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**Regulatory Compliance Statement
for
Food Contact Articles**

DuPont International Operations Sàrl

Hereby declares that the composition of

HEROX® 1100HA

Toothbrush filament

**BL302, BL305, BL306, BL317,
GN406, GN409, GN435,
RD105, RD107,
VT502, VT506, VT509,
YL209, YL223
YL245, WT601**

In which the basic polymer chemically consists of a
copolymer of hexamethylenediamine and sebacic acid,

**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/dm² or 60 mg/kg (Article 12).

SML : - hexamethylenediamine (FCM: 305, CAS : 124-09-4) = 2.4 mg/kg



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Remark concerning 'Dual Use Additives': The following additives are also food additives or flavourings: None to our knowledge (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 "BfG (ex BgVV, ex BGA) Empfehlung" (= Recommendation) X and IX .

Italy

Compliant

The Netherlands

Compliant

Spain

Compliant

Additional information

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.

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.



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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 material/s 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 EMEA 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 are added. No genetically modified organisms (GMO) are added.

Allergen

No additives listed in the FDA 'Food Allergen Labeling and Consumer Protection Act of 2004' or the European Directive 2007/68/EC are added.

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).

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains), except wheatbased glucose syrups and maltoestriins, barley-based glucose syrups and cereals used for making distillates or ethyl alcohol of agricultural origin. **Crustaceans, Eggs, Fish**, except fish gelatine used as carrier for vitamin or carotenoid preparations, fish gelatine or Insinglass used as fining agent in beer and wine. **Peanuts, Soybeans**, except fully refined soybean oil and fat, natural mixed tocopherols (E306), natural D-alpha tocopherol, acetate and succinate, vegetable oils derived phytosterols and esters, plant stanol ester.

Milk (including lactose), except when used for making distillates or ethyl alcohol of agricultural origin,

Lactitol, Nuts i. e. Almond (*Amygdalus communis* L.), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nut (*Bertholletia excelsa*). Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*), except nuts used for making distillates or ethyl alcohol of agricultural origin. **Celery, Mustard, Sesame seeds, Sulphur dioxide and sulphites** at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂, **Lupin and Molluscs or products thereof**.

Ref: European Directive 2007/68/EC, dated 27 November 2007, Annex, ANNEX IIIa, Ingredients referred to in Article 6(3a), (10) and (11).



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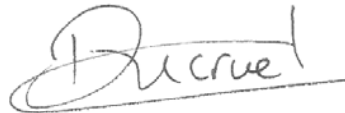
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General requirements applicable in all countries:

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 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 INTERNATIONAL OPERATIONS Sàrl



Ms Sophie Ducruet
Regulatory Affairs Representative, 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, volatilization 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.

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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Regulatory Compliance Statement 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/dm² 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 dm² 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 and **(EU) No 1183/2012** of 30 November 2012 and **(EU) No 202/2014** of 3 March 2014 and **(EU) No 2015/174** of 5 February 2015 and **2016/1416** of 24 August 2016 defining the requirements for plastics materials according to the general framework Regulation (EC) No1935/2004 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'



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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** on the use of colorants in plastic materials coming into contact with food.
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

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

Arrêté (Decree) of 2 January 2003 relatif aux matériaux et objets en matière plastique mis ou destinées 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

Bundesinstitut für Risikobewertung - BfR Empfehlung (= recommendations) zu Materialien für den Lebensmittelkontakt (letzte Überarbeitung: 21/06/2013)

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 positiva de sustancias permitidas para la fabricación de materiales poliméricos destinados a entrar en contacto con los alimentos.

Note:

Declarations according to regulations for other regions are available on request



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