

Declaration of Compliance

APET HS Clear_7900

The product consists of APET top layer/bottom layer and rPET main layer, with or without adhesive on the edge for better sealing.

Product produced in the above material are produced in compliance with the following legislation:

EU Regulation 1935/2004/EC, on materials and articles intended to come into contact with food, Article 3, Article 11, para 5, Article 15, and Article 17

EU Regulation 10/2011/EC and amendments up to and including 2023/1627/EC

EU Regulation 2023/2006/EC (Good Manufacturing Practice) and amendments thereto

EU Regulation 1895/2005/EC (Epoxy derivatives) and amendments thereto

EU Regulation 1907/2006/EC (REACH) and amendments thereto

EU Regulation 2022/1616/EU (Recycled plastics)

EU Directive 94/62/EC (Packaging and Packaging Waste) and amendments thereto

Colour masterbatch is in compliance with Resolution AP (89) or BfR Richtlinien Empfehlung IX

Absorbers are in compliance with Regulation 450/2009/EC and BfR Richtlinien Empfehlung XXXVI / 3 or LIII

As the above-mentioned Regulations develop continuously, our declarations will be adapted accordingly. Therefore we advise the receivers to ask for a new declaration periodically.

Data:

Product can be used for the following types of food:	All
Test conditions: Simulants Conditions/Times	<p>According to Regulation 10/2011/EC (simulant A, B and D2) According to Regulation 10/2011/EC</p> <p>Overall migration: Simulant A (10% ethanol): 10 days/40°C Simulant B (3% acetic acid): 10 days 40°C Simulant D2 (olive oil): 10 days/40°C</p> <p>Specific Migration Simulant A (10% ethanol): 10 days/40°C Simulant B (3% acetic acid): 10 days 40°C Simulant D2 (olive oil): 10 days/40°C</p> <p>All monomers and additives are listed in Annexes I and II of EU Regulation 10/2011 / EC. One or more of the substances are restricted by specific migration limits. All substances with restrictions have been migration tested and the limit values documented in compliance with the restrictions. List of tested substances matches the full list of substances with restriction used in the formulation.</p>
List of substances with restrictions (SML) Cf.	See attached Appendix 1 to Faerch Declaration of Compliance for: APET HS Clear_7900:

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10/2011 / EC, Annex 1, Table 1 & 2 and Annex 2	Eurofins migration report no. APET HS Clear_7900_ 2211051382, 392-2023-00138901, dated 25-05-2023.
Temperature at use: Min Max Time	-40°C 70°C (max. 40°C with absorber and/or adhesive on edge) According to OM2 (Commission Regulation 10/2011/EC Annex V Chapter 3) Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2 ^{^(T- 70)/10} minutes Not suitable for heating in microwave oven.
Dual use additives	E338
Use of recycled plastic	Yes
Functional barrier	Yes. The material or article complies with the requirements of Article 13(2), (3) and (4)
S/V ratio at migration test	6 dm ² /kg
Max. acceptable S/V ratio	15,0 dm ² /kg
Risk assessment - Refer to Article 3 of Regulation (EC) no. 1935/2004	Risk assessment in accordance with the requirements of EU Regulation 10/2011 - Article 19 'Unintentionally added substance' (NIAS screening) showed the following substances: <i>See Table 2</i> Conclusion: presents no danger to human health

Table 2.

'Unintentionally added substance' (NIAS screening) showed the following substances

Names	Identification CAS - EINECS - MICFReference No.
No NIAS substances above the 10 ppb detection limit detected in NIAS screening	

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This document of compliance is made on basis of:

Documentation from suppliers

Global migration

Specific migration

Risk Assessment of substances not included in the EU 10/2011, Annex 1

Holstebro 13-08-2024

Faerch Group



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10/2011/EC
Annex V

Table 3
Standardised testing conditions

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at Contact temperature in [°C] for testing	Intended food contact conditions
OM0	30 min at 40 °C	Any food contact at cold or ambient temperatures and for a short duration (≤ 30 minutes).
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions.
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/ or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of $t = 120/2^{((T-70)/10)}$ minutes.
OM3	2 h at 70 °C	Any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for maximum of $t = 120/2^{((T-70)/10)}$ minutes, which are not followed by long term room temperature or refrigerated storage.
OM4	1 h at 100 °C or at reflux	High temperature applications for all food simulants at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.

Test OM 7 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants in contact with non-polyolefins. In case it is technically not feasible to perform OM 7 with food simulant D2 the test can be replaced as set out in paragraph 3.2.

Test OM 6 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.

Test OM 5 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM 2 covers also food contact conditions described for OM0, OM1 and OM3.'