

DECLARATION OF CONFORMITY FOOD REGULATIONS

Trifilon AB applicable product(s): BioLite240

European Food Law

With regard to the compliance status of the Trifilon product referenced above with the regulation(s) identified below the following can be declared:

EU Food-Contact Regulation

The monomer(s) and the additive(s) intentionally used in the above compound grade are listed in Annex 1 or are authorized in accordance with the requirements of Commission Regulation (EU) No 10/2011 of 14 January 2011, as amended up to Regulation (EU) No 2019/1338, on plastic materials and articles intended to come into contact with food.

The above compound grade complies with the relevant requirements of Regulation (EC) No 1935/2004 in as far as:

- the grade is produced using Good Manufacturing Practice as required in article 3.1 of Regulation (EC) No 1935/2004 and meets the guidelines for Good Manufacturing Practice as specified in Regulation (EC) No 2023/2006 (on good manufacturing practice for materials and articles intended to come in contact with food).
- with respect to Regulation (EC) No 282/2008, no external sources of recycled plastic materials are used for products manufactured according to good manufacturing practice, as laid down in Regulation (EC) No 2023/2006. Regulation (EC) No 282/2008 shall not apply to recycled plastic materials and articles made from unused plastic production offcuts and/or process scraps in compliance with Regulation (EU) No 10/2011 that are recycled within the manufacturing site.
- the production of the above grade ensures traceability as required in article 17.1 of Regulation (EC) No 1935/2004.
- the compound production aids and aids to polymerization are either permitted in one or more EU Member State(s) and/or have been risk assessed based on the following assumptions: 100% migration, 1kg/food packed with 6dm² of packaging, article thickness of 250 microns.

Monomer restrictions

None of the monomers used in the production of this compound is subject to a Specific Migration Limit (SML).

Presence of additives with SML's

The above compound grade does contain one or more additive(s) that is/are subject to a Specific Migration Limit (SML).

Additives:

- Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate EC Ref. No: 68320, Max. concentration*: 1500 ppm, Restriction*: SML = 6mg/kg food - Lipophilic substance
- Calcium Stearate EC Ref. No: Salt of 89040, Max. concentration*: 1000 ppm, Restriction*: Dual use additive
- Polyethylene glycol sorbitan monostearate EC Ref. No: 79280, Max. concentration*: 60 ppm, Restriction*: Dual use additive

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- Maleic anhydride EC Ref No: 19960, Restriction*: SML = 30mg/kg food
- 9,9-bis(methoxymethyl)fluorene EC Ref No: 39815, Restriction*: SML = 5mg/kg food
- Aluminium EC Ref No: NA, Restriction*: SML = 1mg/kg food

* This information is provided for general guidance purposes only and Trifilon provides no guarantees or warranties in respect of this information and has no responsibility or liability for any use by any third party of this information.

Note on Overall Migration Limit ("OML") and on Specific Migration Limits ("SML's"), where applicable:

In all EU countries, finished plastics food-contact materials or articles, made from or containing this product, need to comply with Overall Migration Limit ("OML") requirements and Specific Migration Limits ("SML"), where applicable - as specified in EU Regulation 10/2011- when tested on the food-contact surface with the appropriate food simulants and time/temperature test conditions. This is the responsibility of the user of this compound product.

In addition to the above compositional compliance status certification, the compound user is required to carry out the appropriate overall migration ("OML") and specific migration ("SML") tests on the final material or article to determine the regulatory suitability for contact with different food-types (aqueous, fat/oil, alcoholic, etc.) and various end-use conditions (material or article thickness, pure or in blends, volume, contact time of packaging, temperature of use, etc.), all of which are beyond control of Trifilon.

General Note

The manufacturer of food-contact materials and articles - made from or containing this compound grade - must ensure that the finished materials or articles meet the general regulatory requirements that they do not bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof and do not release constituents in foodstuffs in quantities that can endanger human health.

In addition, the finished food-contact material or article must be technically suitable for the intended use.

This declaration of conformity is issued under the sole responsibility of Trifilon AB. The technical documentation for the described products is available at the address listed above.

Signed for and behalf of Trifilon AB:
Date & Place: 2020-07-10, Nyköping



Johan Thiel, CEO Trifilon

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