

REGULATORY STATEMENT

Product name: Kritilen® BLUE 41834

Product description: Blue masterbatch in pellet form.

1. Regulation (E.C) No. 1935/2004

Regulation No 1935/2004/EC of the European Parliament and of the Council of 27 October 2004, is a framework Regulation setting general rules and requirements for all materials and articles intended to come in contact with food.

According to Article 3: Materials and articles, including active and intelligent materials, shall be manufactured in compliance with good manufacturing practice so that, under foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- a) Endanger human health or
- b) Bring out an unacceptable change in the composition of food or
- c) Bring out deterioration in the organoleptic characteristics of the final product.

For plastic articles & materials, these requirements are laid down and further specified in Regulation No. 10/2011 published on 14 January 2011 and its amendments.

According to the information received from our suppliers, the ingredients in the formulation of KRITILEN BLUE 41834 fulfill the following:

Polymer: KRITILEN BLUE 41834 is based on a polymer produced from monomers included in the UNION LIST of authorized monomers (Section I, Annex 1) of the "EC Commission Regulation 10/2011 relating to Plastic Materials and Articles intended to come in contact with food" and amendment.

Additives: All additives present in the formulation of KRITILEN BLUE 41834 are included in the Union List of authorized monomers and additives of EC 10/2011 .

Pigments/colorants: According to our supplier's information, pigments in the formulation of BLUE 41834 comply with the following:

- a) Resolution AP (89) 1
- b) BfR Recommendation IX (2015)

Migration

Specific Migration Limits (SML): Substances subject to SML restrictions

Ingredient	Ref No	SML (mg/kg) of food or food simulant
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	68320	6

Overall Migration Limits (OML): Since the above mentioned product –KRITILEN BLUE 41834- is only a small part of the final product, our responsibility as masterbatch producer cannot be extended to include the articles in which our client uses our products. Since the overall migration depends on the type of material used or on the present of other components as well as the processing conditions food type etc., migration tests have to be carried out in the final material or article using the right food simulants under foreseeable conditions of use in order to establish the regulatory compliance of the end product.

KRITILEN BLUE 41834 contains calcium carbonate –a substance that when used as direct food additive has the following number E 170. According to our supplier's information the filler is in conformity with the requirements of: Regulation (EU) 10/2011 and amendments.

Dual Use Additives: CaCO₃ as chemical species is authorized as food colorants with E numbers 170. Plastic products colored with BLUE 41834 should not be in contact with acidic media (PH<4.5) in order not to exceed the OML of 60 mg/kg of food or food simulant.

2. Regulation (E.C) No. 2023/2006

PLASTIKA KRITIS SA complies with the provisions of 2023/2006 regulation regarding good manufacturing practice in so far as: the production of the above product is carried out in unit with the necessary quality control system which enables traceability through all stages of production.

3. Regulation (E.C) No. 1907/2006

According to our supplier's information, KRITILEN BLUE 41834 does not contain any of the substances listed on the last updated ECHA candidate list (1907/2006, Annex XIV last update 16/07/2019) of SVHC in a concentration above 0.1% w/w.

4. CONEG and Directive 94/62/EC and amendments

According to our supplier's information, KRITILEN BLUE 41834 fulfills the requirements set in both regulations.

5. Directive 2011/65/EC (RoHS)

According to our supplier's information, KRITILEN BLUE 41834 fulfills the requirements set in the above mentioned directive.

Date: 27/11/2019

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