

**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 20-ARP-C-0140** 

Feluy, September 30, 2020

# POLYPROPYLENE Aceso® PPM H250 grade as produced in Europe

### Toy applications – Toy Safety Directive (Directive 2009/48/EC):

We would like to remind you that it is the responsibility of the toy manufacturer that brings toys on the market to check the compliance of the finished article with the essential safety and health requirements as mentioned in Directive 2009/48/EC.

We confirm that the above Product as supplied may be used to manufacture toys in compliance with relevant requirements of the Toy Safety Directive (Directive 2009/48/EC), as adopted by the European Council. We inform you that we are basing our statement on a toy of 250gr manufactured with the above-mentioned product at 100% and at a daily exposure of 2 hours per day for one year for a 10 kg toddler. Specifically,

The Product:

is not manufactured with any Phthalate prohibited for use in toys outside of applicable restrictions under applicable Community legislation. Nevertheless, we inform you that traces of some Phthalates, may be present in some of our Products, as catalyst modifier residues. These maximum residues would not exceed 1 ppm. We confirm you that our product complies with the restrictions as mentioned in entry 51 and 52 of the Annex XVII of REACH (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006) on the use of these substance in toys and childcare articles (max 0.1% by mass of the plasticized material).

Please find below information relating to Annex II, Part III "Chemical properties" of Directive 2009/48/EC that are deemed necessary for the regulatory evaluation of our product:

- meets applicable requirements set forth in Annex II, Part III, paragraphs 3 and 7 concerning the use of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 above the restriction on the use of these substances in toys and childcare articles. Nevertheless, we inform you that the above-mentioned product may contain, as technically unavoidable residual, the following component classified as CMR as defined in Regulation 1272/2008/EU:
  - Di-*ter*t-butyl-peroxide (CAS 110-05-4). Residual content ≤ 5 ppm.
- meets the limit on allergenic fragrances content set forth in Annex II, Part III, paragraph 11. We can hereby confirm that we do not use "allergenic fragrances" in the manufacturing of the above Product;



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- meets migration limits on heavy metals and other substances set forth in Annex II, Part III, paragraph 13; moreover, all analyses performed on the Product (or a specimen representative of this material) showed results below the prescribed limits of the relevant requirements of European standards EN 71-3 2019, entitled "Safety of Toys – Part 3: Migration of certain elements";
- meets the relevant requirements of European standards EN 71-9, September 2007 "Organic Chemical Compounds- Requirements";
- Is not manufactured with any **Nitrosamines and/or nitrosables** set forth in Annex II, Part III, Paragraph 8.

We note that verification of compliance of the <u>finished toy product</u> with all applicable requirements of the Toy Safety Directive 2009/48/EC remain the sole responsibility of the toy manufacturer.

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### 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.

Unless specifically indicated in a regulatory certificate of compliance, 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 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. 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

B. KLUYSKENS Regulatory Affairs F. RADERMACHER Regulatory Affairs, Manager

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