

*Mit uns wird  
Kunststoff farbig...*

**PlasTeam** Kunststoff  
GmbH

Plasteam Kunststoff GmbH · Postfach 271 · D-58315 Schwelm

Nordstraße 21  
D-58332 Schwelm

TEL. 02336/9388-0  
FAX 02336/9388-20

E-Mail: [info@plasteam.de](mailto:info@plasteam.de)  
Internet: [www.plasteam.de](http://www.plasteam.de)

Ust-IdNr. DE126457760  
Zertifiziert DIN EN ISO 9001:2008

Maren Schumacher  
02336/9388-10

08.08.2011

**Statement**  
PE-FK weiß Nr. 22.677

**RE: 1935/2004/EC:**

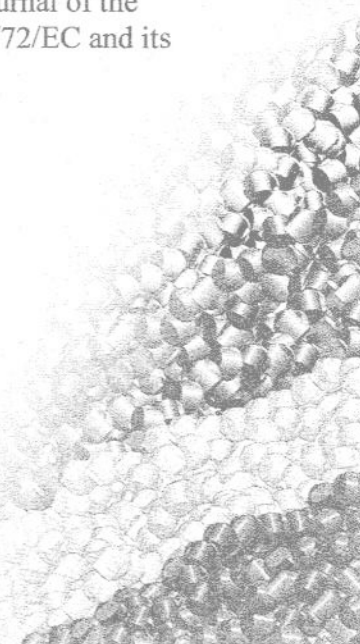
Regulation No. 1935/2004/EC of the European Parliament and of the Council dated 27th October 2004 is a framework regulation covering all materials and articles intended to come into contact with food.

This regulation supersedes the framework regulations 80/590/EEG and 89/109/EEC and specifies general requirements for all materials and articles intended to come into contact with food, such as glass, paper, metal, plastics etc.

According to Article 5 and Annex 1 of the Regulation No. 1935/2004/EC, certain groups of materials and articles, listed in Annex 1, among which plastics are subject to specific measures.

For plastic materials and articles intended to come into contact with foodstuffs, these specific measures are laid down in the Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14th January 2011 (this Regulation replaces Directive 2002/72/EC and its 6 amendments) and its amendment Regulation (EU) No. 321/2011.

- page 2 -



*Mit uns wird  
Kunststoff farbig...*

**PlasTeam** Kunststoff  
GmbH

**RE: Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14th January 2011 and its amendment Regulation (EU) No. 321/2011.**

First, we wish to point out that the scope of the Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14th January 2011 and its amendment Regulation (EU) No. 321/2011 is the final product, not the ingredients of same; consequently, it is incumbent on the end producer to test for specific migration and „over all“ migration.

Also, it should be mentioned that the directive does not treat the pigments in the masterbatch, only of the polymer and the additives.

As outlined in Article 5 of the Regulation, pigments are not within the scope of the regulation:

2. The Union list shall contain
  - (a) Additives excluding colorants

Furthermore is mentioned in Article 6:

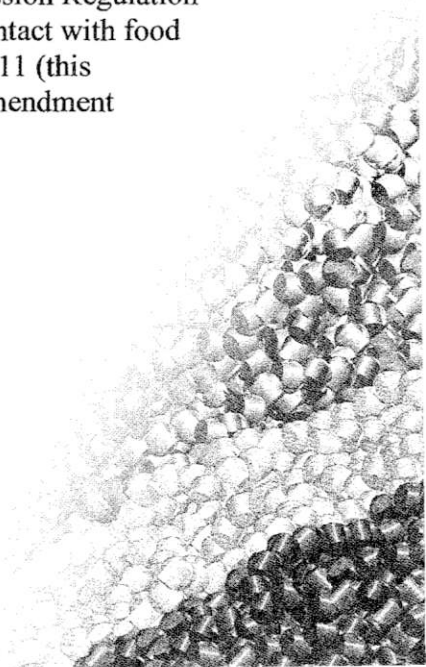
2. By way of derogation from Article 5, colorants and solvents may be used in the manufacture of plastic layers in plastic materials and articles subject to national law.

PE-FK weiß Nr. 22.677 contains the following „dual use“ additive: Tio2.

PE-FK weiß Nr. 22.677 is based on polymers produced from monomers that are all detailed in the positive list of the Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14th January 2011 (this Regulation replaces Directive 2002/72/EC and its 6 amendments) and its amendment Regulation (EU) No. 321/2011.

The additives contained in PE-FK weiß Nr. 22.677 are listed in the Commission Regulation (EU) Nr. 10/2011 on plastic materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14th January 2011 (this Regulation replaces Directive 2002/72/EC and its 6 amendments) and its amendment Regulation (EU) No. 321/2011.

- page 3 -



*Mit uns wird  
Kunststoff farbig...*

**PlasTeam** Kunststoff  
GmbH

#### **Additives added with a Specific Migration Limit:**

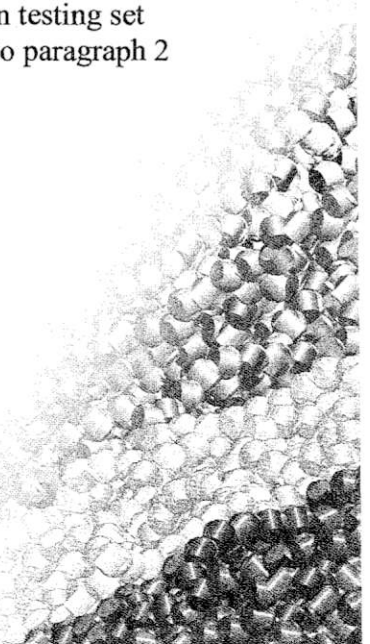
PE-FK weiß Nr. 22.677 contains:

Pigment White 5 which contains Zinc and Barium. A "group SML" of 25 mg/kg expressed as Zinc is applicable to the final food contact item (Commission Regulation (EU) No. 10/2011, Annex II).

The pigments applied in PE-FK weiß Nr. 22.677 meet the purity requirements of EU Resolution AP (89) 1: „On the Use of Colourants in Plastic Materials Coming into Contact with Food“.

Another aspect of the Commissions Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14th January 2011 and its amendment Regulation (EU) No. 321/2011 is the specific and the overall migration

- 1) The final food contact material or article coloured with PE-FK weiß Nr. 22.67 must until the 31st December 2012 comply with the overall and specific migration testing limit requirements as specified in the directive when tested according to 82/711/EC on the food contact surface with the appropriate food simulants and under the time/temperature conditions specified in 85/572/EEC, 93/8/EEC and 97/48/EEC.
- 2) As from 1st January 2013 the supporting documents referred to in Article 16 for materials, articles and substances placed on the market until 31st December 2015, may be based on:
  - a) rules for migration testing set out in Article 18 of Regulation 10/2011; or
  - b) the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC
- 3) As from 1st January 2016, the supporting documents referred to in Article 16 of Regulation (EU) No. 10/2011 shall be based on the rules for migration testing set out in Article 18 of Regulation (EU) No. 10/2011, without prejudice to paragraph 2 of this Article.



*Mit uns wird  
Kunststoff farbig...*

**PlasTeam** Kunststoff  
GmbH

According to the Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14th January 2011 and its amendment Regulation (EU) No. 321/2011 the finished plastic materials and articles shall not release

- 1) Primary aromatic amines excluding those appearing in Table 1 of Annex I in a detectable quantity (DL = 0.01 mg/kg of food or food simulant).
- 2) The following substances in quantities exceeding the specific migration limits below:
  - Barium = 1 mg/kg food or food simulant
  - Cobalt = 0.05 mg/kg food or food simulant
  - Copper = 5 mg/kg food or food simulant
  - Iron = 48 mg/kg food or food simulant
  - Lithium = 0.6 mg/kg food or food simulant
  - Manganese = 0.6 mg/kg food or food simulant
  - Zinc = 25 mg/kg food or food simulant

Consequently, it rests with the producer of the finished product to analyse for possible release of primary aromatic amines + the above mentioned metals and not with the masterbatch supplier (masterbatch being a semi-finished product).

PlasTeam Kunststoff GmbH cannot guarantee whether or not a compound produced from PE-FK weiß Nr. 22.677 will be in conformity with the requirements as stipulated in the Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14th January 2011 and its amendment Regulation (EU) No. 321/2011, because PlasTeam Kunststoff GmbH would not know the further processing parameters. PlasTeam Kunststoff GmbH has not determined whether a compound produced from PE-FK weiß Nr. 22.677 will be in conformity with the limits described in the Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14th January 2011 and its amendment Regulation (EU) No. 321/2011.

**Supplementary Information:**

Since the masterbatch supplier cannot be responsible for the subsequent use of the product, the responsibility to test if the final product complies with the national and international provisions and laws rests with the user of the masterbatch. This product information is based on the present state of our knowledge, information and experience. No responsibility or liability can be assumed for factors lying outside our knowledge and control.

