

SCHEDULE 5

Regulation 3

Authorisation of 6'-Sialyllactose (6'-SL) sodium salt (microbial source)

1. In Table 1 (authorised novel foods), after the entry for 3'-Sialyllactose (3'-SL) sodium salt (microbial source)(1) insert the following entry—

“6'-Sialyllactose (6'-SL) sodium salt (microbial source)	<i>Specified food category</i>	<i>Maximum levels (expressed as 6'-Sialyllactose)</i>	The designation of the novel food on the labelling of the foodstuffs containing it is “6'-Sialyllactose sodium salt”.	Included in the list on 30 June 2022.
	Unflavoured pasteurised and unflavoured sterilised (including UHT) milk products	0.5 g/L	The labelling of food supplements containing 6'-Sialyllactose (6'-SL) sodium salt must bear a statement that they should not be consumed:	This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Unflavoured fermented milk-based products	0.5 g/L (beverages)	(a) if foods containing added 6'-Sialyllactose sodium salt are consumed on the same day,	Applicant: Glycom A/S, Kogle Allé 4, DK-2970 Hørsholm, Denmark.
	Flavoured fermented milk-based products including heat-treated products	2.5 g/kg (products other than beverages)	(b) by infants and young children.	During the period of data protection, the novel food 6'-sialyllactose sodium salt is authorised for placing on the market within Scotland only by Glycom A/S, unless a subsequent applicant obtains authorisation for the novel
	Beverages (flavoured drinks, excluding drinks with a pH less than 5)	0.5 g/L (beverages)		
	Cereal bars	5.0 g/kg		
	Infant formula as defined in Regulation (EU) 609/2013	0.4 g/L in the final product ready for use, marketed as such or reconstituted as instructed		

(1) Inserted by S.S.I. 2022/168.

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<p>Follow-on formula as defined in Regulation (EU) 609/2013</p>	<p>by the manufacturer 0.3 g/L in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</p>	<p>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.</p>
<p>Processed cereal-based food and baby food for infants and young children as defined in Regulation (EU) 609/2013</p>	<p>0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</p>	<p>The data protection will expire at the end of 29 June 2027.</p>
<p>Milk based drinks and similar products intended for young children</p>	<p>2.5 g/kg for products other than beverages 0.3 g/L (beverages) in the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer</p>	
<p>Total diet replacement foods for weight control as defined in Regulation (EU) 609/2013</p>	<p>1.0 g/L (beverages) 10.0 g/kg (products other than beverages)</p>	

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	<p>Food for special medical purposes as defined in Regulation (EU) 609/2013</p> <p>Food supplements as defined in the Food Supplements (Scotland) Regulations 2003, excluding food supplements for infants and young children</p>	<p>In accordance with the particular nutritional requirements of the persons for whom the products are intended</p> <p>1.0 g/day.”</p>			
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2. In Table 2 (specifications), after the entry for 3’ Sialyllactose (3’-SL) sodium salt (microbial source) insert the following entry—

<p>6’-Sialyllactose (6’-SL) sodium salt (microbial source)</p>	<p>Description:</p> <p>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’-sialyl-lactulose, and sialic acid.</p> <p>Source: Genetically modified strain of <i>Escherichia coli</i> K-12 DH1.</p> <p>Definition:</p> <p>Chemical formula: C₂₃H₃₈NO₁₉Na</p> <p>Chemical name: N-Acetyl-α-D-neuraminyl-(2→6)-β-D-galactopyranosyl-(1→4)-D-glucose, sodium salt</p> <p>Molecular mass: 655.53 Da</p> <p>CAS No 157574-76-0</p> <p>Characteristics/Composition:</p> <p>Appearance: White to off-white powder or agglomerate</p> <p>Sum of 6’-Sialyllactose sodium salt, D-Lactose and Sialic acid (% of dry matter): ≥ 94.0 % (w/w)</p> <p>6’-Sialyllactose sodium salt (% of dry matter): ≥ 90.0 % (w/w)</p>
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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: $\leq 1\ 000$ 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”