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DuFlon Industries Pvt Ltd
Attn :- Mr Rajendra Bhatt
Executive Director
C - 101, MIDC Mahad, Dist Raigad - 402309, Maharashtra,

**Declaration of Compliance for
Food Contact Materials**

hereby declares, that the composition of

**PTFE 7A, 669-N, 669, 807-N,
fluoropolymer resin,**

in which the basic polymer chemically consists of a
polymer of tetrafluoroethylene,

has the following status relative to food contact regulations in Europe and the USA:

European Union

compliant with European Regulation (EU) n° 10/2011 as amended, under the condition that the finished article meets the following migration limits:

OML: 10 mg/dm² (Article 12).
SML : tetrafluoroethylene
CAS n°: 116-14-3
FCM substance n°: 281 - Ref. n°: 25120
SML= 0,05 mg/kg Residual amount: ND (detection limit of 0.01 mg/kg)¹

¹ Footnote: based on limited testing on analogue products

Note 1: At the best of our knowledge, this product does not contain any food additives. (see 'references' in the attachment).

Note 2: All monomers and additives used in the composition of the above product are listed in Annex I, the Union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids

Note 3: The products are produced according to our quality management system, which complies with the requirements of the Regulation (EC) n° **2023/2006**, on **good manufacturing practice** for materials and articles intended to come into contact with food.

Presuming appropriate processing following the Good Manufacturing Practices Regulation (EC) n° 2023/2006/EC, the product can be used in the countries of the European Community for the manufacturing of plastic materials and articles for repeated use only according to article 3 of Regulation (EC) No 1935/2004.

As a consequence, compliance is granted in the following countries which do not have additional positive lists of substances:

Denmark, Finland, Greece, Ireland, Luxembourg, Norway, Portugal, Sweden, Switzerland, United Kingdom

Status in countries with additional positive lists of substances or approval letters:

Belgium

Compliant.

France

Compliant.

Germany

An applicable "BfR Empfehlung" (= Recommendation) does not exist.

Based on the compliance of the composition of above product with the regulations in other countries as well as the inclusion of its constituents into the EU Regulation (EU) n°10/2011 with the exception of polymer production aids listed in another country, we are of the opinion, that finished articles fabricated solely with the use of above product meet the requirements of the "LFGB (Lebensmittel und Futtermittelgesetzbuch)" (= food law) of 26 April 2006, § 31, section 1, namely that no substance migrate into the food-stuffs, except those which are non-objectionable to health and which are technically unavoidable.

Italy

Compliant.

The Netherlands

Compliant.

Spain

Compliant.

**USA**

Compliant with the FDA regulation 21 CFR 177.1550 § (a)(2) and (b) when used to manufacture moulded/extruded articles.

For extraction limits see 21 CFR 177.1550 § (e)(3).

For possible compliance with other FDA regulations, please contact your sales representative.

General requirements applicable in all countries:

Manufacturers using the above product for the fabrication of finished materials and articles intended to come into contact with food must ascertain, through the appropriate tests, that these articles comply with the above mentioned restrictions/limitations (OML, SML etc.); furthermore these articles must comply in all countries with the general regulatory requirement that they are produced according to good manufacturing practice and do not bring about an unacceptable change in the composition of the food-stuffs or a deterioration in the organoleptic characteristics thereof.

The present review only refers to applicable food-contact regulations. Medical and pharmaceutical applications are not considered by these regulations. DuPont has established specific rules for medical and pharmaceutical end-uses. Please consult your DuPont representative for such applications.

for E.I. DuPont India Pvt Ltd

A handwritten signature in black ink, appearing to read "Baidyan" or similar, written over a horizontal line.

Mr Sheril V Vaidhyan
Business Manager -India

DuPont Chemicals & Fluoroproducts

This information is given in good faith and is based on data we believe to be reliable and on our current level of knowledge as of the date of this response. Therefore, we advise the recipient to request updates periodically. The information applies only to the specific material designated herein as sold by DuPont and does not apply to use in any process or in combination with any other material.

It is provided at the request of and without charge to our customers. Since conditions of use and applications of above mentioned products are outside DuPont's control, DuPont makes no warranties, express or implied, and assumes no liability in connection with any use of this information.

Regulatory Compliance Statement for Food Contact Materials Attachment

Abbreviations and references:

Abbreviations

OML = Overall Migration Limit expressed as mg/dm² of surface area of material or article,

SML = Specific Migration Limit expressed as mg/kg food or food simulant.

QM = maximum "residual" quantity in the finished article expressed as mg/kg of polymer².

QMA = maximum "residual" quantity on the surface of the finished article in contact with food expressed as mg/6 dm² of the article.

References

Europe

COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and amendments, defining the compositional requirements for plastics materials according to the general framework **Regulation 1935/2004**.

The films/products are produced according to our quality management systems, which comply with the requirements of the Regulation (EC) n° 2023/2006 on Good Manufacturing Practice.

The information provided concerning additives which are also food additives and flavouring ('Dual Use Additives') is based on our current knowledge. Since no official list of 'Dual Use Additives' exists, we refer to the 'EuPC STUDY ON DUAL USE ADDITIVES', (Additive list, version 2, updated on 2 February 2005), which is an incomplete list. The lack of information on this category of additives from certain of our suppliers, which are in front of the same difficulties, do not allow us to guarantee the completeness of the information.

Applicable to any of the EU Member States (i.e. Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom) or in countries which have adopted equivalent legislation (Norway and Switzerland).

Further auxiliary materials are governed by national regulations in countries having positive lists (Belgium, France, Germany, Italy, The Netherlands, Spain) and/or assessed in accordance with internationally recognised scientific principles on risk assessment.

Pigments used in polymer grades compliant with European food contact regulations, meet the purity requirements as specified in the Council of Europe Resolution AP(89)1 on the use of colorants in plastic materials coming into contact with food.

The migration tests for materials and articles intended to come into contact with food-stuffs should be carried out in accordance with European Regulation (EU) No 10/2011, article 18, which refers to the **Annex III and Annex V**, with respect to the transitional provisions as expressed in article 22

All resins comply with the European regulation **1895/2005** 'on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food' (**BADGE, BFDGE, NOGE**).

Countries with additional national provisions

Belgium

² Annex I column 10 expressed as mg/kg in final product



Koninklijk besluit/Arrêté royal of 3 juillet 2005 relating to plastics materials and articles intended to come into contact, as amended

France

Arrêté (Decree) of 2 January 2003 relatif aux matériaux et objets en matière plastique mis ou destinés à être mis au contact des denrées, produits et boissons alimentaires, as amended and Regulations compiled in Brochure No 1227 of "Journaux Officiels", Edition 2005.

Germany

"LFGB (Lebensmittel und Futtermittelgesetzbuch)" (= food law) of 26 April 2006 and " BfR (ex. BgVV, ex BGA) Empfehlungen" (Recommendations) as published in 'Kunststoffe im Lebensmittelverkehr, 65. Lieferung, Stand January 2010'.

Italy

"Decreto Ministeriale" (Ministerial Decree) of 21 March 1973 as amended.

The Netherlands

"VGB (Warenwet)" (Packaging and Utensils Decree) (Stb. 1979, 558), Part Aa, Chapter I, as amended

Spain

The Resolución de 04/11/1982 de la Subsecretaria para la Sanidad, as amended

Switzerland

"Kunststoffverordnung, KsV / Ordonnance sur les Matériaux Plastiques, OPla" (Decree on plastic materials) of 23 November 2005, as amended - SR 817.023.21 Stand 1st April 2010. If a compliance document for the finished material/article is desired, even though not legally required, samples of these articles may be submitted to an approved laboratory for migration testing.

USA

FDA Regulations under code 21 CFR.

