

SUBSTANCE STATEMENT

I, undersigned, Celine BOIGEY, Person Responsible for Regulatory Compliance of Laboratory AGUETTANT, 1 rue Alexander Fleming, 69007 Lyon, declare that for the device **VERSOL® STERILE WATER**:

- No product from animal origin is used during the manufacturing
- In the claimed indications, it does not include any substance that could be considered as a medicine for human use (according to Annex I point 12.1 of Regulation (EU) 2017/745)
- It does not incorporate any substance derived from human blood
- Absence of substances in a concentration greater than 0.1% by mass fraction of carcinogenic, mutagenic or toxic substances for reproduction of category 1A and 1B or substances with properties that disrupt the endocrine system (According to in Annex I, section 10.4.1 of Regulation (EU) 2017/745).
- In the claimed indications, it includes substances or combinations of substances intended to be introduced into the human body and absorbed by the human body or dispersed locally in it (according to Annex I, point 12.2 of Regulation (EU) 2017/745).

Lyon, 12th August 2024

Celine BOIGEY
Person Responsible for Regulatory Compliance

TOTAL RESEARCH & TECHNOLOGY FELUY

Refining & Chemicals / Regulatory Affairs
rc.fer-regaffairs@totalenergies.com

Page 1 of 4

CERTIFICATE N° 21-ARP-C-0300

Feluy, August 2, 2021

POLYPROPYLENE Aceso PPM R021 S01 grade as produced in Europe

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) 2020/1245¹.

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 long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100°C for up to 15 minutes² 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 – 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 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 may contain substance(s) defined as 'dual use additive(s)'³.

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 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 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.

¹ 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.

² 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.

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

Issued by an electronic system

Zone Industrielle C – B-7181 Seneffe (Feluy)
Tél. : +32 (0)64 51 41 11 – E-mail : research-feluy@totalenergies.com

SA TOTAL RESEARCH & TECHNOLOGY FELUY NV
RPM Charleroi 0438.021.316 T.V.A. BE 0438.021.316 – BNP Paribas Fortis IBAN BE48 2100 4738 2027 BIC GEBABEBB

TOTAL RESEARCH & TECHNOLOGY FELUY

Refining & Chemicals / Regulatory Affairs
rc.fer-regaffairs@totalenergies.com

Page 2 of 4

CERTIFICATE N° 21-ARP-C-0300

Feluy, August 2, 2021

POLYPROPYLENE Aceso PPM R021 S01 grade as produced in Europe

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

Substances as mentioned in the Regulation (EU) No 10/2011 Annex I, Annex II and/or Annex IV (6)¹			
Substances	Maximal Residual Level (ppm)	FCM Reference No or CAS RN	Specific Migration Limit or Restriction (ppm)
9,9-bis(methoxymethyl)fluorene	2.8	779	0.05
4-tert-butylphenol	traces*	186	0.05
Distearyl-3,3'-thiodipropionate (DSTDP)	traces*	368	SML(T): 5** expressed as the sum of the substances (FCM 294, 368, 894) and their oxidation products
2,6-di-tert-butyl-4-ethylphenol	traces*	477	4.8

* Non Intentionally Added Substances - impurities or reaction products - 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.

** Group 14 in Table 2 of Annex I of Regulation (EU) 10/2011

Dual Use Additives as listed in Regulations (EC) No 1333/2008⁴ and No 1334/2008⁵			
Substances	Maximal Residual Level (ppm)	FCM Reference No or CAS RN	Restriction (ppm)
E 470a Sodium, potassium and calcium salts of fatty acids and E 470b Magnesium salts of fatty acids	16	105 and 106	Quantum satis

* Non Intentionally Added Substances - impurities or reaction products - 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.

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

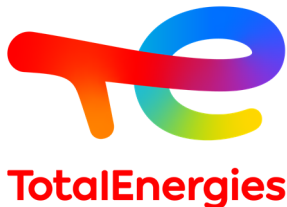
We hereby confirm that the above-mentioned Product, when used in the conditions described in section 1.1 of this document, is expected to meet the relevant requirements laid down in Regulation (EC) No 1935/2004.

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

⁵ 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.

Issued by an electronic system

Zone Industrielle C – B-7181 Seneffe (Feluy)
 Tél. : +32 (0)64 51 41 11 – E-mail : research-feluy@totalenergies.com



TOTAL RESEARCH & TECHNOLOGY FELUY

Refining & Chemicals / Regulatory Affairs
rc.fer-regaffairs@totalenergies.com

Page 3 of 4

CERTIFICATE N° 21-ARP-C-0300

Feluy, August 2, 2021

POLYPROPYLENE Aceso PPM R021 S01 grade as produced in Europe

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. 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.

5. Business Operator

TOTAL PETROCHEMICALS & REFINING SA/NV
Rue de l'Industrie 52
1040 Bruxelles
Belgium

6. Business Operator issuing the Statement of Compliance

TOTAL RESEARCH & TECHNOLOGY FELUY
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.

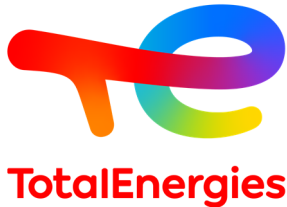
Unless specifically indicated in a regulatory document, the products mentioned herein are not suitable for applications in the pharmaceutical or medical sector. Under no circumstances any products sold by TotalEnergies Raffinage Chimie are suitable for humans or animals in the following applications: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

Issued by an electronic system

Zone Industrielle C – B-7181 Seneffe (Feluy)
Tél. : +32 (0)64 51 41 11 – E-mail : research-feluy@totalenergies.com

SA TOTAL RESEARCH & TECHNOLOGY FELUY NV
RPM Charleroi 0438.021.316 T.V.A. BE 0438.021.316 – BNP Paribas Fortis IBAN BE48 2100 4738 2027 BIC GEBABEBB



TOTAL RESEARCH & TECHNOLOGY FELUY

Refining & Chemicals / Regulatory Affairs
rc.fer-regaffairs@totalenergies.com

Page 4 of 4

CERTIFICATE N° 21-ARP-C-0300

Feluy, August 2, 2021

POLYPROPYLENE Aceso PPM R021 S01 grade as produced in Europe

the products mentioned herein, customers and other users should take all care in determining the suitability of such product for the intended use.

The Companies within TotalEnergies Raffinage Chimie do not accept any liability whatsoever arising from the use of this information or the use, application or processing of any product described herein. No information contained in this publication can be considered as a suggestion to infringe patents. The Companies disclaim any liability that may be claimed for infringement or alleged infringement of patents.

The present Statement of Compliance is valid for a period of 6 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.

TOTAL RESEARCH & TECHNOLOGY FELUY, Regulatory Affairs

Issued by an electronic system

Zone Industrielle C – B-7181 Senefte (Feluy)
Tél. : +32 (0)64 51 41 11 – E-mail : research-feluy@totalenergies.com

SA TOTAL RESEARCH & TECHNOLOGY FELUY NV
RPM Charleroi 0438.021.316 T.V.A. BE 0438.021.316 – BNP Paribas Fortis IBAN BE48 2100 4738 2027 BIC GEBABEBB