

Refining & Chemicals

Total Research & Technology Feluy
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CERTIFICATE 21-ARP-C-0180

Feluy, April 6, 2021

POLYPROPYLENE PPH 9059 S13 grade as produced in Europe**STATEMENT OF COMPLIANCE FOR FOOD CONTACT APPLICATIONS IN EUROPE:****1. Commission Regulation (EU) N°10/2011**

We confirm that the above-mentioned Product fulfils the harmonized requirements on plastic materials and articles intended to come into contact with food as described in the Regulation (EU) 10/2011 amended up to the Regulation (EU) 2019/1338¹.

1.1. Restrictions and/or migration limits:

This Product contains one or more intentionally added substances with specific migration limits and/or restrictions defined in Annex I of Regulation (EU) 10/2011 amended up to the Regulation (EU) 2019/1338¹: more information in paragraph 2.

Experimental tests and/or theoretical calculation for migration carried out on the above-mentioned Product (or a specimen representative of this material) covering 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 with simulants A, B and D2 (single use, polymer used at 100% and thickness up to 250 µm) have shown that the overall and if relevant the specific migration limit(s) - including those related to the metals of Annex II (up to Regulation (EU) 2020/1245¹) - was (were) not exceeded with aqueous foodstuffs and fatty foodstuffs (i.e. simulants A, B and D2).

For other specific conditions of use, not covered above, it pertains to downstream users to check by appropriate overall and/or specific migration tests on the final material or article the suitability for contact with different food-types and various end-use conditions. However, these are beyond the control of TOTAL RESEARCH & TECHNOLOGY FELUY and are a part of the responsibility of the user of the above-mentioned Product.

1.2. Dual use additive:

We inform you that the above-mentioned Product contains one or more substance(s) defined as 'dual use additive(s)'².

¹ For more precisions regarding compliance to (EU) 2020/1245 see paragraph 1.4.

² Dual Use additive following definition given in Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food i.e. a substance that is authorized as additive in plastics and, at the same time, as food additive or flavouring.



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1.3. NIAS

Total is aware of the legal requirements of Regulation (EC) 1935/2004 and (EU) 10/2011, namely materials and articles coming into contact with food shall be manufactured so that they do not transfer their constituents to food in quantities that could endanger human health or bring about unacceptable change to the composition of the food. This does include both constituents intentionally added and non-intentionally added substances (NIAS).

To the best of our knowledge and based on the details received from our suppliers, we provide you with information (if applicable) regarding potential NIAS with restrictions as listed in Regulation (EU) 10/2011 in paragraph 2.

1.4. 15th amendment to Regulation (EU) 10/2011 - (EU) 2020/1245:

According to the 15th amendment to Regulation (EU) 10/2011, plastic materials and articles complying with Regulation (EU) 10/2011 as applicable before the entry into force of this Regulation, and which were first placed on the market before 23 March 2021 may continue to be placed on the market until 23 September 2022 and remain on the market until exhaustion of stocks.

To ensure compliance with Regulation (EU) 2020/1245 we have initiated necessary laboratory tests, some of which may take several months for completeness. Moreover, we are questioning our suppliers about the presence of substances for which the genotoxicity has not been ruled out and which could be present in or originate from the product they sell to us.

2. Disclosure of restrictions according European Regulations (EU) N°10/2011, (EU) N°1333/2008³ and (EU) N°1334/2008⁴

³ REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives

⁴ REGULATION (EC) No 1334/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods

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Substances with restrictions as listed in the (EU) n°10/2011			
Substances	Maximal Residual Level (ppm)	FCM Reference N°	Specific Migration Limit (ppm)
9,9-bis(methoximethyl)fluorene	5.0	779	0.05
Glycerides, castor-oil mono-, hydrogenated, acetates	50	783	SML(T): 60***
1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-s-triazine-2,4,6(1H,3H,5H)-trione	520	661	5
NIAS*			
Substances	Maximal Residual Level (ppm)	FCM Reference N°	Specific Migration Limit (ppm)
4-tert-butylphenol	**	186	0.05
"Dual Use Additives", Substances with restrictions as listed in (EU) n°1333/2008 and 1334/2008			
Substances	Maximal Residual Level (ppm)	FCM Reference N°	Restriction (ppm)
E 475 Polyglycerol esters of fatty acids	50	11	500
E 470a Sodium, potassium and calcium salts of fatty acids	520	9	Quantum satis
E 304 Ascorbyl palmitate	traces	321	10
E 307 Alpha tocopherol	traces	110	10
E 330 Citric acid	traces	139	3000
E 526 Calcium hydroxide	traces	394	Quantum satis
E 570 Fatty acids	traces	9	Quantum satis
E 1520 Propylene glycol	traces	109	-

* We receive the information from some of our suppliers regarding potential NIAS with restrictions as listed in Commission Regulation (EU) 10/2011



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** The formation of these degradation products is strongly dependent on processing conditions. Therefore, we are not able to give a typical quantity of the degradation products occurring after processing of the polymer in your specific conditions of use. Some traces could be present in our resin, but to the best of our knowledge, theoretically the specific migration limit would be not exceeded if the product is used as described in this certificate.

*** Group 32 in Table 2 of Annex I of Regulation (EU) 10/2011

3. Regulation (EC) 1935/2004 of the European Parliament & of the Council (Framework Regulation)

We hereby confirm that the above-mentioned Product, when used under normal or foreseeable conditions of use, is expected to meet the relevant requirements laid down in Regulation (EC) 1935/2004.

Moreover, we inform you that the organoleptic properties are influenced by the conditions of use i.e. temperature, type of packaged foodstuff, storage conditions. Consequently, the packaging has to be controlled by the downstream user following the specific end-use conditions of use.

4. Commission Regulation (EC) 2023/2006 (GMP)

We inform you that the production of the above-mentioned Product is systematically reviewed with regards to good manufacturing practice (GMP) using our ISO 9001 System and following the Plastics Europe guideline specifically dedicated to GMP. Therefore, we can state that the above-mentioned Product meets the relevant requirements laid down in Commission Regulation (EC) 2023/2006.

DISCLAIMER:

Our certificate is only valid for as far as above-mentioned Product was bought from Total or its distributor and does not cover:

- Any modification of the above-mentioned Product by any addition of any other product or ingredient to it;
- Any prejudicial modification of the above-mentioned Product resulting from a processing of it;



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- An inadequate use and/or storage of the above-mentioned Product and/or of the finished articles.

Unless specifically indicated in a regulatory certificate of compliance, the products mentioned herein are not suitable for applications in the pharmaceutical or medical sector. Under no circumstances any products sold by Total Refining & Chemicals are suitable for humans or animals in the following applications: (i) Implantable devices intended for human or animal body (ii) Devices intended to be used in contact with internal body fluids (iii) Devices intended to be used in contact with internal body tissues. Information contained in this publication is true and accurate at the time of publication and to the best of our knowledge. The nominal values stated herein are obtained using laboratory test specimens. Before using one of the products mentioned herein, customers and other users should take all care in determining the suitability of such product for the intended use.

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The present certificate is valid for a period of eighteen months starting from the date first above written and replaces any earlier any earlier certificate relating on this subject which should be considered as null and void. Upon the expiration of this certificate, we can issue a new one at your request. In case of change during this period a new certificate will be issued automatically; kindly forward it to any recipient of the present certificate.

TOTAL RESEARCH & TECHNOLOGY FELUY

A. ANDREEV
Regulatory Affairs

F. RADERMACHER
Regulatory Affairs, Manager

Issued by an electronic system