



BioFlex® Compliance Data Sheet

Material Specification & Regulatory Compliance Documentation

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Applies To: All BioFlex® branded products

1. GENERAL DATA

The material used in the production of BioFlex® products is a specially modified polymer with high melt flow intended for use in medical and medical-related articles. This polymer is modified with an internal lubricant for products requiring a low surface friction.

BioFlex® is characterised by its transparency, high gloss, controlled low friction, good stiffness and good impact strength at ambient temperature. The material can be sterilised with ethylene oxide or steam and has an excellent chemical resistance and good physical properties.

2. STATEMENT ON COMPLIANCE TO REGULATIONS ON MEDICAL USE

We confirm that the material used in the fabrication of BioFlex® products in its pure form (without additives) fulfils the requirements on materials used for articles or components of articles intended for medical use as described in:

- **Council of Europe European Pharmacopoeia**, 5th Edition (2004), and supplement 5.4 (04/2006), Monograph 3.2.2
- **United States Pharmacopoeia XXIV** – Class VI Tests (Biocompatibility). The product has been assigned a FDA Drug Master File.
- **ISO 10993** – The material has successfully passed the biological tests for external communicating devices for indirect blood contact for a prolonged period.

SAFETY DATA SHEET

1. Identification of the Manufacturer

Poli International Co., Ltd, Ratchaburi, Thailand

2. Information on Ingredients

The material used for BioFlex® products contains no substance classified as hazardous, in concentrations which should be taken into account according to EC directives.

3. Hazards Identification

The product is not classified as a dangerous preparation (EC).

4. First Aid Measures

No specific instruction needed.

5. Fire Fighting Measures

Extinguishing agents: Water in spread jet, dry chemicals, foam or carbon dioxide should be used. The product burns, but is not classified as flammable. Principal toxicant in the smoke is carbon monoxide.

6. Accidental Release Measures

All spills of BioFlex® products must be removed immediately to prevent slipping accidents.

7. Handling and Storage

To be stored in a clean and dry condition at ambient temperature.

9. Physical and Chemical Properties

Appearance:	Finished product in the shape of balls or bars/discs
Odour:	Odourless
Transparency:	Transparent
Ignition temperature:	>300°C
Density:	0.9–1.0 g/cm ³
Solubility:	Insoluble in water
Sterilisation:	Can be sterilised by steam

10. Stability and Reactivity

The product is a stable thermoplastic, with no chemical reactivity.

11. Toxicological Information

The product is not dangerous.

12. Ecological Information

The product is not considered dangerous for the environment.

13. Disposal Considerations

Reuse or recycle if not contaminated. The product may be safely used as fuel or landfill. Proper combustion does not require any special flue gas control. No leakage is generated in landfills. Check with local regulations.

14. Transport Information

The product is not regulated by ADR/RiD, IMDG or IATA.

15. Other Information

Application: Finished product to be used in the cosmetic body jewellery industry.

STATEMENT ON CHEMICALS AND REGULATORY COMPLIANCE

We certify that with respect to the regulations and norms listed herein, we do not during manufacturing of the above product use or intentionally incorporate into it any chemicals regulated by said regulations and norms, in amounts which exceed the applicable limits.

Applicable Regulations

- EU Directive 76/768/EEC (Cosmetic Products)
- EU Directive 76/769/EEC (Marketing of dangerous substances)
- EU Directive 94/62/EC, 2004/12/EC, 2005/20/EC (Packaging Waste)
- EU Directive 2000/53/EC (End-of-Life Vehicles)
- EU Directive 2002/95/EC (RoHS)
- EU Directive 2005/1895/EC (Epoxy derivatives)
- California Proposition 65
- EC Regulation No. 2037/2000 (Ozone depleting substances)
- US Clean Air Act, Title VI
- Swedish PRIO Database
- CONEG Toxics in Packaging
- Regulation (EC) No 1907/2006 (REACH)

We also certify that we do not use or intentionally incorporate any of the following materials:

- Asbestos
- Azo colourants or dyestuffs that release any of the amines listed in Directive 2002/61/EC
- Cadmium and cadmium compounds
- Chlorinated paraffins (C10–C13)
- Formaldehyde
- Hexavalent chromium (Cr VI) compounds
- Lead and lead compounds
- Mercury and mercury compounds
- Nickel (with respect to prolonged skin contact)
- Organotin compounds (TBT, DBT, DOT, TPT)
- Pentachlorophenol (PCP)
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ethers (PBDE)
- Polychlorinated biphenyls (PCB)
- Polychlorinated naphthalenes (PCN, >3 chlorine atoms)

Note on Phthalates: The use of DEP, DEHP or DIBP in the catalyst system may result in traces of these phthalates in the product, typically in concentrations below 1 ppm.

Chemical Inventory Listing

The material used in BioFlex® products is listed or exempt from listing on the following chemical inventories: EINECS/ELINCS (EU), TSCA (USA), DSL (Canada), AICS (Australia), ENCS (Japan), ECL (South Korea), IECSC (China).

STATEMENT ON COMPLIANCE TO FOOD CONTACT REGULATIONS

The material used in BioFlex® products complies with the following food contact regulations, confirming its suitability for use in contact with foodstuffs and, by extension, its safety for prolonged skin and body contact:

Country / Region	Regulation / Standard
Austria	Kunststoffverordnung, BGBl. Nr. 476/2003
Belgium	Arrêté Royal (KB/AR) 11.05.1992
Czech Republic	Vyhláška 38/2001
Denmark	Bekendtgørelse Nr. 1065 af 04.11.2005
EU	Commission Regulation (EU) No 10/2011 (Plastic Materials)
EU	Regulation (EC) No 1935/2004 (Framework Regulation)
Finland	KTMp Nr. 268/1992
France	Bulletin Officiel DGCCRF, Brochure 1227 (Matières Plastiques)
Germany	BfR Recommendation (Empfehlung) XXI (Commodities Ordinance)
Italy	Decreto Ministeriale 21.03.1973 (Disciplina degli imballaggi)
Japan	JHPA Standards (Japan Hygienic PVC Association)
Netherlands	Warenwetregeling Verpakkingen- en gebruiksartikelenbesluit
Norway	Forskrift om materialer i kontakt med næringsmidler
Spain	Real Decreto 866/2008
Sweden	SLV Kungörelse om material avsedda att komma i kontakt med livsmedel
Switzerland	Eidgenössische Verordnung über Bedarfsgegenstände (SR 817.023.21)
United Kingdom	The Materials and Articles in Contact with Food Regulations 2012
USA	FDA 21 CFR 170-199 (Food Contact Substances)

Disclaimer

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This compliance data sheet is issued by Poli International Co., Ltd and supersedes all previous versions. The information herein applies specifically to BioFlex® products as manufactured by Poli International Co., Ltd. Any modification or reformulation of the product will require revalidation of the data presented in this document.



Patrick Poli

Director

Poli International Co., Ltd

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