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Date
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Dear Sirs,

Fluon® Coagulated Dispersion (CD) grades CD084E, CD086E, CD086EL and CD086EH with FDA, EU and national regulations for plastics intended for food contact.

UNITED STATES of AMERICA

The above Fluon® grades comply with the compositional requirements of the United States of America FDA regulation 21 CFR 177:1550 – 'Perfluorocarbon Resins' as components of article intended for repeated use in contact with food.

Furthermore, the use of the above Fluon® grades could be used as components of resinous and polymeric coatings under FDA 21 CFR 175.300.

EUROPEAN UNION

Fluon® grades CD084E, CD086EL and CD086EH are made according to a quality management system that meets the requirements of regulation (EC) No 2023/2006 (Good manufacturing practice).

Materials and articles manufactured from Fluon® grades: CD084E, CD086EL and CD086EH, in accordance with good manufacturing practice, and in accordance with the appropriate recommendations, comply with the requirements of the framework regulation (EC) 1935/2004.

Only monomers and starting substances that are listed in Section A of Annex II of Commission Regulation (EU) 10/2011 and subsequent amendments up to Regulation (EU) 2020/1245 are used in the manufacture of the above Fluon® grades.

The monomers tetrafluoroethylene, FCM Ref No 281 and monomer Perfluoro(propyl vinyl ether) FCM Ref No 423 are used in the manufacture of the above Fluon® grades CD084E, CD086EL and CD086EH and are subject to a specific migration limit of 0.05 mg/kg and 0.01mg/kg respectively in food or food simulants.

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

Tests have been performed on behalf of AGC Chemicals Europe Ltd., based on the basic rules for overall and specific migration testing set out in Regulation (EU) No 10/2011, on sintered articles made from a range of Fluon® grades for that purpose. These tests indicate that articles made from these materials are capable of complying with the overall migration limit specified in Regulation (EU) No 10/2011, for use with all types of foodstuffs at high temperatures.

However, compliance with the overall migration and specific migration limits of Commission Regulation (EU) 10/2011 can only be demonstrated by tests carried out on the final article.

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. Some examples, of processing that may affect compliance are the use of additives or colourants mixed with Fluon®.

Since currently there is no complete EU legislation for additives and aids to polymerisation and coatings, the existing national regulations for plastics for food contact of the Member States of the European Union are still applicable.

Germany

'Fluon®' grades comply with the compositional requirements of the German law Bedarfsgegenständeverordnung vom 10. April 1992 and its subsequent amendments

The additives and aids to polymerisation used in the manufacture of these grades comply with the Bundesinstitut für Gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV) Empfehlungen LI. Empfehlung LI specifies migration limits on the final articles. The BgVV recommendations are not legally binding but they are widely respected, and conformity is often required.

France

'Fluon®' grades comply with the compositional requirements of the French Law "Arrêté du 14 septembre 1992 relatif aux matériaux et objets en matière plastique mis ou destinés à être mis au contact des denrées, produits et boissons alimentaire" and "Arrêté du 20 janvier 1994 modifiant l'arrêté du 14 septembre 1992 relatif aux matériaux et objets en matière plastique mis ou destinés à être mis au contact des denrées, produits et boissons alimentaire" and the relevant regulations in Répression des Fraudes et Contrôle de la Qualité.

Belgium

'Fluon®' grades comply with the compositional requirements of the Belgium Law, Arrêté Royal du 11 mai 1992 and its amendment dated 9 July 1993 and the subsequent amendments to date.

The Netherlands

'Fluon®' grades comply with the compositional requirements of the Verpakkingen-en-Gebruiksartikelenbesluit of the Nederlandse Warenwet (Dutch Decree on Packaging and Utensils, Food Law) Hoofdstuk 1 - Kunststoffen and complies with the compositional requirements of Hoofdstuk X - Coatings, as modified in June 1993 and subsequent amendments.

United Kingdom

Materials and articles manufactured from the above Fluon® grades CD084E, CD086EL and CD086EH, in accordance with good manufacturing practice and in accordance with the appropriate recommendations, are capable of complying with the requirements UK Statutory Instrument 2019 No 704 (Amendment) (EU Exit) Materials and Articles in Contact with Food.

The monomers tetrafluoroethylene, FCM Ref No 281 and monomer Perfluoro(propyl vinyl ether) FCM Ref No 423 are used in the manufacture of the above Fluon® grades CD084E, CD086EL and CD086EH and are subject to a specific migration limit of 0.05 mg/kg and 0.01mg/kg respectively in food or food simulants.

Yours sincerely,



Dr Martyn Shenton
Product and Process Steward
AGC Chemicals Europe, Ltd.

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AFLAS® and Fluon® grades are general industrial grades. 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 grades 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 AFLAS® and Fluon® are advised to consult the relevant Health and Safety literature which is available from the AGC Chemicals Europe, Ltd. sales office.