OFFERYNNAU STATUDOL CYMRU

2022 Rhif 575 (Cy. 133)

BWYD, CYMRU

Rheoliadau Bwydydd Newydd (Awdurdodiadau) a Chyflasynnau Mwg (Addasu Awdurdodiadau) (Cymru) 2022

Gwnaed	*24 Mai 2022*
Gosodwyd gerbron Senedd Cymru	*27 Mai 2022*
Yn dod i rym yn unol â rheoliad 1(3) a (4)	

WELSH STATUTORY INSTRUMENTS

2022 No. 575 (W. 133)

FOOD, WALES

The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022

Made	*24 May 2022*
Laid before Senedd Cymru	*27 May 2022*
Coming into force in accordance with regulation 1(3) and (4)	

£11.50

OFFERYNNAU STATUDOL CYMRU

WELSH STATUTORY INSTRUMENTS

2022 Rhif 575 (Cy. 133)

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BWYD, CYMRU

FOOD, WALES

Rheoliadau Bwydydd Newydd (Awdurdodiadau) a Chyflasynnau Mwg (Addasu Awdurdodiadau) (Cymru) 2022

The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022

NODYN ESBONIADOL

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

Mae'r Rheoliadau hyn yn gwneud darpariaeth ynghylch awdurdodiadau cynhyrchion bwyd rheoleiddiedig o ran Cymru. Gwneir Rhan 2 a'r Atodlenni yn unol â Rheoliad (EU) 2015/2283 a ddargedwir ar fwydydd newydd. Gwneir Rhan 3 yn unol â Rheoliad (EC) Rhif 2065/2003 a ddargedwir ar gyflasynnau mwg a ddefnyddir neu y bwriedir iddynt gael eu defnyddio mewn bwydydd neu arnynt.

Mae Rhan 2 a'r Atodlenni yn diweddaru, o ran Cymru, y rhestr o fwydydd newydd awdurdodedig yn Atodiad 1 i Reoliad (EU) 2017/2470 a ddargedwir sy'n sefydlu rhestr yr Undeb o fwydydd newydd—

- mae Atodlen 1 yn diwygio'r cofnod presennol ar gyfer 2'-Ffwcosyl-lactos/Deuffwcosyl-lactos (2'FL/DFL) er mwyn awdurdodi rhoi ar y farchnad y bwyd newydd hwnnw i'w ddefnyddio mewn diodydd wedi eu seilio ar laeth a chynhyrchion tebyg a fwriedir ar gyfer plant ifanc;
- mae Atodlen 2 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad straen penodol o Olew Schizochytrium sp. (FCC-3204) fel bwyd newydd i'w ddefnyddio mewn atchwanegiadau bwyd, ac ar gyfer fformiwla babanod a fformiwla ddilynol;

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision on regulated food product authorisations in relation to Wales. Part 2 and the Schedules are made pursuant to retained (EU) Regulation 2015/2283 on novel foods. Part 3 is made pursuant to retained Regulation (EC) No. 2065/2003 on smoke flavourings used or intended for use in or on foods.

Part 2 and the Schedules update, in relation to Wales, the list of authorised novel foods in Annex 1 to retained Regulation (EU) 2017/2470 establishing the Union list of novel foods—

- Schedule 1 amends the existing entry for 2'-Fucosyllactose/Difucosyllactose (2'FL/DFL) to authorise the placing on the market of that novel food for use in milk-based drinks and similar products intended for young children;
- Schedule 2 inserts a new entry, authorising the placing on the market of a specific strain of Schizochytrium sp. Oil (FCC-3204) as a novel food for use in food supplements, and for infant formula and follow-on formula;

- mae Atodlen 3 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad straen penodol o Olew Schizochytrium sp. (WZU477) fel bwyd newydd i'w ddefnyddio mewn fformiwla babanod a fformiwla ddilynol;
- mae Atodlen 4 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad halen sodiwm 3'-Sialyl-lactos (3'-SL) (ffynhonnell ficrobaidd) fel bwyd newydd i'w ddefnyddio yn y categorïau o fwyd penodedig;
- mae Atodlen 5 yn mewnosod cofnod newydd, sy'n awdurdodi rhoi ar y farchnad halen sodiwm 6'-Sialyl-lactos (6'-SL) (ffynhonnell ficrobaidd) fel bwyd newydd i'w ddefnyddio yn y categorïau o fwyd penodedig.

Mae Rhan 3 yn cynnwys addasiadau i'r awdurdodiadau ar gyfer pum cynnyrch cynradd sy'n creu cyflas mwg yn yr Atodiad i Reoliad (EU) Rhif 1321/2013 a ddargedwir sy'n sefydlu rhestr yr Undeb o gynhyrchion cynradd a awdurdodir i greu cyflas mwg i'w defnyddio yn y modd hwnnw mewn bwydydd neu arnynt. Mae'r diwygiadau'n newid enwau a chyfeiriadau deiliaid awdurdodiad awdurdodiadau'r priod gynhyrchion.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Asesiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, ystyriwyd nad oedd yn angenrheidiol cynnal asesiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn.

- Schedule 3 inserts a new entry, authorising the placing on the market of a specific strain of Schizochytrium sp. Oil (WZU477) as a novel food for use in infant formula and follow-on formula;
- Schedule 4 inserts a new entry, authorising the placing on the market of 3'-Sialyllactose (3'-SL) sodium salt (microbial source) as a novel food for use in the specified food categories;
- Schedule 5 inserts a new entry, authorising the placing on the market of 6'-Sialyllactose (6'-SL) sodium salt (microbial source) as a novel food for use in the specified food categories.

Part 3 contains modifications to the authorisations for five smoke flavouring primary products within the Annex to retained Regulation (EC) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods. The amendments change the names and the addresses of the authorisation holders of the respective product authorisations.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

2022 Rhif 575 (Cy. 133)

BWYD, CYMRU

Rheoliadau Bwydydd Newydd (Awdurdodiadau) a Chyflasynnau Mwg (Addasu Awdurdodiadau) (Cymru) 2022

Gwnaed *24 Mai 2022*

Gosodwyd gerbron Senedd Cymru *27 Mai 2022*

Yn dod i rym yn unol â rheoliad 1(3) a (4)

Mae Gweinidogion Cymru yn gwneud y Rheoliadau a ganlyn drwy arfer y pwerau a roddir gan Erthyglau 12(1) a 32A(3) o, ac yn unol ag Erthyglau 9 a 27(1) o, Reoliad (EU) 2015/2283 Senedd Ewrop a'r Cyngor ar fwydydd newydd(**1**); ac Erthygl 11(4) o Reoliad (EC) Rhif 2065/2003 Senedd Ewrop a'r Cyngor ar gyflasynnau mwg a ddefnyddir neu y bwriedir iddynt gael eu defnyddio mewn bwydydd neu arnynt(**2**).

Fel sy'n ofynnol gan Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor sy'n gosod egwyddorion a gofynion cyffredinol cyfraith bwyd, yn sefydlu Awdurdod Diogelwch Bwyd Ewrop ac yn gosod gweithdrefnau o ran materion diogelwch bwyd(**3**), ymgynghorwyd yn agored ac yn dryloyw â'r cyhoedd wrth lunio a gwerthuso'r Rheoliadau hyn.

(**1**) EUR 2015/2283; yr offerynnau diwygio perthnasol yw O.S. 2019/702 a 2020/1504. Mae'r termau "prescribe", "appropriate authority" a "list" wedi eu diffinio yn Erthygl 3 o Reoliad 2015/2283.

(**2**) EUR 2065/2003; yr offerynnau diwygio perthnasol yw O.S. 2019/860 a 2020/1504. Mae'r termau "prescribe" ac "appropriate authority" wedi eu diffinio yn Erthygl 3 o Reoliad 2065/2003.

(**3**) EUR 178/2002; yr offerynnau diwygio perthnasol yw O.S. 2019/641 a 2020/1504.

2022 No. 575 (W. 133)

FOOD, WALES

The Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022

Made *24 May 2022*

Laid before Senedd Cymru *27 May 2022*

Coming into force in accordance with regulation 1(3) and (4)

The Welsh Ministers make the following Regulations in exercise of the powers conferred by Articles 12(1) and 32A(3) of, and in accordance with Articles 9 and 27(1) of, Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods(**1**); and Article 11(4) of Regulation (EC) No. 2065/2003 of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foods(**2**).

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**3**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

(**1**) EUR 2015/2283; relevant amending instruments are S.I. 2019/702 and 2020/1504. The terms "prescribe", "appropriate authority" and "list" are defined in Article 3 of Regulation 2015/2283.

(**2**) EUR 2065/2003; relevant amending instruments are S.I. 2019/860 and 2020/1504. The terms "prescribe" and "appropriate authority" are defined in Article 3 of Regulation 2065/2003.

(**3**) EUR 178/2002; relevant amending instruments are S.I. 2019/641 and 2020/1504.

RHAN 1

Cyflwyniad

Enwi, rhychwant, cymhwyso a chychwyn

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Bwydydd Newydd (Awdurdodiadau) a Chyflasynnau Mwg (Addasu Awdurdodiadau) (Cymru) 2022.

(2) Mae'r Rheoliadau hyn—

(a) yn rhychwantu Cymru a Lloegr;

(b) yn gymwys o ran Cymru.

(3) Daw Rhannau 1 a 3 o'r Rheoliadau hyn i rym ar 18 Mehefin 2022.

(4) Daw Rhan 2 o'r Rheoliadau hyn i rym ar 30 Mehefin 2022.

RHAN 2

Bwydydd Newydd

Diwygio Rheoliad Gweithredu'r Comisiwn (EU) 2017/2470 sy'n sefydlu rhestr yr Undeb o fwydydd newydd yn unol â Rheoliad (EU) 2015/2283 Senedd Ewrop a'r Cyngor ar fwydydd newydd

2. Yn Rheoliad Gweithredu'r Comisiwn (EU) 2017/2470 sy'n sefydlu rhestr yr Undeb o fwydydd newydd yn unol â Rheoliad (EU) 2015/2283 Senedd Ewrop a'r Cyngor ar fwydydd newydd(**1**), mae'r Atodiad (rhestr o fwydydd newydd) wedi ei ddiwygio yn unol ag Atodlenni 1 i 5.

RHAN 3

Cyflasynnau Mwg

Diwygio Rheoliad Gweithredu'r Comisiwn (EU) Rhif 1321/2013 sy'n sefydlu rhestr yr Undeb o gynhyrchion cynradd a awdurdodir i greu cyflas mwg i'w defnyddio yn y modd hwnnw mewn bwydydd neu arnynt a/neu i gynhyrchu cyflasynnau mwg deilliedig

3. Yn Rheoliad Gweithredu'r Comisiwn (EU) Rhif 1321/2013 sy'n sefydlu rhestr yr Undeb o gynhyrchion cynradd a awdurdodir i greu cyflas mwg i'w defnyddio yn y modd hwnnw mewn bwydydd neu arnynt a/neu i gynhyrchu cyflasynnau mwg deilliedig(**2**), mae'r Atodiad (rhestr ddomestig o gyflasynnau mwg

(**1**) EUR 2017/2470, a ddiwygiwyd gan O.S. 2019/702.
(**2**) EUR 1321/2013, a ddiwygiwyd gan O.S. 2019/860.

PART 1

Introduction

Title, extent, application and commencement

1.—(1) The title of these Regulations is the Novel Foods (Authorisations) and Smoke Flavourings (Modification of Authorisations) (Wales) Regulations 2022.

(2) These Regulations—

(a) extend to England and Wales;

(b) apply in relation to Wales.

(3) Parts 1 and 3 of these Regulations come into force on 18 June 2022.

(4) Part 2 of these Regulations comes into force on 30 June 2022.

PART 2

Novel Foods

Amendment of Commission Implementing Regulation (EU) 2017/2470 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

2. In Commission Implementing Regulation (EU) 2017/2470 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(**1**), the Annex (list of novel foods) is amended in accordance with Schedules 1 to 5.

PART 3

Smoke Flavourings

Amendment of Commission Implementing Regulation (EU) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings

3. In Commission Implementing Regulation (EU) No. 1321/2013 establishing the Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings(**2**), the Annex (domestic list

(**1**) EUR 2017/2470, amended by S.I. 2019/702.
(**2**) EUR 1321/2013, amended by S.I. 2019/860.

awdurdodedig) wedi ei ddiwygio yn unol â rheoliadau 4 i 8.

of authorised smoke flavourings) is amended in accordance with regulations 4 to 8.

Addasu'r awdurdodiad ar gyfer "Scansmoke PB 1110"

4. Yn yr awdurdodiad ar gyfer "Scansmoke PB 1110" (cod unigryw "SF-001"), yng ngholofn 2, yn lle'r cofnodion sy'n cyfateb i "Name of the authorisation holder" ac "Address of the authorisation holder" rhodder—

"proFagus GmbH
Uslarer Strasse 30 37194 Bodenfelde GERMANY"

Modification of authorisation for "Scansmoke PB 1110"

4. In the authorisation for "Scansmoke PB 1110" (unique code "SF-001"), in column 2, for the entries corresponding to "Name of the authorisation holder" and "Address of the authorisation holder" substitute—

"proFagus GmbH
Uslarer Strasse 30 37194 Bodenfelde GERMANY"

Addasu'r awdurdodiad ar gyfer "Zesti Smoke Code 10"

5. Yn yr awdurdodiad ar gyfer "Zesti Smoke Code 10" (cod unigryw "SF-002"), yng ngholofn 2, yn lle'r cofnodion sy'n cyfateb i "Name of the authorisation holder" ac "Address of the authorisation holder" rhodder—

"Kerry Group Plc
Prince's Street Tralee Co. Kerry, V92 EH11 IRELAND"

Modification of authorisation for "Zesti Smoke Code 10"

5. In the authorisation for "Zesti Smoke Code 10" (unique code "SF-002"), in column 2, for the entries corresponding to "Name of the authorisation holder" and "Address of the authorisation holder" substitute—

"Kerry Group Plc
Prince's Street Tralee Co. Kerry, V92 EH11 IRELAND"

Addasu'r awdurdodiad ar gyfer "SmokeEz C-10"

6. Yn yr awdurdodiad ar gyfer "SmokeEz C-10" (cod unigryw "SF-005"), yng ngholofn 2, yn lle'r cofnodion sy'n cyfateb i "Name of the authorisation holder" ac "Address of the authorisation holder" rhodder—

"Kerry Group Plc
Prince's Street Tralee Co. Kerry, V92 EH11 IRELAND"

Modification of authorisation for "SmokeEz C-10"

6. In the authorisation for "SmokeEz C-10" (unique code "SF-005"), in column 2, for the entries corresponding to "Name of the authorisation holder" and "Address of the authorisation holder" substitute—

"Kerry Group Plc
Prince's Street Tralee Co. Kerry, V92 EH11 IRELAND"

Addasu'r awdurdodiad ar gyfer "SmokeEz Enviro-23"

7. Yn yr awdurdodiad ar gyfer "SmokeEz Enviro-23" (cod unigryw "SF-006"), yng ngholofn 2, yn lle'r cofnodion sy'n cyfateb i "Name of the authorisation holder" ac "Address of the authorisation holder" rhodder—

Modification of authorisation for "SmokeEz Enviro-23"

7. In the authorisation for "SmokeEz Enviro-23" (unique code "SF-006"), in column 2, for the entries corresponding to "Name of the authorisation holder" and "Address of the authorisation holder" substitute—

“Kerry Group Plc
Prince’s Street Tralee Co. Kerry, V92 EH11 IRELAND”

“Kerry Group Plc
Prince's Street Tralee Co. Kerry, V92 EH11 IRELAND”

Addasu’r awdurdodiad ar gyfer “Tradismoke™ A MAX”

8. Yn yr awdurdodiad ar gyfer “Tradismoke™ A MAX” (cod unigryw “SF-007”), yng ngholofn 2, yn lle’r cofnodion sy’n cyfateb i “Name of the authorisation holder” ac “Address of the authorisation holder” rhodder—

Modification of authorisation for “Tradismoke™ A MAX”

8. In the authorisation for “Tradismoke™ A MAX” (unique code “SF-007”), in column 2, for the entries corresponding to “Name of the authorisation holder” and “Address of the authorisation holder” substitute—

“J. Rettenmaier & Söhne GmbH + CO KG
Holzmühle 1 73494 Rosenberg GERMANY”

“J. Rettenmaier & Söhne GmbH + CO KG
Holzmühle 1 73494 Rosenberg GERMANY”

Lynne Neagle

Y Dirprwy Weinidog Iechyd Meddwl a Llesiant, o dan awdurdod y Gweinidog Iechyd a Gwasanaethau Cymdeithasol, un o Weinidogion Cymru
24 Mai 2022

Deputy Minister for Mental Health and Wellbeing, under the authority of the Minister for Health and Social Services, one of the Welsh Ministers
24 May 2022

ATODLEN 1

Rheoliad 2

Diwygio amodau defnyddio a manylebau cymysgedd 2'-Ffwcosyl-lactos/Deuffwcosyl-lactos (2'FL/DFL) fel bwyd newydd

1. Yn Nhabl 1 (bwydydd newydd awdurdodedig), yn y cofnod ar gyfer "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)", yng ngholofn 2 (yr amodau y caniateir defnyddio'r bwyd newydd odanynt), ar y diwedd mewnosoder yr amod defnyddio a ganlyn—

"Milk-based drinks and similar products intended for young children	1.2 g/L in the final product ready for use marketed as such or reconstituted as instructed by the manufacturer".

2. Yn Nhabl 2 (manylebau), yn y cofnod ar gyfer "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)", yng ngholofn 2 (manylebau)—

(a) yn yr adran sydd â'r pennawd "Description/Definition", yn lle'r geiriau o "amorphous powder" hyd at "spray drying" rhodder "powder or agglomerates thereof that is produced by a microbial process";

(b) yn yr adran sydd â'r pennawd "Characteristics/Composition", yn lle "Lactose and Fucose" rhodder "D-Lactose, L-Fucose, and 3-Fucosyllactose".

ATODLEN 2

Rheoliad 2

Awdurdodi olew *Schizochytrium* sp. (FCC-3204) fel bwyd newydd

1. Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer "*Schizochytrium* sp. (ATCC PTA-9695) oil" mewnosoder y cofnod a ganlyn—

"***Schizochytrium* sp. (FCC-3204) oil**	*Specified food category*	*Maximum levels of DHA*	The designation of the novel food on the labelling of the foodstuffs containing it is "Oil from the microalgae *Schizochytrium* sp.". The labelling of food supplements containing *Schizochytrium* sp. (FCC-3204) oil must bear a statement that they should not be consumed by infants and children under 3 years of age."		
	Food Supplements as defined in the Food Supplements (Wales) Regulations 2003(**1**), excluding food supplements for infants and children under 3 years of age	1g/day			
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013(**2**)	In accordance with Regulation (EU) No 609/2013			

2. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer "*Schizochytrium* sp. (ATCC PTA-9695) oil" mewnosoder y cofnod a ganlyn—

"***Schizochytrium* sp. (FCC-3204) oil**	**Description/Definition:** The novel food is an oil produced from the strain FCC-3204 of the microalgae *Schizochytrium* sp. **Composition:** Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil Moisture and volatiles: ≤ 0.05 %

(**1**) O.S. 2003/1719 (Cy. 186), y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.
(**2**) EUR 2013/609, a ddiwygiwyd gan O.S. 2019/651 a 2020/1476.

	Unsaponifiables: ≤ 4.5 % Trans-fatty acids: ≤ 1.0 % Docosahexaenoic acid (DHA): ≥ 32.0 % P-anisidine value: ≤ 10”.

ATODLEN 3

Rheoliad 2

Awdurdodi olew *Schizochytrium* sp. (WZU477) fel bwyd newydd

1. Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer "*Schizochytrium* sp. (T18) oil" mewnosoder y cofnod a ganlyn—

"***Schizochytrium* sp. (WZU477) oil**	*Specified food category*	*Maximum levels of DHA*	The designation of the novel food on the labelling of the foodstuffs containing it is "Oil from the microalgae *Schizochytrium* sp.".		Included in the list on 30 June 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Progress Biotech BV, Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den Ijssel, the Netherlands. During the period of data protection, *Schizochytrium* sp. (WZU477) oil is authorised for placing on the market within Wales only by Progress Biotech BV 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 Progress Biotech BV. The data protection ends at the end of 29
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			

					June 2027.”

2. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer “*Schizochytrium* sp. (T18) oil” mewnosoder y cofnod a ganlyn—

“***Schizochytrium* sp. (WZU477) oil**	**Description/Definition:** The novel food is an oil produced from the strain WZU477 of the microalgae *Schizochytrium* sp. **Composition:** Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil Moisture and volatiles: ≤ 0.05 % Unsaponifiables: ≤ 4.5 % Trans-fatty acids: ≤ 1.0 % Docosahexaenoic acid (DHA): ≥ 32.0 % P-anisidine value: ≤ 10”.

ATODLEN 4

Rheoliad 2

Awdurdodi rhoi ar y farchnad halen sodiwm 3'-Sialyl-lactos (3'-SL) (ffynhonnell ficrobaidd) fel bwyd newydd

1. Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer "Selenium-containing yeast (*Yarrowia lipolytica*) biomass" mewnosoder y cofnod a ganlyn—

"**3'-Sialyllactose (3'-SL) sodium salt (microbial source)**	*Specified food category*	*Maximum levels (expressed as 3'-Sialyllactose)*	The designation of the novel food on the labelling of the foodstuffs containing it is "3'-Sialyllactose sodium salt". The labelling of food supplements containing 3'-Sialyllactose sodium salt must bear a statement that they should not be consumed: a) if foods containing added 3'-Sialyllactose sodium salt are consumed the same day; b) by infants and young children.		Included in the list on 30 June 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Alle 4, DK-2970 Horsholm, Denmark. During the period of data protection, 3'-Sialyllactose sodium salt is authorised for placing on the market within Wales only by Glycom A/S 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 Glycom A/S. The data protection ends at the end of 29 June 2027."
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.25 g/L			
	Flavoured fermented milk-based products including heat-treated products	0.25 g/L (beverages) 2.5g/kg (products other than beverages)			
	Unflavoured fermented milk-based products	0.25 g/L (beverages) 0.5 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.25 g/L			
	Cereal bars	2.5g/kg			
	Infant formula as defined in Regulation (EU) No 609/2013	0.2 g/L 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	0.15 g/L 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	0.15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer. 1.25 g/kg (products other than beverages)			
	Milk-based drinks and similar products intended for young children	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013	0.5 g/L (beverages) 5g/kg (products other than beverages)			
	Food for special medical purposes as defined in Regulation	In accordance with the particular nutritional requirements			

	(EU) No 609/2013	of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children	0.5 g/day			

2. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer "Selenium-containing yeast (*Yarrowia lipolytica*) biomass" mewnosoder y cofnod a ganlyn—

"**3'-Sialyllactose (3'-SL) sodium salt (microbial source)**	**Description:** 3'-Sialyllactose (3'-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 3'-sialyl-lactulose, and sialic acid **Source:** Genetically modified strain of *Escherichia coli* K-12 DH1 **Definition:** Chemical formula: $C_{23}H_{38}NO_{19}Na$ Chemical name: N-Acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-Dglucose, sodium salt Molecular mass: 655.53 Da CAS No 128596-80-5 **Characteristics/Composition:** Appearance: White to off-white powder or agglomerate Sum of 3'-Sialyllactose sodium salt, D-Lactose, and Sialic acid (% of dry matter): ≥ 90.0 % (w/w) 3'-Sialyllactose sodium salt (% of dry matter): ≥ 88.0 % (w/w) D-Lactose: ≤ 5.0 % (w/w) Sialic acid: ≤ 1.5 % (w/w) 3'-Sialyl-lactulose: ≤ 5.0 % (w/w) Sum of other carbohydrates: ≤ 3.0 % (w/w) Moisture: ≤ 8.0 % (w/w) Sodium: 2.5 – 4.5 % (w/w) Chloride: ≤ 1.0 % (w/w) pH (20 °C, 5 % solution): 4.5 -6.0

	Residual protein: ≤ 0.01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g *Enterobacteriaceae*: ≤ 10 CFU/g *Salmonella* sp.: Absence in 25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units.”

ATODLEN 5

Rheoliad 2

Awdurdodi rhoi ar y farchnad halen sodiwm 6'-Sialyl-lactos (6'-SL) (ffynhonnell ficrobaidd) fel bwyd newydd

1. Yn Nhabl 1 (bwydydd newydd awdurdodedig), ar ôl y cofnod ar gyfer "3'-Sialyllactose (3'-SL) sodium salt (microbial source)" (fel y'i mewnosodir gan baragraff 1 o Atodlen 4 i'r Rheoliadau hyn) mewnosoder y cofnod a ganlyn—

"**6'-Sialyllactose (6'-SL) sodium salt (microbial source)**	*Specified food category*	*Maximum levels (expressed as 6'-Sialyllactose)*	The designation of the novel food on the labelling of the foodstuffs containing it is "6'-Sialyllactose sodium salt". The labelling of food supplements containing 6'-Sialyllactose sodium salt must bear a statement that they should not be consumed: a) if foods containing added 6'-Sialyllactose sodium salt are consumed the same day; b) by infants and young children.		Included in the list on 30 June 2022. This inclusion is authorised based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Alle 4, DK-2970 Horsholm, Denmark. During the period of data protection, 6'-Sialyllactose sodium salt is authorised for placing on the market within Wales only by Glycom A/S 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 Glycom A/S. The data protection ends at the end of 29
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/L			
	Unflavoured fermented milk-based products	0.5 g/L (beverages) 2.5 g/kg (products other than beverages)			
	Flavoured fermented milk-based products including heat-treated products	0.5 g/L (beverages) 5.0 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a PH less than 5)	0.5 g/L			
	Cereal bars	5.0 g/kg			
	Infant formula as defined in Regulation	0.4 g/L in the final product ready for use, marketed as			

	(EU) No 609/2013	such or reconstituted as instructed by the manufacturer			June 2027.”
	Follow-on formula as defined in Regulation (EU) No 609/2013	0.3 g/L 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	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 2.5 g/kg (products other than beverages)			
	Milk based drinks and similar products intended for young children	0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013	1.0 g/L (beverages) 10.0 g/kg (products other than beverages)			
	Food for special medical	In accordance with the particular			

	purposes as defined under Regulation (EU) No 609/2013	nutritional requirements of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children	1.0 g/day			

2. Yn Nhabl 2 (manylebau), ar ôl y cofnod ar gyfer "3'-Sialyllactose (3'-SL) sodium salt (microbial source)" (fel y'i mewnosodir gan baragraff 2 o Atodlen 4 i'r Rheoliadau hyn) mewnosoder y cofnod a ganlyn—

"**6'-Sialyllactose (6'-SL) sodium salt (microbial source)**	**Description:** 6'-Sialyllactose (6'-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 6'-sialy-llactulose, and sialic acid **Source:** Genetically modified strain of *Escherichia coli* K-12 DH1 **Definition:** Chemical formula: $C_{23}H_{38}NO_{19}Na$ Chemical name: N-Acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Molecular mass: 655.53 Da CAS No 157574-76-0 **Characteristics/Composition:** Appearance: White to off-white powder or agglomerate Sum of 6'-Sialyllactose sodium salt, D-Lactose and Sialic acid (% of dry matter): ≥ 94.0 % (w/w) 6'-Sialyllactose sodium salt (% of dry matter): ≥ 90.0 % (w/w) D-Lactose: ≤ 5.0 % (w/w) Sialic acid: ≤ 2.0 % (w/w)

	6’-Sialyl-lactulose: ≤ 3.0 % (w/w) Sum of other carbohydrates: ≤ 3.0 % (w/w) Moisture: ≤ 6.0 % (w/w) Sodium: 2.5-4.5 % (w/w) Chloride: ≤ 1.0 % (w/w) pH (20 °C, 5 % solution): 4.5-6.0 Residual protein: ≤ 0.01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1 000 CFU/g *Enterobacteriaceae*: ≤ 10 CFU/g *Salmonella* sp.: Absence in 25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units.”

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SCHEDULE 1

Regulation 2

Amendment of the conditions of use and specifications of 2'-Fucosyllactose/Difucosyllactose mixture (2'FL/DFL) as a novel food

1. In Table 1 (authorised novel foods), in the entry for "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)", in column 2 (conditions under which the novel food may be used), at the end, insert the following condition of use—

"Milk-based drinks and similar products intended for young children	1.2 g/L in the final product ready for use marketed as such or reconstituted as instructed by the manufacturer".

2. In Table 2 (specifications), in the entry for "2'-Fucosyllactose/Difucosyllactose mixture ('2'-FL/DFL') (microbial source)", in column 2 (specifications)—

(a) in the section headed "Description/Definition", for the wording from "amorphous powder" to "spray drying" substitute "powder or agglomerates thereof that is produced by a microbial process";

(b) in the section headed "Characteristics/Composition", for "Lactose and Fucose" substitute "D-Lactose, L-Fucose, and 3-Fucosyllactose".

SCHEDULE 2

Regulation 2

Authorisation of *Schizochytrium* sp. (FCC-3204) oil as a novel food

1. In Table 1 (authorised novel foods), after the entry for "*Schizochytrium* sp. (ATCC PTA-9695) oil", insert the following entry—

<table>
<tr><td rowspan="3">"Schizochytrium sp. (FCC-3204) oil</td><td>Specified food category</td><td>Maximum levels of DHA</td><td rowspan="3">The designation of the novel food on the labelling of the foodstuffs containing it is "Oil from the microalgae Schizochytrium sp.".

The labelling of food supplements containing Schizochytrium sp. (FCC-3204) oil must bear a statement that they should not be consumed by infants and children under 3 years of age."</td><td rowspan="3"></td><td rowspan="3"></td></tr>
<tr><td>Food Supplements as defined in the Food Supplements (Wales) Regulations 2003(1), excluding food supplements for infants and children under 3 years of age</td><td>1g/day</td></tr>
<tr><td>Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013(2)</td><td>In accordance with Regulation (EU) No 609/2013</td></tr>
</table>

2. In Table 2 (specifications), after the entry for "*Schizochytrium* sp. (ATCC PTA-9695) oil", insert the following entry—

"***Schizochytrium* sp. (FCC-3204) oil**	**Description/Definition:** The novel food is an oil produced from the strain FCC-3204 of the microalgae *Schizochytrium* sp. **Composition:** Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil Moisture and volatiles: ≤ 0.05 %

(**1**) S.I. 2003/1719 (W. 186), to which there are amendments not relevant to these Regulations.
(**2**) EUR 2013/609, amended by S.I. 2019/651 and 2020/1476.

	Unsaponifiables: ≤ 4.5 % Trans-fatty acids: ≤ 1.0 % Docosahexaenoic acid (DHA): ≥ 32.0 % P-anisidine value: ≤ 10”.

SCHEDULE 3

Regulation 2

Authorisation of *Schizochytrium* sp. (WZU477) oil as a novel food

1. In Table 1 (authorised novel foods), after the entry for "*Schizochytrium* sp. (T18) oil", insert the following entry—

"***Schizochytrium* sp. (WZU477) oil**	*Specified food category*	*Maximum levels of DHA*	The designation of the novel food on the labelling of the foodstuffs containing it is "Oil from the microalgae *Schizochytrium* sp.".		Included in the list on 30 June 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Progress Biotech BV, Canaalstaete, Kanaalweg 33, 2903LR Capelle aan den Ijssel, the Netherlands. During the period of data protection, *Schizochytrium* sp. (WZU477) oil is authorised for placing on the market within Wales only by Progress Biotech BV 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 Progress Biotech BV. The data protection ends at the end of 29
	Infant formula and follow-on formula as defined in Regulation (EU) No 609/2013	In accordance with Regulation (EU) No 609/2013			

					June 2027.”

2. In Table 2 (specifications), after the entry for “*Schizochytrium* sp. (T18) oil”, insert the following entry—

“***Schizochytrium* sp. (WZU477) oil**	**Description/Definition:** The novel food is an oil produced from the strain WZU477 of the microalgae *Schizochytrium* sp. **Composition:** Acid value: ≤ 0.5 mg KOH (potassium hydroxide)/g Peroxide value (PV): ≤ 5.0 meq (milliequivalent)/kg oil Moisture and volatiles: ≤ 0.05 % Unsaponifiables: ≤ 4.5 % Trans-fatty acids: ≤ 1.0 % Docosahexaenoic acid (DHA): ≥ 32.0 % P-anisidine value: ≤ 10”.

SCHEDULE 4

Regulation 2

Authorisation for the placing on the market of 3'-Sialyllactose (3'-SL) sodium salt (microbial source) as a novel food

1. In Table 1 (authorised novel foods), after the entry for "Selenium-containing yeast (*Yarrowia lipolytica*) biomass", insert the following entry—

"**3'-Sialyllactose (3'-SL) sodium salt (microbial source)**	*Specified food category*	*Maximum levels (expressed as 3'-Sialyllactose)*	The designation of the novel food on the labelling of the foodstuffs containing it is "3'-Sialyllactose sodium salt". The labelling of food supplements containing 3'-Sialyllactose sodium salt must bear a statement that they should not be consumed: a) if foods containing added 3'-Sialyllactose sodium salt are consumed the same day; b) by infants and young children.		Included in the list on 30 June 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Glycom A/S, Kogle Alle 4, DK-2970 Horsholm, Denmark. During the period of data protection, 3'-Sialyllactose sodium salt is authorised for placing on the market within Wales only by Glycom A/S 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 Glycom A/S. The data protection ends at the end of 29 June 2027."
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.25 g/L			
	Flavoured fermented milk-based products including heat-treated products	0.25 g/L (beverages) 2.5g/kg (products other than beverages)			
	Unflavoured fermented milk-based products	0.25 g/L (beverages) 0.5 g/kg (products other than beverages)			
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.25 g/L			
	Cereal bars	2.5 g/kg			
	Infant formula as defined in Regulation (EU) No 609/2013	0.2 g/L 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	0.15 g/L 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	0.15 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer. 1.25 g/kg (products other than beverages)			
	Milk-based drinks and similar products intended for young children	0.15 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013	0.5 g/L (beverages) 5g/kg (products other than beverages)			
	Food for special medical purposes as defined in Regulation	In accordance with the particular nutritional requirements			

	(EU) No 609/2013	of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children	0.5 g/day			

2. In Table 2 (specifications), after the entry for "Selenium-containing yeast (*Yarrowia lipolytica*) biomass" insert the following entry—

"**3'-Sialyllactose (3'-SL) sodium salt (microbial source)**	**Description:** 3'-Sialyllactose (3'-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 3'-sialyl-lactulose, and sialic acid **Source:** Genetically modified strain of *Escherichia coli* K-12 DH1 **Definition:** Chemical formula: $C_{23}H_{38}NO_{19}Na$ Chemical name: N-Acetyl-α-D-neuraminyl-(2→3)-β-D-galactopyranosyl-(1→4)-Dglucose, sodium salt Molecular mass: 655.53 Da CAS No 128596-80-5 **Characteristics/Composition:** Appearance: White to off-white powder or agglomerate Sum of 3'-Sialyllactose sodium salt, D-Lactose, and Sialic acid (% of dry matter): ≥ 90.0 % (w/w) 3'-Sialyllactose sodium salt (% of dry matter): ≥ 88.0 % (w/w) D-Lactose: ≤ 5.0 % (w/w) Sialic acid: ≤ 1.5 % (w/w) 3'-Sialyl-lactulose: ≤ 5.0 % (w/w) Sum of other carbohydrates: ≤ 3.0 % (w/w) Moisture: ≤ 8.0 % (w/w) Sodium: 2.5 – 4.5 % (w/w) Chloride: ≤ 1.0 % (w/w) pH (20 °C, 5 % solution): 4.5 -6.0

	Residual protein: ≤ 0.01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1000 CFU/g *Enterobacteriaceae*: ≤ 10 CFU/g *Salmonella* sp.: Absence in 25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units.”

SCHEDULE 5

Regulation 2

Authorisation for the placing on the market of 6'-Sialyllactose (6'-SL) sodium salt (microbial source) as a novel food

1. In Table 1 (authorised novel foods), after the entry for "3'-Sialyllactose (3'-SL) sodium salt (microbial source)" (as inserted by Paragraph 1 of Schedule 4 to these Regulations), insert the following entry—

<table>
<tr>
<td rowspan="8">"6'-Sialyllactose (6'-SL) sodium salt (microbial source)</td>
<td>Specified food category</td>
<td>Maximum levels (expressed as 6'-Sialyllactose)</td>
<td rowspan="8">The designation of the novel food on the labelling of the foodstuffs containing it is "6'-Sialyllactose sodium salt".

The labelling of food supplements containing 6'-Sialyllactose sodium salt must bear a statement that they should not
be consumed:

a) if foods containing added 6'-Sialyllactose sodium salt are consumed the same day;

b) by infants and young children.</td>
<td rowspan="8"></td>
<td rowspan="8">Included in the list on 30 June 2022.

This inclusion is authorised based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.

Applicant: Glycom A/S, Kogle Alle 4, DK-2970 Horsholm, Denmark.

During the period of data protection, 6'-Sialyllactose sodium salt is authorised for placing on the market within Wales only by Glycom A/S 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 Glycom A/S.

The data protection ends at the end of 29 June 2027."</td>
</tr>
<tr>
<td>Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products</td>
<td>0.5 g/L</td>
</tr>
<tr>
<td>Unflavoured fermented milk-based products</td>
<td>0.5 g/L (beverages)

2.5 g/kg (products other than beverages)</td>
</tr>
<tr>
<td>Flavoured fermented milk-based products including heat-treated products</td>
<td>0.5 g/L (beverages)

5.0 g/kg (products other than beverages)</td>
</tr>
<tr>
<td>Beverages (flavoured drinks, excluding drinks with a PH less than 5)</td>
<td>0.5 g/L</td>
</tr>
<tr>
<td>Cereal bars</td>
<td>5.0 g/kg</td>
</tr>
<tr>
<td>Infant formula as defined in Regulation</td>
<td>0.4 g/L in the final product ready for use, marketed as</td>
</tr>
</table>

	(EU) No 609/2013	such or reconstituted as instructed by the manufacturer			
	Follow-on formula as defined in Regulation (EU) No 609/2013	0.3 g/L 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	0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer 2.5 g/kg (products other than beverages)			
	Milk based drinks and similar products intended for young children	0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer			
	Total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013	1.0 g/L (beverages) 10.0 g/kg (products other than beverages)			
	Food for special medical	In accordance with the particular			

	purposes as defined under Regulation (EU) No 609/2013	nutritional requirements of the persons for whom the products are intended			
	Food supplements as defined in the Food Supplements (Wales) Regulations 2003, excluding food supplements for infants and young children	1.0 g/day			

2. In Table 2 (specifications), after the entry for "3'-Sialyllactose (3'-SL) sodium salt (microbial source)" (as inserted by Paragraph 2 of Schedule 4 to these Regulations), insert the following entry—

"**6'-Sialyllactose (6'-SL) sodium salt (microbial source)**	**Description:** 6'-Sialyllactose (6'-SL) sodium salt is a purified, white to off-white powder or agglomerate that is produced by a microbial process and contains limited levels of lactose, 6'-sialy-llactulose, and sialic acid **Source:** Genetically modified strain of *Escherichia coli* K-12 DH1 **Definition:** Chemical formula: $C_{23}H_{38}NO_{19}Na$ Chemical name: N-Acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt Molecular mass: 655.53 Da CAS No 157574-76-0 **Characteristics/Composition:** Appearance: White to off-white powder or agglomerate Sum of 6'-Sialyllactose sodium salt, D-Lactose and Sialic acid (% of dry matter): ≥ 94.0 % (w/w) 6'-Sialyllactose sodium salt (% of dry matter): ≥ 90.0 % (w/w) D-Lactose: ≤ 5.0 % (w/w) Sialic acid: ≤ 2.0 % (w/w) 6'-Sialyl-lactulose: ≤ 3.0 % (w/w)

	Sum of other carbohydrates: ≤ 3.0 % (w/w) Moisture: ≤ 6.0 % (w/w) Sodium: 2.5-4.5 % (w/w) Chloride: ≤ 1.0 % (w/w) pH (20 °C, 5 % solution): 4.5-6.0 Residual protein: ≤ 0.01 % (w/w) **Microbiological criteria:** Aerobic mesophilic bacteria total plate count: ≤ 1 000 CFU/g *Enterobacteriaceae*: ≤ 10 CFU/g *Salmonella* sp.: Absence in 25 g Yeast: ≤ 100 CFU/g Mould: ≤ 100 CFU/g Residual endotoxins: ≤ 10 EU/mg CFU: Colony Forming Units; EU: Endotoxin Units.”

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