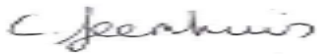


Food Standards (Application A1233 – 2'-FL from a new GM source for infant formula) Variation

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.

6 July 2022



Christel Leemhuis
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC 149 on 15 July 2022. 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 A1233 – 2'-FL from new GM source for infant formula) 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

[1] Schedule 3—Identity and Purity

[1.1] Subsection S3—2(2) (table item dealing with the substance 2'-fucosyllactose sourced from *Escherichia coli* K-12)

Repeal the item, substitute:

2'-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from either *Helicobacter pylori* or *Bacteroides vulgatus* section S3—40

[1.2] Section S3—40

Repeal the section, substitute:

S3—40 Specification for 2'-fucosyllactose sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from either *Helicobacter pylori* or *Bacteroides vulgatus*

For 2'-fucosyllactose (2'-FL) sourced from *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from either *Helicobacter pylori* or *Bacteroides vulgatus*, 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 powder
- (f) 2'-FL—not less than 83%;
- (g) D-lactose—not more than 10.0%;
- (h) L-fucose—not more than 2.0%;
- (i) difucosyl-D-lactose—not more than 5.0 %;
- (j) 2'-fucosyl-D-lactulose—not more than 1.5 %;
- (k) sum of saccharides (2'-FL, D-lactose, L-fucose, difucosyl-D-lactose, 2'-fucosyl-D-lactulose)—not less than 90%;
- (l) pH (20°C, 5% solution)—3.0-7.5;
- (m) water—not more than 9.0%;
- (n) ash, sulphated—not more than 2.0%;
- (o) acetic acid—not more than 1.0%;
- (p) residual proteins—not more than 0.01%;
- (q) microbiological:
 - (i) aerobic mesophilic bacteria total count—not more than 3,000 cfu/g;
 - (ii) yeasts—not more than 100 cfu/g;
 - (iii) moulds—not more than 100 cfu/g;
 - (iv) endotoxins—not more than 10 EU/mg.

[2] **Schedule 26—Food produced using gene technology**

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

Repeal the item, substitute:

1 2'-fucosyllactose

(a) *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Helicobacter pylori*

1. May only be added to infant formula products.
2. During the exclusive use period, may only be sold under the brand GlyCare.
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 A1155 – 2'-FL and LNnT in infant formula and other products) Variation* and ending 15 months after that date.

(b) *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126

1. May only be added to infant formula products.
2. During the exclusive use period, may only be sold under the brand CHR. HANSEN™ 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 A1190 – 2'-FL in infant formula and other products) Variation* and ending 15 months after that date.

(c) *Escherichia coli* K-12 containing the gene for alpha-1,2-fucosyltransferase from *Bacteroides vulgatus*

1. May only be added to infant formula products.
2. During the exclusive use period, may only be sold under the brand Aequival® 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 A1233 – 2'-FL from new GM source for infant formula) Variation* and ending 15 months after that date.