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Regulatory Compliance Statement for Food Contact Materials

DU PONT DE NEMOURS INTERNATIONAL S.A.

hereby declares, that the composition of

TEFLON® 62, 62-N, TE3808
fluoropolymer resin,

in which the basic polymer chemically consists of a

copolymer of tetrafluoroethylene and perfluoroalkylvinylether,

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

European Union

Compliant under the condition that the finished article meets the following migration limits:

OML: 10 mg/dm2 or 60 mg/kg (Article 2).
SML : - tetrafluoroethylene = 0,05 mg/kg
- perfluoropropyl perfluorovinylether = 0.05 mg/kg

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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:

Austria
Compliant. A specific confirming approval letter has not been requested.

Belgium
Compliant.

France
Compliant.

Germany
An applicable "BgVV (ex.BGA) 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 Draft Positive List of Additives (Synoptic 7), we are of the opinion, that finished articles fabricated solely with the use of above product meet the requirements of the "Lebensmittel- und Bedarfsgegenständegesetz" (Food-Utensils Act) of 9 September 1997, § 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.

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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 DU PONT DE NEMOURS INTERNATIONAL S.A.

Dr. Christian L. Guéris
Human Exposure Manager, Europe