

COMMISSION REGULATION (EU) 2022/1037**of 29 June 2022****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****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Articles 10(3) and 14 thereof,Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) The Annex to Commission Regulation (EU) No 231/2012 ⁽³⁾ lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) The Union list of food additives and the specifications for food additives may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application from a Member State or an interested party.
- (4) In December 2019, an application was submitted to the Commission for the authorisation of use of glycolipids as a preservative in flavoured drinks, some other products falling under the category 14.1 'non-alcoholic beverages' and alcohol free beer and malt beverages.
- (5) The European Food Safety Authority ('the Authority') evaluated the safety of the proposed use of glycolipids as a food additive. In the Authority's opinion ⁽⁴⁾ adopted on 4 May 2021, an acceptable daily intake ('ADI') of 10 mg/kg bw per day was established. The Authority noted that the highest estimate of exposure of 3,1 mg/kg bw per day, in toddlers, is within the established ADI and concluded that the exposure to glycolipids does not raise a safety concern at the uses and use levels proposed by the applicant.
- (6) Glycolipids are produced by fungus *Dacryopinax spathularia* in a fermentation process. Glycolipids, when used as a preservative, prolong the shelf life of beverages by protecting them against deterioration caused by micro-organisms and inhibit the growth of pathogenic micro-organisms. Glycolipids are active against yeast, moulds and gram-positive bacteria and can serve as an alternative to other preservatives currently authorised in beverages.
- (7) It is therefore appropriate to authorise the use of glycolipids as a preservative in the beverages covered by the application and to assign E 246 as the E-number to that additive.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁴⁾ EFSA Journal 2021;19(6):6609

- (8) The specifications for glycolipids (E 246) should be included in the Annex to Regulation (EU) No 231/2012 as this additive is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (9) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 29 June 2022.

For the Commission
The President
Ursula VON DER LEYEN

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:

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 *Dacryopinax spathularia* (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 *Dacryopinax spathularia*

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

Salmonella spp.

Absent in 25 g'