

COMMISSION IMPLEMENTING DECISION

of 3 August 2012

authorising the placing on the market of a novel chewing gum base as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council and repealing Commission Implementing Decision 2011/882/EU

(notified under document C(2012) 5406)

(Only the English text is authentic)

(2012/461/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) On 10 October 2007 the company Revolymer Ltd made a request to the competent authorities of the Netherlands to place a novel chewing gum base on the market as a novel food ingredient.
- (2) On 23 April 2009 the competent food assessment body of the Netherlands issued its initial assessment report. In that report it came to the conclusion that the novel chewing gum base can safely be used as a food ingredient.
- (3) The Commission forwarded the initial assessment report to all Member States on 30 April 2009.
- (4) Within the 60 days period laid down in Article 6(4) of Regulation (EC) No 258/97 reasoned objections to the marketing of the product were raised in accordance with that provision.
- (5) Therefore the European Food Safety Authority (EFSA) was consulted on 2 July 2010.
- (6) On 25 March 2011, EFSA in the 'Scientific Opinion on the safety of a "novel chewing gum base (REV-7)" as a novel food ingredient'⁽²⁾ came to the conclusion that the novel chewing gum base was safe at the proposed conditions of use and the proposed levels of intake.
- (7) The novel chewing gum base complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97 and therefore Commission Implementing Decision 2011/882/EU of 21 December 2011 authorising the placing on the market of a novel chewing gum base as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council⁽³⁾ was adopted.

- (8) Article 2 of Implementing Decision 2011/882/EU provided that the designation of the novel chewing gum base authorised thereby on the labelling of the foodstuff containing it shall be 'gum base (1,3-butadiene, 2-methyl-homopolymer, maleated, esters with polyethylene glycol mono-Me ether)'.
- (9) However, while the full chemical name provides for a clear and unambiguous designation of the substance, its length might dominate the labelling of the foodstuff containing it. As chewing gum is frequently sold in packages with limited space on the surface for labelling, it would be appropriate to provide a shorter alternative for the labelling.
- (10) The Chemical Abstract Service (CAS) registry numbers (CAS No) are an international standard for the designation of chemicals, which provides equivalent information to that of the chemical name as regards the nature of the substance.
- (11) It is therefore appropriate to allow the use of the CAS registry number for the designation of the novel chewing gum base authorised by Implementing Decision 2011/882/EU on the labelling of the foodstuff containing it as an alternative to the full chemical name.
- (12) The Annex could have caused misunderstandings as in its title it provided only a part of the chemical name. Furthermore the CAS No should be given in the Annex.
- (13) Therefore, it appears appropriate to repeal and replace Implementing Decision 2011/882/EU by a new Decision with the abovementioned modifications.
- (14) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

The novel chewing gum base as specified in the Annex may be placed on the market in the Union as a novel food ingredient for the use in chewing gum up to a maximum of 8 %.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ EFSA Journal 2011; 9(4):2127.

⁽³⁾ OJ L 343, 23.12.2011, p. 121.

Article 2

The designation of the novel chewing gum base authorised by this Decision on the labelling of the foodstuff containing it shall be 'gum base (including 1,3-butadiene, 2-methyl-homopolymer, maleated, esters with polyethylene glycol mono-Me ether)' or 'gum base (including CAS No: 1246080-53-4)'.

Article 3

Implementing Decision 2011/882/EU is hereby repealed.

Article 4

This Decision is addressed to Revolymer Ltd, 1, NewTech Square, Deeside Industrial Park, Deeside, Flintshire, CH5 2NT, United Kingdom.

Done at Brussels, 3 August 2012.

For the Commission

John DALLI

Member of the Commission

ANNEX

Specifications of the novel chewing gum base

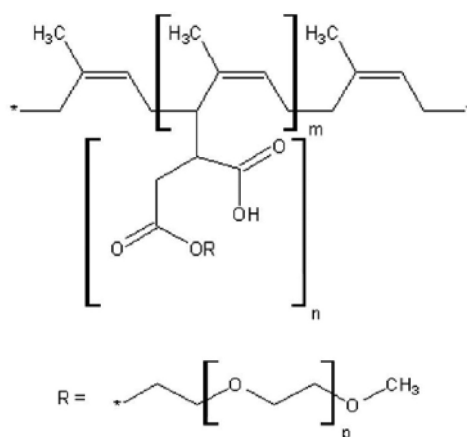
Description

The novel food ingredient is a synthetic polymer (Patent number WO2006016179). It has a white to off-white colour.

It consists of branched polymers of monomethoxypolyethylene glycol (MPEG) grafted onto polyisoprene-graft-maleic anhydride (PIP-g-MA), and unreacted MPEG (less than 35 % by weight).

CAS No 1246080-53-4

Molecular structure of MPEG grafted PIP-g-MA



Characteristics of 1,3-butadiene, 2-methyl-homopolymer, maleated, esters with polyethylene glycol mono-Me ether/
CAS No 1246080-53-4

Moisture	less than 5 %
Aluminium	less than 3 mg/kg
Lithium	less than 0,5 mg/kg
Nickel	less than 0,5 mg/kg
Residual anhydride	less than 15 $\mu\text{mol/g}$
Polydispersity index	less than 1,4
Isoprene	less than 0,05 mg/kg
Ethylene oxide	less than 0,2 mg/kg
Free maleic anhydride	less than 0,1 %
Total oligomeres (less than 1 000 Dalton)	not more than 50 mg/kg
Ethylene glycol	less than 200 mg/kg
Diethylene glycol	less than 30 mg/kg
Monoethylene glycol methyl ether	less than 3 mg/kg
Diethylene glycol methyl ether	less than 4 mg/kg
Triethylene glycol methyl ether	less than 7 mg/kg
1,4-Dioxane	less than 2 mg/kg
Formaldehyde	less than 10 mg/kg