

Refining & Chemicals

Total Research & Technology Feluy
Regulatory Affairs
Tel. : +32 (0)64 51 40 67
rc.fer-regaffairs@total.com

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CERTIFICATE N° 38873

Feluy, March 18, 2020

POLYPROPYLENE Aceso® PPM H250 grade as produced in Europe**STATEMENT OF COMPLIANCE FOR PHARMACOPOEIA APPLICATIONS:****STATEMENT OF COMPLIANCE EUROPEAN PHARMACOPOEIA:**

We hereby certify that the additives (i.e antioxidants, lubricants and/or antibloc agents) of **POLYPROPYLENE Aceso ® PPM H250** are included in the positive list of:

- European pharmacopoeia - 10th Edition (2020) – 10.0.

§ 3.1.3 Polyolefines

§ 3.1.6 Polypropylenes for containers and closures for parenteral and ophthalmic preparations.

Furthermore, we inform you that this Product is tested on a regular basis for physicochemical tests prescribed in § 3.1.6 Polypropylenes for containers and closures for parenteral and ophthalmic preparations.

Moreover, 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 must 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.

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

STATEMENT OF COMPLIANCE WITH PHARMACOPOEIA IN THE USA:

The **POLYPROPYLENE Aceso ® PPM H250** (batch 19P1209 – 2019) was submitted in December 2019 to a study ref. nr 19-B13193 entitled: '*Tests according to United States Pharmacopoeia – according to United States Pharmacopoeia 42NF37 – general chapters: < 661.1> Polypropylene sections ' Identification, Physicochemical Tests , Extractable Metals and phenolic antioxidants'* .Specifically were tested : the Absorbance, Acidity or Alkalinity, Total Organic Carbon (TOC) , extractable metals (as Al, As, Cd, Pb, Co, Ni, V, Cr, Ti, Hg & Zn), Phenolic antioxidants and Identification . Under the conditions of this test, the tested material passes.

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POLYPROPYLENE Aceso® PPM H250 grade as produced in Europe**STATEMENT OF TRANSMISSIBLE BOVINE SPONGIFORM ENCEPHALOPATHY (BSE):**

We hereby confirm that we did receive an indication from our suppliers of additives (by additive is meant the antioxidants which are incorporated into plastic to achieve a technical effect in the finished product) 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).

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 analytical results, please contact directly our ATC (Phone: + 32.64.51.42.48 , FAX: + 32.64.51.46.50 and e-mail: stephane-jean.lecomte@total.com) or our vendor.

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

Under no circumstances are any products sold by Total Refining & Chemicals suitable for humans or animals in the following applications: (i) medical implants material or 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. This disclaimer exclude the following typical applications used for medical devices and/or Pharmaceutical & diagnostic packaging as:

- Disposable non-prefilled syringes
- Needle hubs
- Catheter connections
- Laboratory disposable
- Diagnostic products



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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. The companies within Total Refining & Chemicals 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 certificate is valid for a period of eighteen months starting from the date first above written and replaces 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

C. RAIMOND
Regulatory Affairs

F. RADERMACHER
Regulatory Affairs, Manager

Issued by an electronic system