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## Declaration of Compliance for Food Contact Materials

### DuPont de Nemours International Sàrl

Hereby declares that the composition of

#### **Elvax® 550A resin**

In which the basic polymer chemically consists of a  
**copolymer of ethylene and vinyl acetate,**

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

#### **European Union**

Compliant with the Commission Regulation (EU) 10/2011 as well as the Regulation (EC) No 1935/2004 both as amended, under the condition that the finished article meets the following migration limits:

- OML : -10 mg/dm<sup>2</sup> or 60 mg/kg (Article 12).  
SML : - vinyl acetate (FCM: 231, CAS : 108-05-4) = 12 mg/kg  
- 3,5-di-tert-butyl-4-hydroxytoluene (FCM: 315, CAS : 128-37-0) = 3 mg/kg

Remark concerning 'Dual Use Additives' : The following additive is also a food additive or a flavouring: 3,5-di-tert-butyl-4-hydroxytoluene (E321), (see 'references' in the attachment)

Note 1: All monomers and additives in the composition of the above product are listed in the Union list of authorised substances, see Annex I of the Regulation 10/2011 as amended.

Note 2 : the above product complies with the Annex II of the Regulation 10/2011.

Note 3: The above product is produced according to our quality management systems, which comply 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.

Note 4 : Concerning the Annex IV 'Declaration of Compliance', see the page 6 of the attachment to this document.

As a consequence, compliance is given in all of the EU Member States which do not have additional national substance lists as well as in Norway and Switzerland.

**Status in countries with additional national lists of substances:**

**Belgium**

Compliant.

**France**

Compliant.

**Germany**

Compliant with the applicable "BfR Empfehlung" (=Recommendation) XXXV, part A.

Applicable restriction : Not for contact with oils, fats and fat containing food products in which fat forms the external phase.

**Italy**

Compliant.

**The Netherlands**

Compliant.

**Spain**

Compliant.

**Additional information**

We do not add BADGE, BFDGE, NOGE substances, therefore, are of the opinion that above mentioned products meet the European regulation (EC) 1895/2005 'on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food', although we have not performed the requested migration tests.

We do not add Bisphenol A (FCM 151, named '2,2-bis(4- hydroxyphenyl)propane', CAS 80-05-7). To the best of our knowledge, our raw material suppliers do not intentionally add this substance in the manufacture of their products. However, we do not routinely analyse our resins for this substance nor do we require our raw material suppliers to do so.

### **Content of additives of potential animal origin**

No additive of animal origin is added.

#### *Additional information relative to the use of additives of animal origin in polymer products :*

#### *Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)*

European Commission Decision 00/418/EC and 2001/2/EC regulating the use and inactivation of materials presenting risks as regards transmissible spongiform encephalopathies (TSE) are giving directives for the elimination and recommended treatments to ensure complete inactivation of any TSE/BSE agent for, amongst others, products to be used in contact with food. The plastics industry therefore does assume, when using additives of animal origin certified for food contact applications, that the above mentioned Recommendations have been followed.

Typically, during their production, the additives are subject to multiple extended high temperature - temperatures above 200°C - and high pressure processing steps. Such conditions are described in the WHO/CDS/VPH 95.145 report, European directives 2000/6/EC, European Regulation (EC) No 1069/2009 and in the EMA 410/01 rev. 3 of March 2011 note.

The additional exposure of the plastics materials to temperatures ranging from 150°C to 300°C during half a minute to several minutes both, during compounding and in the final conversion process, represents an additional safety factor ensuring the protection of people's health in respect to TSE/BSE when using plastics materials in food contact.

### **Content of additives of potential vegetal origin**

No additive of vegetal origin is added.

However traces of unintentionally added vegetal origin substance may be present as impurity.

### **Allergen**

No additives listed in the FDA 'Food Allergen Labeling and Consumer Protection Act ' or the European Directive are added.

Such as, but not limited to

Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans or proteins derived thereof, except any highly refined oil and any ingredient derived from such highly refined oil.

*Ref: 'Food Allergen Labelling and Consumer Protection Act of 2004', Section 201 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321).*

ANNEX II, Substances or products causing Allergies or Intolerances , (EU) 1169/2011 of 25 October 2011, as amended.

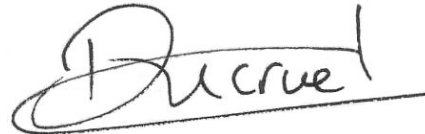
*The commission adopted a Notice dated on 13.7.2017 on the provision of information on substances or products causing allergies or intolerances.*

**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 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 DuPont de Nemours International Sàrl**



Ms Sophie Ducruet  
Regulatory Affairs Specialist, Europe

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### **Important Notice**

Polymer materials, by their nature, are subject to physical and chemical changes over time. Such changes are accelerated by temperature.

Depending on material handling, storage, preparation; processing conditions; article handling, storage and treatment, the chemical nature and content of polymeric materials can be altered.

Such alteration can be absorption; partial or complete elimination by chemical reaction, volatilisation or extraction; the formation of different chemicals.

Processing conditions include processing equipment settings, type, size, design and age of equipment, maintenance conditions including wear and cleanness, chemicals in the working environment. Specific attention has to be given to the avoidance of hydrolysis and material degradation.

In addition physical factors such as radiation, polymer crystallinity, re-crystallisation, shrinkage and mechanical stress can have an influence.

Please also consider that any technical process has an inherent variability.

DuPont's assessment of its polymeric materials is based on their state as raw materials or simple articles like small size plates or films produced under laboratory conditions.

These conditions may be significantly different from articles actually put onto the market. Therefore, any information provided by DuPont may or may not be representative for articles made out of DuPont polymer materials. Such assessment can only be made by the final article producer who also defines the authorised use conditions.

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This information may be subject to revision as new knowledge and experience becomes available. The information relate only to the specific material designated; these data may not be valid for such material used in combination with any other materials or additives or in any process, unless expressly indicated otherwise. The information provided should not be used to establish specification limits nor used alone as the basis of assessment; they are not intended to substitute for any testing you may need to conduct to determine for yourself the suitability of a specific material for your particular purposes. Since DuPont cannot anticipate all variations in actual end-use conditions DuPont makes no warranties and assumes no liability in connection with any use of this information. Nothing in this publication is to be considered as a license to operate under or a recommendation to infringe any patent rights.

## **Declaration of Compliance for Food Contact Materials Attachment**

### **Abbreviations and references:**

#### **Abbreviations**

FCM = Food contact material

Ref. No = EEC packaging material reference number

CAS No = Chemical Abstracts Service (CAS) registry number

OML = Overall Migration Limit expressed as mg/dm<sup>2</sup> of surface area of material or article, or expressed as mg/kg food or food simulant means the maximum permitted amount of non-volatile substances released

SML = Specific Migration Limit expressed as mg/kg food or food simulant means the maximum permitted amount of non-volatile substances released

QMA = maximum "residual" quantity on the surface of the finished article in contact with food expressed as mg/6 dm<sup>2</sup> of the article.

#### **References**

##### **Europe**

Commission Regulation (EU) No 10/2011 of 14 January 2011 as amended by (EU) No 1282/2011 of 28 November 2011, (EU) No 1183/2012 of 30 November 2012, (EU) No 202/2014 of 3 March 2014, (EU) No 2015/174 of 5 February 2015, (EU) 2016/1416 of 24 August 2016, (EU) No 2017/752 of 28 April 2017, (EU) No 2018/79 of 18 January 2018 and (EU) No 2018/213 of 12 February 2018 defining the requirements for plastics materials according to the general framework Regulation (EC) No 1935/2004 and replacing Commission Directive 2002/72/EC and its amendments.

Applicable to all 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).

Some polymer production aids, colorants and solvents are governed by national regulations in countries having positive lists (Belgium, France, Germany, Italy, The Netherlands, Spain).

Commission Regulation (EU) No 10/2011, Annex IV (Declaration of compliance), point 8 addresses mainly restrictions related to the compliance with OML / SML limits which are inherently related to end-use articles and their specified use conditions.

DuPont has not made systematic evaluations of the use condition limits of its materials compliant for use in food contact applications. There is unlimited set of possible conditions under which the respect of OML / SML would be needed to be tested and evaluated. And even then the results / assessments developed on laboratory samples and under laboratory production conditions may not be representative for industrial production conditions\* or any material combination in blends or multilayer constructions.

For the above reasons, no specifications as mentioned in the Commission Regulation (EU) No 10/2011, Annex IV (Declaration of compliance), point 8 have been established for DuPont raw materials.

\*Please refer to 'Important Notice'

The information provided concerning additives which are also food additives and flavouring ('Dual Use Additives') is based on the provisions of Article 11 (3) of Regulation (EU) No 10/2011.

The migration tests for materials and articles intended to come into contact with food-stuffs should be carried out in accordance with Regulation (EU) No 10/2011, Article 18.

Council of Europe Resolution AP(89)1 defines the purity requirements of pigments used in polymers grades being compliant with the food contact regulations.

Council of Europe Resolution AP(92)2 on control of aids to polymerisation for plastics materials and articles intended to come into contact with foodstuff.

Regulation (EU) 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).

Due to regulatory interpretation issues, supplier certification concerning Regulation (EC) n° 2023/2006 (GMP) and Dual Use Additives may not be complete for all suppliers.

Source for national legislations :

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm)

Document : "EU and National Laws"

Belgium

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

France

Regulations compiled in Brochure No 1227 of "Journaux Officiels", Edition 2005.

Germany

"LFGB (Lebensmittel und Futtermittelgesetzbuch)" (= German Food and Feed Code) of 01-09-2005 as amended and " BfR (ex. BgVV, ex BGA) Empfehlungen" (Recommendations) [https://bfr.ble.de/kse/faces/DBEmpfehlung\\_en.jsp](https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp)'.

Italy

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

The Netherlands

Commodities Act Regulation on packagings and consumer articles coming into contact with foodstuffs (Commodities Act (Packagings and Consumer Articles) Regulation) - Chapter I Plastic articles and materials (Table I-1 Polymerisation auxiliaries and their decomposition products that are still permitted for use at the national level).

Spain

Real Decreto 847/2011, de 17 de junio, por el que se establece la lista positive de sustancias permitidas para la fabricación de materiales poliméricos destinados a entrar en contacto con los alimentos.

Switzerland

Verordnung des EDI über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen /

Ordonnance du DFI sur les matériaux et objets destinés à entrer en contact avec les denrées alimentaires (Decree on materials and articles coming into contact with food) of 16 December 2016, – SR 817.023.21 Stand 16 December 2016. , section 5: Plastic Materials and articles and annex 2.

Note:

Declarations according to regulations for other regions are available on request