

SCHEDULE 7

Regulation 2(3)(d)

“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)-D-glucose, 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:

Status: This is the original version (as it was originally made).

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

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'-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 \rightarrow 6)- β -D-galactopyranosyl-(1 \rightarrow 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: $\leq 1\ 000$ 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”
