

STATEMENT OF COMPLIANCE WITH FOOD CONTACT REGULATIONS

Product Reference: MODIC P553E
Type of product: intermediate plastic material
Polymer Type (main component): modified polypropylene
Product form: plastic pellets

We confirm that the composition of this product and all ingredients used to produce the compound mentioned above complies with the following Regulations, Legislations, Recommendations or Communications for the production of food packaging and other food contact applications as described in this declaration:

- Regulation (EC) 1935/2004 of the 27th October 2004¹
- Regulation (EC) 2023/2006 of the 21th of December 2006 as currently amended
- Regulation (EU) No 10/2011 dated from the 14th January 2011, up to its amendment of the 8th of August 2019 (No 2019/1338), as further described below
- BfR, Bundesinstitut für Risikobewertung of Germany
- Commodity Act Packaging and Food Utensils Regulation of The Netherlands and its amendments up to and including 1028394-156011-VGP of the 26th October 2016
- FDA 21 CFR of the USA of 1st April 2016, as further described below

¹applicable articles 3.1, 11.5, 15 and 17.

Dual use Additives:

This product contains no Dual Use Additive (DUA).

Compounds with a specific migration limit:

Compound	FCM	CAS number	Limit [mg/kg]
N,N-bis(2-hydroxyethyl)alkyl(C ₈ -C ₁₈)amine	19	Group restriction 7	SML(T) = 1.2 Expressed as tertiary amine
Maleic anhydride	234	108-31-6	SML(T) = 30 Expressed as maleic anhydride
Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	433	2082-79-3	SML = 6
9,9-bis(methoxymethyl)-9H-fluorene	779	182121-12-6	SML = 0.05
Aluminium	-	7429-90-5	SML = 1

SML : Specific Migration Limit [mg/kg]

ND : Non Detectable

Compliance verification EU:

It is the responsibility of the converter or packer to verify for the finished product the overall and the specific migrations required by Regulation (EU) 10/2011, as well as the sensory performance.

MODIC P553E can be considered to be suitable for contact with foodstuff and no limit can be exceeded, even if the film has a thickness of 100 µm.

The overall migration should not exceed the Overall Migration Limit (OML) of 10 mg/dm² (60 mg/kg of simulant). For each substance subject to specific migration (see table above), the migration of the substance should not exceed its limit (SML). For further details about migration testing, please refer to the current version of the regulation (EU) No 10/2011.

In accordance with Article 19 of the Regulation (EU) 10/2011, the NIAS (Non Intentionally Added Substances) have been risk assessed and comply with the requirements in article 3 of the Framework Regulation (EC) 1935/2004.

Commodity Act Packaging and Food Utensils Regulation of the Netherlands:

Compound	CAS number	Limit [mg/kg]
Dicumylperoxide	80-43-3	SML(T) = 0.05

FDA related information:

MCPP manufactures a compound containing a mixture of raw materials rather than an article. Therefore, MCPP requested information from suppliers providing raw materials contained in MODIC P553E.

The information provided in this statement addresses the compositional requirements of 21 CFR §175.105 “Adhesives” or related subparts.

MODIC P553E is composed of components which are permitted for use in 21 CFR §175.105 “Adhesives”.

Please note that it is the responsibility of the finished article manufacturer to establish that a functional barrier is present between the MODIC and the packaged food in accordance with Section §175.105.

This statement of Compliance is established on the base of our existing knowledge. It replaces all previous compliance statements relating to the subject. This statement is valid until further revision. This information is valid for the material as it leaves the MCPP production facility and does not include any additives, pigments etc. subsequently used or added by the buyer or a third party.

Signature:



Regulatory Affairs Manager Europe

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