Regulatory Data Sheet
meliflex M8035
(Development code: R2920B)

Product description
This is to confirm that referenced product is thermoplastic polyolefin compound based on polyethylene.

The product is produced under Good Manufacturing Practice (EU Commission Regulation No 2023/2006) and as per MELITEK's dedicated medical service concept that included production on dedicated and segregated lines, extensive line clearance, no change in formulation, change control management and traceability for 13 years.

Manufacturing Facility Certifications
MELITEK is certified to the ISO 9001:2008 Quality standard. Certificate is available upon request.

REACH
For information on MELITEK and the European Union regulation for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) see MELITEK website, www.melitek.com/reach.

This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list that was current as of the effective date of this regulatory datasheet. Current information on SVHC can be found at the ECHA website.
http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp.

US FDA Food Contact Status
When used unmodified and processed in accordance with Good Manufacturing Practices (GMP) for food contact applications, this product will comply with the U.S. Food and Drug Administration's food additive regulation at 21 CFR 177.1520(c) 3.2c. This product may be used to produce articles or components of articles used in contact with food to all food types described in Table 1 and Conditions of Use C-H described in Table 2 of U.S. FDA's regulation at 21 CFR § 176.170(c).

This product complies with the requirements of FDA regulation 21CFR 178.2010 (Antioxidants and/or stabilizers for polymers) or applicable Food Contact Notifications (FCN) for additives used.

European Commission Regulation (EU) No 10/2011 (Food Contact)
The composition of this product complies with the requirements for use in contact with non-fatty foodstuffs under European Commission Regulation (EU) No 10/2011, including any subsequent amendments that are in force prior to the effective date of this statement.

European Pharmacopoeia (Eur Ph)
This product is in compliance with the formulation requirements of the European Pharmacopoeia, monograph 3.1.3 (7th edition) and contains only additives listed in monograph 3.1.3.

ISO 10993-5 Elution Test, Biological Evaluation of Medical Devices
The product is non-cytotoxic and is designed to meet the requirements of the Elution Test, ISO 10993-5 Biological Evaluation of Medical Devices Part 5; Tests for In Vitro Cytotoxicity.

USP <88> USP Biological Test for Plastics, class VI
The material is designed to meet the requirements of USP class VI (USP <88> Biological Test for Plastics, Class VI-70°C).

Hartvig Jensensvej 1
DK-4840 Nr. Alslev . Denmark
Tel. +45 70 250 255
Fax +45 70 250 277
info@melitek.com
www.melitek.com

Animal Derived Components
This product contains one or more additive(s)/substance(s) synthesized from animal extracts, i.e. hydrolysis, etc. of animal fats (tallow) into fatty acids. The manufacturing process of the fatty acids includes a multi-step chemical treatment involving high temperatures, high pressures, and long residence times. These processing conditions greatly exceed the requirements as specified in Section 6.4 of the "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" (EMA/410/01 Rev. 3 – July 1, 2011), adopted by the European Commission and published in the Official Journal of the European Union March 5, 2011 (2011/C 73/01). Further, only Category 3 materials or equivalent as defined by Article 6 of European Parliament and Council Regulation (EC) No 1774/2002 are used as raw materials for the fatty acids. Thus, the tallow derivatives (irrespective of the geographical origin according to the Note for Guidance) used in the manufacturing of this product are therefore considered compliant with the EMA Note for Guidance referenced above.

Food Allergens
To the best of our knowledge, there are no raw materials, including additives that have their origin in peanuts, soybeans, milk, eggs, fish, shellfish, tree nuts, mustard, celery, sesame, and/or wheat or gluten. No sulfates or sulfites are used in the manufacturing of this material. This evaluation is based on information provided by our raw material and additive suppliers for the presence of the allergen-stimulating substances shown above. Therefore, although we believe this product to be free of the specified known allergy stimulating food substances, we cannot guarantee this.

Materials from Genetically Modified Organisms
To the best of our knowledge, there are no raw materials, including additives that have been derived from genetically modified organisms (GMO). This is based on information from our raw material suppliers. Therefore, although we believe this product to be GMO free, we cannot guarantee it at this time.

Kosher
One or more of the raw materials used in the manufacture of this product originated in whole or in part from animal sources. The animal sourced raw material(s) have been chemically altered from their original structure and have undergone significant chemical processing, and is/are therefore considered synthetic. Because of this modification and processing, kosher compliance is claimed for the above product containing the raw material(s) of animal origin.

EU Directive 2011/65/EU (RoHS)
This product complies with the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS). It is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB), or polybrominated diphenyl ethers (PBDE). EU Directive 2002/95/EC, as amended, will be repealed effective January 3, 2013.

EU Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), latest amended by EU Directive 2008/34/EC
EU Directive 2002/96/EC on WEEE: Selective treatment of the waste (Article 6.1 and Annex II). None of the substances listed in Annex II are intentionally added or used in the formulation of this product.

Heavy Metals, EU 94/62/EC and Coalition of Northeastern Governors (CONEG)
This product conforms to the Coalition of Northeastern Governors (CONEG) and the European Directive 94/62/EC, as amended, on Packaging and Packaging Waste, Article 11. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

Cosmetics Regulation (EC) No. 1223/2009
Based on the formulation of the product and information from supplies of raw materials used in the formulation, we confirm that no prohibited, restricted, or substances to be notified are intentionally used in the production of the product.

Hartvig Jensensvej 1
DK-4840 Nr. Alslev . Denmark
Tel. +45 70 250 255
Fax +45 70 250 277
info@melitek.com
www.melitek.com

EU Directive 2009/48 "Safety of Toys"
Chapter III of Annex II of the Directive regulates the chemical properties of toys. The restricted substances are CMR substances categories 1A, 1B and 2 under the CLP Regulation (EC) No 1272/2008 and allergenic fragrances. Furthermore it sets migration limits for a number of metals and organic tins.
With this statement, we confirm that the product fulfils the criteria of the Directive.

European Standard EN 71 "Safety of Toys"
This product is not manufactured or formulated with any raw materials having migration of elements exceeding the values given in Part 3 of EN71 and none of the restricted substances in Part 9 of EN71 are intentionally added to the product.

ASTM F963 - Standard Consumer Safety for Toy Safety
This product is not formulated with antimony, arsenic, barium, cadmium, chromium, mercury, lead or selenium. To the best of our knowledge, it does not contain these substances above the limits set in ASTM F 963-95, Section 4.3.5.2., Table 1.

Consumer Product Safety Improvement Act of 2008 (CPSIA)
This product is not manufactured or formulated with lead, di-(2-ethylhexyl)phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). To the best of our knowledge, it does not contain these materials above the limits set in the Consumer Product Safety Improvement Act of 2008, Title 1, Sections 101 and 108.

Canadian Environmental Protection Act Challenge Substances
This product is not intentionally manufactured or formulated with the Batch Lists of Canadian Environmental Protection Agency (CEPA) Challenge Substances released as of the effective date of this document. However, we do not analyze for these specific substances.
(http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index-eng.php)

Bisphenol A
This product is not manufactured or formulated with Bisphenol A (CAS# 80-05-7).

Natural Rubber or Latex
This product is not intentionally manufactured or formulated with natural rubber or natural latex; however, we do not analyze for these specific substances or compounds.

Phthalates
The above mentioned product is not intentionally manufactured or formulated with phthalate esters; however, we do not analyze for these specific substances or compounds.

Halogenated Flame Retardants
This product is not intentionally manufactured or formulated with halogenated or phosphorous based flame retardants; however, we do not analyze for these specific substances or compounds.

Fluorotelomers, Perfluorooctanoic acid (PFOA) and Derivatives
This product is not intentionally manufactured or formulated with Fluorotelomers, Perfluorooctanoic acid (PFOA), or Perfluorooctane sulfonate (PFOS); however, we do not analyze for these specific substances or compounds.

Residual Volatile Organic Compounds (VOC)
The residual volatiles in this product are a maximum of 1500 ppm of straight chain aliphatic hydrocarbons. Limited laboratory data has indicated that approximately 50% of the residual volatiles are emitted during processing.

Clean Air Act
This product is not manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1990, as amended (58 FR 8136).

Hartvig Jensensvej 1
DK-4840 Nr. Alslev . Denmark
Tel. +45 70 250 255
Fax +45 70 250 277
info@melitek.com
www.melitek.com

California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)
This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels which would require a warning under the statute.

Statement on Chemicals
We certify that during manufacturing of this product we do not use or intentionally add any of the chemicals restricted by the above mention regulations and standards and their subsequent amendments in amounts which exceed the applicable limits. For further clarification, we certify that this product does not intentionally contain any of the following substances:

- Acrylamide
- Alkylphenols or Alkylphenolethoxylates; TNPP
- Antimony, Arsenic, Beryllium, Bismuth
- Aromatic Amines (restricted in Regulation 1907/2006/EC, Annex XVII)
- Artificial Musks
- Asbestos
- Azocolorants (restricted in Regulation 1907/2006/EC, Annex XVII)
- Azodicarbonamide, semicarbazide
- Benzophenones (e.g. 4-MBP, 4-HBP, 2,2´-Dimethoxy-2-phenylacetophenone)
- BHA
- Biocides (Pesti-, Herbi-, Insecti-, Fungi-, Bactericides)
- Bisphenols and their compounds (e.g. NOGE, BFDGE, BADGE)
- Brominated flame retardants (e.g. PBB, PBDE)
- Cadmium, Chromium (VI), Lead, Mercury
- CFC, HCFC
- CMR substances Categories 1A, 1B according to Regulation 1272/2008/EC Colophony (rosin)
- 4,4'- Diaminodiphenylmethane (MDA)
- Di-2-ethyl-hexyl maleate (DEHM)
- Dimethylfumarate (DMF), Dibutylfumarate
- Dioxins and furans
- Endocrine disruptors: Category 1 substances in the European Commission EDS database
- 2-Ethylhexanoic acid, Ethoxyquin, ITX, Thiurams
- Formaldehyde
- Fragrances
- Furfural
- Genetically modified materials (GMO)
- Glycol ethers (EGME, EGMEA, EGEE, EGEEA)
  Glyoxal
- Gold, Indium, Nickel, Palladium
- Halogenated organic compounds
- Melamine, Cyanuric acid
- Nanomaterials (>50% of particles <100 nm)
  Natural rubbers, Latex
- Nitrosamines
- Organotin compounds
- Parabens
- PBT and vPvB substances according to EC Regulation No.1907/2006 (REACH)
- Pentachlorophenol (PCP)
- PFOA, PFOS
- Plasticisers (e.g. Adipates, ESBO, Phthalates)
- Polychlorinated Bi-, Terphenyls and Naphthalenes
- Polycyclic aromatic hydrocarbons (PAH)
- Radioactive substances
- Recycled materials
- Selenium, Silver, Tellurium, Thorium
- Styrene monomer
- SVHC on "Candidate List of Substances of Very High Concern for Authorisation"
- Thiuram mix
- Tin, Gold, Tantalum, Tungsten
- UV-hardeners (e.g. ITX, Titanyl-acetylacetone)
- Vinylchloride, Vinylidenechloride, PVC or PVDC

As above mentioned product is not intentionally manufactured or formulated with above listed chemicals;, we do not analyze for these specific substances or compounds.

If you require additional information, please do not hesitate to contact us.

Best regards,
MELITEK

Jesper Laursen
Business Director

Nr. Alslev, Denmark on November 2015

Hartvig Jensensvej 1
DK-4840 Nr. Alslev . Denmark
Tel. +45 70 250 255
Fax +45 70 250 277
info@melitek.com
www.melitek.com

IMPORTANT

Above regulatory clearances are valid as long as the compound is unaltered by the addition of unregulated substances, and providing that good manufacturing practices are employed and the end use is as described above.

MELITEK STATEMENT ON 'MEDICAL POLICY & DISCLAIMER'

MELITEK products have not been designed for nor are they promoted or intended for use in: a) medical devices categorized by either the United States Food and Drug Administration or the International Standards Organization (ISO) as an "implant" device; or "Permanent" as defined under US Pharmacopoeia (USP) or ISO standards; or
(b) active implantable medical devices as defined in EU Directive 90/385/EEC as amended; or
(c) medical devices for "Long Term" use as defined in EU Directive 93/42/EEC as amended.
Without limiting the generality of this statement, MELITEK products shall not be used in any medical device application intended for:
(1) exposure to human tissue or body fluids for 30 days or greater;
(2) "plastic" (cosmetic or reconstructive) surgery use;
(3) reproductive implants or any birth control device; or
(4) any critical component in a permanently (greater than 30 days) implanted medical device that supports or sustains human life.
It is the sole responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, with all applicable laws and regulations.
MELITEK MAKES NO REPRESENTATION, PROMISE, OR EXPRESS OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OR LAWFULNESS OF MELITEK'S PRODUCTS FOR USE IN ANY MEDICAL DEVICE UNLESS EXPRESSLY STATED IN A WRITTEN AGREEMENT SIGNED BY A DULY AUTHORIZED MELITEK REPRESENTATIVE.

Hartvig Jensensvej 1
DK-4840 Nr. Alslev . Denmark
Tel. +45 70 250 255
Fax +45 70 250 277
info@melitek.com
www.melitek.com