COMMISSION REGULATION (EU) 2025/666

of 4 April 2025

amending Annex II and Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium carboxy methyl cellulose, cellulose gum (E 466) and the Annex to Commission Regulation (EU) No 231/2012 as regards specifications for cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469)

(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. Annex III to Regulation (EC) No 1333/2008 lays down a Union list of food additives, including carriers, approved for use in food additives, food enzymes, food flavourings, nutrients and their conditions of use.

(2) Commission Regulation (EU) No 231/2012 ([3]) lays down specifications for food additives that are listed in Annexes II and III to Regulation (EC) No 1333/2008.

(3) The Union lists of 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.

(4) Cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469) are food additives authorised in accordance with Regulation (EC) No 1333/2008.

(5) On 16 January 2018, the European Food Safety Authority ('the Authority') issued a scientific opinion on the re-evaluation of celluloses E 460(i), E 460(ii), E 461, E 462, E 463, E 464, E 465, E 466, E 468 and E 469 as food additives ([4]). As regards the use of sodium carboxy methyl cellulose, cellulose gum (E 466) in 'Dietary foods for infants for special medical purposes and special formulae for infants' (food category 13.1.5.1) and 'Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC' (food category 13.1.5.2), the Authority concluded that the available data did not allow an adequate assessment of the safety of use in foods belonging to these food categories. As regards the other uses of sodium carboxy methyl cellulose, cellulose gum (E 466) and the uses of the other food additives re-evaluated, the Authority concluded that there was no need

([1]) OJ L 354, 31.12.2008, p. 16, ELI: http://data.europa.eu/eli/reg/2008/1333/2024-04-23.
([2]) OJ L 354, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1331/2021-03-27.
([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, ELI: http://data.europa.eu/eli/reg/2012/231/2024-04-23).
([4]) *EFSA Journal* 2018;16(1):5047.

for a numerical acceptable daily intake and that there would be no safety concerns for their reported uses and use levels. However, the Authority recommended to revise the maximum limits for toxic elements (arsenic, lead, mercury and cadmium) in the specifications set out in Regulation (EU) No 231/2012 for those food additives to ensure that they will not be a significant source of exposure to the mentioned toxic elements through food.

(6) On 18 July 2018, the Authority launched a public call for technical and toxicological data on sodium carboxy methyl cellulose, cellulose gum (E 466) for uses as a food additive in foods for all population groups, including infants below 16 weeks of age, to collect the data needed to address its recommendations for that food additive. Business operators provided data in response to the call.

(7) On 9 December 2022, the Authority issued a 'scientific opinion on the re-evaluation of sodium carboxy methyl cellulose (E 466) as a food additive in foods for infants below 16 weeks of age and follow-up of its re-evaluation as food additive for uses in foods for all population groups' ([5]). Due to the persisting lack of data, the Authority did not perform an assessment of the safety of use of sodium carboxy methyl cellulose, cellulose gum (E 466) in food categories 13.1.5.1 and 13.1.5.2. However, the Authority recommended lowering the maximum limits for toxic elements in that food additive and changing the word 'solution' to 'dispersion', based on the consideration that hydrocolloids form colloidal dispersions in water instead of true solutions, in its specifications as laid down in Regulation (EU) No 231/2012.

(8) The Authority clarified on 16 April 2024 that the latter recommendation was also applicable to other hydrocolloid food additives such as microcrystalline cellulose (E 460 (i)), powdered cellulose (E 460 (ii)), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), low substituted hydroxypropyl cellulose (L-HPC) (E 463a), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), cross-linked sodium carboxymethylcellulose, cross linked cellulose gum (E 468) and enzymatically hydrolysed carboxymethylcellulose (E 469) ([6]).

(9) On 29 August 2023, the Commission launched a public call for technical data on the permitted food additives microcrystalline cellulose (E 460(i)), powdered cellulose (E 460(ii)), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), cross-linked carboxy methyl cellulose (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469), requesting data on toxic elements. Business operators provided data on those toxic elements in response to the call.

(10) Taking into account the re-evaluation by the Authority, it is appropriate to withdraw the authorisation for sodium carboxy methyl cellulose, cellulose gum (E 466) in food categories 13.1.5.1 and 13.1.5.2 and to remove it from Section B of Part 5 of Annex III to Regulation (EC) No 1333/2008 containing food additives added in nutrients intended to be used in foodstuffs for infants and young children listed in Point 13.1 of Part E of Annex II to that Regulation. It is also appropriate to amend the specifications for cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469) contained in the Annex to Regulation (EU) No 231/2012. In particular, the current maximum limits for toxic elements should be reduced to ensure that food additives will not be a significant source of exposure to those toxic elements in food, taking into account the level which is currently achievable by the application of good manufacturing practices. Furthermore, the word 'solution' should be changed to 'dispersion'.

(11) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.

([5]) *EFSA Journal* 2022;20(12):7665.

([6]) Minutes of the 63rd Working Group meeting on Specifications of Food Additives. Available at https://www.efsa.europa.eu/sites/default/files/wgs/food-ingredients-and-packaging/wg-fafwgSpecificationsFAs.pdf.

(12) Considering that the Authority did not identify an immediate health concern linked to the presence of toxic elements not exceeding the currently applicable limits in the food additives cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469) and to allow the food business operators, including small and medium enterprises, to adapt to the new more stringent specifications laid down in this Regulation, the application of the new specifications should be deferred and a transitional period should be provided for the use of those additives lawfully placed on the market before the date of application of this Regulation.

(13) For the same reasons, it is appropriate that a transitional period is provided for foods, containing cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) or enzymatically hydrolysed carboxy methyl cellulose (E 469) that have been lawfully placed on the market before the date of application of this Regulation.

(14) Considering that the Authority did not identify an immediate health concern linked to the use of sodium carboxy methyl cellulose, cellulose gum (E 466) for uses in foods other than in food categories 13.1.5.1 and 13.1.5.2 and in nutrient preparations to be used in 'Dietary foods for infants and young children for special medical purposes as defined in Directive 1999/21/EC', and to allow food business operators, including small and medium enterprises, to find alternatives for sodium carboxy methyl cellulose, cellulose gum (E 466) in those food categories and nutrient preparations, the application of the new conditions of use should be deferred and a transitional period should be provided for products placed on the market before the date of application of this Regulation. Considering the different steps needed for product reformulation for foods belonging to food categories 13.1.5.1 and 13.1.5.2, and to ensure the availability of foods belonging to these food categories which are specifically formulated for diagnosed patients with inborn errors of metabolism that use these foods as a significant source of nutrition to meet their dietary needs, the period of deferred application should be sufficiently long.

(15) 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

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

Article 3

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

Article 4

1. The food additives cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) and enzymatically hydrolysed carboxy methyl cellulose (E 469) that have been lawfully placed on the market before 27 October 2025 may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until the exhaustion of stocks.

2. Foods, containing cellulose (E 460), methyl cellulose (E 461), ethyl cellulose (E 462), hydroxypropyl cellulose (E 463), hydroxypropyl methyl cellulose (E 464), ethyl methyl cellulose (E 465), sodium carboxy methyl cellulose, cellulose gum (E 466), cross-linked sodium carboxy methyl cellulose, cross linked cellulose gum (E 468) or enzymatically hydrolysed carboxy methyl cellulose (E 469) that have been lawfully placed on the market before 27 October 2025, may be placed on the market until their date of minimum durability or 'use-by date'.

3. Foods belonging to food categories 13.1.5.1 'Dietary foods for infants for special medical purposes and special formulae for infants' and 13.1.5.2 'Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC' and containing sodium carboxy methyl cellulose, cellulose gum (E 466) in accordance with Annexes II and III to Regulation (EC) No 1333/2008, that have been lawfully placed on the market before 27 April 2027 may continue to be marketed until their date of minimum durability or 'use-by date'.

Article 5

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

Articles 1 and 2 shall apply from 27 April 2027. Article 3 shall apply from 27 October 2025.

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

Done at Brussels, 4 April 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

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

(1) in category 13.1.5.1 (Dietary foods for infants for special medical purposes and special formulae for infants), the entry concerning the food additive E 466 (Sodium carboxy methyl cellulose, Cellulose gum) is deleted;

(2) in category 13.1.5.2 (Dietary foods for babies and young children for special medical purposes as defined in Directive 1999/21/EC), the entry concerning the food additive E 466 (Sodium carboxy methyl cellulose, Cellulose gum) is deleted.

ANNEX II

In Section B of Part 5 of Annex III to Regulation (EC) No 1333/2008 the entry concerning the food additive E 466 (Sodium carboxy methyl cellulose, Cellulose gum) is deleted.

ANNEX III

The Annex to Regulation (EU) No 231/2012 is amended as follows:

(1) the entry for 'E 460 (i) Microcrystalline cellulose, cellulose gel' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-34-6';

(b) the specification 'Purity' is replaced by the following:

'**Purity**	
Loss on drying	Not more than 7 % (105 °C, 3 hours)
Water soluble matter	Not more than 0,24 %
Sulphated ash	Not more than 0,5 % (800 ± 25 °C)
Starch	Not detectable To 20 ml of the dispersion obtained in Identification, suspension test, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced
Carboxyl groups	Not more than 1 %
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg';

(2) the entry for 'E 460 (ii) powdered cellulose' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-34-6';

(b) the specification 'Purity' is replaced by the following:

'**Purity**	
Loss on drying	Not more than 7 % (105 °C, 3 hours)
Water soluble matter	Not more than 1,0 %
Sulphated ash	Not more than 0,3 % (800 ± 25 °C)
Starch	Not detectable To 20 ml of the dispersion obtained in Identification, suspension test, add a few drops of iodine solution and mix. No purplish to blue or blue colour should be produced
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,3 mg/kg
Mercury	Not more than 0,2 mg/kg
Cadmium	Not more than 0,1 mg/kg';

(3) the entry for 'E 461 methyl cellulose' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-67-5';

(b) the specification 'Einecs' is replaced by the following:

'Einecs	618-391-7';

(c) the specification 'Identification' is replaced by the following:

'**Identification**	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal dispersion. Insoluble in ethanol, ether and chloroform. Soluble in glacial acetic acid
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal dispersion)';

(d) the specification 'Purity' is replaced by the following:

'**Purity**	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 1,5 % (800 ± 25 °C)
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg';

(4) the entry for 'E 462 ethyl cellulose' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-57-3';

(b) the specification 'Einecs' is replaced by the following:

'Einecs	618-384-9';

(c) the specification 'pH' is replaced by the following:

'pH	Neutral to litmus (1 % colloidal dispersion)';

(d) the specification 'Purity' is replaced by the following:

'**Purity**	
Loss on drying	Not more than 3 % (105 °C, 2 hours)
Sulphated ash	Not more than 0,4 %
Arsenic	Not more than 0,5 mg/kg

Lead	Not more than 0,5 mg/kg
Mercury	Not more than 0,5 mg/kg
Cadmium	Not more than 0,5 mg/kg’;

(5) the entry for ‘E 463 hydroxypropyl cellulose’ is amended as follows:

(a) the following specification is inserted after the ‘Definition’:

‘CAS number	9004-64-2’;

(b) the specification ‘Einecs’ is replaced by the following:

‘Einecs	618-388-0’;

(c) the specification ‘Identification’ is replaced by the following:

‘**Identification**	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal dispersion. Soluble in ethanol. Insoluble in ether
Gas chromatography	Determine the substituents by gas chromotography
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal dispersion)’;

(d) the specification ‘Purity’ is replaced by the following:

‘**Purity**	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 0,5 % determined at 800 ± 25 °C
Propylene chlorohydrins	Not more than 0,1 mg/kg
Arsenic	Not more than 0,5 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 0,5 mg/kg
Cadmium	Not more than 0,5 mg/kg’;

(6) the entry for ‘E 463a low-substituted hydroxypropyl cellulose (L-HPC)’ is amended as follows:

(a) the specification ‘Einecs number’ is replaced by the following:

‘Einecs	618-388-0’;

(b) the specification ‘pH’ is replaced by the following:

‘pH	Not less than 5,0 and not more than 7,5 (1 % colloidal dispersion)’;

(c) the specification 'Purity' is replaced by the following:

'**Purity**	
Loss on drying	Not more than 5,0 % (105 °C, 1 hour)
Residue on ignition	Not more than 0,8 % determined at 800 °C ± 25 °C
Propylene chlorohydrins	Not more than 0,1 mg/kg (on an anhydrous basis) (gas chromatography–mass spectrometry (GC–MS))
Arsenic	Not more than 0,5 mg/kg
Lead	Not more than 0,5 mg/kg
Mercury	Not more than 0,5 mg/kg
Cadmium	Not more than 0,15 mg/kg';

(7) the entry for 'E 464 hydroxypropyl methyl cellulose' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-65-3',

(b) the specification 'Einecs' is replaced by the following:

'Einecs	618-389-6';

(c) the specification 'Identification' is replaced by the following:

'**Identification**	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal dispersion. Insoluble in ethanol
Gas chromatography	Determine the substituents by gas chromatography
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal dispersion)';

(d) the specification 'Purity' is replaced by the following:

'**Purity**	
Loss on drying	Not more than 10 % (105 °C, 3 hours)
Sulphated ash	Not more than 1,5 % for products with viscosities of 50 mPa.s or above Not more than 3 % for products with viscosities below 50 mPa.s
Propylene chlorohydrins	Not more than 0,1 mg/kg
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg';

(8) the entry for 'E 465 ethyl methyl cellulose' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-59-5. The CAS number 9004-69-7 has also been assigned to ethyl methyl cellulose';

(b) the specification 'Identification' is replaced by the following:

'**Identification**	
Solubility	Swelling in water, producing a clear to opalescent, viscous, colloidal dispersion. Soluble in ethanol. Insoluble in ether
pH	Not less than 5,0 and not more than 8,0 (1 % colloidal dispersion)';

(c) the specification 'Purity' is replaced by the following:

'**Purity**	
Loss on drying	Not more than 15 % for the fibrous form, and not more than 10 % for the powdered form (105 °C to constant weight)
Sulphated ash	Not more than 0,6 %
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg';

(9) the entry for 'E 466 sodium carboxy methyl cellulose, cellulose gum' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	9004-32-4';

(b) the specification 'Einecs' is replaced by the following:

'Einecs	618-378-6';

(c) the specification 'Identification' is replaced by the following:

'**Identification**	
Solubility	Yields a viscous colloidal dispersion in water. Insoluble in ethanol
Foam test	A 0,1 % dispersion of the sample is shaken vigorously. No layer of foam appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers)
Precipitate formation	To 5 ml of a 0,5 % dispersion of the sample, add 5 ml of 5 % solution of copper sulphate or of aluminium sulphate. A precipitate appears. (This test permits the distinction of sodium carboxymethyl cellulose from other cellulose ethers and from gelatine, locust bean gum and tragacanth)

Colour reaction	Add 0,5 g powdered carboxy methyl cellulose sodium to 50 ml of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear dispersion is produced, and use the dispersion for the following test: To 1 mg of the sample, diluted with an equal volume of water, in a small test tube, add 5 drops of 1-naphthol solution. Incline the test tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface
pH	Not less than 5,0 and not more than 8,5 (1 % colloidal dispersion)';

(d) the specification 'Purity' is replaced by the following:

'**Purity**	
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups (-CH_2COOH) per anhydroglucose unit
Loss on drying	Not more than 12 % (105 °C to constant weight)
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg
Total glycolate	Not more than 0,4 %, calculated as sodium glycolate on the anhydrous basis
Sodium	Not more than 12,4 % on the anhydrous basis';

(10) the entry for 'E 468 cross-linked sodium carboxymethyl cellulose, cross-linked cellulose gum' is amended as follows:

(a) the following specification is inserted after the 'Definition':

'CAS number	74811-65-7';

(b) the specification 'Einecs' is replaced by the following:

'Einecs	629-739-2';

(c) the specification 'pH' is replaced by the following:

'pH	Not less than 5,0 and not more than 7,0 (1 % dispersion)';

(d) the specification 'Purity' is replaced by the following:

'**Purity**	
Loss on drying	Not more than 6 % (105 °C, 3 hours)
Water soluble matter	Not more than 10 %
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit
Sodium content	Not more than 12,4 % on anhydrous basis

Arsenic	Not more than 0,2 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg’;

(11) the entry for ‘E 469 enzymatically hydrolysed carboxymethylcellulose, enzymatically hydrolysed cellulose gum’ is amended as follows:

(a) the specification ‘Identification’ is replaced by the following:

‘**Identification**	
Solubility	Soluble in water, insoluble in ethanol
Foam test	Vigorously shake a 0,1 % dispersion of the sample. No layer of foam appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from alginates and natural gums
Precipitate formation	To 5 ml of a 0,5 % dispersion of the sample, add 5 ml of a 5 % solution of copper or aluminium sulphate. A precipitate appears. This test distinguishes sodium carboxymethyl cellulose, whether hydrolysed or not, from other cellulose ethers and from gelatine, carob bean gum and tragacanth gum
Colour reaction	Add 0,5 g of the powdered sample to 50 ml of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear dispersion is produced. Dilute 1 ml of the dispersion with 1 ml of water in a small test tube. Add 5 drops of 1-naphthol TS. Incline the tube, and carefully introduce down the side of the tube 2 ml of sulphuric acid so that it forms a lower layer. A red-purple colour develops at the interface
Viscosity (60 % solids)	Not less than 2 500 kgm– 1s– 1 at 25 °C corresponding to an average molecule weight of 5 000 Da
pH	Not less than 6,0 and not more than 8,5 (1 % colloidal dispersion)’;

(b) the specification ‘Purity’ is replaced by the following:

‘**Purity**	
Loss on drying	Not more than 12 % (105 °C to constant weight)
Degree of substitution	Not less than 0,2 and not more than 1,5 carboxymethyl groups per anhydroglucose unit on the dried basis
Sodium chloride and sodium glycolate	Not more than 0,5 % singly or in combination
Residual enzyme activity	Passes test. No change in viscosity of test dispersion occurs, which indicates hydrolysis of the sodium carboxymethyl cellulose
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg
Cadmium	Not more than 0,1 mg/kg’