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SANTE/11416/2021 ANNEX CIS
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ANNEX CIS)
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ANNEXES 1 to 2

ANNEXES

to the

COMMISSION REGULATION (EU) .../...

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of glycolipids as a preservative in beverages

ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

- (a) In Part B, point 3 "Additives other than colours and sweeteners", the following new entry is inserted after the entry for food additive E 243:

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E 246	Glycolipids
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- (b) Part E is amended as follows:

- (1) In Category 14.1.4 (Flavoured drinks), the entry for E 246 (Glycolipids) is inserted after the entry for E 242:

	'E 246	Glycolipids	50		excluding dairy based drinks'
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- (2) In Category 14.1.5.2 (Other), the entry for E 246 (Glycolipids) is inserted after the entry for E 242:

	'E 246	Glycolipids	20	(93)	only liquid tea concentrates and liquid fruit and herbal infusion concentrates'
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- (3) In Category 14.2.1 (Beer and malt beverages), the entry for E 246 (Glycolipids) is inserted after the entry for E 220 - 228:

	'E 246	Glycolipids	50		only alcohol free beer and malt beverages'
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ANNEX II

In the Annex to Regulation (EU) No 231/2012, the following new entry is inserted after the entry for food additive E 243:

E 246 GLYCOLIPIDS	
Synonyms	
Definition	The naturally occurring glycolipids are obtained by a fermentation process using the wild type strain MUCL 53181 of the fungus <i>Dacryopinax spathularia</i> (edible sweet osmanthus ear mushroom). Glucose is used as a carbon source. The solvent-free downstream process includes filtration and microfiltration to remove microbial cells, precipitation and washing with buffered water to purify. The product is pasteurized and spray-dried. The production process does not chemically modify the glycolipids or change their innate composition.
CAS number	2205009-17-0
Chemical name	Glycolipids from <i>Dacryopinax spathularia</i>
Assay	Not less than 93 % total glycolipid content on the dried basis.
Description	Beige to light brown powder, weak characteristic odour
Identification	
Solubility	Complies (10 g/l in water)
pH	Between 5,0 and 7,0 (10 g/l in water)
Turbidity	Not more than 28 NTU (10 g/l in water)
Purity	
Water content	Not more than 5 % (Karl Fischer Method)
Protein	Not more than 3 % (factor N x 6,25)
Fat	Not more than 2 % (gravimetric)
Sodium	Not more than 3,3 %
Arsenic	Not more than 1 mg/kg
Lead	Not more than 0,7 mg/kg
Cadmium	Not more than 0,1 mg/kg

Mercury	Not more than 0,1 mg/kg
Nickel	Not more than 2 mg/kg
Microbiological criteria	
Total aerobic count	Not more than 100 colonies per gram
Yeast and moulds	Not more than 10 colonies per gram
Coliforms	Not more than 3 MPN per gram
<i>Salmonella</i> spp.	Absent in 25 g