Corpus Piercing

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
Dongguan Sensagem Technology Co., 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 ºC 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.2037/2000and subsequent amendments on Ozone layer depleting substances
• US Clean Air Act, Title VI, Classes I and I(EPA Final Rule; Federal Register8136,11.2.1993) 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, Polychlorinatedbiphenyls (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:

Acrylamide2-EHA, Ethoxyquin,ITX, Thiuram, Alergenes as described in Annex Ia of EU-Genetically modified materials (GMO) Directive2003/89/ECNatural rubbers, Latex, Alkyltin compounds, Octyl-or Nonylphenols or-phenolethoxylates Antimony, Berylium, Nickel, Selenium Plasticisers (e.g. Adipates, ESBO), Aromatic Amines, Polycyclic aromatic hydrocarbons(PAH), Articficial 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 Directive99/45/EC, which refers to Directive 67/548/EEC and subsequent amendments, reference is made in the SDS for the above product.

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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	KunststofverordnungNr. 476/2003 und ÄnderungNr. 242/2005
Belgium	Koninlijk Besluit- Arêté Royal, du11 mai 1992et10 décembre2002 (M.B. 20/2/2003)
The Czech Republic	Vyhlaska Ministerstva zdravotnictvi c.38/2001Sb.a c.186/2003Sb.
Denmark	Fødevare direktoratets Bekentgørelse nr. 802(19.08.2005)
EU Regulation	(EC)No1935/2004and Commission Directives 2002/72/EC, 2004/1/EC and2004/19/EC
Finland	KTM Asetukset 953/2002ja 181/2005
France	Repression des Fraudes(2002),No1227,et Arêté du 2janvier2003 et Arêté du 29 mars 2005
Germany	Bedarfgegenständeverordnung 10.April 1992, Änderungen 11.April 1994, 17. April1997,21.Dezember 2000 und7.April 2003, und BfR- Empfehlungen (2005)
Great Britain	Statutory Instruments, 1998No. 1376, 2000 No.3162,2002 No.2364 and No.3008,2004 No.3113,and 2005No. 325 and BPF-BIBRA (1995),
Italy	Decreti Ministeriale26.4.1993N. 220, 28.10.1994N. 735, 24.9.1996N. 572, 6.2.197N. 91, 22.7.1998N. 338, 15.6.2000N. 210, 28.3.2003N. 123, e Decreto Ministeriale 21.3.1973, N 104, Alegato I, Sezione 1, Parte B
The Netherlands	Warenwet (2003), Hoofdstuk 1, Kunststofen
Norway	Sosial- oghelse departmentets forskrift 1993-12-21-1381
Portugal	Decreto-Lein.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. IVSFS2005:14
Switzerland	Verordnung der EDI über Material en und Gegenstände aus Kunststof 26.6.1995, Änderungen30.1.1998 und15.12.2003
USA	FDA, CFR, Title 21(2005), 177.1520 (a)(3)(i)(c)(1), (b)and(c)3.1aOlefin 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. Sensagem shall not be under a duty to notify you of any changes to the regulations.

Insofar as products supplied by Sensagem 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 Sensagem ' 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 Se'nsagem'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.