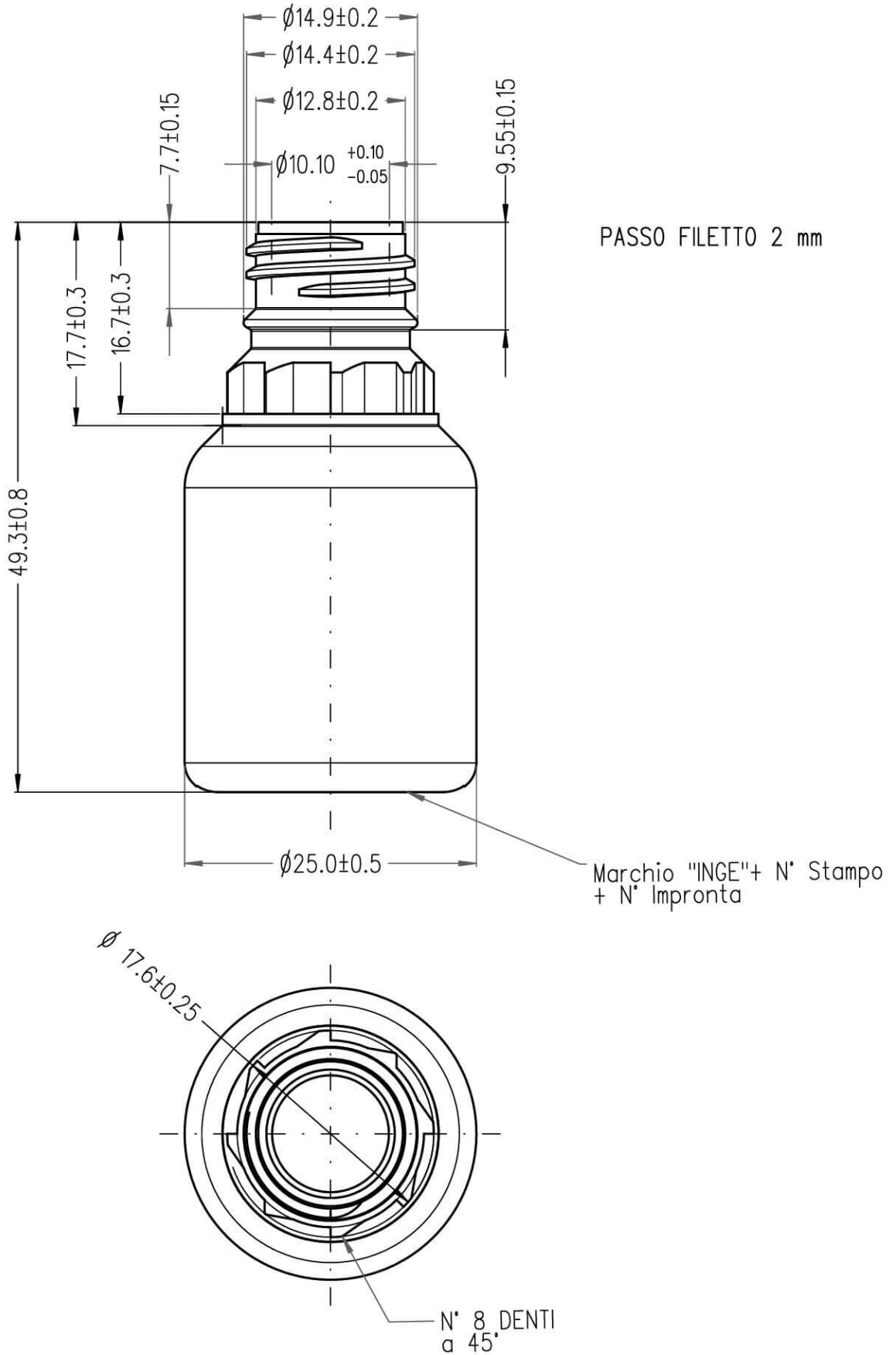


ATTENZIONE : Modificare esclusivamente con C.A.D.



Rv.	Varianti	Data	Firma

Edizione	Data	16/12/2011
Reparto	Firma UT	
Disegnatore	Visto CQ	
	Muscolo	

Rv.	Varianti	Data	Firma

Unita' di misura SI: mm	Tolleranze : dove non siano diversamente specificate +/-			A 4
descrizione	peso g:	st.pilota n.	st.di produzione n.	
	2,4±0.6	/	S0/664	
FLACONE C.ta' UTILE 10ml C.ta' R.B. 15±1ml	materiale	macchina	scala	
	PP	/	2 : 1	
Accessori: Capsula MV273 + Piolo MV274	data	disegno n.	rv.0	fg. n.
	16/12/2011	02/1640		X

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CERTIFICATE N° 22-ARP-C-0005

Feluy, February 1, 2022

POLYPROPYLENE Aceso ® PPM R020 grade as produced in Europe (Lavera site)

1. STATEMENT OF COMPLIANCE EUROPEAN PHARMACOPOEIA:

We hereby certify that the composition of **POLYPROPYLENE Aceso ® PPM R020** meets the requirements of the

- European pharmacopoeia - 10th Edition (10.5 - 2021)

§ 3.1.3 Polyolefins

§ 3.1.6 Polypropylene for containers and closures for parenteral preparations and for ophthalmic preparations - tested on batches nr 21P1687 (10.4 - 2021) and 21P2107 (10.5 - 2021) .

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 R020** (batch 16P2224 – 2016) was submitted in December 2017 to a study ref. nr 16-B6435 entitled: '*Tests according to United States Pharmacopoeia – according to United States Pharmacopoeia 39NF34– 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 excepted Infra-Red Spectrum and Differential scanning calorimetry.

USP requires to use an homopolymer Propylene as reference standard.

The presence of ethylene in the natural composition of the random copolymer (Polypropylene Aceso ® PPM R020) explain that the criteria described in the USP is not met.

In addition, we inform you that the **POLYPROPYLENE Aceso ® PPM R020** contains a type of additive, commonly used in polypropylenes, which is not included in the USP list. We shall supply the TOTALREFINING & CHEMICALS proprietary information needed to perform the risk assessment for your application.

Moreover an In Vitro cytotoxicity test on the **POLYPROPYLENE Aceso® PPM R020** (batch 16P2224 – 2016) was conducted to evaluate the potential for cytotoxicity. This study (ref. nr 17-B0093-N1 – dated on January 12, 2017) entitled 'qualitative MEM-elution: Dye Exclusion' according to "ISO 10993-5, 2009: Biological Evaluation of Medical

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CERTIFICATE N° 22-ARP-C-0005

Feluy, February 1, 2022

POLYPROPYLENE Aceso ® PPM R020 grade as produced in Europe (Lavera site)

Devices –Part 5: Tests for In vitro Cytotoxicity” and “USP 39 NF 34, 2016: < 87> Biological reactivity test, in vitro”. Under the conditions of this test, the extract of the test item is considered non-cytotoxic

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.

The Companies within TotalEnergies 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 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

Issued by an electronic system

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CERTIFICATE N° 22-ARP-C-0005

Feluy, February 1, 2022

POLYPROPYLENE Aceso ® PPM R020 grade as produced in Europe (Lavera site)

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.

TotalEnergies One Tech Belgium, Regulatory Affairs

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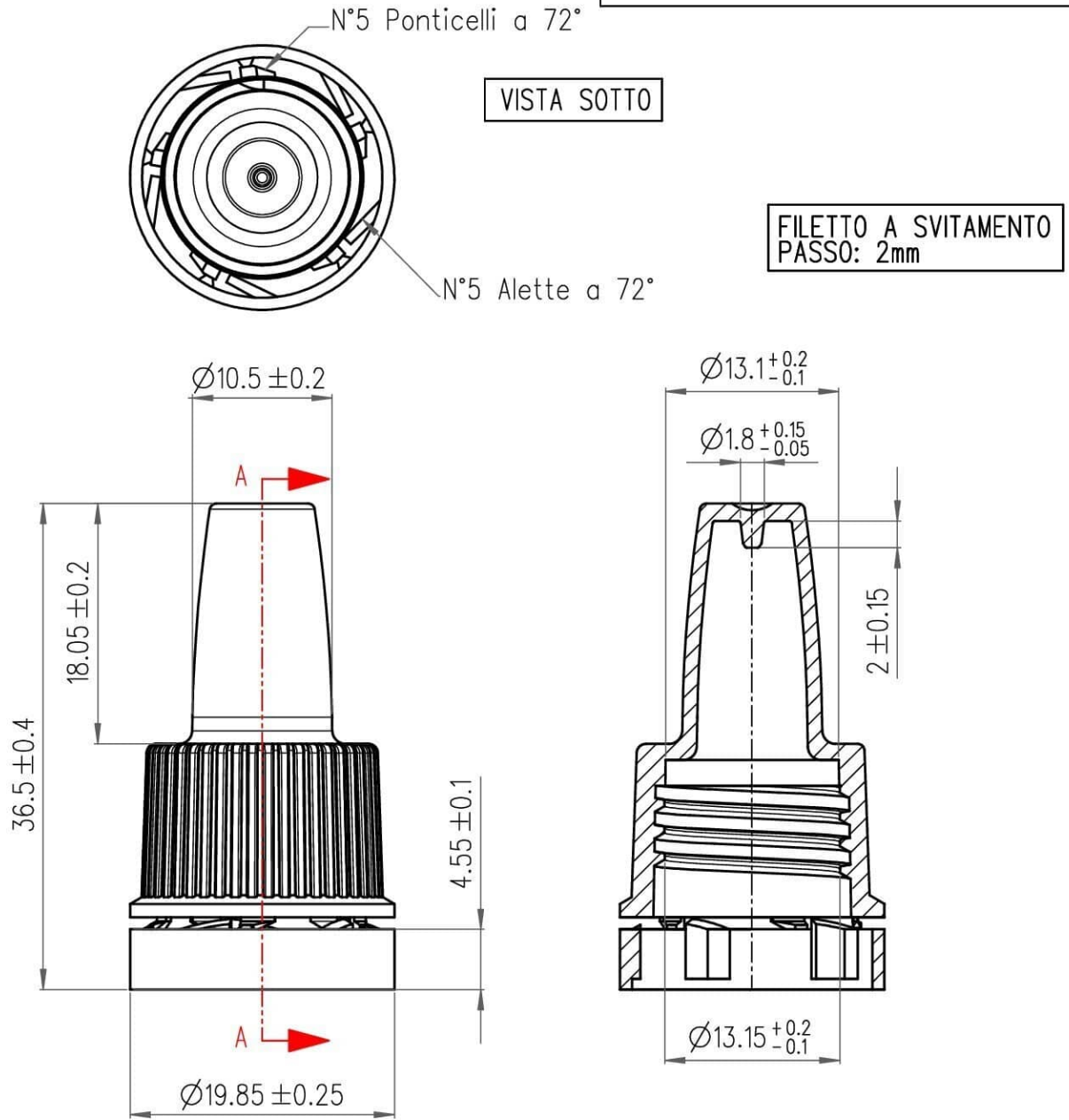
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Rv.	Varianti	Data	Firma

Edizione	I	Data	24/01/2017
Reporto	TP	Firma UT	
Disegnatore	Muscato	Visto CQ	

Rv.	Varianti	Data	Firma

ATTENZIONE : Modificare esclusivamente con C.A.D.



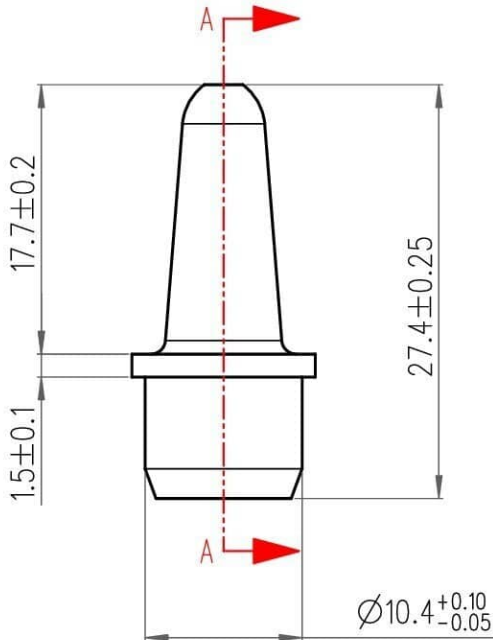
Unità di misura SI: mm	Tolleranze : dove non siano diversamente specificate +/- _____ / _____			A 4
	descrizione	peso g:	st.pilota n.	st.di produzione n.
		2 ± 0.15	/	TP/1346/B
	CAPSULA SIGILLO	materiale PP Grado 18 - 20	macchina /	scala 2 : 1
		data 24/01/2017	disegno n. 07/1674 Rv0	fg. n. 1/1

ATTENZIONE : Modificare esclusivamente con C.A.D.

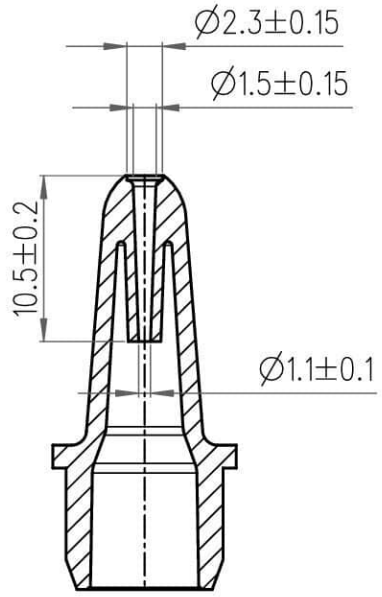
Rv.	Varianti	Data	Firma

Edizione	I	Data	19/06/2024
Reparto	TP	Firma UT	
Disegnatore	Muscato	Visto CQ	

Rv.	Varianti	Data	Firma



Sezioni A-A



VISTA SOPRA

Unita' di misura SI: mm	Tolleranze : dove non siano diversamente specificate +/- <u> </u> / <u> </u> A 4		
	descrizione	peso g:	st.pilota n.
		0.75 ± 0.1	/
	CONTAGOCCE	materiale	macchina
		PP 5 Grado 5 - 8,5	/
		st.di produzione n.	scala
		TP/1384	2 : 1
		disegno n.	fg. n.
		02/1993 Rv0	1/1



Polypropylene Bormed™ HF840MO

STATEMENT ON CHEMICALS, REGULATIONS AND STANDARDS

We certify that during manufacturing of this product we do not use or intentionally add any of the chemicals restricted by the following regulations and standards and their subsequent amendments in amounts which exceed the applicable limits.

- **Annex XVII** of the REACH Regulation **1907/2006/EC** - Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles
- **Annex XIV** of the REACH Regulation **1907/2006/EC** - List of substances subject to authorisation
- Model Toxics in Packaging Legislation, February 2021
Directive **94/62/EC** (Packaging and packaging waste - PPW) and related **EN13428** and **CR13695** - Sum of Cd, Cr(VI), Hg and Pb < 100 ppm
- Directive **2000/53/EC** (End of life vehicles - ELV) - Cr(VI), Hg and Pb < 0.1 wt%, Cd < 0.01 wt%
- Directive **2011/65/EU** (Restriction of the use of certain Hazardous Substances in electrical and electronic equipment - RoHS) and all other RoHS legislations worldwide that restrict some or all of the following substances - Pb, Hg, Cr(VI), PBB, PBDE, DEHP, BBP, DBP, DIBP < 0.1 wt%, Cd < 0.01 wt%
- Directive **2012/19/EU** (Waste Electrical & Electronic Equipment - WEEE) - Annex VII - No ingredients used which require selective waste treatment
- **Proposition 65** list of chemicals known to the State of California to cause cancer or reproductive toxicity - no warning labels are required for this product
- Regulation **1005/2009/EC** (Substances that deplete the ozone layer)
- **US Clean Air Act**, Title VI, Classes I and II (EPA Final Rule; Federal Register 8136, 11.2.1993) on substances that deplete the ozone layer
- Regulation (EU) **2019/1021** on persistent organic pollutants (POPs), repealing 850/2004/EC
- Regulation **1169/2011/EU** - Annex II (allergens)
- Food Allergen Labelling and Consumer Protection Act of 2004 (FALCPA) - Major food allergens
- Global Automotive Declarable Substance List (**GADSL**)
- No use of prohibited or declarable substances above threshold limits
- Swiss **SR 814.018** (Verordnung über die Lenkungsabgabe auf flüchtigen organischen Verbindungen - VOCV) - VOC's according to Annexes 1 & 2 < 3 wt%
- Regulation **1223/2009/EC** (cosmetic products) - prohibited and restricted substances
- European Standard **EN 71-3:2019** "Safety of Toys", Part 3: "Migration of certain elements" - Migration below limits for toy material category III in Table 2, and **EN 71-9:2005+A1:2007** "Organic chemical compounds - Requirements" (Tables 2 A-I).
- Directive **2009/48/EC** (safety of toys)
- Japanese CSCL; Class I or II Specified Chemical Substances
- Japanese PRTR law; Class I or Class II Designated Chemical Substances

Bormed is a trademark of the Borealis group.

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Polypropylene

Bormed HF840MO

Regarding classification of the above product according to REGULATION (EC) No 1272/2008 and its subsequent amendments, reference is made in the SDS/PSIS for the above product.

We also certify that during the manufacturing of the above product we do not use or intentionally incorporate into it any of the following materials:

Acrylamide	Glycol ethers (e.g. EGME, EGMEA, EGEE, EGEEA)
Aromatic Amines (restricted in Regulation 1907/2006/EC, Annex XVII)	Glyoxal
Artificial Musks	Halogenated organic compounds
Asbestos	Mechanically recycled materials
Azocolorants (restricted in Regulation 1907/2006/EC, Annex XVII)	Melamine, Cyanuric acid
Azodicarbonamide, semicarbazide	MOAH (mineral oil aromatic hydrocarbons)
Benzophenones (e.g. 4-MBP, 4-HBP, 2,2'-Dimethoxy-2-phenylacetophenone)	Nanomaterials (>50% of particles <100 nm)
Biocides (Pesti-, Herbi-, Insecti-, Fungi-, Bactericides)	Natural rubbers, Latex
Bisphenols and their compounds (e.g. NOGE, BFDGE, BADGE)	Nitrosamines, Nitrates, Nitrites
CFC, HCFC	Octyl- and Nonylphenols and Octyl- or Nonylphenoethoxylates; TNPP
CMR substances Categories 1A, 1B according to Regulation 1272/2008/EC	Organotin compounds
Colophony (rosin)	Oxo-degradable additives
4,4'- Diaminodiphenylmethane (MDA)	Parabens
Di-2-ethyl-hexyl maleate (DEHM)	PBT and vPvB substances according to EC Regulation No.1907/2006 (REACH)
Dimethylfumarate (DMF), Dibutylfumarate	PFAS (e.g. PFOA, PFOS)
1,4-Dioxane	Phthalates
Elements: Antimony, Arsenic, Beryllium, Bismuth, Cobalt, Gold, Indium, Lanthanites, Nickel, Palladium, Selenium, Silver, Tellurium, Thorium, Tin, Tantalum, Tungsten	Plasticisers (e.g. Adipates, ESBO, Phthalates)
Heavy metals: Cadmium, Chromium (VI), Lead, Mercury	Polychlorinated Bi-, Terphenyls and Naphthalenes
Endocrine disruptors: Category 1 substances in the European Commission EDS database or substances identified as ED at EU level	Polychlorinated dibenzodioxins and dibenzofurans
2-Ethylhexanoic acid, Ethoxyquin, ITX, Thiurams	Polycyclic aromatic hydrocarbons (PAH) as restricted in Regulation 1907/2006/EC, Annex XVII
Flame retardants (halogenated or phosphorus based)	Quaternary ammonium compounds
Formaldehyde	Radioactive substances
Fragrances	Silicones (polysiloxanes)
Furfural	Styrene, Polystyrene
	SVHC on "Candidate List of Substances of Very High Concern for Authorisation"
	Thiuram mix
	UV-hardeners (e.g. ITX, Titanyl-acetylacetone)
	Vinylchloride, Vinylidenechloride, PVC, CPVC or PVDC



Polypropylene Bormed HF840MO

The substances used in the manufacturing of the above product, and if applicable the basic polymer(s), are listed in the following chemical inventories:

Australia/AIICS
Canada/DSL
China/IECSC
Europe/EINECS or ELINCS or NLP
Japan/ENCS and ISHL
Korea/KECL
New Zealand/NZIoC
Philippines/PICCS
Taiwan/TCSI
USA/TSCA (all relevant ingredients designated as active)

Prepared by Borealis, Group Product Stewardship / Esa Arola

Disclaimer

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication; however we do not assume any liability whatsoever for the accuracy and completeness of such information.

Borealis makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.

It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

No liability can be accepted in respect of the use of Borealis' products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.