



AGC Chemicals Europe, Ltd
PO Box 4, Thornton Cleveleys,
Lancashire FY5 4QD U.K.
Tel: +44 (0) 1253 861800
Fax: +44 (0) 1253 861950
E-mail: info@agcce.com
www.agcce.com

To Whom it May Concern

February 2017

Dear Sirs,

FLUON® GRADES: AD309E, AD309EL, AD309EB

COMPLIANCE WITH USA and EU REGULATIONS FOR PLASTICS FOR FOOD CONTACT

THE UNITED STATES FDA

The above Fluon® grades are approved under FDA food contact notification FCN No.1723 as a base resin or coating for repeat-use applications with all food types without temperature limitation.

THE EUROPEAN REGULATIONS FOR PLASTICS FOR FOOD CONTACT

The above Fluon® grades comply with the applicable requirements of the EU “framework regulation” for food contact materials, (EC) 1935/2004 and the “good manufacturing practice regulation”, (EC) 2023/2006.

Only monomers and starting substances that are listed in Annex I of Commission Regulation (EU) No 10/2011¹ “on plastic materials and articles intended to come into contact with food” (PIM), are used in the manufacture of the above Fluon® grades. The monomer tetrafluoroethylene CAS No 116-14-3 (REF No 25120) used in the manufacture of the above Fluon® grades is subject to a specific migration limit of 0.05 mg/kg in food or food simulants. The monomer (perfluorobutyl)ethylene, PM/Ref 22931, used in the manufacture of the above Fluon® grades is subject to the restrictions that it is only to be used in fluoropolymers that are sintered at high temperatures and that migration into food or food simulants shall not be detectable.

The polymer production aid used in the manufacture of the above Fluon® grades is listed in an amendment to Regulation (EU) No 10/2011 with the restriction that it must be used in the polymerisation of fluoropolymers that are processed at temperatures higher than 300°C for at least 10 minutes.

Finished articles are also subject to an overall migration limit of 10 mg/dm² or 60 mg/kg.

Compliance with the overall migration limit and specific migration limits in Regulation (EU) 10/2011 can only be demonstrated by tests carried out on the final article.

Since currently Regulation (EU) 10/2011 does not include plastic coatings on non-polymeric substrates for food contact then the existing national regulations for plastics for food contact of the Member States of the European Union are still applicable.

Fully sintered coatings made from the above Fluon® grades comply with the following:

Germany

Bfr recommendations Empfehlung LI.

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¹ References to Regulation (EU) No 10 /2011 include subsequent amendments up to and including Regulation (EU) No 2016/1416



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Belgium

Moniteur Belge: dated 9 November 1993 and subsequent amendments.

France

'Journal Official de la Republique Francaise'.

Holland

(Verapukkingen - en - Gebruiksartikelen besluit, Nederlandse Warenwet) Section 24.

United Kingdom

The "Materials and Articles in Contact with Food Regulations 2010" (Statutory Instrument 2010 No 2225) apply to materials and articles which are in their finished state and are intended to come into contact with food.

They require that such materials and articles must be manufactured in accordance with good manufacturing practice, which is further defined in Regulation 4 in terms of avoiding any danger to human health or a deterioration in the organoleptic characteristics of food. Moreover, when such materials and articles are sold they must, unless they are by nature clearly intended for such use, be accompanied by the description 'for food use' or an indication of the particular use for which they are intended. This information may be presented either on the material or article itself, or on an attached label, or in 'accompanying documents'.

These Regulations do not apply to products such as Fluon[®] Aqueous Dispersion grades which must be further processed in order to make finished materials or articles. The polymer cannot be described as 'for food use' because it is supplied in an unfinished state. Recognising that customers will require some assurance from us, we can indicate that Fluon[®] Aqueous Dispersion grades are suitable for making finished materials and articles to comply with SI No 2225. Finished materials and articles made from these grades using good manufacturing practice and according to our appropriate recommendations including fully sintering do not under normal conditions of use transfer their constituents to foods with which they are likely to be in contact in quantities which endanger human health or which, in our experience, bring about an unacceptable deterioration in the organoleptic characteristics of such food.

It is our view that in each particular case it must be the responsibility of the manufacturer of the finished material or article to ensure that it complies with the Regulations and it is recommended that this party should conduct such tests as are necessary to ensure compliance.



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The reference to other published Member States regulations of the European Union can be found on the following link:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/ReferencesEurNatLeg_20091026.pdf

Please contact our sales office if you require further information telephone number +44 (0) 1253 861 963

Yours faithfully

**GP Andrews
Product Steward**

FOOD CONTACT

Information contained in this publication (and otherwise supplied to users) is based on our general experience and is given in good faith, but we are unable to accept responsibility in respect of factors that are outside our knowledge or control. All conditions, warranties and liabilities of any kind relating to such information, expressed or implied, whether arising under statute, tort or otherwise are excluded to the fullest extent permissible in law. The user is reminded that his legal responsibility may extend beyond compliance with the information provided. Freedom under patents, copyright and registered designs cannot be assumed.

Fluon® gradess are general industrial gradess. It is the responsibility of the purchaser to check that the specification is appropriate for any individual application. Particular care is required for special applications such as pharmaceutical, medical devices or food. Not all gradess are suitable for making finished materials and articles for use in contact with foodstuffs. It is advisable to contact the AGC Chemicals Europe, Ltd sales office for the latest position. Users of Fluon® are advised to consult the relevant Health and Safety literature which is available from the AGC Chemicals Europe, Ltd sales office.