

Refining & Chemicals

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CERTIFICATE N° 35058

Feluy, June 5, 2013

POLYPROPYLENE PPM H250 grade as produced in Europe**STATEMENT OF COMPLIANCE FOR PHARMACOPOEIA APPLICATIONS:****1.STATEMENT OF COMPLIANCE WITH EUROPEAN PHARMACOPOEIA:**

We hereby certify that the composition of **POLYPROPYLENE PPM H250** meets the requirements of :

- European pharmacopoeia – 7th Edition (2013)– 7.7.

§ 3.1.3 Polyolefines

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

The above-mentioned Product is regularly tested according § 3.1.6 Polypropylenes for containers and closures for parenteral and ophthalmic preparations, however the Product is not tested on each batch as prescribed by the European pharmacopoeia. It pertains as usual to the manufacturer of the finished articles to check according to the rules of the profession and the usual practice, the compatibility of the above-mentioned Product with the products or preparations to be packed.

2. STATEMENT OF COMPLIANCE WITH PHARMACOPOEIA IN THE USA :

We inform you that the above-mentioned Product is in compliance with **the Biological reactivity tests, in vitro (elution test), <87>**, required by the USP 30-NF 25. The test has been conducted by an accredited laboratory in accordance with the GLP FDA requirements described in the 21 CFR 58 (revised as of April 1st, 2007) and in accordance with the requirements of the OECD Good Laboratory Practices, reference ENV/MC/CHEM (98) 17, adopted by council on November 26th, 1997.

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.

Unless specifically indicated, the products mentioned herein are not suitable for applications in the pharmaceutical or medical sector. **Under no circumstances are any products sold by Total Refining & Chemicals suitable for human in the following applications: (i) implantable devices intended for human or animal body (ii) Devices intended to used in contact with internal body fluids (iii) Devices intended to be used in contact with internal body tissues.** 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.

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Moreover we inform you that the above-mentioned Product is in compliance with the physicochemical tests plastics described in the **<661> containers** focused on Polypropylene containers applications. Specifically were tested: the non-volatile Residue, Residue on ignition, heavy metals and buffering capacity required by the USP 30-NF 25. The procedures were conducted in conformance with good laboratory practice and ISO 17025.

The above-mentioned Product has also a DMF in the USA referenced as N° 14902.

3. STATEMENT OF COMPLIANCE WITH CANADIAN PHARMACOPOEIA:

The above-mentioned Product has a DMF in Canada referenced as 2005-161.

For obtaining more information regarding the Pharmacopoeia, please contact directly our ATC (Phone : +32.64.51.43.07, Fax : +32.64.51.46.50, e-mail: Fabienne.radermacher@total.com) or our vendor.

DISCLAIMER :

Our certificate 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.

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The present certificate is valid for a period of eighteen months starting from the date first above written. 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. WYLIN
Regulatory Affairs, Manager

Issued by an electronic system

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