

## REGULATORY STATEMENT

**Product name:** Kritilen® Black 440P

**Product description:** Black 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 BLACK 440P fulfill the following:

**Polymer:** KRITILEN BLACK 440P 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 amendments.

**Additives:** All additives present in the formulation of KRITILEN BLACK 440P are included in the Union List of authorized monomers and additives of EC 10/2011 and amendments.

**Carbon Black** : According to our supplier's information, carbon black present in the formulation of KRITILEN BLACK 440P fulfils the following:

- Commission Regulation (EU )10/2011 and amendments – **up to 6%** addition of BLACK 440P in the final article.
- BfR Recommendation IX- Colorants for the coloration of plastics and other polymers for materials and articles.
- Resolution AP (89) 1

Carbon black present in BLACK 440P does not fulfil FDA requirements (part 178.3297)

## 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 BLACK 440P- 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.

**Dual Use Additives:** No dual use additives are present.

## 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 BLACK 44OP 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 BLACK 44OP fulfills the requirements set in both regulations.

### **5. Directive 2011/65/EC (RoHS) and amendments**

According to our supplier's information, KRITILEN BLACK 44OP fulfills the requirements set in the above mentioned directive.

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