

Polypropylene

Bormed™ DM55pharm-11

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
- **CONEG**: 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 71-3:2021** "Safety of Toys", Part 3: "Migration of certain elements" - Migration below limits for toy material category III in Table 2, and **EN 71-9:2019+A1:2021** "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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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	Fragrances
Aromatic Amines (restricted in Regulation 1907/2006/EC, Annex XVII)	Furfural
Artificial Musk	Glycol ethers (e.g. EGME, EGMEA, EGEE, EGEEA)
Asbestos	Glyoxal
Azocolorants (restricted in Regulation 1907/2006/EC, Annex XVII)	Halogenated organic compounds
Azodicarbonamide, semicarbazide	Mechanically recycled materials
Benzophenones (e.g. 4-MBP, 4-HBP, 2,2'-Dimethoxy-2-phenylacetophenone)	Melamine, Cyanuric acid
BHA or BHT	MOAH (mineral oil aromatic hydrocarbons)
Biocides (Pesti-, Herbi-, Insecti-, Fungi-, Bactericides)	Nanomaterials (>50% of particles <100 nm)
Bisphenols and their compounds (e.g. NOGE, BFDGE, BADGE)	Natural rubbers, Latex
CFC, HCFC	Nitrosamines, Nitrates, Nitrites
CMR substances Categories 1A, 1B according to Regulation 1272/2008/EC	Octyl- and Nonylphenols and Octyl- or Nonylphenoethoxylates; TNPP
Colophony (rosin)	Organotin compounds
4,4'- Diaminodiphenylmethane (MDA)	Oxo-degradable additives
Di-2-ethyl-hexyl maleate (DEHM)	Parabens
Dimethylfumarate (DMF), Dibutylfumarate	PBT and vPvB substances according to EC Regulation No.1907/2006 (REACH)
1,4-Dioxane	PFAS (e.g. PFOA, PFOS)
Elements: Antimony, Arsenic, Beryllium, Bismuth, Cobalt, Gold, Indium, Lanthanites, Nickel, Palladium, Selenium, Silver, Tellurium, Thorium, Tin, Tantalum, Tungsten	Phthalates
Heavy metals: Cadmium, Chromium (VI), Lead, Mercury	Plasticisers (e.g. Adipates, ESBO, Phthalates)
Endocrine disruptors: Category 1 substances in the European Commission EDS database or substances identified as ED at EU level	Polychlorinated Bi-, Terphenyls and Naphthalenes
2-Ethylhexanoic acid, Ethoxyquin, ITX, Thiurams	Polychlorinated dibenzodioxins and dibenzofurans
Flame retardants (halogenated or phosphorus based)	Polycyclic aromatic hydrocarbons (PAH) as restricted in Regulation 1907/2006/EC, Annex XVII
Formaldehyde	Quaternary ammonium compounds
	Radioactive substances
	Silicones (polysiloxanes)
	Styrene, Polystyrene
	SVHC on "Candidate List of Substances of Very High Concern for Authorisation"
	Thiuram mix
	Tri-tert-butylphenol
	UV-hardeners (e.g. ITX, Titanyl-acetylacetone)
	Vinylchloride, Vinylidenechloride, PVC, CPVC or PVDC

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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

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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.