

STATEMENT ON FOOD CONTACT COMPLIANCE AND SAFETY EVALUATION



Summary

Materials in contact with food are subject to European Framework Regulation (EC) 1935/2004. Among other requirements, this Regulation states, in Article 3, that materials in contact with food should not release substances that could be harmful to human health. In order proof that Sustonable products comply with this regulation, migration tests were performed at an external laboratory with different simulants on Sustonable Magnolia white which yielded results below the overall migration limit of 10 mg/dm².

Detailed description

Sustonable product contains post-consumer recycled PET (rPET), which, under Framework Regulation (EC) 1935/2004, would be subject to an authorization of the recycling process under Regulation (EC) 282/2008. The rPET used in our product does not originate from a recycling process that has been authorized in accordance with Regulation (EC) 282/2008. As the contact of our product with food is incidental and short-term, Sustonable has instead performed a risk-based evaluation to assess the safety of our materials under Article 3 of Regulation (EC) 1935/2004.

As the rPET used is plastic, we have evaluated the substances that could potentially be present in this plastic, which have a restriction under Regulation (EU) 10/2011 on plastic food contact materials. Per Annex IV of this Regulation, they are communicated here, with their specific migration limit (SML):

Substance	SML (mg	/Kg food)	Substance	SML (mg/Kg food)
Terephthalic acid (FCM 785)		7.5 (T)	Antimony (Annex II)	
Isophthalic acid (FCM 291) 5 (T)		5 (T)	Cobalt (Annex II	0.05
Ethyleneglycol (FCM 227) 30		30 (T)	Manganese (Anr	nex II) 0.6
Diethyleneglycol (FCM 263)		30 (T)	Iron (Annex II)	
Acetaldehyde (FCM 128)		6 (T)	Aluminum (Anne	ex II) 1
1,1,1-trimethylol	propane (FCM	141) 6		

In a migration test on samples of our product Magnolia White, with simulants covering all types of food (A, B, D2) or worst-case simulant B for the Annex II substances, at a condition of 30 minutes at 40°C, none of these substances were detected to migrate above 10% of their listed SML, when applying the conventional EU food contact ratio of 6dm² of material in contact with 1 kg of food.

Overall migration tests in simulants A, B, and D2 at condition OM0 were performed on Sustonable Magnolia white by an external laboratory and yielded results below the overall migration limit of 10 mg/dm².



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In addition, to assess potential risks associated with the use of rPET material, an analytical screening by GC-MS was performed in 95% ethanol, at a condition of 2 hours at 70°C. In this study, a factor of 3 dm² per kg of food was used, originating from the Dutch Commodities Act, for materials that do not completely envelop the food but also do not have a negligibly small contact area.

Substances detected to migrate were either below available food contact regulatory limits, migrated at or below 10 ppb, or were known non-intentionally added substances (NIAS) associated with plastics, with a limited risk profile.

3rd of June 2021

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