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Date
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Dear Sirs,

Fluon® Coagulated Dispersion (CD) grade CD090E with FDA, EU and national regulations for plastics intended for food contact.

UNITED STATES of AMERICA

The above Fluon® grade complies 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.

EUROPEAN UNION

Fluon® grades 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 the above Fluon® grade, 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 281, Perfluoro(propyl vinyl ether) FCM Ref No 423 and hexafluoropropylene FCM No 282 are used in the manufacture of the Fluon® grade CD090E are subject to a specific migration limit of 0.05 mg/kg, 0.05mg/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 performed on behalf of AGC Chemicals Europe Ltd, on articles made from a range of Fluon® grades, for that purpose, indicate that these materials are capable of complying with the overall migration limit and specific migration limit specified in Commission Regulation (EU) 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®.

United Kingdom

Materials and articles manufactured from the above Fluon® CD090, in accordance with good manufacturing practice and in accordance with the appropriate recommendations, are capable of complying with the requirements of UK Statutory Instrument 2019 No. 704 Materials and Articles in Contact with Food.

The monomers tetrafluoroethylene, FCM Ref 281, Perfluoro(propyl vinyl ether) FCM Ref No 423 and hexafluoropropylene FCM No 282 are used in the manufacture of the Fluon® grade CD090E are subject to a specific migration limit of 0.05 mg/kg, 0.05mg/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.