



**COUNCIL OF
THE EUROPEAN UNION**

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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	4 April 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	Annexes to D031929/02
Subject:	ANNEXES to the COMMISSION REGULATION (EU) No .../. 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 polyvinyl alcohol-polyethylene glycol-graft-co-polymer in solid food supplements

Delegations will find attached document Annexes to D031929/02.

Encl.: Annexes to D031929/02



Brussels, **XXX**
SANO/10013/2014 ANNEX
(POOL/E3/2014/10013/10013-EN
ANNEX.doc) D031929/02
[...](2014) **XXX** draft

ANNEXES 1 to 2

ANNEXES

to the

COMMISSION REGULATION (EU) No .../..

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 polyvinyl alcohol-polyethylene glycol-graft-co-polymer in solid food supplements

ANNEX I

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

- (1) In Part B, point 3 "Additives other than colours and sweeteners", the following new entry is inserted after the entry for food additive E 1208 Polyvinylpyrrolidone-vinyl acetate copolymer:

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E 1209	Polyvinyl alcohol-polyethylene glycol- <i>graft</i> -co-polymer
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"

- (2) In Part E, in food category 17.1 "Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms", the following new entry is inserted after the entry for food additive E 1208:

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	E 1209	Polyvinyl alcohol-polyethylene glycol- <i>graft</i> -co-polymer	100 000		
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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 E 1208 (Polyvinylpyrrolidone-vinyl acetate copolymer):

E 1209 POLYVINYL ALCOHOL-POLYETHYLENE GLYCOL-<i>GRAFT</i>-COPOLYMER	
Synonyms	Macrogol poly(vinyl alcohol) grafted co-polymer; poly(ethan-1,2-diol-graft-ethanol); ethenol, polymer with oxirane, graft ; oxirane, polymer with ethanol, graft; ethylene oxide-vinyl alcohol graft co-polymer
Definition	Polyvinyl alcohol-polyethylene glycol-graft-co-polymer is a synthetic co-polymer that consists of approximately 75 % PVA units and 25 % PEG units.
CAS number	96734-39-3
Chemical name	Polyvinyl alcohol-polyethylene glycol- <i>graft</i> -co-polymer
Chemical formula	
Weight Average Molecular Weight	40 000 to 50 000 g/mol
Description	White to faintly yellow powder
Identification	
Solubility	Freely soluble in water and dilute acids and dilute solutions of alkali hydroxides; practically insoluble in ethanol, acetic acid, acetone, and chloroform
IR Spectrum	Must comply
pH value	5.0 – 8.0
Purity	
Ester Value	10 to 75 mg/g KOH
Dynamic viscosity	50 to 250 mPa·s
Loss on drying	Not more than 5 %
Sulphated Ash	Not more than 2 %
Vinyl Acetate	Not more than 20 mg/kg
Acetic acid/Total Acetate	Not more than 1.5 %
Ethylene glycol	Not more than 50 mg/kg
Diethylene glycol	Not more than 50 mg/kg
1,4-Dioxane	Not more than 10 mg/kg
Ethylene oxide	Not more than 0.2 mg/kg
Arsenic	Not more than 3 mg/kg

Lead	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg