

**(SD-001) Statement regarding compliance  
Polypropylene Pink**

**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 in 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 in contact 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 in contact with foodstuffs, these specific measures are laid down in the Commission Regulation (EU) No. 10/2011 on plastics materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14 January 2011 (this Regulation replaces Directive 2002/72/EC and its 6 amendments) and its amendments Regulation (EU) No. 321/2011, No. 1282/2011, No. 1183/2012, No. 202/2014, No. 865/2014 and No. 174/2015.
- RE: Regulation (EU) No. 10/2011 on plastics materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14 January 2011 and its amendments Regulation (EU) No. 321/2011, No. 1282/2011, No. 1183/2012, No. 202/2014, No. 865/2014 and No. 174/2015
- First, we wish to point out that the scope of the Commission Regulation (EU) No. 10/2011 on plastics materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14 January 2011 and its amendments Regulation (EU) No. 321/2011, No. 1282/2011, No. 1183/2012, No. 202/2014, No. 865/2014 and No. 174/2015 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.

**Pigments:**

- Also, it should be mentioned that the directive does not treat the pigments in the masterbatches, 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
- (b) 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.
- The pigments applied in MB PE Pink 28839 meet the purity requirements of EU Resolution AP (89) 1: "On the Use of Colourants in Plastic Materials Coming into Contact with Food".

Date of issue	16-03-17	Revision No.	001	Revised by	SB
Authorised by	S. Britton	Document No.	SD-001	Page 1 of 4	

### Dual Use Additives:

- MB PE Pink 28839 contains the following migrating “dual use” additive added by the manufacturer: Calcium stearate.
- One of the polymers used in MB PE Pink 28839 might contain the following migrating “dual use” additive: E 470a Calcium salts of fatty acids.

### Polymers:

- MB PE Pink 28839 is based on polymers produced from monomers that are all detailed in the positive list of the Commission Regulation (EU) No. 10/2011 on plastics materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14 January 2011 (this Regulation replaces Directive 2002/72/EC and its 6 amendments) and its amendments Regulation (EU) No. 321/2011, No. 1282/2011, No. 1183/2012, No. 202/2014, No. 865/2014 and No. 174/2015.
- One of the polymers used in MB PE Pink 28839 contains the following substances for which a Specific Migration Limit is established:
- Acrylic Acid (FCM Substance No 147; Ref. No 10690; CAS No 79-10-7) which has got a Specific Migration Limit (Total):  $SML(T) = 6 \text{ mg/kg}$  (expressed as acrylic acid).
- Zinc has got a Specific Migration Limit:  $SML = 25 \text{ mg/kg}$  (Commission Regulation (EU) No. 10/2011, Annex II).

### Additives:

- The additives contained in MB PE Pink 28839 are listed in the Commission Regulation (EU) No. 10/2011 on plastics materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14 January 2011 (this Regulation replaces Directive 2002/72/EC and its 6 amendments) and its amendments Regulation (EU) No. 321/2011, No. 1282/2011, No. 1183/2012, No. 202/2014, No. 865/2014 and No. 174/2015.
- One of the polymers used in MB PE Pink 28839 might contain the following additives for which a Specific Migration Limit is established:
- 9,9-bis(methoxymethyl)-9H-fluorene (PM Ref. No. 39815) which has got a Specific Migration Limit =  $0.05 \text{ mg/kg}$ .
- N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine (PM Ref. No. 39090) which has got a Specific Migration Limit (Total) =  $1.2 \text{ mg/kg}$  (expressed as tertiary amine).
- N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides (PM Ref. No. 39120) which has got a Specific Migration Limit (Total) =  $1.2 \text{ mg/kg}$  (expressed as tertiary amine excluding HCl).
- Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate (PM Ref. No. 68320) which has got a Specific Migration Limit =  $6 \text{ mg/kg}$ .

Date of issue	16-03-17	Revision No.	001	Revised by	SB
Authorised by	S. Britton	Document No.	SD-001	Page 2 of 4	

**Additive added by the manufacturer with Specific Limits:**

MD PE PINK 28839 contains:

- Approx. 0.012% 3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt (Ref. No. 46880) which has got Specific Migration Limit = 6 Mg/Kg
- Another aspect of the Commission's Regulation (EU) No. 10/2011 on plastics materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14 January 2011 and its amendments Regulation (EU) No. 321/2011, No. 1282/2011, No. 1183/2012, No. 202/2014, No. 865/2014 and No. 174/2015 is the specific and the overall migration
- The final food contact material or article coloured with MB PE Pink 28839 must until the December 31st 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.
- As from 1 January 2013 the supporting documents referred to in Article 16 for materials, articles and substances placed on the market until 31 December 2015, may be based on:
- Rules for migration testing set out in Article 18 of Regulation 10/2011; or the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC
- As from 1 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.
- According to the Commission Regulation (EU) No. 10/2011 on plastics materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14 January 2011 and its amendments Regulation (EU) No. 321/2011, No. 1282/2011, No. 1183/2012, No. 202/2014, No. 865/2014 and No. 174/2015 the finished plastic material and articles shall not release
- 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).
- 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 analyze for possible release of primary aromatic amines + the above mentioned metals and not with the masterbatch producer (masterbatch being a semi-finished product).
- Teknisk Agentur cannot guarantee whether or not a compound produced from MB PE Pink 28839 will be in conformity with the requirements as stipulated in the Commission Regulation (EU) No. 10/2011 on plastics materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14 January 2011 and its amendments

Date of issue	16-03-17	Revision No.	001	Revised by	SB
Authorised by	S. Britton	Document No.	SD-001	Page 3 of 4	

**Compliance with confidence**

- Regulation (EU) No. 321/2011, No. 1282/2011, No. 1183/2012, No. 202/2014, No. 865/2014 and No. 174/2015, because Teknisk Agentur would not know the further processing parameters.
- Teknisk Agentur has not determined whether a compound produced from MB PE Pink 28839 will be in conformity with the limits as described in the Commission Regulation (EU) No. 10/2011 on plastics materials and articles intended to come into contact with food published in the Official Journal of the European Union on 14 January 2011 and its amendments Regulation (EU) No. 321/2011, No. 1282/2011, No. 1183/2012, No. 202/2014, No. 865/2014 and No. 174/2015.

**Supplementary Information:**

- Since the masterbatch producer cannot be responsible for the subsequent use of his 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.

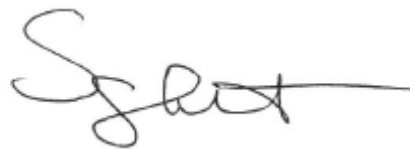
**RE: 2023/2006/EC**

- The manufacturer is certified according to the ISO 9001:2008 quality system, hence we find that
- we fulfil the requirements in EU directive 2023/2006 of 22th December 2006 on good
- manufacturing practice for materials and articles intended to come into contact with food.

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Date of issue	16-03-17	Revision No.	001	Revised by	SB
Authorised by	S. Britton	Document No.	SD-001	Page 4 of 4	