

# Compliance Summary

## BioBarb, FlatBioEndCap, BioEndCap and Bio Y



Biopure works closely with our raw materials suppliers and can state that for the manufacture of our fluid path polypropylene components, 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 (superseding Directive 76/769/EEC) – Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles
- CONEG “Toxics in Packaging” Model Legislation, rev. 2008 Directive 94/62/EC (Packaging and packaging waste - PPW) and related EN13428 and CR13695 – Sum of Cd, Cr, 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) – Cr(VI), Hg, Pb, PBB, PBDE, DEHP, BBP, DBP, DIBP < 0.1 wt%, Cd < 0.01 wt%
- Directive 2012/19/EU (Waste Electrical & Electronic Equipment – WEEE, repealing 2002/96/EC) – Annex VII – No ingredients used which require selective waste treatment (As, Hg, PCB, PCT, CFC, HCFC, HFC, brominated FR)
- Chemicals List of Proposition 65 of the State of California and subsequent amendments, as known to the State of California to cause cancer or reproductive toxicity
- Regulation 1005/2009/EC (Substances that deplete the ozone layer) – Prohibition of CFC’s, HCFC’s, Halons, CCl<sub>4</sub>, Trichloroethane, HBFC’s
- 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 850/2004/EC on persistent organic pollutants (POPs)
- Regulation 1169/2011/EU – Annex II (allergens) repealing Annex IIIa of Directives 2003/89/EC, 2006/142/EC, 2007/68/EC
- Global Automotive Declarable Substance List (GADSL) and VDA232-101 – 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 “on cosmetic products” – prohibited and restricted substances
- Directive 2009/48/EC (safety of toys)
- European Standard EN 71-3:2013+A1:2014 “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).
- Japanese CSCL; Class I and II Specified Chemical Substances
- Japanese PRTR law; Class I or Class II Designated Chemical Substances

Additionally, during the manufacturing of the aforementioned fluidpath components we do not use or intentionally incorporate any of the following materials:

Acrylamide	PBT and vPvB substances according to EC Regulation No.1907/2006 (REACH)
Antimony, Arsenic, Beryllium, Bismuth	PFOA, PFOS
Aromatic Amines (restricted in Regulation 1907/2006/EC, Annex XVII),	Phthalates
Artificial Musks	Plasticisers (e.g. Adipates, ESBO, Phthalates)
Asbestos	Polychlorinated Bi-, Terphenyls and Naphthalenes
Azocolorants (restricted in Regulation 1907/2006/EC, Annex XVII) Azodicarbonamide, semicarbazide	Polychlorinated dibenzodioxins and dibenzofurans
Benzophenones (e.g. 4-MBP, 4-HBP, 2,2'-Dimethoxy-2-phenylacetophenone)	Polycyclic aromatic hydrocarbons (PAH)
Biocides (Pesti-, Herbi-, Insecti-, Fungi-, Bactericides),	Radioactive substances
Bisphenols and their compounds (e.g. NOGE, BFDGE, BADGE)	Recycled materials
Cadmium, Chromium (VI), Lead, Mercury CFC, HCFC CMR substances Categories 1A, 1B according to Regulation 1272/2008/EC	Selenium, Silver, Tellurium, Thorium
Colophony (rosin)	Styrene, Polystyrene
4,4'- Diaminodiphenylmethane (MDA)	SVHC on "Candidate List of Substances of Very High Concern for Authorisation"
Di-2-ethyl-hexyl maleate (DEHM)	Thiuram mix
Dimethylfumarate (DMF), Dibutylfumarate	Tin, Gold, Tantalum, Tungsten
1,4-Dioxane	UV-hardeners (e.g. ITX, Titanyl-acetylacetone)
Endocrine disruptors: Category 1 substances in the European Commission EDS database	Vinylchloride, Vinylidenechloride, PVC or PVDC
2-Ethylhexanoic acid, Ethoxyquin, ITX, Thiurams	
Flame retardants (halogenated or phosphorus based)	
Formaldehyde	
Fragrances	

Glycol ethers (EGME, EGMEA, EGEE, EGEEA)	
Glyoxal	
Gold, Indium, Nickel, Palladium	
Halogenated organic compounds,	
Melamine, Cyanuric acid	
MOAH (mineral oil aromatic hydrocarbons)	
Nanomaterials (>50% of particles <100 nm)	
Natural rubbers, Latex	
Nitrosamines, Nitrates, Nitrites	
Octyl- and Nonylphenols and Octyl- or Nonylphenoethoxylates; TNPP	
Organotin compounds	
Parabens	

As confirmed by our raw material supplier, the raw material used in the manufacturing of the aforementioned products, and if applicable the basic polymer(s), are listed in the following chemical inventories:

Australia/AICS Canada/DSL China/IECSC Europe/EINECS or ELINCS or NLP Japan/ENCS Korea/KECL New Zealand/NZIoC Philippines/PICCS Taiwan/TCSI USA/TSCA



## Fluid Technology Group

*Disclaimer: This information in this document has been provided for the purpose of detailing the regulatory compliance statements associated with the raw materials, processing and final product. Unless otherwise stated, Watson-Marlow Fluid Technology Group (WMFTG) has not performed analytical determination to establish the substances levels but has relied on the information provided by raw material suppliers. It is the responsibility of the end user to determine the suitability of the product and associated information for their intended applications. This information was correct on the date of publication. For further updates, please contact your local WMFTG representative.*