

## REGULATORY STATEMENT

**Product name:** Kritilen® White 170

**Product description:** White 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 WHITE 170 fulfill the following:

**Polymer:** KRITILEN WHITE 170 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 WHITE 170 are included in the Union List of authorized monomers and additives of EC 10/2011 and amendments.

**Pigments/colorants:** According to our supplier's information, TiO<sub>2</sub> and all of its surface treatment components are listed in the Union list of authorized substances of EC 10/2011 and amendments.

## 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
Aluminium		1

**Overall Migration Limits (OML):** Since the above mentioned product –KRITILEN WHITE 170- 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:** TiO<sub>2</sub> as a chemical species is listed in Annex II as an authorized food colorant in Regulation EC1333/2008 and amendments with E number 171. According to our supplier's information, there is no reason for TiO<sub>2</sub> when included in a plastic layer to migrate into food because it is a highly insoluble substance. The grade of TiO<sub>2</sub> used in the formulation of WHITE 170 does not fulfill the purity criteria E171 used to color foodstuffs.

## 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 WHITE 170 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 WHITE 170 fulfills the requirements set in both regulations.

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

According to our supplier's information, KRITILEN WHITE 170 fulfills the requirements set in the above mentioned directive.

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