

# Declaration of Compliance

## PP St Cl – 9430 Clear

Product produced from PP.

**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 amendment 321/2011/EC, 1282/2011/EC, 1183/2013/EC, 202/2014/EC, 2015/174/EC, 2016/1416/EC, 2017/752/EC, 2018/79/EC, 2018/213/EC, 2018/831/EC, 2019/37/EC, 2019/1338/EC and 2020/1245/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 282/2008/EC (Recycled plastics) and amendments thereto

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:**

<b>Product can be used for the following types of food:</b>	All
<b>Test conditions:</b> Simulants Conditions/Times	<p>According to Regulation 10/2011/EC(simulant A, B and D2) According to Regulation 10/2011/EC</p> <p><b>Overall migration - OM5, see Annex V (or harder)</b> Simulant A (10% ethanol): 4 hours 80°C + 10 days/60°C Simulant B (3% acetic acid): 4 hours/100°C + 10 days/60°C Simulant D2 (olive oil): 1 hour/121°C + 10 days/60°C</p> <p><b>Specific Migration</b> Simulant A (10% ethanol): 4 hours 80°C + 10 days/60°C Simulant B (3% acetic acid): 4 hours/100°C + 10 days/60°C Simulant D2 (olive oil): 1 hour/121°C + 10 days/60°C 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>

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List of substances with restrictions (SML) Cf. 10/2011 / EC, Annex 1, Table 1 & 2 and Annex 2	See attached Appendix 1 to Faerch Declaration of Compliance for: PP St Cl – 9430 Clear: Eurofins migration report no PP St Cl 9430 Clear - 392-2019-00291501_Rev1, dated 09-10-2019
<b>Temperature at use:</b> Min Max Time	-20°C (from -20°C to 0°C – handle with care) 121°C (max 40°C with absorber) According to OM5 (Commission Regulation 10/2011/EC Annex V Chapter 3) High temperature applications up to 121 °C. Testing for 10 days at 60°C shall cover long term storage above 6 months at room temperature and below. Suitable for heating in microwave oven.
<b>Dual use additives</b>	E470a, E470b, E471, E475, E570
<b>Use of recycled plastic</b>	No
<b>Functional barrier</b>	No
<b>S/V ratio at migration test</b>	6 dm <sup>2</sup> /kg
<b>Max acceptable S/V ratio</b>	10,7 dm <sup>2</sup> /kg
<b>Risk assessment</b> - 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> <b>Conclusion:</b> presents no danger to human health

**Table 2.**

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

Names	Identification CAS - EINECS – N° de Réf. MCDA
2,4-di-tert-butylphenol	96-76-4

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, 28-09-2021

**Faerch Group**

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PP St CI – 9430 Clear



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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 $70\text{ °C} \leq T \leq 100\text{ °C}$ 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 $70\text{ °C} \leq T \leq 100\text{ °C}$ 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.'