



AGC Chemicals Europe, Ltd.
Hillhouse International
Fleetwood Road North
Thornton Cleveleys
Lancashire, FY5 4QD, UK
Telephone: +44 (0) 1253 209600
www.agcce.com

Your ref

Our ref

Direct Phone

Direct e-mail
Martyn.shenton@agcce.com

Date
20th April 2021

Dear Sirs,

Fluon® Coagulated Dispersion (CD) grades CD122E, CD123E, CD127E, CD128E, CD141E, CD141E HT and CD142E 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 is cleared under the following parts of the Federal Code of Regulations:

- As components of adhesives under FDA 21 CFR 175.105.
- As components of resinous and polymeric coatings under FDA 21 CFR 175.300.
- As components of rubber articles intended for repeated use under FDA 21 CFR 177.2600.
- As Lubricants with incidental food contact under FDA 21 CFR 178.3570.

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® grades, 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 monomer tetrafluoroethylene, FCM No 281 are used in the manufacture of the above Fluon® grades are subject to a specific migration limit of 0.05 mg/kg 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® grades, 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 monomer tetrafluoroethylene, FCM No 281 are used in the manufacture of the above Fluon® grades are subject to a specific migration limit of 0.05 mg/kg in food or food simulants.

Yours sincerely,



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

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.

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.