

BioFLEX

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 in ambient temperature. The material can be sterilised with ethylene oxide or steam and has an excellent chemical resistance and good physical properties.

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.

USA The product has passed the Class VI tests (Bio-compatibility) of the United States Pharmacopoeia XXIV and has been assigned a FDA Drug Master File.

Additional Information: The material has successfully passed the biological tests according to ISO 10993 – external communicating devices for indirect blood contact for a prolonged period.

BioFLEX

SAFETY DATA SHEET

1. Identification of the Manufacturer

Europierce Worldwide Ltd

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 spill of BioFlex Products must be removed immediately to prevent slipping accidents.

7. Handling and storage

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

9. Physical and chemical properties

Appearance: finished product in the shape of balls or bars/discs, odourless, transparent

Ignition temperature: > 300 °C Density: 0.9 – 1.0 g/cm³ Solubility: insoluble in water.

The Product can be sterilized 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.

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STATEMENT ON CHEMICALS AND CERTAIN REGULATIONS AND NORMS

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.

- EU Directive 76/768/EEC and subsequent amendments relating to cosmetic products
- EU Directive 76/769/EEC and subsequent amendments, relating to the marketing and use of certain dangerous substances and preparations.
- EU Directive 94/62/EC, 2004/12/EC and 2005/20/EC on packaging and packaging waste (PPW)
- EU Directive 2000/53/EC and subsequent amendments on end-of-life vehicles (ELV)
- EU Directive 2002/95/EC and subsequent amendments on certain hazardous substances in electrical and electronic equipment (ROHS)
- EU Directive 2005/1895/EC on the use of certain epoxy derivatives
- Chemicals List of Proposition 65 of the State of California and subsequent amendments, as known to the State of California to cause cancer
- EC Regulation No.2037/2000 and subsequent amendments on Ozone layer depleting substances
- US Clean Air Act, Title VI, Classes I and I (EPA Final Rule; Federal Register 8136, 11.2.1993) on substances that deplete the ozone layer
- Swedish National Chemical Inspectorate's Observation List (1996) and List of Restricted Chemical Substances in Sweden (1996), as amended in their PRIO Database
- CONEG "Toxics in Packaging" Model Legislation, rev.2004

The following chemicals are examples of chemicals regulated by the above regulations and norms:

Asbestos, Polybrominated biphenyls (PBB), Arsenic compounds, Polybrominated diphenyl ethers (PBDE), Azo colorants (restricted), Chlorinated hydrocarbons, Bisphenol-A, BADGE, BFDGE, NOGE, Polychlorinated biphenyls (PCB), Cadmium, Chromium (VI), Lead, Mercury Formaldehyde, CFC, HCFC Pentachlorophenol, Dioxines and furanes Etc.

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

Acrylamide 2-EHA, Ethoxyquin, ITX, Thiuram, Alergenes as described in Annex Ia of EU-Genetically modified materials (GMO) Directive 2003/89/EC Natural rubbers, Latex, Alkyltin compounds, Octyl- or Nonylphenols or phenoethoxylates Antimony, Beryllium, Nickel, Selenium Plasticisers (e.g. Adipates, ESBO), Aromatic Amines, Polycyclic aromatic hydrocarbons (PAH), Artificial Musks, Vinylchloride or PVC, BHA or BHT, Biocides (e.g. Triclosan), Brominated flame retardants.

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 1ppm.

Further we certify that the substances used in the manufacturing of the above product are listed in the following chemical inventories: Europe/EINECS or ELINCS, USA/TSCA, Canada/DSL or NDSL, Australia/AICS, Korea/KECI, Japan/ENCS and the Philippines/PICCS.

Regarding classification of the above product according to the EU Directive 99/45/EC, which refers to Directive 67/548/EEC and subsequent amendments, reference is made in the SDS for the above product.

BioFLEX

STATEMENT ON COMPLIANCE TO FOOD CONTACT REGULATIONS

We confirm that this product fulfils the requirements on materials used for articles or components of articles intended to come into contact with food as described in:

Austria	Kunststoffverordnung Nr. 476/2003 und Änderung Nr. 242/2005
Belgium	Koninklijk Besluit- Arrêté Royal, du 11 mai 1992 et 10 décembre 2002 (M.B. 20/2/2003)
The Czech Republic	Vyhlasaka Ministerstva zdravotnictvi c.38/2001 Sb. a c.186/2003 Sb.
Denmark	Fødevare direktoratets Bekendtgørelse nr. 802 (19.08.2005)
EU Regulation	(EC) No 1935/2004 and Commission Directives 2002/72/EC, 2004/1/EC and 2004/19/EC
Finland	KTM Asetukset 953/2002 ja 181/2005
France	Repression des Fraudes (2002), No 1227, et Arrêté du 2 janvier 2003 et Arrêté du 29 mars 2005
Germany	Bedarfsgegenständeverordnung 10. April 1992, Änderungen 11. April 1994, 17. April 1997, 21. Dezember 2000 und 7. April 2003, und BfR- Empfehlungen (2005)
Great Britain	Statutory Instruments, 1998 No. 1376, 2000 No. 3162, 2002 No. 2364 and No. 3008, 2004 No. 3113, and 2005 No. 325 and BPF-BIBRA (1995),
Italy	Decreto Ministeriale 26.4.1993 N. 220, 28.10.1994 N. 735, 24.9.1996 N. 572, 6.2.197 N. 91, 22.7.1998 N. 338, 15.6.2000 N. 210, 28.3.2003 N. 123, e Decreto Ministeriale 21.3.1973, N 104, Allegato I, Sezione 1, Parte B
The Netherlands	Warenwet (2003), Hoofdstuk 1, Kunststoffen
Norway	Sosial- og helse departementets forskrift 1993-12-21-1381
Portugal	Decreto-Lei.º 4/2003 de 10 de Janeiro de 2003
Spain	Real Decretos 2207/1994, 442/2001, 118/2003, Orden ministerial SCO/983/2003 y ANAIP (1982), Anexo 1, Anexo 4
Sweden	Statens Livsmedelsverks kungörelse LIVSFS 2003:2, ändr. LIVSFS 2004:31 och ändr. IVSFS 2005:14
Switzerland	Verordnung der EDI über Material en und Gegenstände aus Kunststoff 26.6.1995, Änderungen 30.1.1998 und 15.12.2003
USA	FDA, CFR, Title 21 (2005), 177.1520 (a)(3)(i)(c)(1), (b) and (c) 3.1a Olefin polymers

Migration limits Used monomers and additives are not regulated with specific migration limits. Substances authorised as food additives are not present in the end product in such quantities that migration to foodstuffs could exceed the limits set in the relevant food legislation or have a technological function in the final food.

Disclaimer

The information contained herein is to our knowledge accurate and reliable as of the date of publication. It is the customer's responsibility to inspect and test our products in order to satisfy himself as to the suitability of the products for the customer's particular purpose. The customer is also responsible for the appropriate, safe and legal use, processing and handling of our products. Europierce Worldwide Ltd shall not be under a duty to notify you of any changes to the regulations.

Insofar as products supplied by Europierce Worldwide Ltd or its subsidiary companies are used in conjunction with third party materials, it is the responsibility of the customer to obtain all necessary information relating to the third party materials and ensure that Europierce Worldwide Ltd's products when used together with these materials are suitable for the customer's particular purpose. No liability can be accepted in respect of the use of Europierce Worldwide Ltd's 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.