



**Makrolon® WB 1239 550360**

**General**

Makrolon® WB 1239 550360 may be used for the manufacture of articles intended for food contact as outlined below. Makrolon® WB 1239 550360 belongs to the group of polycarbonate plastics.

**Europe**

**Regulation (EC) 1935/2004**

This statement has the purpose of a declaration of compliance as required by Regulation (EC) 1935/2004.

Makrolon® WB 1239 550360 is manufactured applying rules on Good Manufacturing Practice (GMP) which are considered appropriate for plastic raw materials as required by Regulation (EC) 1935/2004 and (EC) 2023/2006. This includes the use of procedures to cover traceability from the incoming starting materials to the outgoing food contact material.

**Commission Regulation (EU) 10/2011**

Makrolon® WB 1239 550360 is manufactured only with monomers and additives that are authorized under the 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. All monomers and additives used for the manufacture of Makrolon® WB 1239 550360 are listed in Annex I of the Commission Regulation (EU) No. 10/2011 and its amendments.

**Specific limits**

The table below provides information on certain restrictions which must be observed according to Commission Regulation (EU) No. 10/2011:

CAS number	Name	Restrictions (QM=max. permitted quantity of residual in plastic ; SML=specific migration limit in food or simulant)
000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	SML = 0.6 mg/kg, not to be used for the manufacture of polycarbonate infant feeding bottles
000075-44-5	Carbonyl chloride	QM = 1 mg/kg in final product
000108-95-2	Phenol	SML = 3 mg/kg
000098-54-4	4-tert-Butylphenol	SML = 0.05 mg/kg
027955-94-8	1,1,1-Tris(4-hydroxyphenyl)ethane	SML = 0.005 mg/kg
007440-50-8	Copper	SML = 5 mg/kg

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This information and our technical advice - whether verbal, in writing or by ways of trial - are given in good faith but without warranty, and this also applies where proprietary rights of third parties are involved.

The information is provided by Covestro Deutschland AG without assumption of any liability. If any of the above mentioned regulations change after the date of declaration, this declaration is no longer valid. Covestro Deutschland AG will strive to keep this information up-to-date.

Our advice does not release you from the obligation to verify the information provided – especially that contained in our safety data and technical information sheets –, to check for updates of any information provided by us and to test our products as to their suitability for the intended processes and uses. The application, use and processing of our products and the products manufactured by you on the basis of our technical advice are beyond our control and, therefore, entirely your own responsibility.

Our products are sold in accordance with the current version of our General Conditions of Sale and Delivery.  
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**Assessment:**

The above mentioned limits have been met in exemplary investigations by virgin material representative of the composition of Makrolon® WB 1239 550360. The material was tested with food simulants B and D1 (see Annex III of the Commission Regulation (EU) No. 10/2011) for 2 h at 100°C (or at boiling point) followed by 10 days at 40°C and evaluated for a surface/volume ratio of 6:1.

It is the responsibility of the user of our products, who manufactures materials or articles intended for food contact or brings them into contact with food, to assure their compliance with limits and other provisions set by the applicable regulations.

**Germany**

**BfR Recommendations on Food Contact Materials**

(Bundesinstitut für Risikobewertung/Federal Institute for Risk Assessment)

The colorants used comply with the requirements of Recommendation IX "Colorants for plastics and other polymers used in commodities", issued by the Federal Institute for Risk Assessment (BfR), status: 2010-01-01.

**Consumer Goods Ordinance**

(Bedarfsgegenständeverordnung)

With respect to its monomer and additive composition, Makrolon® WB 1239 550360 complies with the requirements of the German Consumer Goods Ordinance (up to the 20th amendment, published in Bundesgesetzblatt 2011 part I no. 6, 2011-02-07).

**France**

From 1st January 2015, Makrolon® WB 1239 550360 is not permitted for any food contact applications in France.

**Belgium**

Makrolon® WB 1239 550360 is not permitted for food contact articles intended for children up to the age of 3 years according to the law of 24th January 1977 on the protection of consumer health regarding food contact articles as amended in September 2012.



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**Denmark**

Makrolon® WB 1239 550360 is not permitted for food contact articles intended for children up to the age of 3 years according to Decree on infant formula and formulas for infants and toddlers (No. 1504 of December 13, 2007) and Decree on processed baby foods for infants and toddlers (No. 355 of June 17, 1998) as amended in July 2010.

**USA**

Makrolon® WB 1239 550360 may be used in compliance with FDA regulation 21 CFR § 177.1580 (Polycarbonate resins) in single and repeated-use applications intended to contact FDA food type VI – B (non-alcoholic beverages) under conditions of use B through G, as described in 21 CFR § 175.300 Tables 1 and 2. The use of Makrolon® WB 1239 550360 is subject to the limitations of § 177.1580 and any other applicable regulation.

**China**

The use of products containing 2,2-Bis (4-hydroxyphenyl)propane (Bisphenol A or "BPA") is restricted for infant feeding bottles according to Announcement 2011/15 of the Ministry of Health.

One of the colorants used for Makrolon® WB 1239 550360 is not yet authorized for polycarbonates by the Chinese standard GB 9685-2008 ("Hygienic standards for uses of additives in food containers and packaging materials") and its amendments (status: May 2013). However from a global scientific point of view, there should not be any doubt that the colorant is suitable for said application, as it complies with most relevant regulations in the international context (Council of Europe Resolution AP(89), BfR Recommendation IX, French Positive List (Circulaire 176), FDA Regulation 21 CFR § 170.3(e)(1), JHOSPA Positive List 2-32 Dyestuffs (04.2009)). An application for approval of the colorant is under preparation which will re-establish the authorization of the product for food contact use.

**BSE Statement (Bovine Spongiform Encephalitis)**

All chemicals used for the production of Makrolon® WB 1239 550360 are of petrochemical / synthetic origin.

Therefore we are convinced that there is no risk of contamination with BSE/TSE germs.



Statement on Food Contact Use

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### **Comment**

The entire confirmation only applies to the granules as supplied by Covestro Deutschland AG.

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