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To Whom it may Concern

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Dear Sirs,

## **FLUON® GRADES CD086EL, CD086EH, CD090E AND CD126E**

### **COMPLIANCE WITH FDA AND EU REGULATIONS FOR PLASTICS FOR FOOD CONTACT**

The compliance of the above Fluon® grades with the USA Food and Drug Administration (FDA) and European Union regulations for plastics intended for food contact is as follows:

#### **UNITED STATES OF AMERICA**

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

Also the use of the above Fluon® grades as components of coatings is cleared under FDA 21CFR 175.300 – Resins and polymeric coatings.

#### **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 Annex I of Commission Regulation (EU) No 10/2011<sup>1</sup> are used in the manufacture of the above Fluon® grades.

The monomer tetrafluoroethylene, PM/Ref 25120, used in the manufacture of the above Fluon® grades and the monomer perfluoropropyl perfluorvinyl ether PM/Ref 22937 used in the manufacture of Fluon® grades CD086EL, CD086EH and CD090E are subject to a specific migration limit of 0.05 mg/kg in food or food simulants.

The monomer hexafluoropropylene PM/Ref 18430 used in the manufacture of Fluon® grades CD090E and CD126E is subject to the restriction that migration into food or food simulants shall not be detectable.

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<sup>1</sup> References to Regulation (EU) No 10 /2011 include subsequent amendments up to and including Regulation (EU) No 2015/174



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The polymer production aid used in the manufacture of Fluon® CD086EL, CD086EH, CD090E and CD126E 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) No 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 processing aids, additives or colourants mixed with Fluon®.

**Yours faithfully**

**GP Andrews**  
**Product Steward**

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