Food Standards (Application A1283 – 2′-FL from GM *Corynebacterium glutamicum* in infant formula products) Variation

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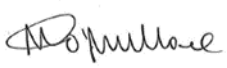
The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

9 August 2024



Matthew O'Mullane, General Manager Risk Management and Intelligence
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 170 on 15 August 2024. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1283 – 2'-FL from GM* Corynebacterium glutamicum *in infant formula products) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 3—Identity and purity

[1] Subsection S3—2(2) (table, before the table item dealing with 2′-fucosyllactose sourced from *Escherichia coli* BL21)

Insert:

2′-fucosyllactose sourced from *Corynebacterium glutamicum*	section S3—51

[2] After section S3—50

Insert:

S3—51 Specification 2′-fucosyllactose sourced from *Corynebacterium glutamicum*

For 2′-fucosyllactose (2′-FL) sourced from *Corynebacterium glutamicum*, the specifications are the following:

(a) chemical name—α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→4)-D-glucopyranose;

(b) chemical formula—$C_{18}H_{32}O_{15;}$

(c) molecular weight—488.44 g/mol;

(d) CAS number—41263-94-9;

(e) description—white to off-white/ivory powder;

(f) 2′-FL—not less than 94% (water free);

(g) D-lactose—not more than 3.0% (water free);

(h) L-fucose—not more than 3.0% (water free);

(i) 3-fucosyllactose—not more than 3.0% (water free);

(j) difucosyl-D-lactose—not more than 2.0% (water free);

(k) glucose—not more than 3.0% (water free);

(l) galactose—not more than 3.0% (water free);

(m) water—not more than 9.0%;

(n) ash, sulphated—not more than 0.5%;

(o) ethanol—not more than 1,000 mg/kg (for crystallised product from solvent only);

(p) residual proteins—not more than 0.005%;

(q) lead—not more than 0.02 mg/kg;

(r) arsenic—not more than 0.03 mg/kg;

(s) cadmium—not more than 0.01 mg/kg;

(t) mercury—not more than 0.05 mg/kg;

(u) microbiological:

(i) total plate count—not more than 500 cfu/g;

(ii) coliforms—not more than 10 cfu/g;

(iii) yeasts and moulds—not more than 100 cfu/g;

(iv) aflatoxin M1—not more than 0.025 µg/kg;

(v) residual endotoxins—not more than 10 EU/mg

Schedule 26—Food produced using gene technology

[3] Subsection S26—3(7) (table, table item 1)

Insert:

	(e) *Corynebacterium glutamicum* containing the gene for alpha-1,2-fucosyltransferase from *Pseudopedobacter saltans*	1. May only be added to infant formula products. 2. During the exclusive use period, may only be sold under the brand Momstamin 2′-FL. 3. For the purposes of condition 2 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1283 - 2'-FL from GM* Corynebacterium glutamicum *in infant formula products) Variation* and ending 15 months after that date.