

**TotalEnergies One Tech Belgium**

Refining & Chemicals / Regulatory Affairs  
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**CERTIFICATE N° 22-ARP-C-0145**

Feluy, March 16, 2022

POLYETHYLENE LOTRENE® Q1018N grade as produced by Qatofin Company Limited Q.P.J.S.C. (in Qatar)

**STATEMENT OF COMPLIANCE FOR FOOD CONTACT APPLICATIONS IN EUROPE**

**1. Commission Regulation (EU) No 10/2011**

We confirm that the above-mentioned Product fulfils the requirements on plastic materials and articles intended to come into contact with food as described in the Regulation (EU) No 10/2011 as amended up to the Regulation (EU) 2020/1245<sup>1</sup>.

**1.1. Restrictions and/or migration limits:**

This Product may contain one or more intentionally added substances with specific migration limits and/or restrictions defined in Annex I of Regulation (EU) No 10/2011 as amended up to the Regulation (EU) 2020/1245: more information in section 2.

Experimental tests and/or theoretical calculation of migration carried out on the above-mentioned Product (or a specimen representative of this material) covering any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to 70 °C for up to 2 hours, or heating up to 100°C for up to 15 minutes<sup>2</sup> with simulant D2 (single use, polymer used at 100% and thickness up to 100 µm) have shown that the overall and if relevant the specific migration limit(s) - including those related to the metals of Annex II – were not exceeded.

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 TotalEnergies One Tech Belgium 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 may contain substance(s) defined as 'dual use additive(s)<sup>3</sup>'. Dual use additives mean additives which are covered by a listing in the Union list and which are also listed as food additives or flavourings in regulations (EC) No 1333/2008 and (EC) No 1334/2008 and their implementing measures. More information in section 2 here below. We inform that you must check in the above-mentioned regulations the restrictions that may apply in your application.

**1.3. NIAS:**

TotalEnergies is aware of the legal requirements of Regulations (EC) No 1935/2004 and (EU) No 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

<sup>1</sup> To meet the requirements of Regulation (EU) 2020/1245 we have initiated tests and our suppliers were questioned about the presence of substances specifically targeted by this regulation. This declaration has been established to the best of our knowledge and based on the available information at the time of edition of this document. A new document will be edited if a new evidence on the subject changes our statement.

<sup>2</sup> For other temperature, you may use the formulation included in Table 3 of Chapter 3 of Regulation (EU) No 10/2011: T where 70 °C ≤ T ≤ 100 °C for a maximum of  $t = 120/2^{((T-70)/10)}$  minutes.

<sup>3</sup> As defined in article 11 (3) of Regulation (EU) No 10/2011.

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composition of the food. It does include both constituents intentionally added and non-intentionally added substances (NIAS).

To the best of our knowledge and based on the information received from our suppliers, you will find here below and in section 2 relevant information needed to establish your risk assessment under article 19 and Annex IV (6) of Regulation (EU) No 10/2011 as amended up to (EU) 2020/1245.

Please find below a non-exhaustive list of NIAS that you may find in our product:

2,4-di-tert-Butylphenol (CAS RN® 96-76-4)

Tris-(2,4-di-tert-butylphenyl)phosphate (CAS RN® 95906-11-9)

2,6-di-tert-butyl-p-benzoquinone (CAS RN® 719-22-2)

3,5-di-tert-butyl-4-hydroxybenzaldehyde (CAS RN® 1620-98-0)

3,5-di-tert-butyl-4-hydroxy acetophenone (CAS RN® 14035-33-7)

7,9-di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione (CAS RN® 82304-66-3)

3-(3,5-di-tert-butyl-4-hydroxyphenyl) methylpropanoate (CAS RN® 6386-38-5)

3-(3,5-di-tert-butyl-4-hydroxyphenyl) propanoic acid (CAS RN® 20170-32-5)

**2. Relevant information required by Regulation (EU) No 10/2011**

<b>Substances as mentioned in the Regulation (EU) No 10/2011 Annex I, Annex II and/or Annex IV (6)<sup>1</sup></b>			
<b>Substances</b>	<b>Maximal Residual Level (ppm)</b>	<b>FCM Reference No or CAS RN</b>	<b>Specific Migration Limit or Restriction (ppm)</b>
2,6-di-tert-butyl-4-ethylphenol	Traces *	477	4.80
Butadiene	Traces *	223	SML in food = not detectable 1 mg/kg in final product
1-hexene	Traces *	356	3
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	556	433	6
4-tert-butylphenol	Traces *	186	0.05
Aluminium	< 100		1

\* Non Intentionally Added Substances – impurities, reaction products or others - with restrictions as mentioned in Commission Regulation (EU) No 10/2011 and/or national legislations may be present. The presence of these substances might depend on processing conditions. Therefore, we are not able to give a typical quantity of these substances 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 restrictions would be met if the product is used in the conditions described in section 1.1. of this document.

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<b>Dual Use Additives as listed in Regulations (EC) No 1333/2008<sup>4</sup> and No 1334/2008<sup>5</sup></b>		
<b>Substances</b>	<b>Maximal Residual Level (ppm)</b>	<b>FCM Reference No or CAS RN</b>
E943a n-Butane	Traces *	106-97-8
E290 Carbon Dioxide	Traces *	124-38-9
E511 Magnesium Chloride	Traces *	7786-30-3
E551 Silicon Dioxide	Traces *	7631-86-9
E530 Magnesium oxide	Traces *	1309-48-4
E528 Magnesium Hydroxide	Traces *	1309-42-8
E507 Hydrochloric acid	Traces *	7647-01-0
E470a Sodium, potassium and calcium salts of fatty acids	696	1592-23-0
E529 Calcium oxide	Traces *	1305-78-8

\* Non Intentionally Added Substances – impurities, reaction products or others - with restrictions as mentioned in Commission Regulation (EU) No 10/2011 and/or national legislations may be present. The presence of these substances might depend on processing conditions. Therefore, we are not able to give a typical quantity of these substances occurring after processing of the polymer in your specific conditions of use. Some traces could be present in our resin.

### **3. Regulation (EC) No 1935/2004 of the European Parliament & of the Council (Framework Regulation)**

We hereby confirm that the above-mentioned Product, when used in the conditions described in section 1.1 of this document, is expected to meet the relevant requirements laid down in Regulation (EC) No 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 must be controlled by the downstream user following the specific end-use conditions of use.

### **4. General Use Conditions (Food Contact application)**

It pertains to downstream users of materials intended to come into contact with food, to ensure that the final materials or articles do not bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics which render it unfit.

It pertains to downstream users to check by appropriate tests on the final material or article the suitability for contact with different food-types and various end-use conditions. For high temperature applications tests shall be carried out under the worst foreseeable conditions of use in which physical or other changes do not take place and specific precautions must be taken during the end-use in the most severe temperatures to ensure that the polymer remains functional. The maximum testing temperature is governed by the phase transition temperature of the polymer.

<sup>4</sup> REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives.

<sup>5</sup> 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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### **5. Commission Regulation (EC) No 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) No 2023/2006.

### **6. Business Operator**

Production Plant:  
Qatofin Company Limited Q.P.J.S.C  
Building 135,  
C Ring Road 230  
P.O. Box: 55013  
Doha,  
Qatar

Importer in Europe:  
TotalEnergies Petrochemicals France  
Place Jean Millier 2  
92400 Courbevoie  
France

### **7. Business Operator issuing the Statement of Compliance**

TotalEnergies One Tech Belgium (acting in the name of and on behalf of TotalEnergies Petrochemicals France)  
Zone Industrielle Feluy C  
7181 Seneffe  
Belgium

### **DISCLAIMER:**

Our Statement of Compliance is only valid for as far as above-mentioned Product was bought from TotalEnergies 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;
- An inadequate use and/or storage of the above-mentioned Product and/or of the finished articles.

Unless specifically indicated in a regulatory document, the products mentioned herein are not suitable for applications in the pharmaceutical or medical sector. Under no circumstances any products sold by TotalEnergies 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.

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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 Statement of Compliance is valid for a period of 9 months starting from the date first above written and replaces any earlier Statement relating on this subject which should be considered as null and void. Upon the expiration of this Statement, we can issue a new one at your request. In case of change during this period a new Statement will be issued automatically; kindly forward it to any recipient of the present Statement.

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