

COMMISSION REGULATION (EU) 2023/440**of 28 February 2023****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 carbomer in food supplements****(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 Article 10(3) and Article 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) Commission Regulation (EU) No 231/2012 ⁽³⁾ lays down specifications for food additives including colours and sweeteners that are listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (3) Those lists 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.
- (4) On 22 April 2020, an application was submitted for authorisation of the use of carbomer as a bulking agent and stabiliser in solid food supplements and as stabiliser and thickener in liquid food supplements. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) The European Food Safety Authority evaluated the safety of crosslinked polyacrylic acid polymers (carbomer) when used as food additive ⁽⁴⁾ and concluded that its use in liquid food supplements at the maximum use level of 30 000 mg/kg and in solid food supplements at the typical use level of 200 000 mg/kg is of no safety concern.
- (6) Carbomer is intended for use in solid food supplements for the controlled extended release of nutrients, allowing smaller size of tablets that are easier for consumers to swallow. In liquid food supplements, carbomer is intended for use in formulations with a wide range of flow and rheological properties that are stable with a lower level of polymer.
- (7) It is therefore appropriate to authorise the food additive 'carbomer' (E 1210) as a bulking agent and a stabiliser in solid and as a stabiliser and thickener in liquid food supplements.
- (8) The specifications for carbomer (E 1210) should be included in Regulation (EU) No 231/2012 as it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.

⁽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(8):6693.

- (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, 28 February 2023.

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 entry is inserted after the entry for food additive E 1209:

'E 1210	Carbomer'
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- (b) Part E is amended as follows:

- (1) in food category 17.1 'Food supplements supplied in a solid form, excluding food supplements for infants and young children', the following entry is inserted after the entry for food additive E 1209:

	'E 1210	Carbomer	200 000'		
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- (2) in food category 17.2 'Food supplements supplied in a liquid form, excluding food supplements for infants and young children', the following entry is inserted after the entry for food additive E 969:

	'E 1210	Carbomer	30 000'		
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ANNEX II

In the Annex to Regulation (EU) No 231/2012 the following entry is inserted after the entry for E 1209:

E 1210 CARBOMER

Synonyms	carbomer, carboxypolymethylene; carbomer homopolymer		
Definition	High-molecular mass polymers obtained by polymerisation of acrylic acid and crosslinking with allyl pentaerythritol. The polymers are synthesised in ethyl acetate using a peroxide to initiate free-radical polymerisation.		
CAS No	9007-20-9 (primary CAS), 9003-01-4 (secondary CAS)		
Chemical name	Carbomer homopolymer, allyl pentaerythritol cross-linked		
Chemical formula	$-(\text{CH}_2\text{-CH})_m\text{-}(\text{XM})_p$ COOH		
	m : number of monomer units; XM : crosslinker, p : number of crosslinker units, with m >> p		
Weight average molecular weight			
Assay	Carboxylic acid content not less than 56 % and not more than 68 % (on dried substance)		
Description	White or almost white, fluffy, hygroscopic powder or granules		
Identification			
Attenuated total reflective infra-red spectroscopy Proton nuclear magnetic resonance spectroscopy	Characteristic of the compound		
Viscosity (Brookfield viscosimetry, 20 rpm) 25 °C	Type B 29 400-39 400 mPa.s	Type A 4 000-11 000 mPa.s	Type A
Physical form	powder	powder	granules
Pass through 40 mesh, % 425 µm	-	-	95 min
Pass through 100 mesh, % 150 µm	-	-	10 max
Solubility	Insoluble in water. Water-swellaable and forms hydrogels in aqueous dispersions.		

Purity	
Residual monomers	Acrylic acid not more than 100 mg/kg
Residual crosslinker	tri and tetra-allyl pentaerythritol not more than 1 000 mg/kg
Residual solvent	Ethyl acetate not more than 0,5 % w/w
2-ethylhexanol	not more than 100 mg/kg
2-ethylhexylacetate	not more than 100 mg/kg
Lower molecular weight fraction < 1 000 Da	Not more than 0,75 % w/w
Loss on drying	Not more than 2 %
Sulphated ashes	Not more than 2,5 %
