PolyOne
Plastic Compounds & Colors

Regulatory Information Sheet

Product reference:

CC10002498BG FDM 65-WT-97 WT PET MINI BEADS MB

Food contact regulations

When legislation specifies maximum migration levels, these must always be verified on the finished product using the recognized test methods of the country concerned.

This product, when used with good manufacturing practice in the prescribed resins, conforms to the following regulations regarding food contact applications:

NOTE: *Finished materials / articles manufactured with the above-mentionned product must comply with the following restrictions when placed on the market in any of the EU member states or in non-EU countries which have adopted the same legislation (CH, N), as all these countries has adopted the food contact Commission Regulation 10/2011 for plastics*

Europe	Compliant

COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and its amendments: No 321/2011, No 1282/2011. This Regulation is a specific measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004. This Regulation should establish the specific rules for plastic materials and articles to be applied for their safe use and repeal Commission **Directive 2002/72/EC** of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs.

Purity requirements given in Resolution AP(89)1 of Council of Europe on the use of colourants in plastic materials coming into contact with food.

Components with SML	7,5 mg/kg of food for Ref. n° 24910 - FCM n° 785 - expressed as terephthalic acid - SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref n° 24910, 24940 and 23187. 30 mg/kg of food for Ref. n° 15760 & 16990 - FCM n° 263 and 227 - SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref n° 13326, 15760, 16990, 47680, 53650 and 89440. 5 mg/kg of food for Ref. n° 19150 - FCM n° 291 - expressed as isophthalic acid - SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Ref n° 19150 and 19180 0,04 mg/kg of food for Ref. n° 35760 - FCM n° 398 - SML expressed as antimony. The migration limit might be exceeded at very high temperature.
Dual-use additive (Annex IV of EU 10/2011)	phosphoric acid (E 338)

Remark: The final food contact material or article made from or containing this product as a component, needs to comply with overall migration limit requirements – as specified in various legislations – when tested on the food contact surface with the appropriate food simulants and time/temperature test conditions. This is part of the responsibility of the user of this polymer product.

Indeed, appropriate overall migration tests on the final material or article determine the regulatory suitability for contact with different food types (fat/oil, alcoholic,…) and various end-use conditions (thickness, pure or in blends, volume, contact time of packaging, temperature of use,…), which are beyond control of PolyOne Color & Additives Europe.

Framework Directive

This product is in compliance with **Regulation n° 1935/2004** of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EC and 89/109/EC. Particularly, article 3 "General Requirements":

1. Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal and foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:
   (a) endanger human health,
   or
   (b) bring about an unacceptable change in the composition of the food,
   or
   (c) bring about a deterioration in the organoleptic characteristics thereof.
2. The labeling, advertising and presentation of a material or article shall not mislead the consumers.

Please refer to compliance with food contact regulations in EU for more information about specific migration limits of some components.

Good Manufacturing Practices

According to the manufacturing process of the above-mentioned masterbatch, PolyOne Color & Additives Europe applies the general rules and recommendations laid down in Regulation n° 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending **Regulation n° 2023/2006** of the European Parliament and of the Council of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Packaging

No intentional addition of
1. Lead.
2. Mercury.
3. Cadmium.
4. Hexavalent Chromium.
Therefore, compliance with:
• Article 11 of European Parliament and Council Directive **94/62/EC** of 20 December 1994 on packaging and packaging waste (last amended by Directive 2005/20/EC).
• The requirements of the Model Toxics in Packaging Legislation developed in 1989 by the **CONEG** (Coalition Of NorthEastern Governors) (United States of America).
• Article 4 of the French "**Décret n° 98-638** du 20 juillet 1998 relatif à la prise en compte des exigences liées à l'environnement dans la conception et la fabrication des emballages".

Remark: This, however, does not exclude that trace levels of those substances may be unintentionally present. PolyOne Color & Additives Europe does not check the non detection of those substances.

Pharmacopoeia

For the following reasons, PolyOne Color & Additives Europe cannot declare the above-mentioned product to be physiologically safe for the purpose of coloring pharmaceuticals and medical devices:
• There are no general purity requirements for colorants for these applications.
• The specifications in the various monographs of the European Pharmacopoeia on specific substances (e.g. iron oxide, titanium oxide, etc.) are not part of normal quality control.
• Colorants are produced by large-scale industrial processes and not primarily for the medical sector.
• All the regulations relevant to medical applications specify testing of the final product (Medical Device Directive 93/42/EC, ISO 10993 and/or USP Class VI requirements).

Miscellaneous

No intentional addition of
1. BADGE: 2, 2-bis (4-hydroxyphenyl) propane bis (2, 3-epoxypropyl) ether.
2. BFDGE: bis (hydroxyphenyl) methane bis (2, 3-epoxypropyl) ethers.
3. NOGE: novolac glycidyl ethers.
Or some of their derivatives - Therefore, compliance with Commission Regulation 1895/2005/EC of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (this Regulation repeals Directive 2002/16/EC & 2004/13/EC).

No intentional addition of Azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amine listed in the appendix of 2002/61/EC. Therefore, compliance with Directive 2002/61/EC of the European Parliament and of the Council of 19 July 2002 amending for the nineteenth time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (Azocolourants).

No intentional addition of Diarylide pigments.

No intentional addition of Bisphenol A (CAS Reg. Nr: 80-05-7 - 25068-38-6)

No intentional addition of Phthalates.

Remark: This, however, does not exclude that trace levels of those substances may be unintentionally present. PolyOne Color & Additives Europe does not check the non detection of those substances.

Comment

This certificate remains valid 12 months after the date issue or until changes of the cited regulations become effective.

This declaration applies only to the raw materials used in the manufacture of the product mentioned, and may not be extended to end products obtained by:

• Any ulterior modification due to the addition of any other substances not in conformity with the related regulations,
• An improper use of the masterbatch or end product,
• Any processing technique or conditions of use which could lead to the masterbach deterioration.

This declaration does not waive the responsibility of the user who must check whether the end products are appropriate for the specific intended use.

It is our understanding that the above-mentioned product is used in an unaltered form and within the appropriate plastic molding conditions.

Date : **17/01/2012**

For the Supplier,

Maude ERPICUM

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