

## **Bayferrox<sup>®</sup> and COLORTHERM<sup>®</sup> pigments for coloring food packaging and other articles for food-contact applications**

Edition: 2012-04-27  
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### **General**

Plastics which are used to make articles which come into brief contact with foods or packaging materials which have long-term contact with foods must satisfy a series of requirements relating to health hazards arising from any contamination of the food by constituents of the plastic.

As there is no European Directive covering colorants for articles used in food-contact applications, national regulations have to be applied. It is unlikely that a European Directive will come into force for some years yet. The basis for such a Directive may be Council of Europe Resolution AP (89) 1. This largely concerns the ban on the visual migration of colorants, which is of significance for organic pigments and dyes, and the soluble content of certain heavy metals and aromatic amines in the pigments used.

### **Regulations governing colorants**

In various European countries, the use of inorganic pigments is governed by threshold values for their soluble content of certain elements. In Japan, absolute values are specified.

Colorants which satisfy these requirements may be used to color plastics for food-contact applications. In France, Japan and the USA, it must also be borne in mind that the chemical substance forming the basis of the colorant must be included in a positive list or must be proven not to migrate into foods. The legislation and regulations valid in the individual countries are summarized in Table 1.

Table 2 summarizes the inorganic pigments of the LANXESS product lines complying with the legal requirements in the countries specified.

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### **Table 1: National regulations on the purity requirements for pigments used to color products for food-contact applications**

#### **Australia**

Australian Standard 2070.6 (1984)

#### **European Union (Council of Europe)**

Resolution AP (89)1 on the use of colorants in plastic materials coming into contact with food.

#### **Germany**

Recommendation IX (colorants for coloring of plastics and articles of daily use) of the Federal Institute for Risk Assessment (BfR) dated 2010-01-01.

#### **Belgium**

Koninklijk Besluit dated 11.5.1992; Warenwetgeving (1), aanvulling nr. 18 - September 1992

#### **France**

Circulaire 176 dated 2.12.1959, published in the Journal Officiel of 30.12.1959 incl. amendments. The colorants must not only comply with the purity requirements of the Resolution AP (89) 1, but also be included in the positive list.

#### **Netherlands**

Warenwet/Regeling Verpakkingen - en gebruiksartikelenbesluit; Uitvoeringsvoorschriften CIII-55, entered into force on 21.8.1991.

As well as defining the content of soluble heavy metals in pigments, this regulation specifies maximum permissible migration values for the pigmented articles.

#### **United Kingdom**

Plastics for food contact applications, a code of practice for safety in use: BPF in connection with BIBRA, revised edition 1986.

Like BfR Recommendation IX, this code is not a legal norm. However, it is considered as state of the technology.

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### Table 1: continuation

#### Italy

Decreto Ministeriale dated 21.3.1973, published in Gazzetta Ufficiale No. 104 of 20.4.1973; last amendment in Decreto Ministeriale No. 338 of 22.7.98.

#### Spain

Resolucion dated 4.11.1982 (BOE 282 of 24.11.1982) in accordance with Article 5 of Royal Decree 211/1992 of March 5, 1992. All colorants are permitted which conform with the migration values defined in Appendix III of the Resolucion. Pigments used in foodcontact applications must be notified to the Health Ministry. All Bayferrox pigments which satisfy BfR Recommendation IX can be used in Spain.

#### USA

The use of pigments for coloring plastics for food-contact applications is regulated by the Code of Federal Regulations 21 (CFR 21). For this application iron oxide and chrome oxide – besides other approved substances - are listed in FDA ("Food and Drug Administration") § 178.3297 (Colorants for Polymers). In some cases limitations of use have to be met.

#### Japan

Since 1977, Japan has maintained a positive list for colorants which can be used in plastics for food-contact applications. It is issued by the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA) and, strictly speaking therefore, is not a legal requirement.

A further prerequisite for the use of colorants is that they contain no more than 100 ppm lead, 50 ppm arsenic, 50 ppm mercury and 100 ppm cadmium. These requirements are satisfied with few exceptions by our inorganic color pigments (see Table 2).

#### Brazil

In 2010 the National Agency of Sanitary Surveillance has published Resolution – RDC no. 52 von 26. November 2010 for the regulation on colorants in plastic packages and equipment destined to be in contact with food.

Amongst others specific migration limits are defined for some metals which most of our products do comply with.

# Inorganic Pigments

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**Table 2: Coloring food packaging and other articles for food-contact applications with inorganic color pigments of LANXESS**

| Bayferrox   | EC AP (89)1 | Germany | Belgium | United Kingdom | France | Nether-lands | Italy | Spain | Australia | Brazil | Japan                         | USA             |
|---|-------------|---------|---------|----------------|--------|--------------|-------|-------|-----------|--------|-------------------------------|-----------------|
| 110 – 180,<br>130 B, 130 BM<br>105 M – 180 M<br>120 N, 120 NM, 180 NM | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | X                             | X <sup>1)</sup> |
| 306 – 318,<br>318 M, 318 MB, 360                                      | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | X                             | X <sup>1)</sup> |
| 303 T   | X           | X       | V       | V              | -      | V            | V     | V     | V         | X      | X                             | X <sup>2)</sup> |
| 415, 420, 1420, 1420 M, 3420,   | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | X<br>ohne<br>415 und<br>1420M | X <sup>1)</sup> |
| 600 – 686,<br>excl. 645 T   | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | X                             | X <sup>1)</sup> |
| 645 T   | X           | X       | V       | V              | -      | V            | V     | V     | V         | X      | X                             | X <sup>2)</sup> |
| 910 – 943<br>3905 – 3920  | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | X                             | X <sup>1)</sup> |
| 960   | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | X                             | X <sup>1)</sup> |

**General remark:**

**Regulatory Compliance Information:** Some of the end uses of the products described in this publication must comply with applicable regulations, such as the FDA, BfR, NSF, USDA, and CPSC. If you have any questions on the regulatory status of these products, contact your LANXESS Corporation representative, the LANXESS Regulatory Affairs Manager in Pittsburgh, PA or the Health, Safety, Environment and Quality Department (HSEQ) of LANXESS Deutschland GmbH in Germany.

**Health and Safety Information:** Appropriate literature has been assembled which provides information concerning the health and safety precautions that must be observed when handling the LANXESS products mentioned in this publication. For materials mentioned which are not LANXESS products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be followed. Before working with any of these products, you must read and become familiar with the available information on their hazards, proper use and handling. This cannot be overemphasized. Information is available in several forms, e.g., material safety data sheets, product information and product labels. Consult your LANXESS representative in Germany or contact the Health, Safety, Environment and Quality Department (HSEQ) of LANXESS Germany or - for business in the USA - the LANXESS Product Safety and Regulatory Affairs Department in Pittsburgh, PA.

As the food contact regulation of each country may differ, it is the responsibility of the manufacturer of the finished articles to ensure compliance with the respective country's regulation (migration resp. extraction limits, e.g.).

|                                |  |
|--------------------------------|--|
| x approved without restriction | x <sup>1)</sup> According to § 178.3297  |
| V under verification           | x <sup>2)</sup> according to an external opinion letter for use in all polymers at a maximum level of 2%, subject to this limitation and any other applicable FDA regulations.   |
|                                | x <sup>3)</sup> For plastics with food contact application up to a concentration of 5% with the following exceptions:<br>- olefin polymers according to § 177.1520<br>- rubber articles for multiple use according to § 177.2600, concentration not more than 10 % |

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**Table 2: continuation**

| COLORTHERM            | EC AP (89)1 | Germany | Belgium | United Kingdom | France | Nether-lands | Italy | Spain | Australia | Brazil | Japan | USA             |
|-----------------------|-------------|---------|---------|----------------|--------|--------------|-------|-------|-----------|--------|-------|-----------------|
| Red 110 M – Red 180 M | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | X     | X <sup>1)</sup> |
| Red 520               | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | -     | X <sup>1)</sup> |
| Black 318             | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | -     | X <sup>1)</sup> |
| Black 303 T           | X           | X       | V       | V              | -      | V            | V     | V     | V         | X      | X     | X <sup>2)</sup> |
| Brown 645 T           | X           | X       | V       | V              | -      | V            | V     | V     | V         | X      | X     | X <sup>2)</sup> |
| Yellow 10             | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | -     | X <sup>1)</sup> |
| Yellow 20             | X           | X       | X       | X              | X      | X            | X     | X     | V         | X      | V     | X <sup>2)</sup> |
| Yellow 30             | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | X     | X <sup>2)</sup> |
| Yellow 3950           | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | X     | X <sup>2)</sup> |
| COLORTHERM Green      | EC AP (89)1 | Germany | Belgium | United Kingdom | France | Nether-lands | Italy | Spain | Australia | Brazil | Japan | USA             |
| all grades            | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | X     | X <sup>3)</sup> |

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| Z-grades              | EC AP (89)1 | Germany | Belgium | United Kingdom | France | Nether-lands | Italy | Spain | Australia | Brazil | Japan | USA             |
|-----------------------|-------------|---------|---------|----------------|--------|--------------|-------|-------|-----------|--------|-------|-----------------|
| Bayferrox 512 Z       | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | -     | X <sup>1)</sup> |
| Bayferrox 360 Z       | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | -     | X <sup>1)</sup> |
| Bayferrox 920 Z       | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | -     | X <sup>1)</sup> |
| COLORTHERM Green GN-Z | X           | X       | X       | X              | X      | X            | X     | X     | X         | X      | -     | X <sup>1)</sup> |

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