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To Whom It May Concern

September 2015

Dear Sirs,

FLUON® GRADES FL1650, FL1679, FL1680, FL1690, FL1690H, FL1690ND, L169E, TL-368 and XL1607 COMPLIANCE WITH FDA, EU AND NATIONAL REGULATIONS FOR PLASTICS FOR FOOD CONTACT

The compliance of the above Fluon® grades with the USA Food and Drug Administration (FDA), European Union and national 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 21 CFR 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 21CFR175.300 (Resinous and polymeric coatings) and as components of adhesives is cleared under FDA21CFR 175.105 (Adhesives).

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 10/2011¹ are used in the manufacture of the above Fluon® grades.

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



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The monomer tetrafluoroethylene, PM/Ref 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.

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 additives or colourants mixed with 'Fluon'.

EUROPEAN NATIONAL REGULATIONS AND RECOMMENDATIONS

Additives, as defined by the European Commission, are not used in the manufacture of the above Fluon® grades.

There is no detailed EU legislation for aids to polymerisation, so the national regulations for plastics for food contact of the Member States of the European Communities are still applicable. The user's attention is drawn to the requirements of the Dutch Decree on Packaging and Utensils which includes a positive list of aids to polymerisation, as well as regulations for coatings, and to the BfR recommendations, which also include aids to polymerisation.



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GERMANY

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

The aids to polymerisation used in the manufacture of these grades comply with the Bundesinstitut für Risikobewertung (BfR, Federal Institute for Risk Assessment) Empfehlung LI. Empfehlung LI specifies migration limits on the final article.

The BfR recommendations are not legally binding but they are widely respected and conformity is often required

THE NETHERLANDS

The above Fluon® grades comply with the compositional requirements of the Verpakkingen-en-Gebruiksartikelenbesluit of the Nederlandse, Warenwet (Dutch Decree on Packaging and Utensils, Food Law) Chapter 1 - Plastics and complies with the compositional requirements of Chapter X - Coatings, of 1993 and subsequent amendments to date.

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® 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.