

## PLA PROCESS AID 04533

### Food contact compliance in European Union

We give you the position of the components of this product with reference to requirements on products, as articles or components of articles, intended for use in contact with food.

#### European Union

Components of this product meet requirements of the following regulations:

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food.

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:

Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 and Commission Regulation (EU) No 1282/2011 of 28 November 2011;

Commission Regulation (EU) No 1183/2012 of 30 November 2012; Commission Regulation (EU) No 202/2014 of 3 March 2014; Commission Regulation (EU) No 865/2014 of 8 August 2014; Commission Regulation (EU) 2015/174 of 5 February 2015.

Conformity to Regulation (EC) No 1935/2004 is given not directly to our products but on the Viba Quality Management System which in compliance with UNI EN ISO 9001 and follows requirements of Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

Viba Quality Management System ensures traceability one step up and one step down of its activities and for all its products.

The conformity is given on the basis that all the ingredients contained in the product are listed in the annexes of the above mentioned EC Directives and/or Regulations on plastics in contact with food.

**Limit in dosage:** None

#### Overall Migration

Please note that according to the rules of Directive 82/711/EEC, its amendment 93/8/EEC and according to the provisions of the Regulation (EC) No. 1935/2004 and Commission Regulation (EU) No 10/2011, the overall migration limit has to be controlled on the finished articles intended to come into contact with foodstuffs.

The overall migration has to be tested on the final materials and articles because it could depend on the type of material used or on different components, as well as on the processing conditions.

So, in addition to the above compositional compliance status certification, appropriate overall migration tests on the final material or article has to be carried on in order to determine the regulatory suitability for contact with different food types and various end-use conditions.

#### Substance restricted by SML and/or Dual use

This product contains the following substances:

| <u>EC ref.n.</u> | <u>Dual use</u> | <u>Substance / SML / comments</u>  |
|------------------|-----------------|--|
| 18430            | No              | Hexafluoropropylene<br>SML = ND (DL = 0,01 mg/kg)<br>Data not available, carry out specific migration (SML) test |
| 26140            | No              | Vinylidene fluoride<br>SML = 5 mg/kg<br>Data not available, carry out specific migration (SML) test              |

Specific migration limit applicable to the substances identified by EC ref. n. 18430 and 26140, are met in the finished article when the product is used at a level of limits in dosage indicated in this declaration.

The data related to the max content of a substance with SML come from the ones given by our raw material suppliers. They can be used as an indication to determine which tests should be performed and which tests can be replaced by calculations.

This product does not contains dual use additives (substances regulated for Food contact application by Regulation (UE) No 10/2011 and for Food application by Regulations (EC) No 1333/2008 and (EC) No 1334/2008) with specific migration limit.

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### Food contact compliance in European Union Member States

The status of the components of the product with reference to the single Member States is identically the same of the one reported in the European Union section.

On this purpose please take into consideration the limits and restriction reported in EU section.

### Food contact compliance in Switzerland

#### Switzerland

The current status of food approval of the product is unknown due to a lack of information of the raw materials used and/or due to the fact that some ingredients are still under evaluation by the competent Authorities. Therefore at the moment we can only ask you to consider this product as not food approved.

### Food contact compliance in United States of America

We give you the position of the components of this product with reference to requirements on products, as articles or components of articles, intended for use in contact with food.

#### United States of America

Components of this product meet requirements of the following regulations:

Food and Drug Administration/FDA, 21 CFR § 177: Indirect food additives: Polymers. Food and Drug Administration/FDA, 21 CFR § 178: Indirect food additives: Adjuvants, production aids, and sanitizers.

**Limit in dosage:** Max. 13.33%

### Food contact compliance in Australia

#### Australia

The current status of food approval of the product is unknown due to a lack of information of the raw materials used and/or due to the fact that some ingredients are still under evaluation by the competent Authorities. Therefore at the moment we can only ask you to consider this product as not food approved.

### Food contact compliance in Japan

#### Japan

The current status of food approval of the product is unknown due to a lack of information of the raw materials used and/or due to the fact that some ingredients are still under evaluation by the competent Authorities. Therefore at the moment we can only ask you to consider this product as not food approved.

We wish to point out that the final food-contact material or article, made from or containing this product as a component, needs to comply with overall migration testing limit requirements, when tested on the food contact surface. This aspect of the final materials and articles should be checked by the converter/user of the product, because it could depend on the type of material used or on different components, as well as on processing conditions.

Our declaration is only regarded to above mentioned product, supplied in original packaging, and not cover any subsequent modification of the composition of the product whatever that modification may be.

Viba is not able to give a confirmation that above product fulfils requirements for food contact for any other Country not cited in this declaration.

This declaration replaces all previous ones relating to this subject.



# Position under Food Regulation

Release 3.3a

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**PLA PROCESS AID 04533**

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The information contained in this document are the current state of our knowledge.

We believe that they are correct, but they are not as absolute guarantees of the product. In view of the many factors which may influence the process and the application of our product, the final user has the responsibility of making all the assessments and the necessary checks to the specific final use for which the product is intended.