

Refining & Chemicals

Total Research & Technology Feluy
 Regulatory Affairs
 Tel. : +32 (0)64 51 40 67
 Fax.: +32 (0)64 51 41 49
 rc.fer-regaffairs@total.com

Letter: ARP/20L00366

Feluy, 25/03/2020

To whom it may concern

POLYPROPYLENE Aceso® PPM H250

ELEMENTAL IMPURITIES FOLLOWING ICH GUIDELINE Q3D

Please find here under analysis results performed on the here above mentioned product(s) or on a representative grade of it, concerning heavy metal content according to GUIDELINE FOR ELEMENTAL IMPURITIES Q3D(R1) EMA/CHMP/ICH353369/2013- Current Step 5 version dated 28 March 2019 Table 5.1.

Elements to be considered in the Risk Assessment according to ICH Q3D 2019

Element	Class	Method	Unit	Limit of quantification	Value
Cd	1	ICP	ppm	0.025	<LQ
Pb	1	ICP	ppm	0.05	<LQ
As	1	ICP	ppm	0.025	<LQ
Hg	1	ICP	ppm	0.025	<LQ
Co	2A	ICP	ppm	0.05	<LQ
V	2A	ICP	ppm	0.05	<LQ
Ni	2A	ICP	ppm	0.025	<LQ
Tl	2B	ICP	ppm	0.1	<LQ
Au	2B	ICP	ppm	NA*	NA*
Pd	2B	ICP	ppm	0.1	<LQ
Ir	2B	ICP	ppm	0.25	<LQ
Os	2B	ICP	ppm	0.25	<LQ
Rh	2B	ICP	ppm	0.25	<LQ
Ru	2B	ICP	ppm	0.25	<LQ
Se	2B	ICP	ppm	1.0	<LQ
Ag	2B	ICP	ppm	1.0	<LQ
Pt	2B	ICP	ppm	1	<LQ
Li	3	ICP	ppm	0.025	<LQ
Sb	3	ICP	ppm	0.1	<LQ
Ba	3	ICP	ppm	0.1	<LQ
Mo	3	ICP	ppm	0.1	<LQ
Cu	3	ICP	ppm	0.1	<LQ
Sn	3	ICP	ppm	0.1	<LQ
Cr	3	ICP	ppm	0.05	<LQ

NA*: not analyzed.

Issued by an electronic system

1/2

SA TOTAL RESEARCH & TECHNOLOGY FELUY NV

Zone Industrielle C – B-7181 Seneffe (Feluy)
 Tél. : +32 (0)64 51 41 11 - Fax. : +32 (0)64 54 08 45 - Courriel : research-feluy@total.com
 RPM Charleroi 0438.021.316 T.V.A. BE 0438.021.316 – BNP Paribas Fortis IBAN BE48 2100 4738 2027 BIC GEBABEBB



Refining & Chemicals

Total Research & Technology Feluy
Regulatory Affairs
Tel. : +32 (0)64 51 40 67
Fax.: +32 (0)64 51 41 49
rc.fer-regaffairs@total.com

We inform you that the metals not analyzed are not intentionally added to the here above mentioned product(s) during the manufacturing process. However, we cannot guarantee that there is no trace amount of some of these metals, as impurity or otherwise, in the here above mentioned product(s).

Our certificate does not cover:

- any modification of the warranted product by any addition of any other product to it,
- any prejudicial modification of the warranted product resulting from a processing of the product,
- an inadequate use and/or storage of the material and of the finished articles.

The present certificate is valid until **January 31st, 2023**. It can then be renewed upon request.

We are at your disposal for any further information you may need and remain,

Yours faithfully,
Total Research & Technology Feluy

B. KLUYSKENS
Regulatory Affairs

F. RADERMACHER
Regulatory Affairs, Manager

