TotalEnergies One Tech Belgium

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

CERTIFICATE N° 22-ARP-C-0045

Feluy, March 17, 2022

POLYPROPYLENE Aceso ® PPM H250S01 grade as produced in Europe (Gonfreville site)

1. STATEMENT OF COMPLIANCE EUROPEAN PHARMACOPOEIA:

We hereby certify that the composition of **Polypropylene Aceso ® PPM H250S01** meets the requirements of the

- European pharmacopoeia - 10th Edition (10.3 & 10.4 - 2021)

§ 3.1.3 Polyolefins

§ 3.1.6 Polypropylene for containers and closures for parenteral preparations and for ophthalmic preparations (10.3 & 10.4 - 2021) tested on batches nr 130029.

Furthermore, although samples were tested on a regular basis according to § 3.1.6 Polypropylene for containers and closures for parenteral preparations and for ophthalmic preparations, we remind you that the compatibility of the medicinal product with the plastic material depends on the physical state of the active substance and the pharmaceutical dosage form and route of application of the medicinal product. Consequently, the packaging has to be controlled following the specific end-use conditions as described in guideline on plastic immediate packaging materials issued by EMEA and specific adequate Regulations dedicated for medical and/or pharmaceutical applications.

It pertains as usual to the manufacturer of the finished articles according to the rules of the profession and the usual practice, to verify the compatibility of the Product with the products or preparations to be packed.

2. STATEMENT OF COMPLIANCE WITH PHARMACOPOEIA IN THE USA:

The **POLYPROPYLENE Aceso ® PPM H250S01** (batch 931164- 2019) was submitted in January 2020 to studies ref. nr 19-B13195 entitled: '*Tests according to United States Pharmacopoeia – according to United States Pharmacopoeia 42 NF 37 – 2019 – Chapter* ***<661.1>*** *Polypropylene sections ' Identification, Physicochemical Tests , Extractable Metals and Plastic Additives'* official after 1st December 2025 .Specifically were tested : the Absorbance, Acidity, Alkalinity, Total Organic Carbon (TOC) , extractable metals (as Al, As, Cd, Pb, Co, Ni, V, Cr, Ti, Hg & Zn), non Phenolic antioxidants, Phenolic antioxidants and Identification. The tested material passes those tests. According the end user application (dosage form, low or high-risk situation ..) it is the material user's responsibility to evaluate the need to perform for other testing as extractable metals or biological tests . We shall supply the TotalEnergies proprietary information (as formulation) needed to perform your risk assessment upon request.

Moreover an *In Vitro* cytotoxicity test on the **POLYPROPYLENE Aceso® PPM H250S01** (batch 731128 – 2017) was conducted to evaluate the potential for cytoxicity. This study (ref. nr 17-B7672 – dated on November 9, 2017) entitled '*qualitative MEM-elution: Dye Exclusion*' according to "ISO 10993-5, 2009: Biological Evaluation of Medical Devices –Part 5: Tests for *In vitro* Cytotoxicity" and "USP 40 NF 35, 2017: **< 87>** Biological reactivity test, *in vitro*". Under the conditions of this test, the extract of the test item is considered non-cytotoxic.

Issued by an electronic system

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3. STATEMENT OF TRANSMISSIBLE BOVINE SPONGIFORM ENCEPHALOPATHY (BSE):

We hereby confirm that we did receive an indication from our suppliers of additives used in the above-mentioned Product mentioning the absence of any substances which are of animal origin. Based on the above, we are confident that the above-mentioned Product is free of SRM (Specified Risk Materials).

4. NOTE:

The use of the here above-mentioned Product for any medical or pharmaceutical applications is under the entire responsibility of your company. Results and conclusion apply only to test articles tested and are provided solely for information. Any extrapolation of these data to other articles is the customer's responsibility. For obtaining more information regarding the Pharmacopoeia, please contact directly our ATC(Phone:+32.64.51.42.48, e-mail: stephane-jean.lecomte@total.com) or our vendor.

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.

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.
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 18 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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