Novel Food | Specifications |
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| | Alpha-Tocopherol: 20–50 mg<br>Beta and Gamma-Tocopherols: 2–15 mg<br>Delta-Tocopherol: 0,1–2 mg |
| **Citicoline** | **Description/Definition:**<br>Citicoline is produced by a microbial process.<br>Citicoline is composed of cytosine, ribose, pyrophosphate and choline.<br>White crystalline powder<br>Chemical name: Choline cytidine 5′-pyrophosphate, Cytidine 5′-(trihydrogen diphosphate) P’-[2-(trimethylammonio)ethyl]ester inner salt<br>Chemical formula: $C_{14}H_{26}N_4O_{11}P_2$<br>Molecular weight: 488,32 g/mol<br>CAS No.: 987-78-0<br>pH (sample solution of 1 %): 2,5-3,5<br>**Purity:**<br>Assay value: ≥ 98 % of dry matter<br>Loss on drying (100 °C for 4 hours): ≤ 5,0 %<br>Ammonium: ≤ 0,05 %<br>Arsenic: Not more than 2 ppm<br>Free phosphoric acids: ≤ 0,1 %<br>5′-Cytidylic acid: ≤ 1,0 %<br>**Microbiological criteria:**<br>Total plate count: ≤ $10^3$ CFU/g<br>Yeast and moulds: ≤ $10^2$ CFU/g<br>*Escherichia coli*: Absence in 1 g |
| ***Clostridium butyricum*** | **Description/Definition:**<br>*Clostridium butyricum* (CBM-588) is a Gram-positive, spore-forming, obligate anaerobic, non-pathogenic, non-genetically modified bacterium. Depository number FERM BP-2789 |

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|---|---|
| | **Microbiological criteria:**<br>Total viable aerobic count: ≤ $10^3$ CFU/g<br>*Escherichia coli*: Not detected in 1 g*Staphylococcus aureus*: Not detected in 1 g<br>*Pseudomonas aeruginosa*: Not detected in 1 g<br>Yeast and moulds: ≤ $10^2$ CFU/g |
| **Extract of defatted cocoa powder** | Cocoa (*Theobroma cacao* L.) Extract<br>Appearance: Dark brown powder free of visible impurities<br>Physical and chemical properties:<br>Polyphenol content: Min 55,0 % GAE<br>Theobromine content: Max 10,0 %<br>Ash content: Max 5,0 %<br>Moisture content: Max 8,0 %<br>Bulk density: 0,40-0,55 g/$cm^3$<br>pH: 5,0-6,5<br>Residual solvent: Max 500 ppm |
| **Low fat cocoa extract** | Low fat Cocoa (*Theobroma cacao* L.) extract<br>Appearance: Dark red to purple powder<br>Cocoa extract, concentrate: Min 99 %<br>Silicon dioxide (technological aid): Max 1,0 %<br>Cocoa flavanols: Min. 300 mg/g<br>— Epicatechin: Min. 45 mg/g<br>Loss on drying: Max. 5,0 % |
| **Coriander seed oil from *Coriandrum sativum*** | **Description/Definition:**<br>Coriander seed oil is an oil containing glycerides of fatty acids that is produced from the seeds of the coriander plant *Coriandrum sativum* L.<br>Slight yellow colour, bland taste |

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| | CAS No.: 8008-52-4<br>Composition of fatty acids:<br>Palmitic acid (C16:0): 2-5 %<br>Stearic acid (C18:0): < 1,5 %<br>Petroselinic acid (cis-C18:1(n-12)): 60-75 %<br>Oleic acid (cis-C18:1 (n-9)): 8-15 %Linoleic acid (C18:2): 12-19 %<br>α-Linolenic acid (C18:3): < 1,0 %<br>Trans fatty acids: ≤ 1,0 %<br>**Purity:**<br>Refractive index (20 °C): 1,466-1,474<br>Acid value: ≤ 2,5 mg KOH/g<br>Peroxide value (PV): ≤ 5,0 meq/kg<br>Iodine value: 88-110 units<br>Saponification value: 186-200 mg KOH/g<br>Unsaponifiable matter: ≤ 15 g/kg |
| ***Crataegus pinnatifida* dried fruit** | **Description/Definition:**<br>Dried fruits of *Crataegus pinnatifida* species belonging to the *Rosaceae* family and native to north China and Korea.<br>**Composition:**<br>Dry matter: 80 %<br>Carbohydrates: 55 g/kg fresh weight<br>Fructose: 26,5–29,3 g/100 g<br>Glucose: 25,5–28,1 g/100 g<br>Vitamin C: 29,1 mg/100 g fresh weight<br>Sodium: 2,9 g/100 g fresh weight<br>Compotes are products obtained by thermal processing of the edible part of one or several species of fruits, whole or in pieces, sieved or not, without significant concentration. Sugars, water, cider, spices and lemon juice may be used. |

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| Authorised Novel Food | Specifications |
|---|---|
| **α-cyclodextrin** | **Description/Definition:**<br>A non-reducing cyclic saccharide consisting of six α-1,4-linked D-glucopyranosyl units produced by the action of cyclodextrin glucosyltransferase (CGTase, EC 2.4.1.19) on hydrolyzed starch. Recovery and purification of α-cyclodextrin may be carried out using one of the following procedures: precipitation of a complex of α-cyclodextrin with 1-decanol, dissolution in water at elevated temperature and re-precipitation, steam-stripping of the complexant, and crystallisation of α-cyclodextrin from the solution; or chromatography with ion-exchange or gel filtration followed by crystallisation of α-cyclodextrin from the purified mother liquor; or membrane separation methods such as ultra-filtration and reverse osmosis: Description: Virtually odourless, white or almost white crystalline solid.<br>Synonyms: α-cyclodextrin, α-dextrin, cyclohexaamylose, cyclomaltohexaose, α-cycloamylase<br>Chemical name: Cyclohexaamylose<br>CAS No.: 10016-20-3<br>Chemical formula: $(C_6H_{10}O_5)_6$<br>Formula weight: 972,85<br>Assay: ≥ 98 % (dry basis)<br>**Identification:**<br>Melting range: Decomposes above 278 °C<br>Solubility: Freely soluble in water; very slightly soluble in ethanol<br>Specific rotation: $[\alpha]_D^{25}$: Between +145° and +151° (1 % solution)<br>Chromatography: The retention time for the major peak in a liquid chromatogram of the sample corresponds to that for α-cyclodextrin in a chromatogram of reference α-cyclodextrin (available from *Consortium für Elektrochemische Industrie GmbH, München, Germany or Wacker Biochem Group, Adrian, MI, USA*) using the conditions described in the METHOD OF ASSAY<br>**Purity:**<br>Water: ≤ 11 % (Karl Fischer Method)<br>Residual complexant: ≤ 20 mg/kg<br>(1-decanol)<br>Reducing substances: ≤ 0,5 % (as glucose)<br>Sulphated ash: ≤ 0,1 %<br>Lead: ≤ 0,5 mg/kg<br>**Method of assay:**<br>Determine by liquid chromatography using the following conditions:<br>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 |

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| Authorised Novel Food | Specifications |
|---|---|
| | Reference solution: Weigh accurately about 100 mg of α-cyclodextrin into a 10 ml volumetric flask and add 8 ml of deionised water. Dissolve the sample completely using an ultra-sonification bath and dilute to the mark with purified deionised water.<br>Chromatography: Liquid chromatograph equipped with a refractive index detector and an integrating recorder.<br>Column and packing: Nucleosil-100-$NH_2$ (10 μm) (*Macherey & Nagel Co. Düren*, Germany) or similar<br>Length: 250 mm<br>Diameter: 4 mm<br>Temperature: 40 °C<br>Mobile phase: acetonitrile/water (67/33, v/v)<br>Flow rate: 2,0 ml/min<br>Injection volume: 10 μlProcedure: 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:<br>% α-cyclodextrin (dry basis) = 100 × ($A_S/A_R$) ($W_R/W_S$)<br>where<br>$A_S$ and $A_R$ are the areas of the peaks due to α-cyclodextrin for the sample solution and reference solution, respectively.<br>$W_S$ and $W_R$ are the weights (mg) of the test sample and reference α-cyclodextrin, respectively, after correcting for water content. |
| **γ-cyclodextrin** | **Description/Definition:**<br>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.<br>Virtually odourless, white or almost white crystalline solid<br>Synonyms: γ-cyclodextrin, γ-dextrin, cyclooctaamylose, cyclomaltooctaose, γ-cycloamylase<br>Chemical name: Cyclooctaamylose<br>CAS number: 17465-86-0<br>Chemical formula: $(C_6H_{10}O_5)_8$<br>Assay: ≥ 98 % (dry basis) |

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| Authorised Novel Food | Specifications |
|---|---|
| | **Identification:**<br>Melting range: Decomposes above 285 °C<br>Solubility: Freely soluble in water; very slightly soluble in ethanol<br>Specific rotation: $[\alpha]_D^{25}$: between + 174° and + 180° (1 % solution)<br>**Purity:**<br>Water: ≤ 11 %<br>Residual complexant (8-cyclohexadecen-1-one (CHDC)): ≤ 4 mg/kg<br>Residual solvent (n-decane): ≤ 6mg/kg<br>Reducing substances: ≤ 0,5 % (as glucose)<br>Sulphated ash: ≤ 0,1 % |
| **Dextran preparation produced by *Leuconostoc mesenteroides*** | 1. **Powdered form:**<br>Carbohydrates: 60 % with: (Dextran: 50 %, Mannitol: 0,5 %, Fructose: 0,3 %, Leucrose: 9,2 %)<br>Protein: 6,5 %<br>Lipid: 0,5 %<br>Lactic acid: 10 %<br>Ethanol: traces<br>Ash: 13 %<br>Moisture: 10 %<br>2. **Liquid form:**<br>Carbohydrates: 12 % with: (Dextran: 6,9 %, Mannitol: 1,1 %, Fructose: 1,9 %, Leucrose: 2,2 %)<br>Protein: 2,0 %<br>Lipid: 0,1 %<br>Lactic acid: 2,0 %<br>Ethanol: 0,5 %<br>Ash: 3,4 %<br>Moisture: 80 % |

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| Authorised Novel Food | Specifications |
|---|---|
| **Diacylglycerol oil of plant origin** | **Description/Definition:**<br>Manufactured from glycerol and fatty acids derived from edible vegetable oils, in particular from soybean oil (*Glycine max*) or rapeseed oil (*Brassica campestris, Brassica napus*) using a specific enzyme.<br>**Acylglycerol Distribution:**<br>Diacylglycerols (DAG): ≥ 80 %<br>1,3-Diacylglycerols (1,3-DAG): ≥ 50 %<br>Triacylglycerols (TAG): ≤ 20 %<br>Monoacylglycerols (MAG): ≤ 5,0 %<br>**Fatty Acid Composition (MAG, DAG, TAG):**<br>Oleic acid (C18:1): 20-65 %<br>Linoleic acid (C18:2): 15-65 %<br>Linolenic acid (C18:3): ≤ 15 %<br>Saturated fatty acids: ≤ 10 %<br>**Others:**<br>Acid value: ≤ 0,5 mg KOH/g<br>Moisture and volatile: ≤ 0,1 %<br>Peroxide value (PV): ≤ 1,0 meq/kg<br>Unsaponifiables: ≤ 2,0 %<br>Trans fatty acids≤ 1,0 %<br>MAG = monoacylglycerols, DAG = diacylglycerols, TAG = triacylglycerols |
| **Dihydrocapsiate (DHC)** | **Description/Definition:**<br>Dihydrocapsiate is synthesised by enzyme-catalysed esterification of vanillyl alcohol and 8-methylnonanoic acid. Following the esterification dihydrocapsiate is extracted with n-hexane.<br>Viscous to colourless to yellow liquid<br>Chemical formula: $C_{18}$ $H_{28}$ $O_4$<br>CAS No: 205687-03-2<br>**Physical-chemical properties:**<br>Dihydrocapsiate: > 94 %<br>8-Methylnonanoic acid: < 6,0 %<br>Vanillyl acohol: < 1,0 %<br>Other synthesis related substances: < 2,0 % |

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| Authorised Novel Food | Specifications |
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| ▼M13 | |
| **Dried aerial parts of *Hoodia parviflora*** | **Description/Definition:**<br>It is the whole dried aerial parts of *Hoodia parviflora* N.E.Br., (family *Apocynaceae*)<br>**Characteristics/Composition**<br>Plant material: Aerial parts of at least 3-year-old plants<br>Appearance: Light green to tan fine powder<br>Solubility (water): > 25 mg/mL<br>Moisture: < 5,5 %<br>$A_w$: < 0,3<br>pH: < 5,0<br>Protein: < 4,5 g/100 g<br>Fat: < 3 g/100 g<br>Carbohydrate (including dietary fibre): < 80 g/100 g<br>Dietary fibre: < 55 g/100 g<br>Total sugars: < 10,5 g/100 g<br>Ash: < 20 %<br>**Hoodigosides**<br>P57: 5–50 mg/kg<br>L: 1 000–6 000 mg/kg<br>O: 500–5 000 mg/kg<br>Total: 1 500–11 000 mg/kg<br>**Heavy metals:**<br>Arsenic: < 1,00 mg/kg<br>Mercury: < 0,1 mg/kg<br>Cadmium: < 0,1 mg/kg<br>Lead: < 0,5 mg/kg<br>**Microbiological criteria:**<br>Aerobic plate count: < $10^5$ CFU/g<br>*Escherichia coli*: < 10 CFU/g |

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| Authorised Novel Food | Specifications |
|---|---|
| | *Staphylococcus aureus*: < 50 CFU/g<br>Total coliforms: < 10 CFU/g<br>Yeast: ≤ 100 CFU/g<br>Mould: ≤ 100 CFU/g<br>*Salmonella* species: Negative/25 g<br>*Listeria monocytogenes*: Negative/25 g<br>CFU: Colony Forming Units |

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|---|---|
| **Dried extract of *Lippia citriodora* from cell cultures** | **Description/Definition:**<br>Dried extract of *Lippia citriodora* (Palau) Kunth from cell cultures HTN®Vb. |
| ***Echinacea angustifolia* extract from cell cultures** | **Description/Definition:**<br>Extract of the roots of *Echinacea angustifolia* obtained from plant tissue culture which is substantially equivalent to a root extract from *Echinacea angustifolia* obtained in ethanol-water titrated to 4 % echinacoside. |
| ***Echinacea purpurea* extract from cell cultures** | **Description/Definition:**<br>Dried extract of *Echinacea purpurea* from cell cultures HTN®Vb |
| ***Echium plantagineum* oil** | **Description/Definition:**<br>Echium oil is the pale yellow product obtained by refining oil extracted from the seeds of *Echium plantagineum* L. Stearidonic acid: ≥ 10 % w/w of total fatty acids<br>Trans fatty acids: ≤ 2,0 % (w/w of total fatty acids)<br>Acid value: ≤ 0,6 mg KOH/g<br>Peroxide value (PV): ≤ 5,0 meq $O_2$/kg<br>Unsaponifiable content: ≤ 2,0 %<br>Protein content (total nitrogen): ≤ 20 µg/ml<br>Pyrrolizidine alkaloids: Not detectable with a detection limit 4,0 µg/kg |

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| Authorised Novel Food | Specifications |
|---|---|
| **Epigallocatechin gallate as a purified extract from green tea leaves (*Camellia sinensis*)** | **Description/Definition:**<br>A highly purified extract from the leaves of green tea (*Camellia sinensis (L.) Kuntze*) in the form of a fine, off-white to pale pink powder. It is composed of a minimum of 90 % epigallo-catechin gallate (EGCG), and has a melting point between approx. 210 and 215 °C<br>Appearance: off-white to pale pink powder<br>Chemical name: polyphenol (-) epigallocatechin-3-gallate<br>Synonyms: epigallocatechin gallate (EGCG)<br>CAS No.: 989-51-5<br>INCI name: epigallocatechin gallate<br>Molecular mass: 458,4 g/mol<br>Loss on drying: max 5,0 %<br>**Heavy metals:**<br>Arsenic: max 3,0 ppm<br>Lead: max 5,0 ppm<br>**Assay:**<br>Min. 94 % EGCG (on dry material)<br>max. 0,1 % caffeine<br>Solubility: EGCG is fairly soluble in water, ethanol, methanol and acetone |
| **L-ergothioneine** | **Definition**<br>Chemical name (IUPAC): (2S)-3-(2-thioxo-2,3-dihydro-1*H*-imidazol-4-yl)-2-(trimethylammonio)-Propanoate<br>Chemical formula: $C_9H_{15}N_3O_2S$<br>Molecular mass: 229,3 Da<br>CAS No.: 497-30-3 |

| *Parameter* | *Specification* | *Method* |
|---|---|---|
| Appearance | White powder | Visual |
| Optical rotation | $[\alpha]_D \geq (+)\ 122°$ (c = 1, $H_2O$)[a)] | Polarimetry |

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| Authorised Novel Food | Specifications | | |
|---|---|---|---|
| | Chemical purity | ≥ 99,5 %<br>≥ 99,0 % | HPLC [Eur. Ph. 2,2.29]<br>1H-NMR |
| | Identification | Compliant with the structure<br>C: 47,14 ± 0,4 %<br>H: 6,59 ± 0,4 %<br>N: 18,32 ± 0,4 % | 1H-NMR<br>Elemental analysis |
| | Total residual solvents<br>(methanol, ethyl acetate, isopropanol, ethanol) | [Eur. Ph. 01/2008:50400]<br>< 1 000 ppm | Gas chromatography<br>[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 |
| | **Heavy metals**[b) c)] | | |
| | Lead | < 3,0 ppm | ICP/AES |
| | Cadmium | < 1,0 ppm | (Pb, Cd) |
| | Mercury | < 0,1 ppm | Atomic fluorescence (Hg) |
| | **Microbiological specifications**[b)] | | |
| | Total viable aerobic count (TVAC) | ≤ 1 x $10^3$ CFU/g | [Eur. Ph. 01/2011:50104] |
| | Total yeast and mould count (TYMC) | ≤ 1 x $10^2$ CFU/g | |
| | *Escherichia coli* | Absence in 1 g | |

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| Authorised Novel Food | Specifications |
|---|---|
| | 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;<br>CFU: colony-forming units.<br>a) Lit. $[\alpha]_D$ = (+) 126,6° (c = 1, $H_2O$)<br>b) Analyses conducted on each batch<br>c) Maximum levels in accordance with Regulation (EC) No 1881/2006 |
| **Ferric Sodium EDTA** | **Description/Definition:**<br>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.<br>Chemical formula: $C_{10}H_{12}FeN_2NaO_8$ * $3H_2O$<br>Chemical characteristics:<br>pH of 1 % solution: 3,5-5,5<br>Iron: 12,5-13,5 %<br>Sodium: 5,5 %<br>Water: 12,8 %<br>Organic matter (CHNO): 68,4 %<br>EDTA: 65,5-70,5 %<br>Water insoluble matter: ≤ 0,1 %<br>Nitrilo-triacetic acid: ≤ 0,1 % |
| **Ferrous ammonium phosphate** | **Description/Definition:**<br>Ferrous ammonium phosphate is a grey/green fine powder, practically insoluble in water and soluble in dilute mineral acids.<br>CAS No.: 10101-60-7<br>Chemical formula: $FeNH_4PO_4$<br>Chemical characteristics:<br>pH of 5 % suspension in water: 6,8-7,8<br>Iron (total): ≥ 28 % |

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| Authorised Novel Food | Specifications |
|---|---|
| | Iron (II): 22-30 % (w/w)<br>Iron (III): ≤ 7,0 % (w/w)<br>Ammonia: 5-9 % (w/w)<br>Water: ≤ 3,0 % |
| **Fish peptides from *Sardinops sagax*** | **Description/Definition:**<br>The novel food ingredient is a peptide mixture, which is obtained by an alkaline protease-catalysed hydrolysis of fish (*Sardinops sagax*) muscle, subsequent isolation of the peptide fraction by column chromatography, concentration under vacuum and spray drying.<br>Yellowish white powderPeptides ([1]) (short chain peptides, dipeptides and tripeptides with a molecular weight of less than 2 kDa): ≥ 85 g/100 g<br>Val-Tyr (dipeptide): 0,1-0,16 g/100 g<br>Ash: ≤ 10 g/100 g<br>Moisture: ≤ 8 g/100 g<br>([1]) Kjeldahl method |
| **Flavonoids from *Glycyrrhiza glabra*** | **Description/Definition:**<br>Flavonoids derived from the roots or rootstock of *Glycyrrhiza glabra* L. are extracted with ethanol followed by further extraction of this ethanolic extract with medium-chain triglycerides. It is a dark-brown coloured liquid, containing 2,5 % to 3,5 % of glabridin.<br>Moisture: < 0,5 %<br>Ash: < 0,1 %<br>Peroxide value (PV): < 0,5 meq/kg<br>Glabridin: 2,5-3,5 % of fat<br>Glycyrrhizinic acid: < 0,005 %<br>Fat including polyphenol-type substances: ≥ 99 %<br>Protein: < 0,1 %<br>Carbohydrates: not detectable |
| **Fucoidan extract from the seaweed *Fucus vesiculosus*** | **Description/Definition:**<br>Fucoidan from the seaweed *Fucus vesiculosus* is extracted using aqueous extraction in acidic solution and filtration processes without the use of organic solvents. The resulting extract is concentrated and dried to yield the fucoidan extract with the following specifications: |

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| Authorised Novel Food | Specifications |
|---|---|
| | Off-white to brown powder<br>Odour and Taste: Bland odour and taste<br>Moisture: < 10 % (105 °C for 2 hours)<br>pH value: 4,0-7,0 (1 % suspension at 25 °C)<br>**Heavy metals:**<br>Arsenic (inorganic): < 1,0 ppm<br>Cadmium: < 3,0 ppm<br>Lead: < 2,0 ppm<br>Mercury: < 1,0 ppm |
| | **Microbiological criteria:**<br>Total aerobic microbial count: < 10 000 CFU/g<br>Yeast and mould count: < 100 CFU/g<br>Total enterobacteria count: Absence/g<br>*Escherichia coli*: Absence/g<br>*Salmonella*: Absence/10 g<br>*Staphylococcus aureus*: Absence/g<br>Composition of the two permitted types of extracts, based on the level of fucoidan:<br>*Extract 1:*<br>Fucoidan: 75-95 %<br>Alginate: 2,0-5,5 %<br>Polyphloroglucinol: 0,5-15 %<br>Mannitol: 1-5 %<br>Natural salts/Free Minerals: 0,5-2,5 %<br>Other carbohydrates: 0,5-1,0 %<br>Protein: 2,0-2,5 %<br>*Extract 2:*<br>Fucoidan: 60-65 % |

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| Authorised Novel Food | Specifications |
|---|---|
| | Alginate: 3,0-6,0 %<br>Polyphloroglucinol: 20-30 %<br>Mannitol: < 1,0 %<br>Natural salts/Free Minerals: 0,5-2,0 %<br>Other carbohydrates: 0,5-2,0 %<br>Protein: 2,0-2,5 % |
| **Fucoidan extract from the seaweed *Undaria pinnatifida*** | **Description/Definition:**<br>Fucoidan from seaweed *Undaria pinnatifida* is extracted using aqueous extraction in acidic solution and filtration processes without the use of organic solvents. The resulting extract is concentrated and dried to yield the fucoidan extract with the following specifications:<br>Off-white to brown powder<br>Odour and Taste: Bland odour and tasteMoisture: < 10 % (105 °C for 2 hours)<br>pH value: 4,0-7,0 (1 % suspension at 25 °C)<br>**Heavy metals:**<br>Arsenic (inorganic): < 1,0 ppm<br>Cadmium: < 3,0 ppm<br>Lead: < 2,0 ppm<br>Mercury: < 1,0 ppm<br>**Microbiology:**<br>Total aerobic microbial count: < 10 000 CFU/g<br>Yeast and mould count: < 100 CFU/g<br>Total enterobacteria count: Absence/g<br>*Escherichia coli*: Absence/g<br>*Salmonella*: Absence/10 g<br>*Staphylococcus aureus*: Absence/g<br>Composition of the two permitted types of extracts, based on the level of fucoidan:<br>*Extract 1:*<br>Fucoidan: 75-95 %<br>Alginate: 2,0-6,5 % |

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| Authorised Novel Food | Specifications |
|---|---|
| | Polyphloroglucinol: 0,5-3,0 %<br>Mannitol: 1-10 %<br>Natural salts/Free Minerals: 0,5-1,0 %<br>Other carbohydrates: 0,5-2,0 %<br>Protein: 2,0-2,5 %<br>*Extract 2:*<br>Fucoidan: 50-55 %<br>Alginate: 2,0-4,0 %<br>Polyphloroglucinol: 1,0-3,0 %<br>Mannitol: 25-35 %<br>Natural salts/Free Minerals: 8-10 %<br>Other carbohydrates: 0,5-2,0 %<br>Protein: 1,0-1,5 % |
| **2′-Fucosyllactose (synthetic)** | **Definition:**<br>Chemical name: α-L-Fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)- D-glucopyranose<br>Chemical formula: $C_{18}H_{32}O_{15}$<br>CAS No: 41263-94-9<br>Molecular weight: 488,44 g/mol<br>**Description:**<br>2′-fucosyllactose is a white to off-white powder that is produced by a chemical synthesis process.<br>**Purity:**<br>2'-Fucosyllactose: ≥ 95 %<br>D-Lactose: ≤ 1,0 w/w %<br>L-Fucose: ≤ 1,0 w/w %<br>Difucosyl- D-lactose isomers: ≤ 1,0 w/w %<br>2′-Fucosyl- D-lactulose: ≤ 0,6 w/w %<br>pH (20 °C, 5 % solution): 3,2-7,0<br>Water (%): ≤ 9,0 %<br>Ash, sulphated: ≤ 0,2 % |

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| Authorised Novel Food | Specifications | |
|---|---|---|
| | Acetic acid: ≤ 0,3 %<br>Residual solvents (methanol, 2-propanol, methyl acetate, acetone): ≤ 50,0 mg/kg singly, ≤ 200,0 mg/kg in combination<br>Residual proteins: ≤ 0,01 %<br>**Heavy Metals:**<br>Palladium: ≤ 0,1 mg/kg<br>Nickel: ≤ 3,0 mg/kg<br>**Microbiological criteria:**<br>Aerobic mesophilic bacteria total count: ≤ 500 CFU/g<br>Yeasts and Moulds: ≤ 10 CFU/g<br>Residual endotoxins: ≤ 10 EU/mg | |
| **2'-Fucosyllactose (microbial source)** | **Definition:**<br>Chemical name: α-L-Fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose<br>Chemical formula: $C_{18}H_{32}O_{15}$<br>CAS No: 41263-94-9<br>Molecular weight: 488,44 g/mol | |
| | **Source:**<br>Genetically modified strain of *Escherichia coli* K-12 | **Source:**<br>Genetically modified strain of *Escherichia coli* BL21 |
| | **Description:**<br>2′-Fucosyllactose is a white to off-white powder that is produced by a microbial process.<br>**Purity:**<br>2'-Fucosyllactose: ≥ 90 %<br>D-Lactose: ≤ 3,0 %<br>L-Fucose: ≤ 2,0<br>Difucosyl-D-lactose: ≤ 2,0 %<br>2′-Fucosyl-D-lactulose: ≤ 1,0 %<br>pH (20 °C, 5 % solution): 3,0-7,5<br>Water: ≤ 9,0 % | **Description:**<br>2′-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. 2'-Fucosyllactose is produced by a microbiological process.<br>**Purity:**<br>2'-Fucosyllactose: ≥ 90 %<br>Lactose: ≤ 5,0 %<br>Fucose: ≤ 3,0 %<br>3-Fucosyllactose: ≤ 5,0 %<br>Fucosylgalactose: ≤ 3,0 %<br>Difucosyllactose: ≤ 5,0 % |

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| Authorised Novel Food | Specifications | |
|---|---|---|
| | Sulphated ash: ≤ 2,0 %<br>Acetic acid: ≤ 1,0 %<br>Residual proteins: ≤ 0,01 %<br>**Microbiological criteria:**<br>Aerobic mesophilic bacteria total count: ≤ 3 000 CFU/g<br>Yeasts: ≤ 100 CFU/g<br>Moulds: ≤ 100 CFU/g<br>Endotoxins: ≤ 10 EU/mg | Glucose: ≤ 3,0 %<br>Galactose: ≤ 3,0 %<br>Water: ≤ 9,0 % (powder)<br>Ash, sulphated: ≤ 0,5 % (powder and liquid)<br>Residual proteins: ≤ 0,01 % (powder and liquid)**Heavy Metals:**<br>Lead: ≤ 0,02 mg/kg (powder and liquid);<br>Arsenic: ≤ 0,2 mg/kg (powder and liquid)<br>Cadmium: ≤ 0,1 mg/kg (powder and liquid)<br>Mercury: ≤ 0,5 mg/kg (powder and liquid)<br>**Microbiological criteria:**<br>Total plate count: ≤ $10^4$ CFU/g (powder), ≤ 5 000 CFU/g (liquid)<br>Yeasts and Moulds: ≤ 100 CFU/g (powder); ≤ 50 CFU/g (liquid)<br>Enterobacteriaceae/Coliforms: absence in 11g (powder and liquid)<br>*Salmonella*: negative/100 g (powder), negative/200 ml (liquid)<br>*Cronobacter*: negative/100 g (powder), negative/200 ml (liquid)<br>Endotoxins: ≤ 100 EU/g (powder), ≤ 100 EU/ml (liquid)<br>Aflatoxin M1: ≤ 0,025 µg/kg (powder and liquid) |
| **Galacto-oligosaccharide** | **Description/Definition:**<br>**Galacto-oligosaccharide is produced from milk lactose by an enzymatic process using β-galactosidases from *Aspergillus oryzae*, *Bifidobacterium bifidum*, *Pichia pastoris*, *Sporobolomyces singularis*, *Kluyveromyces lactis*, *Bacillus circulans*, and *Papiliotrema terrestris*.**<br>GOS: min 46 % Dry Matter (DM)<br>Lactose: max 40 % DM<br>Glucose: max 27 % DM<br>Galactose: min 0,8 % DM<br>Ash: max 4,0 % DM<br>Protein: max 4,5 % DM<br>Nitrite: max. 2 mg/kg | |

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| Authorised Novel Food | Specifications |
|---|---|
| **Glucosamine HCl from *Aspergillus niger* and genetically modified strain of *E. coli* K-12** | White crystalline odourless powder<br>Molecular formula: $C_6H_{13}NO_5 \cdot HCl$<br>Relative molecular mass: 215,63 g/mol<br>D-Glucosamine HCl 98,0-102,0 % of reference standard (HPLC)<br>Specific rotation + 70,0° - + 73,0° |
| **Glucosamine sulphate KCl from *Aspergillus niger* and genetically modified strain of *E. coli* K-12** | White crystalline odourless powder<br>Molecular formula: $(C_6H_{14}NO_5)_2SO_4 \cdot 2KCl$<br>Relative molecular mass: 605,52 g/mol<br>D-Glucosamine Sulphate 2KCl 98,0-102,0 % of reference standard (HPLC)<br>Specific Rotation +50,0° to +52,0° |
| **Glucosamine sulphate NaCl from *Aspergillus niger* and genetically modified strain of *E. coli* K-12** | White crystalline odourless powder<br>Molecular formula: $(C_6H_{14}NO_5)_2SO_4 \cdot 2NaCl$<br>Relative molecular mass: 573,31 g/mol<br>D-Glucosamine HCl: 98-102 % of reference standard (HPLC)<br>Specific Optical Rotation: +52° - +54° |
| **Guar Gum** | **Description/Definition:**<br>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 %).<br>Appearance: White to yellowish powder<br>Molecular weight: Between 50 000 – 8 000 000 Daltons<br>CAS number: 9000-30-0<br>Einecs Number: 232-536-8<br>Purity: As specified by Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([1]) & by Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins ([2]). |

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| Authorised Novel Food | Specifications |
|---|---|
| | **Physico-chemical properties:Powder**<br>Shelf-life: 2 years<br>Colour: White<br>Odour: Light<br>Average diameter of particles: 60-70μm<br>Moisture: Max 15 %<br>Viscosity * at 1 hour —<br>Viscosity * at 2 hours: Min 3 600 mPa.s<br>Viscosity * at 24 hours: Min 4 000 mPa.s<br>Solubility: Soluble in hot and cold water<br>pH for 10g/L, at 25 °C - 6-7,5<br>**Flakes**<br>Useful life: 1 year<br>Colour: White/off white with absence or minimal presence of black spots<br>Odour: Light<br>Average diameter of particles: 1-10 mm<br>Moisture: Max 15 %<br>Viscosity * at 1 hour: Min 3 000 mPa.s<br>Viscosity * at 2 hours —<br>Viscosity * at 24 hours —<br>Solubility — Soluble in hot and cold water<br>pH for 10g/L, at 25 °C - 5-7,5<br><br>(*) The measurements of viscosity are carried out under the following conditions: 1 %, 25 °C, 20 rpm |
| **Heat-treated milk products fermented with *Bacteroides xylanisolvens*** | **Description/Definition:**<br>Heat-treated fermented milk products are produced with *Bacteroides xylanisolvens* (DSM 23964) as starter culture. |

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| Authorised Novel Food | Specifications |
|---|---|
| | Semi-skimmed milk (between 1,5 % and 1,8 % fat) or skimmed milk (0,5 % fat or less) is pasteurised or ultra-heat-treated before starting the fermentation with *Bacteroides xylanisolvens* (DSM 23964). The resulting fermented milk product is homogenised and then heat-treated to inactivate *Bacteroides xylanisolvens* (DSM 23964). The final product does not contain viable cells of *Bacteroides xylanisolvens* (DSM 23964)([1]).<br>([1]) Modified DIN EN ISO 21528-2. |
| **Hydroxytyrosol** | **Description/Definition:**<br>Hydroxytyrosol is a pale yellow viscous liquid obtained by chemical synthesis<br>Molecular formula: $C_8H_{10}O_3$<br>Molecular weight: 154,6 g/mol<br>CAS No: 10597-60-1<br>Moisture ≤ 0,4 %<br>Odour: CharacteristicTaste: Slightly bitter<br>Solubility (water): Miscible with water<br>pH: 3,5-4,5<br>Refractive Index: 1,571-1,575<br>**Purity:**<br>Hydroxytyrosol: ≥ 99 %<br>Acetic acid: ≤ 0,4 %<br>Hydroxytyrosol acetate: ≤ 0,3 %<br>Sum of homovanillic acid, iso-homovanilic acid, and 3-methoxy-4hydroxyphenylglycol: ≤ 0,3 %<br>**Heavy Metals**<br>Lead: ≤ 0,03 mg/kg<br>Cadmium: ≤ 0,01 mg/kg<br>Mercury: ≤ 0,01 mg/kg<br>**Residual Solvents**<br>Ethyl acetate: ≤ 25,0 mg/kg<br>Isopropanol: ≤ 2,50 mg/kg<br>Methanol: ≤ 2,00 mg/kg<br>Tetrahydrofuran: ≤ 0,01 mg/kg |

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| Authorised Novel Food | Specifications |
|---|---|
| **Ice Structuring Protein type III HPLC 12** | **Description/Definition:**<br>The Ice Structuring Protein (ISP) preparation is a light-brown liquid produced by submerged fermentation of a genetically-modified strain of food-grade baker's yeast (*Saccharomyces cerevisiae*) in which a synthetic gene for the ISP has been inserted into the yeast's genome. The protein is expressed and secreted into the growth medium where it is separated from the yeast cells by micro-filtration and concentrated by ultra-filtration. As a result, the yeast cells are not transferred into the ISP preparation as such or under an altered form. The ISP preparation consists of native ISP, glycosylated ISP and proteins and peptides from the yeast and sugars as well as acids and salts commonly found in food. The concentrate is stabilised with 10 mM citric acid buffer.<br>Assay: ≥ 5 g/l active ISP<br>pH: 2,5-3,5<br>Ash: ≤ 2,0 %<br>DNA: Not detectable |
| **Aqueous extract of dried leaves of *Ilex guayusa*** | **Description/Definition:**<br>Dark brown liquid. Aqueous extracts of dried leaves of *Ilex guayusa.*<br>**Composition:**<br>Protein: < 0,1 g/100 ml<br>Fat: < 0,1 g/100 ml<br>Carbohydrate: 0,2–0,3 g/100 ml<br>Total sugars: < 0,2 g/100 ml<br>Caffeine: 19,8–57,7 mg/100 ml<br>Theobromine: 0,14–2,0 mg/100 ml<br>Chlorogenic acids: 9,9–72,4 mg/100ml |
| **Isomalto-oligosaccharide** | **Powder:**<br>Solubility (water) (%): > 99<br>Glucose (% dry basis): ≤ 5,0<br>Isomaltose + DP3 to DP9 (% dry basis): ≥ 90<br>Moisture (%): ≤ 4,0<br>Sulphated ash(g/100 g): ≤ 0,3<br>**Heavy metals:**<br>Lead (mg/kg): ≤ 0,5<br>Arsenic (mg/kg): ≤ 0,5 |

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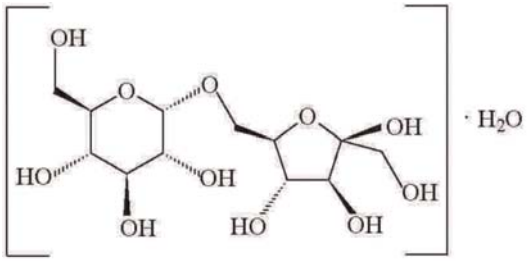
| | **Syrup:**<br>Dried solids (g/100 g): > 75<br>Glucose (% dry basis): ≤ 5,0<br>Isomaltose + DP3 to DP9 (% dry basis): ≥ 90<br>pH: 4 - 6<br>Sulphated ash(g/100 g): ≤ 0,3<br>**Heavy metals:**<br>Lead (mg/kg): ≤ 0,5<br>Arsenic (mg/kg): ≤ 0,5 |
| **Isomaltulose** | **Description/Definition:**<br>A reducing 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<br>Chemical name: 6-O-α-D-glucopyranosyl-D-fructofuranose, monohydrate<br>CAS No.: 13718-94-0<br>Chemical formula: $C_{12}H_{22}O_{11} \cdot H_2O$<br>Structural formula<br>  <br>Formula weight: 360,3 (monohydrate) |

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| | **Purity:**<br>Assay: ≥ 98 % on the dry basis<br>Loss on drying: ≤ 6,5 % (60 °C, 5 hours)<br>**Heavy metals:**<br>Lead: ≤ 0,1 mg/kg<br>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'<br>([1]) Food and Nutrition Paper 5 Rev. 2 — Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA), 1991, 322 pp., English, ISBN 92-5-102991-1. |
| **Lactitol** | **Description/Definition:**<br>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.<br>Chemical name: 4-O-β-D-Galactopyranosyl-D-glucitol<br>Chemical formula: $C_{12}H_{24}O_{11}$<br>Molecular weight: 344,31 g/mol<br>CAS No: 585-86-4<br>**Purity:**<br>Solubility (in water): Very soluble in water<br>Specific rotation $[\alpha]_D^{20}$ = + 13° to + 16°<br>Assay: ≥ 95 % d.b (d.b — expressed on the dry weight basis)<br>Water: ≤ 10,5 %<br>Other polyols: ≤ 2,5 % d.b<br>Reducing sugars: ≤ 0,2 % d.b<br>Chlorides: ≤ 100 mg/kg d.b<br>Sulphates: ≤ 200 mg/kg d.b<br>Sulphated ash: ≤ 0,1 % d.b<br>Nickel: ≤ 2,0 mg/kg d.b<br>Arsenic: ≤ 3,0 mg/kg d.b<br>Lead: ≤ 1,0 mg/kg d.b |

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| **Lacto-*N*-neotetraose (synthetic)** | **Definition:**<br>Chemical name: β-D-Galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)- D-glucopyranose<br>Chemical formula: $C_{26}H_{45}NO_{21}$<br>CAS No: 13007-32-4<br>Molecular weight: 707,63 g/mol<br>**Description:**<br>Lacto-*N*-neotetraose is a white to off-white powder. Produced by a chemical synthesis process and is isolated by crystallisation.<br>**Purity:**<br>Assay (water free): ≥ 96 %<br>D-Lactose: ≤ 1,0 %<br>Lacto-N-triose II: ≤ 0,3 %<br>Lacto-N-neotetraose fructose isomer: ≤ 0,6 %<br>pH (20 °C, 5 % solution): 5,0-7,0<br>Water: ≤ 9,0 %<br>Ash, sulphated: ≤ 0,4 %<br>Acetic acid: ≤ 0,3 %Residual solvents (methanol, 2-propanol, methyl acetate, acetone): ≤ 50 mg/kg singly, ≤ 200 mg/kg in combination<br>Residual proteins: ≤ 0,01 %<br>Palladium: ≤ 0,1 mg/kg<br>Nickel: ≤ 3,0 mg/kg<br>**Microbiological criteria:**<br>Aerobic mesophilic bacteria total count: ≤ 500 CFU/g<br>Yeasts: ≤ 10 CFU/g<br>Moulds: ≤ 10 CFU/g<br>Residual endotoxins: ≤ 10 EU/mg |
| **Lacto-*N*-neotetraose (microbial source)** | **Definition:**<br>Chemical name: β-D-Galactopyranosyl-(1→4)-2-acetamido-2-deoxy-β-D-glucopyranosyl-(1→3)-β-D-galactopyranosyl-(1→4)-D-glucopyranose<br>Chemical formula: $C_{26}H_{45}NO_{21}$<br>CAS No: 13007-32-4<br>Molecular weight: 707,63 g/mol |

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| | **Source:**<br>Genetically modified strain of *Escherichia coli* K-12<br>**Description:**<br>Lacto-*N*-neotetraose is a white to off-white powder that is produced by a microbiological process. Lacto-*N*-neotetraose is isolated by crystallisation.<br>**Purity:**<br>Assay (water free): ≥ 92 %<br>D-Lactose: ≤ 3,0 %<br>Lacto-N-triose II: ≤ 3,0 %<br>*para*-Lacto-N-neohexaose: ≤ 3,0 %<br>Lacto-N-neotetraose fructose isomer: ≤ 1,0 %<br>pH (20 °C, 5 % solution): 4,0-7,0<br>Water: ≤ 9,0 %<br>Ash, sulphated: ≤ 0,4 %<br>Residual solvents (methanol): ≤ 100 mg/kg<br>Residual proteins: ≤ 0,01 %<br>**Microbiological criteria:**<br>Aerobic mesophilic bacteria total count: ≤ 500 CFU/g<br>Yeasts: ≤ 10 CFU/g<br>Moulds: ≤ 10 CFU/g<br>Residual endotoxins: ≤ 10 EU/mg |
| **Lucerne leaf extract from *Medicago sativa*** | **Description/Definition:**<br>The Lucerne (*Medicago sativa* L.) is processed within 2 hours after harvest. It is chopped and crushed. By passing through an oleaginous-type press, the Lucerne provides a fibrous residue and press juice (10 % of dry matter). The dry matter of this juice contains about 35 % of crude protein. The press juice (pH 5,8-6,2) is neutralised. Preheating and vapour injection allows coagulation of proteins associated with carotenoid and chlorophyll pigments. The protein precipitate is separated by centrifugation and thereafter dried. After adding ascorbic acid the Lucerne protein concentrate is granulated and stored in inert gas or in cold storage.<br>**Composition:**<br>Protein: 45-60 %<br>Fat: 9-11 %<br>Free carbohydrates (soluble fibre): 1-2 % |

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| | Polysaccharides (insoluble fibre): 11-15 %<br>including cellulose: 2-3 %<br>Minerals: 8-13 %<br>Saponins: ≤ 1,4 %<br>Isoflavones: ≤ 350 mg/kg<br>Coumestrol: ≤ 100 mg/kg<br>Phytates: ≤ 200 mg/kg<br>L-canavanine: ≤ 4,5 mg/kg |
| **Lycopene** | **Description/Definition:**<br>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.<br>Chemical name: Lycopene<br>CAS No.: 502-65-8 (*all*-trans lycopene)<br>Chemical formula: $C_{40}H_{56}$<br>Formula weight: 536,85 Da |
| **Lycopene from *Blakeslea trispora*** | **Description/Definition:**<br>The purified lycopene from *Blakeslea trispora* consists of ≥ 95 % lycopene and ≤ 5 % other carotenoids. It is presented either as a powder in a suitable matrix or an oily dispersion. The colour is dark red or red-violet. Anti-oxidative protection has to be assured.<br>Chemical name: Lycopene<br>CAS No.: 502-65-8 (all trans lycopene)<br>Chemical formula: $C_{40}H_{56}$<br>Formula weight: 536,85 Da |
| **Lycopene from tomatoes** | **Description/Definition:**<br>The purified lycopene from tomatoes (*Lycopersicon esculantum* L.) consists of ≥ 95 % lycopene and ≤ 5 % other carotenoids. It is presented either as a powder in a suitable matrix or an oily dispersion. The colour is dark red or red-violet. Anti-oxidative protection has to be assured. |

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| Authorised Novel Food | Specifications |
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| | Chemical name: Lycopene<br>CAS No.: 502-65-8 (all trans lycopene)<br>Chemical formula: $C_{40}H_{56}$<br>Formula weight: 536,85 Da |
| **Lycopene oleoresin from tomatoes** | **Description/Definition:**<br>Lycopene oleoresin from tomatoes is obtained by solvent extraction of ripe tomatoes (*Lycopersicon esculentum Mill.*) with subsequent removal of the solvent. It is a red to dark brown viscous, clear liquid.<br>Total lycopene: 5-15 %<br>Thereof trans-lycopene: 90-95 %<br>Total carotenoids (calculated as lycopene): 6,5-16,5 %<br>Other carotenoids: 1,75 %<br>(Phytoene/phytofluene/β-carotene): (0,5-0,75/0,4-0,65/0,2-0,35 %)<br>Total tocopherols: 1,5-3,0 %<br>Unsaponifiable matter: 13-20 %<br>Total fatty acids: 60-75 %<br>Water (Karl Fischer): ≤ 0,5 % |
| **Magnesium citrate malate** | **Description/Definition:**<br>Magnesium citrate malate is a white to yellowish-white, amorphous powder.Chemical formula: $Mg_5(C_6H_5O_7)_2(C_4H_4O_5)_2$<br>Chemical name: Pentamagnesium di-(2-hydroxybutanedioate)-di-(2- hydroxypropane-1,2,3-tricarboxylate)<br>CAS No.: 1259381-40-2<br>Molecular weight: 763,99 Daltons (anhydrous)<br>Solubility: Freely soluble in water (about 20 g in 100 ml)<br>Description of the physical state: Amorphous powder<br>Assay magnesium: 12,0-15,0 %<br>Loss on drying (120 °C/4 hours): ≤ 15 %<br>Colour (solid): White to yellowish-white<br>Colour (20 % aqueous solution): Colourless to yellowish |

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| | Appearance (20 % aqueous solution): Clear solution<br>pH (20 % aqueous solution): Approx. 6,0<br>**Impurities:**<br>Chloride: ≤ 0,05 %<br>Sulphate: ≤ 0,05 %<br>Arsenic: ≤ 3,0 ppm<br>Lead: ≤ 2,0 ppm<br>Cadmium: ≤ 1 ppm<br>Mercury: ≤ 0,1 ppm |
| **Magnolia Bark Extract** | **Description/Definition:**<br>Magnolia bark extract is obtained from the bark of the plant *Magnolia officinalis* L. and produced with supercritical carbon dioxide. The bark is washed and oven dried to reduce moisture content before being crushed and extracted with supercritical carbon dioxide. The extract is dissolved in medical-grade ethanol and re-crystallised to yield magnolia bark extract.<br>Magnolia bark extract is mainly composed of two phenolic compounds, magnolol and honokiol.<br>Appearance: Light brownish powder<br>**Purity:**<br>Magnolol: ≥ 85,2 %<br>Honokiol: ≥ 0,5 %<br>Magnolol & Honokiol: ≥ 94 %<br>Total Eudesmol: ≤ 2 %<br>Moisture: 0,50 %<br>**Heavy metals:**<br>Arsenic (ppm): ≤ 0,5<br>Lead (ppm): ≤ 0,5<br>Methyl eugenol (ppm): ≤ 10<br>Tubocurarine (ppm): ≤ 2,0<br>Total Alkaloid (ppm): ≤ 100 |

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| **Maize-germ oil high in unsaponifiable matter** | **Description/Definition:**<br>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').<br>**Purity:**<br>Unsaponifiable matter: > 9,0 g/100 g<br>Tocopherols: ≥ 1,3 g/100 g<br>α-tocopherol (%): 10-25 %<br>β-tocopherol (%): < 3,0 %<br>γ-tocopherol (%): 68-89 %<br>δ-tocopherol (%): < 7,0 %<br>Sterols, triterpenic alcohols, methylsterols: > 6,5 g/100 g<br>Fatty acids in triglycerides:<br>palmitic acid: 10,0-20,0 %<br>stearic acid: < 3,3 %<br>oleic acid: 20,0-42,2 %<br>linoleic acid: 34,0-65,6 %<br>linolenic acid: < 2,0 %<br>Acid value: ≤ 6,0 mg KOH/g<br>Peroxide value (PV): ≤ 10 mEq $O_2$/kg<br>**Heavy metals:**<br>Iron (Fe): < 1 500 µg/kg<br>Copper (Cu): < 100 µg/kg<br>**Impurities:**<br>Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene: < 2 µg/kg<br>Treatment with active carbon is required to ensure that polycyclic aromatic hydrocarbons (PAH) are not enriched in the production of 'maize-germ oil high in unsaponifiable matter' |
| **Methylcellulose** | **Description/Definition:**<br>Methyl cellulose is cellulose obtained directly from natural strains of fibrous plant material and partially etherified with methyl groups.<br>Chemical name: Methyl ether of cellulose |

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| | Chemical formula: The polymers contain substituted anhydroglucose units with the following general formula:<br>C6H7O2(OR1)(OR2)(OR3) where R1, R2, R3 each may be one of the following:<br>— H<br>— $CH_3$ or<br>— $CH_2CH_3$<br>Molecular weight: Macromolecules: from about 20 000 (n about 100) up to about 380 000 g/mol (n about 2 000)<br>Assay: Content not less than 25 % and not more than 33 % of methoxyl groups ($-OCH_3$) and not more than 5 % of hydroxyethoxyl groups ($-OCH_2CH_2OH$)<br>Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder.<br>Solubility: Swelling in water, producing a clear to opalescent, viscous, colloidal solution. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid.<br>**Purity:**<br>Loss on drying: ≤ 10 % (105 °C, 3 hours)<br>Sulphated Ash: ≤ 1,5 % determined at 800 ± 25 °C<br>pH: ≥ 5,0 and ≤ 8,0 (1 % colloidal solution)<br>**Heavy metals:**<br>Arsenic: ≤ 3,0 mg/kg<br>Lead: ≤ 2,0 mg/kg<br>Mercury: ≤ 1,0 mg/kg<br>Cadmium: ≤ 1,0 mg/kg |
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| **1-Methylnicotinamide chloride** | **Definition:**<br>Chemical name: 3-carbamoyl-1-methyl-pyridinium chloride<br>Chemical formula: $C_7H_9N_2OCl$<br>CAS No: 1005-24-9<br>Molecular weight: 172,61 Da<br>**Description**<br>1-Methylnicotinamide chloride is white or off-white, crystalline solid produced by a chemical synthesis process.<br>**Characteristics/Composition**<br>Appearance: White – off-white, crystalline solid<br>Purity: ≥ 98,5 % |

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| | Trigonelline: ≤ 0,05 %<br>Nicotinic Acid: ≤ 0,10 %<br>Nicotinamide: ≤ 0,10 %<br>Largest unknown impurity: ≤ 0,05 %<br>Sum of unknown impurities: ≤ 0,20 %<br>Sum of all impurities: ≤ 0,50 %<br>Solubility: soluble in water and methanol. Practically insoluble in 2-propanol and dichloromethane<br>Moisture: ≤ 0,3 %<br>Loss on drying: ≤ 1,0 %<br>Residue on ignition: ≤ 0,1 %<br>**Residual Solvents and Heavy Metals**<br>Methanol: ≤ 0,3 %<br>Heavy metals: ≤ 0,002 %<br>**Microbiological criteria:**Total aerobic microbial count: ≤ 100 CFU/g<br>Mould/yeast: ≤ 10 CFU/g<br>Enterobacteriaceae: absence in 1 g<br>*Pseudomonas aeruginosa*: absence in 1 g<br>*Staphylococcus aureus*: absent in 1 g<br>CFU: Colony Forming Units |

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| **(6S)-5-methyltetrahydrofolic acid, glucosamine salt** | **Description/Definition:**<br>Chemical name: N-[4-[[[(6S)-2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4-oxo-6-pteridinyl]methyl]amino]benzoyl]-L-glutamic acid, glucosamine salt<br>Chemical formula: $C_{32}H_{51}N_9O_{16}$<br>Molecular weight: 817,80 g/mol (anhydrous)<br>CAS No.: 1181972-37-1<br>Appearance: Creamy to light-brown powder<br>**Purity:**<br>Diastereoisomeric purity: At least 99 % of (6S)-5-methyltetrahydrofolic acid |

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| | Glucosamine assay: 34-46 % in dry basis<br>5-Methyltetrahydrofolic acid assay: 54-59 % in dry basis<br>Water: ≤ 8,0 %<br>**Heavy metals:**<br>Lead: ≤ 2,0 ppm<br>Cadmium: ≤ 1,0 ppm<br>Mercury: ≤ 0,1 ppm<br>Arsenic: ≤ 2,0 ppm<br>Boron: ≤ 10 ppm<br>**Microbiological criteria:**<br>Total aerobic microbial count: ≤ 100 CFU/g<br>Yeasts and moulds: ≤ 100 CFU/g<br>*Escherichia coli*: Absence in 10g |
| **Monomethylsilanetriol (Organic Silicon)** | **Description/Definition:**<br>Chemical name: Silanetriol, 1-methyl-<br>Chemical formula: $CH_6O_3Si$<br>Molecular weight: 94,14 g/mol<br>CAS No: 2445-53-6<br>**Purity:**<br>Organic Silicon (monomethylsilanetriol) preparation (aqueous solution):<br>Acidity (pH): 6,4-6,8<br>Silicon: 100-150 mg Si/l<br>**Heavy metals:**<br>Lead: ≤ 1,0 µg/l<br>Mercury: ≤ 1,0 µg/l<br>Cadmium: ≤ 1,0 µg/l<br>Arsenic: ≤ 3,0 µg/l<br>**Solvents:**<br>Methanol: ≤ 5,0 mg/kg (residual presence) |

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| **Mycelial extract from Shiitake mushroom (*Lentinula edodes*)** | **Description/Definition:**<br>The novel food ingredient is a sterile aqueous extract obtained from the mycelium of *Lentinula edodes* cultivated in a submerged fermentation. It is a light brown, slightly turbid liquid.<br>Lentinan is a β-(1-3) β-(1-6)-D-glucan which has a molecular weight of approximately $5 \times 10^5$ Daltons, a degree of branching of 2/5 and a triple helical tertiary structure.<br>**Purity/Composition of the mycelial extract from *Lentinula edodes*:**<br>Moisture: 98 %<br>Dry matter: 2 %<br>Free glucose: < 20 mg/ml<br>Total protein([1]): < 0,1 mg/ml<br>N-containing constituents([2]): < 10 mg/ml<br>Lentinan: 0,8 – 1,2 mg/ml\<br>([1]) Bradford method<br>([2]) Kjeldahl method |
| **Noni fruit juice (*Morinda citrifolia*)** | **Description/Definition:**<br>Noni fruits (fruits of *Morinda citrifolia* L.) are pressed. The obtained juice is pasteurised. An optional fermentation step before or after the pressing may occur.<br>Rubiadin: ≤ 10 µg/kg<br>Lucidin: ≤ 10 µg/kg |
| **Noni fruit juice powder (*Morinda citrifolia*)** | **Description/Definition:**<br>Seeds and skin of the sun-dried fruits of *Morinda citrifolia* are separated. The obtained pulp is filtered to separate juice from the flesh. Desiccation of the produced juice occurs in one or two ways:<br>Either by atomisation using maize maltodextrins, this mixture is obtained by keeping the rates of inflow of the juice and maltodextrins constant<br>Or by zeodratation or drying and then mixing with an excipient, this process allows the juice to be dried initially and then mixed with maltodextrins (same amount as used in atomisation). |
| **Noni fruit puree and concentrate (*Morinda citrifolia*)** | **Description/Definition:**<br>The fruits of *Morinda citrifolia* are harvested by hand. Seeds and skin may be separated mechanically from the pureed fruits. After pasteurisation, the puree is packaged in aseptic containers and stored under cold conditions. |

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| | *Morinda citrifolia* concentrate is prepared from *M. citrifolia* puree by treatment with pectinolytic enzymes (50– 60 °C for 1-2 h). Then the puree is heated to inactivate the pectinases and then immediately cooled. The juice is separated in a decanter centrifuge. Afterwards the juice is collected and pasteurised, prior to being concentrated in a vacuum evaporator from a brix of 6 to 8 to a brix of 49 to 51 in the final concentrate.<br>**Composition:**<br>**Puree:**<br>Moisture: 89-93 %<br>Protein: < 0,6 g/100 g<br>Fat: ≤ 0,4 g/100 g<br>Ash: < 1,0 g/100 g<br>Total carbohydrates: 5-10 g/100 g<br>Fructose: 0,5-3,82 g/100 g<br>Glucose: 0,5-3,14 g/100 g<br>Dietary fibre: < 0,5-3 g/100 g<br>5,15-dimethylmorindol (1): ≤ 0,254 µg/ml<br>Lucidin (1): Not detectable<br>Alizarin (1): Not detectable<br>Rubiadin (1): Not detectable<br>**Concentrate:**<br>Moisture: 48-53 %<br>Protein: 3-3,5 g/100 g<br>Fat: < 0,04 g/100 g<br>Ash: 4,5-5,0 g/100 g<br>Total carbohydrates: 37-45 g/100 g<br>Fructose: 9-11 g/100 g<br>Glucose: 9-11 g/100 g<br>Dietary fibre: 1,5-5,0 g/100 g<br>5,15-dimethylmorindol ([1]): ≤ 0,254 µg/ml<br>([1]) *By an HPLC-UV method developed and validated for the analysis of anthraquinones in Morinda citrifolia puree and concentrate. Limits of detection: 2,5 ng/ml (5,15 dimethylmorindol); 50,0 ng/ml (lucidin); 6,3 ng/ml (alizarin) and 62,5 ng/ml (rubiadin).* |

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| **Noni leaves (*Morinda citrifolia*)** | **Description/Definition:**<br>After cutting, the leaves of *Morinda citrifolia* are subject to drying and roasting steps. The product has a particle size ranging from broken leaves to coarse powder with fines. It is of greenish brown to brown colour.<br>**Purity/Composition:**<br>Moisture: < 5,2 %<br>Protein: 17- 20 %<br>Carbohydrate: 55-65 %<br>Ash: 10-13 %<br>Fat: 4-9 %<br>Oxalic acid: < 0,14 %<br>Tannic acid: < 2,7 %<br>5,15-dimethylmorindol: < 47 mg/kg<br>Rubiadin: non detectable, ≤ 10 µg/kg<br>Lucidin: non detectable, ≤ 10 µg/kg |
| **Noni fruit powder (*Morinda citrifolia*)** | **Description/Definition:**<br>Noni fruit powder is made from pulped noni (*Morinda citrifolia L.)* fruits by freeze-drying. Fruits are pulped and seeds are removed. After freeze-drying during which water is removed from noni fruits, the remaining noni pulp is milled to a powder and encapsulated.<br>**Purity/Composition**<br>Moisture: 5,3-9 %<br>Protein: 3,8-4,8 g/100 g<br>Fat: 1-2 g/100 g<br>Ash: 4,6-5,7 g/100 g<br>Total carbohydrates: 80-85 g/100 g<br>Fructose: 20,4-22,5 g/100 g<br>Glucose: 22-25 g/100 g<br>Dietary fibre: 15,4-24,5 g/100 g<br>5,15-dimethylmorindol ([1]): ≤ 2,0 µg/ml<br>([1]) *By an HPLC-UV method developed and validated for the analysis of anthraquinones in Morinda citrifolia fruit powder. Limits of detection: 2,5 ng/ml (5,15 dimethyl-morindol)* |

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| ***Odontella aurita* microalgae** | Silicon: 3,3 %<br>Crystalline silica: max 0,1-0,3 % as impurity |
| **Oil enriched with phytosterols/ phytostanols** | **Description/Definition:**<br>Oil enriched with phytosterols/phytostanols is composed of an oil fraction and a phytosterol fraction.<br>**Acylglycerol Distribution:**<br>Free fatty acids (expressed as oleic acid): ≤ 2,0 %<br>Monoacylglycerols (MAG): ≤ 10 %<br>Diacylglycerols (DAG): ≤ 25 %<br>Triacylglycerols (TAG): Making up the balance<br>**Phytosterol fraction:**<br>β-sitosterol: ≤ 80 %<br>β-sitostanol: ≤ 15 %<br>campesterol: ≤ 40 %<br>campestanol: ≤ 5,0 %<br>stigmasterol: ≤ 30 %<br>brassicasterol ≤ 3,0 %<br>other sterols/stanols: ≤ 3,0 %<br>**Others:**<br>Moisture and volatile: ≤ 0,5 %<br>Peroxide value (PV): < 5,0 meq/kg<br>Trans fatty acids: ≤ 1 %<br>Contamination/Purity (GC-FID or equivalent method) of phytosterols/phytostanols:<br>Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 %. |
| **Oil extracted from squids** | Acid value: ≤ 0,5 KOH/g oil<br>Peroxide value (PV): ≤ 5 meq $O_2$/kg oil<br>p-Anisidine value: ≤ 20<br>Cold test at 0 °C: ≤ 3 hours<br>Moisture: ≤ 0,1 % (w/w) |

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| Authorised Novel Food | Specifications | | |
|---|---|---|---|
| | Unsaponifiable matter: ≤ 5,0 %Trans fatty acids: ≤ 1,0 %<br>Docosahexaeonic acid: ≥ 20 %<br>Eicosapentaenoic acid: ≥ 10 % | | |
| **Pasteurised fruit-based preparations produced using high-pressure treatment** | *Parameter* | *Target* | *Comments* |
| | 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 | |
| | $^{o}$ Brix | 7 to 42 | Assured by added sugars |
| | $a_w$ | < 0,95 | Assured by added sugars |
| | Final storage | 60 days maximum at + 5 °C maximum | Equivalent to storage regimen for conventionally processed product |
| **Phosphated maize starch** | **Description/Definition:**<br>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.<br>The novel food ingredient is a white or nearly white powder.<br>CAS No: 11120-02-8<br>Chemical formula: $(C_6H_{10}O_5)_n$ $[(C_6H_9O_5)_2PO_2H]x$ $[(C_6H_9O_5)PO_3H_2]y$<br>n = number of glucose units; x, y = degrees of substitution<br>The chemical characteristics of phosphated distarch phosphate:<br>Loss on drying: 10-14 %<br>pH: 4,5-7,5<br>Dietary fibre: ≥ 70 %<br>Starch: 7-14 % | | |

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| Authorised Novel Food | Specifications |
|---|---|
| | Protein: ≤ 0,8 %<br>Lipids: ≤ 0,8 %<br>Residual bound phosphorus: ≤ 0,4 % (as phosphorus) 'high amylose maize' as source |
| **Phosphatidylserine from fish phospholipids** | **Description/Definition:**<br>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.<br>**Specification of the phosphatidylserine product manufactured from fish phospholipids:**<br>Moisture: < 5,0 %<br>Phospholipids: ≥ 75 %<br>Phosphatidylserine: ≥ 35 %<br>Glycerides: < 4,0 %<br>Free L-serine: < 1,0 %<br>Tocopherols: < 0,5 % ([1])<br>Peroxide value (PV): < 5,0 meq $O_2$/kg<br>([1]) Tocopherols may be added as antioxidants according to Commission Regulation (EU) No 1129/2011 |
| **Phosphatidylserine from soya phospholipids** | **Description/Definition:**<br>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).<br>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.<br>**Characteristics of Phosphatidylserine from soya phospholipids:**<br>**Powder form:**<br>Moisture: < 2,0 %<br>Phospholipids: ≥ 85 %<br>Phosphatidylserine: ≥ 61 %<br>Glycerides: < 2,0 %<br>free L-serine: < 1,0 %<br>Tocopherols: < 0,3 % |

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| Authorised Novel Food | Specifications |
|---|---|
| | Phytosterols: < 0,2 %<br>**Liquid form:**<br>Moisture: < 2,0 %<br>Phospholipids: ≥ 25 %<br>Phosphatidylserine: ≥ 20 %<br>Glycerides: not applicable<br>free L-serine: < 1,0 %<br>Tocopherols: < 0,3 %<br>Phytosterols: < 0,2 % |
| **Phospholipid product containing equal amounts of phosphatidylserine and phosphatidic acid** | **Description/Definition:**<br>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.<br>**Specification of the product:**<br>Moisture: ≤ 2,0 %<br>Total phospholipids: ≥ 70 %<br>Phosphatidylserine: ≥ 20 %<br>Phosphatidic acid: ≥ 20 %<br>Glycerides: ≤ 1,0 %<br>Free L-serine: ≤ 1,0 %<br>Tocopherols: ≤ 0,3 %<br>Phytosterols: ≤ 2,0 %<br>Silicon dioxide is used with a maximum content of 1,0 % |
| **Phospholipides from egg yolk** | 85 % and 100 % pure Phospholipides from egg yolk |
| **Phytoglycogen** | **Description:** White to off-white powder which is an odourless, colourless, flavourless polysaccharide derived from non-GM sweet corn using conventional food processing techniques<br>**Definition:** Glucose polymer $(C_6H_{12}O_6)n$ with linear linkages of α(1 – 4) glycosidic bonds branched every 8 to 12 glucose units by α(1 – 6) glycosidic bonds |

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| Authorised Novel Food | Specifications |
|---|---|
| | **Specifications:**<br>Carbohydrates: 97 %<br>Sugars: 0,5 %<br>Fibre: 0,8 %<br>Fat: 0,2 %<br>Protein: 0,6 % |
| **Phytosterols/phytostanols** | **Description/Definition:**<br>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.<br>**Composition** (with GC-FID or equivalent method):<br>β-sitosterol: < 81 %<br>β-sitostanol: < 35 %<br>campesterol: < 40 %<br>campestanol: < 15 %<br>stigmasterol: < 30 %<br>brassicasterol: < 3,0 %<br>other sterols/stanols: < 3,0 %<br>**Contamination/Purity** (GC-FID or equivalent method):<br>Phytosterols and phytostanols extracted from sources other than vegetable oil suitable for food have to be free of contaminants, best ensured by a purity of more than 99 % of the phytosterol/phytostanol ingredient. |
| **Plum kernel oil** | **Description/Definition:**<br>Plum kernel oil is a vegetable oil obtained by cold pressing of plum (*Prunus domestica*) kernels.<br>**Composition:**<br>Oleic acid (C18:1): 68 %<br>Linoleic acid (C18:2): 23 %<br>γ-Tocopherol:80 % of total tocopherols<br>β-Sitosterol: 80-90 % of total sterols<br>Triolein: 40-55 % of triglycerides<br>Cyanhydric acid: maximum 5 mg/kg oil |

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| Authorised Novel Food | Specifications |
|---|---|
| **Potato proteins (coagulated) and hydrolysates thereof** | Dry substance: ≥ 800 mg/g<br>Protein (N * 6,25): ≥ 600 mg/g (dry substance)<br>Ash: ≤ 400 mg/g (dry substance)<br>Glycoalkaloid (total): ≤ 150 mg/kg<br>Lysinoalanine (total): ≤ 500 mg/kg<br>Lysinoalanine (free): ≤ 10 mg/kg |
| **Prolyl oligopeptidase (enzyme preparation)** | **Specification of the enzyme:**<br>Systematic name: Prolyl oligopeptidase<br>Synonyms: Prolyl endopeptidase, proline-specific endopeptidase, endoprolylpeptidase<br>Molecular weight: 66 kDa<br>Enzyme Commission number: EC 3.4.21.26<br>CAS number: 72162-84-6<br>Source: A genetically modified strain of *Aspergillus niger* (GEP-44)<br>**Description:** Prolyl oligopeptidase is available as an enzyme preparation containing approximately 30 % maltodextrin.<br>**Specifications of the enzyme preparation of prolyl oligopeptidase:**<br>Activity: > 580 000 PPI([1])/g (> 34,8 PPU([2])/g)<br>Appearance: Microgranulate<br>Colour: Off-white to orange yellowish. The colour may change from batch to batch<br>Dry Matter: > 94 %<br>Gluten: < 20 ppm<br>**Heavy metals:**<br>Lead: ≤ 1,0 mg/kg<br>Arsenic: ≤ 1,0 mg/kg<br>Cadmium: ≤ 0,5 mg/kg<br>Mercury: ≤ 0,1 mg/kg<br>**Microbiological criteria:**<br>Total aerobic plate count: ≤ $10^3$ CFU/g<br>Total yeasts and moulds: ≤ $10^2$ CFU/g<br>Sulphite reducing anaerobes: ≤ 30 CFU/g |

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| Authorised Novel Food | Specifications |
|---|---|
| | *Enterobacteriaceae*: < 10 CFU/g<br>*Salmonella*: Absence in 25 g<br>*Escherichia coli*: Absence in 25 g<br>*Staphylococcus aureus*: Absence in 10 g<br>*Pseudomonas aeruginosa*: Absence in 10 g<br>*Listeria monocytogenes*: Absence in 25 g<br>Antimicrobial activity: Absent<br>Mycotoxins: Below limits of detection: Aflatoxin B1, B2, G1, G2 (< 0,25 µg/kg), total Aflatoxins (< 2,0 µg/kg), Ochratoxin A (< 0,20 µg/kg), T-2 Toxin (< 5 µg/kg), Zearalenone (< 2,5 µg/kg), Fumonisin B1 and B2 (< 2,5 µg/kg)<br>([1]) PPI – Protease Picomole International<br>([2]) PPU – Prolyl Peptidase Units or Proline Protease Units |
| **Protein extract from pig kidneys** | **Description/Definition:**<br>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.<br>Basic Product:<br>Specification: pig kidney protein excerpt with natural content of Diamin oxidase (DAO):<br>Physical condition: liquid<br>Colour: brownish<br>Appearance: slightly turbid solution<br>pH value: 6,4-6,8<br>Enzymatic activity: > 2 677 kHDU DAO/ml (DAO REA (DAO Radioextractionassay))<br>**Microbiological criteria:**<br>*Brachyspira* spp.: negative (Real Time PCR)<br>*Listeria monocytogenes*: negative (Real Time PCR)<br>*Staphylococcus aureus*: < 100 CFU/g<br>Influenza A: negative (Reverse Transcription Real Time PCR)<br>*Escherichia coli*: < 10 CFU/g |

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| Authorised Novel Food | Specifications |
|---|---|
| | Total aerobic microbiological count: < $10^5$ CFU/g<br>Yeasts/moulds count: < $10^5$ CFU/g<br>*Salmonella*: Absence/10g<br>Bile salt resistant enterobacteriaceae: < $10^4$ CFU/g<br>**Final product:**<br>Specification pig kidney protein excerpt with natural content of DAO (E.C. 1.4.3.22) in an enteric coated formulation:<br>Physical condition: solid<br>Colour: yellow grayAppearance: micropellets<br>Enzymatic activity: 110-220 kHDU DAO/g pellet (DAO REA (DAO Radioextractionassay))<br>Acid stability 15 min 0,1M HCl followed by 60 min Borat pH = 9,0: > 68 kHDU DAO/g pellet (DAO REA (DAO Radioextractionassay))<br>Humidity: < 10 %<br>*Staphylococcus aureus*: < 100 CFU/g<br>*Escherichia coli*: < 10 CFU/g<br>Total aerobic microbiological count: < $10^4$ CFU/g<br>Total combined yeasts/moulds count: < $10^3$ CFU/g<br>*Salmonella*: Absence/10g<br>Bile salt resistant enterobacteriaceae: < $10^2$ CFU/g |
| ▼M10<br>**Pyrroloquinoline quinone disodium salt** | **Definition:**<br>Chemical name: disodium 9-carboxy-4,5-dioxo-1*H*-pyrrolo[5,4-f]quinoline-2,7-dicarboxylate<br>Chemical formula: $C_{14}H_4N_2Na_2O_8$<br>CAS No: 122628-50-6<br>Molecular weight: 374,17 Da<br>**Description**<br>Pyrroloquinoline quinone disodium salt is a reddish–brown powder produced by the non-genetically modified bacterium *Hyphomicrobium denitrificans* strain CK-275. |

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|---|---|
| | **Characteristics/Composition**<br>Appearance: Reddish-brown powder<br>Purity: ≥ 99,0 % (dry weight)<br>UV absorbance (A322/A259): 0,56 ± 0,03<br>UV absorbance (A233/A259): 0,90 ± 0,09<br>Moisture: ≤ 12,0 %<br>**Residual Solvent**<br>Ethanol: ≤ 0,05 %<br>**Heavy metals**<br>Lead: < 3 mg/kg<br>Arsenic: < 2 mg/kg<br>**Microbiological criteria:**<br>Total viable cell count: ≤ 300 CFU/g<br>Mould/yeast: ≤ 12 CFU/g<br>Coliforms: absent in 1 g<br>*Hyphomicrobium denitrificans*: ≤ 25 CFU/g<br>CFU: Colony Forming Units |

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| **Rapeseed oil high in unsaponifiable matter** | **Description/Definition:**<br>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.<br>**Purity:**<br>Unsaponifiable matter: > 7,0 g/100 g<br>Tocopherols: > 0,8 g/100 g<br>α-tocopherol (%): 30-50 %<br>γ-tocopherol (%): 50-70 %<br>δ-tocopherol (%): < 6,0 %<br>Sterols, triterpenic alcohols, methylsterols: > 5,0 g/100 g |

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| Authorised Novel Food | Specifications |
|---|---|
| | **Fatty acids in triglycerides:**<br>palmitic acid: 3-8 %<br>stearic acid: 0,8-2,5 %<br>oleic acid: 50-70 %<br>linoleic acid: 15-28 %<br>linolenic acid: 6-14 %<br>erucic acid: < 2,0 %<br>Acid value: ≤ 6,0 mg KOH/g<br>Peroxide value (PV): ≤ 10 mEq $O_2$/kg<br>**Heavy metals:**<br>Iron (Fe): < 1 000 µg/kg<br>Copper (Cu): < 100 µg/kg<br>**Impurities:**<br>Polycyclic aromatic hydrocarbons (PAH) Benzo(a)pyrene: < 2 µg/kg<br>Treatment with active carbon is required to ensure that polycyclic aromatic hydrocarbons (PAH) are not enriched in the production of 'rapeseed oil high in unsaponifiable matter. |
| **Rapeseed Protein** | **Definition:**<br>Rapeseed protein is an aqueous protein-rich extract from rapeseed press cake originating from non-genetically modified *Brassica napus* L. and *Brassica rapa* L.<br>**Description:**<br>White to off-white, spray dried powder<br>Total protein: ≥ 90 %<br>Soluble protein: ≥ 85 %<br>Moisture: ≤ 7,0 %<br>Carbohydrates: ≤ 7,0 %<br>Fat: ≤ 2,0 %<br>Ash: ≤ 4,0 %<br>Fibre: ≤ 0,5 %<br>Total glucosinolates: ≤ 1 mmol/kg |

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|---|---|
| | **Purity:**<br>Total phytate: ≤ 1,5 %<br>Lead: ≤ 0,5 mg/kg<br>**Microbiological criteria:**<br>Yeast and mould count: ≤ 100 CFU/g<br>Aerobic bacteria count: ≤ 10 000 CFU/g<br>Total coliform count: ≤ 10 CFU/g<br>*Escherichia coli:* Absence in 10 g<br>*Salmonella*: Absence in 25 g |
| **Trans-resveratrol** | **Description/Definition:**<br>**Synthetic** *Trans*-resveratrol is off-white to beige crystals.<br>Chemical name: 5-[(E)-2-(4-hydroxyphenyl)ethenyl]benzene-1,3-diol<br>Chemical formula: $C_{14}H_{12}O_3$<br>Molecular weight: 228,25 Da<br>CAS No: 501-36-0<br>**Purity:**<br>*Trans*-resveratrol: ≥ 98 %-99 %<br>Total by-products (related substances): ≤ 0,5 %<br>Any single related substance: ≤ 0,1 %<br>Sulphated ash: ≤ 0,1 %<br>Loss on drying: ≤ 0,5 %<br>**Heavy metals:**<br>Lead: ≤ 1,0 ppm<br>Mercury: ≤ 0,1 ppm<br>Arsenic: ≤ 1,0 ppm<br>**Impurities:**<br>Diisopropylamine: ≤ 50 mg/kg<br>***Microbial source***: A genetically modified strain of *Saccharomyces cerevisiae*<br>Appearance: Off-white to slight yellow powder |

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|---|---|
| | Particle size: 100 % less than 62,23 µm<br>Trans-resveratrol content: Min. 98 % w/w (dry weight basis)<br>Ash: Max. 0,5 % w/w<br>Moisture: Max. 3 % w/w |
| **Rooster comb extract** | **Description/Definition:**<br>Rooster comb extract is obtained from *Gallus gallus* by enzymatic hydrolysis of rooster comb and by subsequent filtration, concentration and precipitation steps. The principal constituents of rooster comb extract are the glycosaminoglycans hyaluronic acid, chondroitin sulphate A and dermatan sulphate (chondroitin sulphate B). White or almost white hygroscopic powder.<br>Hyaluronic acid: 60-80 %<br>Chondroitin sulphate A: ≤ 5,0 %Dermatan sulphate (chondroitin sulphate B): ≤ 25 %<br>pH: 5,0-8,5<br>**Purity:**<br>Chlorides: ≤ 1,0 %<br>Nitrogen: ≤ 8,0 %<br>Loss on drying: (105 °C for 6 hours): ≤ 10 %<br>**Heavy metals:**<br>Mercury: ≤ 0,1 mg/kg<br>Arsenic: ≤ 1,0 mg/kg<br>Cadmium: ≤ 1,0 mg/kg<br>Chromium: ≤ 10 mg/kg<br>Lead: ≤ 0,5 mg/kg<br>**Microbiological criteria:**<br>Total viable aerobic count: ≤ $10^2$ CFU/g<br>*Escherichia coli*: Absence in 1 g<br>*Salmonella*: Absence in 1 g<br>*Staphylococcus aureus*: Absence in 1 g<br>*Pseudomonas aeruginosa*: Absence in 1g |

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| **Sacha Inchi oil from *Plukenetia volubilis*** | **Description/Definition:**<br>Sacha inchi oil is a 100 % cold pressed vegetable oil obtained from the seeds of *Plukenetia volubiis* L. It is a transparent, fluid (liquid) and shiny oil at room temperature. It has a fruity, light, green vegetable taste without undesirable flavours.<br>Aspect, limpidity, shine, colour: Fluid at room temperature, clean, shiny yellow gold<br>Odour and taste: Fruity, vegetable without non acceptable taste or odour<br>**Purity:**<br>Water and Volatiles: < 0,2 g/100 g<br>Impurities insoluble in hexane: < 0,05 g/100 g<br>Oleic acidity: < 2,0 g/100 g<br>Peroxide value (PV): < 15 meq $O_2$/kg<br>Trans fatty acids: < 1,0 g/100 g<br>Total unsaturated fatty acids: > 90 %Omega 3 alpha linolenic acid (ALA): > 45 %<br>Saturated fatty acids: < 10 %<br>No trans fatty acids (< 0,5 %)<br>No erucic acid (< 0,2 %)<br>More than 50 % of tri-linolenin and di-linolenin-triglycerides<br>Phytosterols composition and level<br>No cholesterol (< 5,0 mg/100 g) |
| **Salatrims** | **Description/Definition:**<br>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.<br>Glycerol ester disribution:<br>Triacylglycerols: > 87 %<br>Diacylglycerols: ≤ 10 %<br>Monoacylglycerols: ≤ 2,0 %<br>Fatty acid composition:<br>MOLE % LCFA (long chain fatty acids): 33-70 % |

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|---|---|
| | MOLE % SCFA (short chain fatty acids): 30-67 %<br>Saturated long chain fatty acids: < 70 % by weight<br>Trans fatty acids: ≤ 1,0 %<br>Free fatty acids as oleic acid: ≤ 0,5 %<br>Triacylglycerol profile:<br>Triesters (short/long of 0,5 to 2,0): ≥ 90 %<br>Triesters (short/long = 0): ≤ 10 %<br>Unsaponifiable material: ≤ 1,0 %<br>Moisture: ≤ 0,3 %<br>Ash: ≤ 0,1 %<br>Colour: ≤ 3,5 Red (Lovibond)<br>Peroxide value (PV): ≤ 2,0 Meq/Kg |
| ***Schizochytrium sp.* oil rich in DHA and EPA** | Acid value: ≤ 0,5 mg KOH/g<br>Peroxide value (PV): ≤ 5,0 meq/kg oil<br>Oxidative stability: All food products containing *Schizochytrium sp.* oil rich in DHA and EPA should demonstrate oxidative stability by appropriate and recognised national/international test methodology (e.g. AOAC)<br>Moisture and volatiles: ≤ 0,05 %<br>Unsaponifiables: ≤ 4,5 %<br>Trans-fatty acids: ≤ 1 %<br>DHA content: ≥ 22,5 %<br>EPA content: ≥ 10 % |
| ***Schizochytrium* sp. (ATCC PTA-9695) oil** | Peroxide value (PV): ≤ 5,0 meq/kg oil<br>Unsaponifiables: ≤ 3,5 %<br>Trans-fatty acids: ≤ 2,0 %<br>Free fatty acids: ≤ 0,4 %<br>Docosapentaenoic acid (DPA) n-6: ≤ 7,5 %<br>DHA content: ≥ 35 % |

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|---|---|
| ***Schizochytrium* sp. oil** | Acid value: ≤ 0,5 mg KOH/g<br>Peroxide value (PV): ≤ 5,0 meq/kg oil<br>Moisture and volatiles: ≤ 0,05 %<br>Unsaponifiables: ≤ 4,5 %<br>Trans-fatty acids: ≤ 1,0 %<br>DHA content: ≥ 32,0 % |
| ***Schizochytrium* sp. (T18) oil** | Acid value: ≤ 0,5 mg KOH/g<br>Peroxide value (PV): ≤ 5,0 meq/kg oil<br>Moisture and volatiles: ≤ 0,05 %<br>Unsaponifiables: ≤ 3,5 %<br>Trans-fatty acids: ≤ 2,0 %<br>Free fatty acids: ≤ 0,4 %<br>DHA content: ≥ 35 % |
| **Fermented soybean extract** | **Description/Definition:**<br>Fermented soybean extract is an odourless milk-white coloured powder. It is comprised of 30 % fermented soybean extract powder and 70 % resistant dextrin (as carrier) from corn-starch, which is added during the processing. Vitamin $K_2$ is removed during the manufacturing process.<br>Fermented soybean extract contains nattokinase isolated from natto, a foodstuff produced by the fermentation of non-genetically modified soybeans (*Glycine max* (L.)) with a selected strain of *Bacillus subtilis* var. natto.<br>Nattokinase activity: 20 000 -28 000 Fibrin degradation unit/g([1])<br>Identity: Confirmable<br>Condition: No offensive taste or smell<br>Loss on drying: ≤ 10 %<br>Vitamin $K_2$: ≤ 0,1 mg/kg<br>**Heavy metals:**<br>Lead: ≤ 5,0 mg/kg<br>Arsenic: ≤ 3,0 mg/kg<br>**Microbiological criteria:**<br>Total viable aerobic count: ≤ $10^3$ CFU([3])/g |

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| Authorised Novel Food | Specifications |
|---|---|
| | Yeast and mould: ≤ $10^2$ CFU/g<br>Coliforms: ≤ 30 CFU/g<br>Spore-forming bacteria: ≤ 10 CFU/g<br>*Escherichia coli*: Absence/25 g<br>*Salmonella*: Absence/25 g<br>*Listeria*: Absence/25 g<br>([1]) Assay method as described by Takaoka et al. (2010). |
| **Spermidine-rich wheat germ extract (*Triticum aestivum*)** | **Description/Definition:**<br>Spermidine-rich wheat germ extract is obtained from non-fermented, non-sprouting wheat germs (*Triticum aestivum*) by the process of solid-liquid extraction targeting specifically, but not exclusively polyamines.<br>Spermidine: 0,8-2,4 mg/g<br>Spermine: 0,4-1,2 mg/g<br>Spermidine trichloride < 0,1 µg/gPutrescine: < 0,3 mg/g<br>Cadaverine: < 0,1 µg/g<br>**Mycotoxins:**<br>Aflatoxins (total): < 0,4 µg/kg<br>**Microbiological criteria:**<br>Total aerobic bacteria: < 10 000 CFU/g<br>Yeast and moulds: < 100 CFU/g<br>*Escherichia coli:* < 10 CFU/g<br>*Salmonella:* Absence/25g<br>*Listeria monocytogenes:* Absence/25g |
| **Sucromalt** | **Description/Definition:**<br>Sucromalt is a complex mixture of saccharides which is produced from sucrose and a starch hydrolysate by means of an enzymatic reaction. In this process, glucose units are attached to saccharides from the starch hydrolysate by means of an enzyme produced by the bacterium *Leuconostoc citreum* or by means of a recombinant strain of the production organism *Bacillus licheniformis*. The resulting oligosaccharides are characterised by the presence of α-(1→6) and α-(l→3) glycosidic compounds. The overall product is syrup, in addition to these oligosaccharides, contains mainly fructose but also the disaccharide leucrose and other disaccharides.<br>Total solids: 75-80 % |

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|---|---|
| | Moisture: 20-25 %<br>Sulphatase: Max 0,05 %<br>pH: 3,5-6,0<br>Conductivity < 200 (30 %)<br>Nitrogen < 10 ppm<br>Fructose: 35-45 % d.w.<br>Leucrose: 7-15 % d.w.<br>Other disaccharides: Max 3 %<br>Higher saccharides: 40-60 % d.w |
| **Sugar cane fibre** | **Description/Definition:**<br>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.<br>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.<br>Moisture: ≤ 7,0 %<br>Ash: ≤ 0,3 %<br>Total Dietary Fibre (AOAC) dry basis (all insoluble): ≥ 95 %<br>of which: Hemicellulose (20-25 %) and cellulose (70-75 %)<br>Silica (ppm): ≤ 200<br>Protein: 0,0 %<br>Fat: Trace<br>pH: 4-7<br>**Heavy metals:**<br>Mercury (ppm): ≤ 0,1<br>Lead (ppm): ≤ 1,0<br>Arsenic (ppm): ≤ 1,0<br>Cadmium (ppm): ≤ 0,1<br>**Microbiological criteria:**<br>Yeast and moulds (CFU/g): ≤ 1 000<br>*Salmonella*: Absence<br>*Listeria monocytogenes*: Absence |

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| Authorised Novel Food | Specifications |
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| **Sunflower oil extract** | **Description/Definition:**<br>The sunflower extract is obtained by a concentration factor of 10 of the unsaponifiable fraction of refined sunflower oil extracted from the seeds of the sunflower, *Helianthus Annuus* L.<br>**Composition:**<br>Oleic acid (C18:1): 20 %<br>Linoleic acid (C18:2): 70 %<br>Unsaponifiable matter: 8,0 %<br>Phytosterols: 5,5 %<br>Tocopherols: 1,1 % |
| **Dried *Tetraselmis chuii* micro-algae** | **Description/Definition:**<br>The dried product is obtained from the marine microalgae *Tetraselmis chuii*, belonging to the *Chlorodendraceae* family, cultivated in sterile sea water in closed photobioreactors insulated from the outside air.<br>**Purity/Composition:**<br>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 %<br>Humidity: ≤ 7,0 %<br>Proteins: 35-40 %<br>Ashes: 14-16 %<br>Carbohydrates: 30-32 %<br>Fibre: 2-3 %<br>Fat: 5-8 %<br>Saturated fatty acids: 29-31 % of total fatty acids<br>Monounsaturated fatty acids: 21-24 % of total fatty acids<br>Polyunsaturated fatty acids: 44-49 % of total fatty acids<br>Iodine: ≤ 15 mg/kg |

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| ***Therapon barcoo*/Scortum** | **Description/Definition:**<br>Scortum/*Therapon barcoo* is a species of fish in the family Terapontidae. It is an endemic fresh water species from Australia. It is now reared in fish farms.<br>Taxonomic Identification: Class: Actinopterygii > order: Perciformes > family: Terapontidae > genus: *Therapon* or *Scortum barcoo*<br>Composition of fish flesh:<br>Protein (%): 18-25<br>Moisture (%): 65-75<br>Ash (%): 0,5-2,0<br>Energy (KJ/Kg): 6000-11500<br>Carbohydrates (%): 0,0<br>Fat (%): 5-15<br>Fatty acids (mg FA/g fillet):<br>Σ PUFA n-3: 1,2-20,0<br>Σ PUFA n-6: 0,3-2,0<br>PUFA n-3/n-6: 1,5-15,0<br>Total omega 3 acids: 1,6-40,0<br>Total omega 6 acids: 2,6-10,0 |
| **D-Tagatose** | **Description/Definition:**<br>Tagatose is produced by isomerization of galactose by means of chemical or enzymatic conversion, or by epimerization of fructose by means of enzymatic conversion. These are single-step conversions.<br>Appearance: White or almost white crystals<br>Chemical name: D-tagatose<br>Synonym: D-*lyxo*-Hexulose<br>CAS number: 87-81-0<br>Chemical formula: $C_6H_{12}O_6$<br>Formula weight: 180,16 (g/mol) |

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| | **Purity:**<br>Assay: ≥ 98 % on a dry weight basis<br>Loss on drying: ≤ 0,5 % (102 °C, 2 hours)<br>Specific Rotation: $[\alpha]_D^{20}$: – 4 to – 5,6° (1 % aqueous solution)([1])<br>Melting range: 133– 137 °C<br>**Heavy metals:**<br>Lead: ≤ 1,0 mg/kg(*)<br>(*) Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in FNP 5. 'Instrumental methods'([1]).<br>([1]) Food and nutrition paper 5 Rev 2 – Guide to specifications for general notices, general analytical techniques, identification tests, test solutions and other reference materials (JECFA) 1991, 307 p.; English – ISBN 92-5-102991-1 |
| **Taxifolin-rich extract** | **Description:**<br>Taxifolin-rich extract from the wood of Dahurian Larch (*Larix gmelinii* (Rupr.) Rupr) is a white to pale-yellow powder that crystallizes from hot aqueous solutions.<br>**Definition:**<br>Chemical name: [(2R,3R)-2-(3,4 dihydroxyphenyl)-3,5,7-trihydroxy-2,3-dihydrochromen-4-one, also called (+) trans (2R,3R)- dihydroquercetin]<br>Chemical formula: $C_{15}H_{12}O_7$<br>Molecular mass: 304,25 Da<br>CAS No: 480-18-2<br>**Specifications:**<br>*Physical parameter*<br>Moisture: ≤ 10 %*Compound analysis*<br>Taxifolin (m/m): ≥ 90,0 % of the dry weight<br>***Heavy Metals, Pesticide***<br>Lead: ≤ 0,5 mg/kg<br>Arsenic: ≤ 0,02 mg/kg<br>Cadmium: ≤ 0,5 mg/kg<br>Mercury: ≤ 0,1 mg/kg |

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| | Dichlorodiphenyltrichloroethane (DDT): ≤ 0,05 mg/kg<br>***Residual solvents***<br>Ethanol: < 5 000 mg/kg<br>***Microbiological criteria***<br>Total Plate Count (TPC): ≤ $10^4$ CFU/g<br>Enterobacteria: ≤ 100/g<br>Yeast and Mould : ≤ 100 CFU/g<br>*Escherichia coli*: Absence/1 g<br>*Salmonella*: Absence/10 g<br>*Staphylococcus aureus*: Absence/1 g<br>*Pseudomonas*: Absence/1g<br>**Usual range of components of the Taxifolin-rich extract (as per dry substance)**<br>*Extract component* — *Content, usual observed range (%)*<br>Taxifolin — 90 – 93<br>Aromadendrin — 2,5 – 3,5<br>Eriodictyol — 0,1 – 0,3<br>Quercetin — 0,3 – 0,5<br>Naringenin — 0,2 – 0,3<br>Kaempferol — 0,01 – 0,1<br>Pinocembrin — 0,05 – 0,12<br>Unidentified flavonoids — 1 – 3<br>Water(*) — 1,5<br>(*) 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 %. |

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| **Trehalose** | **Description/Definition:**<br>A non-reducing disaccharide that consists of two glucose moieties linkes by an α-1,1-glucosidic bond. It is obtained from liquefied starch or from sucrose by a multistep enzymatic process. The commercial product is the dihydrate. Virtually odourless, white or almost white crystals with a sweet taste<br>Synonyms: α,α-trehalose<br>Chemical name: α-D-glucopyranosyl-α-D-glucopyranoside, dihydrate<br>CAS No.: 6138-23-4 (dihydrate)<br>Chemical formula: $C_{12}H_{22}O_{11} \cdot 2H_2O$ (dihydrate)<br>Formula weight: 378,33 (dihydrate)<br>Assay: ≥ 98 % on the dry basis<br>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'<br>**Method of assay:**<br>Principle: trehalose is identified by liquid chromatography and quantified by comparison to a reference standard containing standard trehalose<br>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<br>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.<br>Apparatus: liquid chromatography equipped with a refractive index detector and integrating recorder<br>Conditions:<br>Column: Shodex Ionpack KS-801 (Showa Denko Co.) or equivalent<br>— length: 300 mm<br>— diameter: 10 mm<br>— temperature: 50 °C<br>Mobile phase: water<br>flow rate: 0,4 ml/min<br>Injection volume: 8 µl<br>Procedure: inject separately equal volumes of the sample solution and the standard solution into the chromatograph.<br>Record the chromatograms and measure the size of response of the trehalose peak<br>Calculate the quantity, in mg, of trehalose in 1 ml of the sample solution by the following formula: |

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| | % trehalose = 100 × ($R_U/R_S$) ($W_S/W_U$)<br>where<br>$R_S$ = peak area of trehalose in the standard preparation<br>$R_U$ = peak area of trehalose in the sample preparation<br>$W_S$ = weight in mg of trehalose in the standard preparation<br>$W_U$ = weight of dry sample in mg<br>**Characteristics:**<br>Identification:<br>Solubility: Freely soluble in water, very slightly soluble in ethanol<br>Specific rotation: $[\alpha]_D^{20}$ = +179° (5 % aqueous solution, dihydrate), +199° (5 % aqueous solution, anhydrous substance)<br>Melting point: 97 °C (dihydrate)<br>**Purity:**<br>Loss on drying: ≤ 1,5 % (60 °C, 5h)<br>Total ash: ≤ 0,05 %<br>**Heavy metals:**<br>Lead: ≤ 1,0 mg/kg |
| **UV treated mushrooms (*Agaricus bisporus*)** | **Description/Definition:**<br>Commercially grown *Agaricus bisporus* to which UV light treatment is applied to harvested mushrooms.<br>UV radiation: a process of radiation in ultraviolet light within the wavelength of 200-800 nm.<br>**Vitamin $D_2$:**<br>Chemical name: (3β,5Z,7E,22E)-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol<br>Synonym: Ergocalciferol<br>CAS No: 50-14-6<br>Molecular weight: 396,65 g/mol<br>**Contents:**<br>Vitamin $D_2$ in the final product: 5-10 µg/100 g fresh weight at the expiration of shelf life |

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| **UV-treated baker's yeast (*Saccharomyces cerevisiae*)** | **Description/Definition:**<br>Baker's yeast (*Saccharomyces cerevisiae*) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin $D_2$ (ergocalciferol). Vitamin $D_2$ content in the yeast concentrate varies between 1 800 000-3 500 000 IU vitamin D/100 g (450-875 µg/g).<br>Tan-coloured, free-flowing granules<br>**Vitamin $D_2$:**<br>Chemical name: (5Z,7E,22E)-3S-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol<br>Synonym: Ergocalciferol<br>CAS No.: 50-14-6<br>Molecular weight: 396,65 g/mol<br>**Microbiological criteria for the yeast concentrate:**<br>Coliforms: $\leq 10^3$/g<br>*Escherichia coli*: $\leq$ 10/g<br>*Salmonella*: Absence in 25g |
| **UV-treated bread** | **Description/Definition:**<br>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 $D_2$ (ergocalciferol).<br>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/$cm^2$.<br>**Vitamin $D_2$:**<br>Chemical name: (5Z,7E,22E)-3S-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol<br>Synonym: Ergocalciferol<br>CAS No: 50-14-6<br>Molecular weight: 396,65 g/mol<br>**Contents:**<br>Vitamin $D_2$ (ergocalciferol) in the final product: 0,75-3 µg/100 g([1])<br>Yeast in dough: 1-5 g/100 g ([2])<br>([1]) EN 12821, 2009, European Standard.<br>([2]) Recipe calculation. |

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| **UV-treated milk** | **Description/Definition:**<br>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 $D_3$ (cholecalciferol) concentrations by conversion of 7-dehydrocholesterol to vitamin $D_3$.<br>UV radiation: A process of radiation in ultraviolet light within the wavelength of 200-310 nm with energy input of 1 045 J/l.<br>**Vitamin $D_3$:**<br>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-methyl-idenecyclohexan-1-ol<br>Synonym: Cholecalciferol<br>CAS No: 67-97-0<br>Molecular weight: 384,6377 g/mol<br>**Contents:**<br>Vitamin $D_3$ in the final product:<br>Whole milk([1])0,5-3,2 µg/100 g([2])<br>Semi-skimmed milk(1): 0,1–1,5 µg/100 g([2])<br>([1]) As defined by Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).<br>([2]) HPLC |
| **Vitamin $K_2$ (menaquinone)** | This novel food is produced by a synthetic or microbiological process.<br>Vitamin $K_2$ (2-methyl-3-all-trans-polyprenyl-1,4-naphthoquinones), or the menaquinone series, is a group of prenylated naphthoquinone derivatives. The number of isoprene residues, where 1 isoprene unit consists of 5 carbons comprising the side chain, is used to characterise the menaquinone homologues containing primarily MK-7 and to a smaller extent MK-6.<br>Vitamin $K_2$ (menaquinones) series with menaquinone-7 (MK-7)(n = 6) being $C_{46}H_{64}O_2$, menaquinone-6 (MK-6)(n = 5) being $C_{41}H_{56}O_2$ and menaquinone-4 (MK-4)(n = 3) being $C_{31}H_{40}O_2$.<br>Chemical Name: (all-E)-2-(3,7,11,15,19,23,27-Heptamethyl-2,6,10,14,18,22,26-octacosaheptaenyl)-3-methyl-1,4-naphtalenedione<br>CAS Number: 2124-57-4<br>Molecular formula: $C_{46}H_{64}O_2$ |

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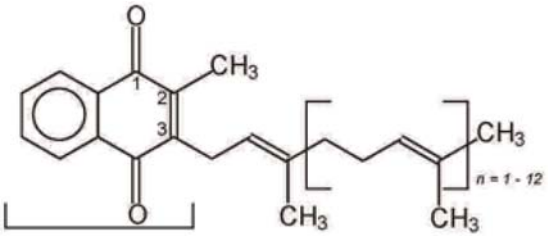
| | Molecular weight: 649 g/mol<br>  <br><br>*2-methyl-1,4-naphthoquinone (menadione moiety)*<br>***Specification of synthetic Vitamin $K_2$ (menaquinone-7)***<br>Appearance: Yellow powder<br>Purity: Max 6,0 % cis-isomer, max 2,0 % other impurities<br>Content: 97-102 % Menaquinone-7 (including at least 92 % all-trans Menaquinone-7)<br>***Specifications of microbiologically produced Vitamin $K_2$ (menaquinone-7)***<br>Source: *Bacillus subtilis* spp. natto and *Bacillus licheniformis*<br>Appearance: Yellow powder or oil suspension |
| **Wheat bran extract** | **Description/Definition:**<br>White crystalline powder obtained by enzymatic extraction from *Triticum aestivum* L. bran, rich in arabinoxylan oligosaccharides<br>Dry matter: Min. 94 %<br>Arabinoxylan oligosaccharides: Min 70 % of dry matter<br>Average degree of polymerisation of arabinoxylan oligosaccharides: 3-8<br>Ferulic acid (bound to arabinoxylan oligosaccharides): 1-3 % of dry matter<br>Total poly/oligosaccharides: Min 90 %<br>Protein: Max 2 % of dry matter<br>Ash: Max 2 % of dry matter |

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| | **Microbiological parameters:**<br>Mesophilic bacteria – total count: Max 10 000/g<br>Yeasts: Max 100/g<br>Fungi: Max 100/g<br>*Salmonella*: Absence in 25g<br>*Bacillus cereus*: Max 1000/g<br>*Clostridium perfringens*: Max 1000/g |
| **Yeast beta-glucans** | **Description/Definition:**<br>Beta-glucans are complex, high molecular mass (100–200 kDa) polysaccharides, found in the cell wall of many yeasts and cereals.<br>The chemical name for 'yeast beta-glucans' is (1-3),(1-6)-ß-D-glucans.<br>Beta-glucans consist of a backbone of ß-1-3-linked glucose residues that are branched by ß-1-6-linkages, to which chitin and mannoproteins are linked by ß-1-4-bonds.<br>Beta-glucans are isolated from yeast *Saccharomyces cerevisiae*.<br>The tertiary structure of the glucan cell wall of *Saccharomyces cerevisiae* consists of chains of ß-1,3-linked glucose residues, branched by ß-1,6-linkages, forming a backbone to which are linked chitin via ß-1,4- bonds, ß-1,6-glucans and some mannoproteins.<br>This novel food is available in three different forms: soluble, insoluble and insoluble in water, but dispersible in many liquid matrices.<br>**Chemical characteristics yeast (*Saccharomyces cerevisiae*) beta-glucans:**<br>**Soluble form:**<br>Total carbohydrates: > 75 %<br>Beta-glucans (1,3/1,6): > 75 %<br>Ash: < 4,0 %<br>Moisture: < 8,0 %<br>Protein: < 3,5 %<br>Fat: < 10 %<br>**Insoluble form:**<br>Total carbohydrates: > 70 %<br>Beta-glucans (1,3/1,6): > 70 % |

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| | Ash: ≤ 12 %<br>Moisture: < 8,0 %<br>Protein: < 10 %<br>Fat: < 20 %<br>**Insoluble in water, but dispersible in many liquid matrices:**<br>(1,3)-(1,6)-ß-D-Glucans: > 80 %<br>Ash: < 2,0 %<br>Moisture: < 6,0 %<br>Protein: < 4,0 %<br>Total fat: < 3,0 %<br>*Microbiological data for insoluble in water, but dispersible in many liquid matrices:*<br>Total plate count: < 1 000 CFU/g<br>Enterobacteriaceae: < 100 CFU/g<br>Total coliforms: < 10 CFU/g<br>Yeast: < 25 CFU/g<br>Mould: < 25 CFU/g<br>*Salmonella*: Absence in 25 g<br>*Escherichia coli*: Absence in 1 g<br>*Bacillus cereus*: < 100 CFU/g<br>*Staphylococcus aureus*: Absence in 1 g<br>*Heavy metals for insoluble in water, but dispersible in many liquid matrices:*<br>Lead: < 0,2 mg/g<br>Arsenic: < 0,2 mg/g<br>Mercury: < 0,1 mg/g<br>Cadmium: < 0,1 mg/g |

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| **Zeaxanthin** | **Description/Definition:**<br>Zeaxanthin is a naturally occurring xanthophyll pigment, it is an oxygenated carotenoid.<br>The synthetic zeaxanthin is presented either as a spray-dried powder of gelatin or starch base ('beadlets') with added α-tocopherol and ascorbyl palmitate or as a corn oil suspension with added α-tocopherol. Synthetic zeaxanthin is produced by a multi-step chemical synthesis from smaller molecules.<br>Orange-red crystalline powder with little or no odour.<br>Chemical formula: $C_{40}H_{56}O_2$<br>CAS No: 144-68-3<br>Molecular weight: 568,9 daltons<br>**Physical-chemical properties:**<br>Loss on drying: < 0,2 %<br>*All*-trans zeaxanthin: > 96 %<br>Cis-zeaxanthin: < 2,0 %<br>Other carotenoids: < 1,5 %<br>Triphenylphosphine oxid (CAS No 791-28-6): < 50 mg/kg |
| **Zinc L-pidolate** | **Description/Definition:**<br>Zinc L-pidolate is a white to off-white powder, with characteristic odour.<br>International non-proprietary name (INN): L-pyroglutamic acid, Zinc salt<br>Synonyms: Zinc 5-oxoproline, Zinc pyroglutamate, Zinc pyrrolidone carboxylate, Zinc PCA, L-Zinc pidolate<br>CAS No.: 15454-75-8<br>Molecular formula: $(C_5\ H_6\ NO_3)_2\ Zn$<br>Relative anhydrous molecular mass: 321,4<br>Appearance: White to slightly white powder<br>**Purity:**<br>Zinc L-pidolate (purity): ≥ 98 %<br>pH (10 % aqueous sol.): 5,0-6,0 |

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| | Specific rotation: 19,6°- 22,8°<br>Water: ≤ 10,0 %<br>Glutamic acid: < 2,0 %<br>**Heavy metals:**<br>Lead: ≤ 3,0 ppm<br>Arsenic: ≤ 2,0 ppm<br>Cadmium: ≤ 1,0 ppm<br>Mercury: ≤ 0,1 ppm<br>**Microbiological criteria:**<br>Total viable mesophilic count: ≤ 1 000 CFU/g<br>Yeasts and moulds: ≤ 100 CFU/g<br>Pathogen: Absence |

([1]) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

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