

Issued to AGRO RUBÍN a.s. Svijanský Újezd 55 463 45 Pěnčín

27/04/2017

# Statement on Compliance to Food contact regulations LIFOCOLOR-CR-MODRY 5011 F/PS-SB

At the time of issuing this declaration, we can confirm the compliance with the following Directives and Regulations as far as it regards the above mentioned product. All data refer only to the mentioned product, LIFOCOLOR FARBEN has no influence on the subsequent processing, therefore, this statement does not apply to the finished product:

### **Regulation (EC) No. 1935/2004**

**Articel 3** We declare that the composition of the above mentioned product complies with the relevant requirements of Article 3 of the above regulation, provided that the end-use restrictions are met under normal conditions of use. The organoleptic characteristics of food contact materials are influenced by converting conditions, time and temperature of storage and type of food, therefore compliance with article 3 must be verified and tested by the producer of the final packaging material.

**Articel 5** (specific measures for groups of materials and articles) and Annex I define different groups of materials for which specific measures may be adopted. This includes Plastics and Plastic Additives which are covered by Directive EC 10/2011 relating to plastic materials and articles intended to come into contact with foodstuffs.

**Articel 17** The traceability of the raw materials used in one production lot is ensured up to the raw material suppliers by the introduced quality assurance system at LIFOCOLOR FARBEN.

## Commission Regulation (EC) No. 2023/2006

The compliance with Regulation (EC) No. 2023/2006, as described in Article 4 *Conformity with good manufacturing practice*, requests the implementation of:

- Article 5 Quality assurance system,
- Article 6 Quality control system and
- Article 7 Documentation.

There are systems in place which control and document as required for Food Contact Good Manufacturing Practice.

#### European Resolution AP (89) I

The used colorants meet the requirements of Resolution AP (89) I of the Council of Europe "On the use of colourants in plastic materials coming into contact with food" (13.09.1989) with respect to the maximum permissible limits of heavy metal, primary aromatic amines, sulfonated amines, aromatic and polychlorinated biphenyls.

This confirmation expires after 12 months .



#### **BfR IX- Recommendation**

The colorants used in above mentioned masterbatch are recommended by the manufacturer for coloring plastic articles. The colorants meet the purity requirements laid down in the BfR Recommendation IX "Farbmittel zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände" (01.02.2015).

Please consider that according to the updated BfR IX Recommendation (purity requirements point 2) plastic materials shall not release primary aromatic amines in a detectable quantity into food or food simulants.

## Directive (EC) No. 2002/61 relating to restrictions on the marketing and use of certain dangerous substances and preparations (azo colorants)

For the preparation of its masterbatches LIFOCOLOR does not use any AZO-dyes, which are restricted according to EC-Directive 2002/61.

## Directive (EC) No. 10/2011 on plastic materials and articles intended to come into contact with food

The polymer carrier of the colour concentrate complies with the EC-Commission Directive 10/2011 and its amendments (1282/2011/EC, 321/2011/EC, 1183/2012/EC, 202/2014/EC, 174/2015/EC and 1416/2016/EC). The polymer carrier also meets the German Bedarfsgegenständeverordnung (23.12.97 and last amendment 24.06.13).

The masterbatch contains intentionally following monomers/additives, which are restricted according Annex I by a specific migration limit (SML) or a maximal concentration in the end article (QM):

- SML = 18 mg/kg (PM.-Ref. 92560)
- SML = 9 mg/kg (PM.-Ref. 94400)

The masterbatch contains intentionally following substances authorised as direct food additives according to Regulation (EC) No. 1333/2008 or Regulation (EC) No. 1334/2008 ("Dual-Use-Additves"), which could migrate into the foodstuff:

• Calciumstearat (E470a)

Intentionally follwing chemical elements are present in above mentioned masterbatch for which a specific migration limit is set according to Annex II of Directive (EC) No. 10/2011:

• SML = 5 mg/kg (Zinc)

According to the Amendment 2016/1416/EC the reduced SML-limit for Zinc shall apply from 14.09.2018.

Please consider that according to Annex II plastic materials shall not release primary aromatic amines, excluding those appearing in Table 1 (Annex I), in a detectable quantity into food or food simulants. The detection limit is 0.01 mg/kg.

Compliance with overall (OML) and specific migration limits (SML) apply to the final article intended to come in contact with food, which shall be measured from the finished food contact article by using real food or appropriate food simulants.

This confirmation expires after 12 months .



### Directive (EC) No. 2002/16 and (EC) No. 1895/2005

Herewith we confirm that according to its formulation, the above mentioned masterbatch does not intentionally contain epoxy derivates, which are restricted according to (EC) No. 2002/16 and (EC) No. 1895/2005.

#### Directive (EC) No. 94/62 on packaging and packaging waste

We confirm that the mentioned masterbatch does not contain intentionally pigments based on cadmium, lead, mercury or Chrom(VI). The sum of cadmium, lead, mercury and chromium (VI) does not exceed the maximum value of 100 ppm (0.01 %). Thus, the Directive (EC) No. 94/62 (20.12.94) as last amended by Regulation (EC) No. 2/2013 and as well the CONEG (USA) requirements (01.01.1994) are met.

The data above represent the current state of knowledge of our information. During the processing of the product attention should be paid to proper process conditions and compliance with the recommended processing conditions.

In addition, no warranty is connected with this declaration that the product is suitable for a particular purpose. It is the responsibility of both the manufacturers of finished food contact articles as well as the industrial food packer to make sure that these articles in their actual use meet both the technical and regulatory requirements of the intended application.

LIFOCOLOR FARBEN GmbH & Co. KG

Dething Steffman

i. A. Dr. Bettina Hoffmann

Product Safety