Animal-Derived Materials in Medical Applications

The information presented is intended for educational purposes only, and does not represent or replace animal origin policies set forth by industry suppliers, manufacturers or governing parties

Animal-Derived Materials (ADM)

Any substance derived from the body of any animal

Common examples include fat, flesh, blood, milk and eggs

ADMs may be used in food, cosmetics, pharmaceuticals and medical devices industries

Recent regulatory trends have increased demand for materials free of ADMs

ADMs in Polymers

ADMs are used in polymers to stabilize formulations, enhance properties and aid in processing

Commonly used ADMs in polymers include stearates, which impart lubricity, improve flow and inactivate polymerization catalysts

Stearates are found in a variety of polymers, including grades of polyethylene (PE) and polypropylene (PP)

ADMs are also used as additives in masterbatches or compounds, and as wetting and dispersion aids

Common ADMs in Polymers

Stearate Acid

Calcium Stearate

Zinc Stearate

Ethylene Bis-stearamide

These ingredients are most often rendered from animal sources (tallow), however vegetable derived additives are available

Stearic Acid

Melting point: 70°C

Foundational Stearate for further derivatization

Found in various animal and plant fats

Animal derived stearate acid is often a product of tallow

Calcium Stearate

Melting point: 155°C

Used as a lubricant, dispersant, stabilizer & nucleating agent

Enhances release properties

Commonly used as an acid scavenger in PE, PP, PS & PVC to improve stability

Zinc Stearate

Melting point: 125°C

Used to provide enhanced lubricity & thermal stability

Improves pigment wetting

Commonly used in polyolefins and PVC as a lubricant

Ethylene Bis-stearamide

Melting point: 145°C

Used as a lubricant and dispersion aid

Anti-tack properties

Will not degrade materials (non-reactive with condensation resins)

Concerns with ADMs

Global outbreaks of bovine spongiform encephalopathy (BSE; "mad cow disease") have raised concerns over the safety of ADMs

Creutzfeldt-Jakob Disease (CJD), a human neurodegenerative disorder

- This disease is rapidly progressive and always fatal
- Infection with this disease leads to death usually within 1 year of onset of illness
- According to the CDC, Variant CJD is linked to outbreaks of "mad cow disease" it is believed that similar prions are responsible for both diseases

ADMs in Medical Device Manufacturing

Polymers / additives containing ADMs are often used to manufacture medical device components (i.e., coatings, tubing, connectors, packaging)

ADMs can comprise a major part of a finished device (i.e., bovine heart valves, bone substitutes, collagen injection)

Concerns over leachables has resulted in the demand for ADM free solutions

Medical resins that may contain ADMs include PE, PP , PVC, Acetal, TPU, TPV, among others

International Standards Organization (ISO)

ISO 22442 identifies four areas of compliance for ADMs in medical device manufacturing:

- Application of risk management
- Controls on sourcing, collection and handling
- Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents
- Principles for elimination and/or inactivation of TSE agents and validation assays for those processes

FDA Regulation

The FDA does not prohibit the use of ADMs in medical device manufacturing. They do, however offer guidance pertaining to the collection, storage, manufacturing and sterilization of these materials.

The FDA guidance is:

- Intended to help suppliers & manufacturers identify potential risks
- Consistent with ISO directives
- Last updated in January of 2014
- Available by visiting: www.fda.gov/RegulatoryInformation/Guidances/

FDA Guidance – ADM Collection

For streamlined approval, medical manufacturers should obtain the following documentation for all ADMs used in their devices (if available). This information may be requested by the FDA as part of a 510k clearance or other submission.

- Animal species used
- Specific tissue(s) used
- Animal's country of origin and country of residence
- Methods for monitoring animal's health
- Long-term health of the herd (breeding history, vaccinations, inspections)
- Animal feed composition & feed history
- USDA status of the abattoir
- Animal age at sacrifice, sacrifice methods
- Pre & post mortem inspections
- Methods and conditions for transporting animal tissue

EU Regulation

The Commission of the European Union (EU) published the "TSE Directive" in 2003

In support of this Directive, the Commission issued revised regulations regarding the use of TSE-relevant animal tissues in medical devices

New regulations impose additional compliance requirements on medical manufacturers, incl. assessment and management practices intended to reduce the potential risk of TSE transmission

Risk assessment regulations is consistent with ISO standards

Common Materials Containing ADMs

The following materials are examples of materials that contain ingredients that would be classified as ADMs

- Lubrizol Pellethane®
- Lubrizol Estane®
- Lubrizol Carbothane®
- Lubrizol Isoplast®
- Covestro Texin®
- Covestro Makrolon ®
- Chevron- Phillips Marlex®
- Dupont Delrin®
- Lyondell-Basell ProFax®
- Exxon Santoprene®
- Mitsui TPX®
- PolyOne NEUSOFT ®
- Tekni-Plex Colorite® PVC (some grades)

Common Materials Free of ADMs

The following are examples of materials, frequently used in medical manufacturing, that are free from ingredients that would be classified as ADMs

- Arkema Pebax®
- Arkema Rilsan®
- Arkema Rilsamid®
- Arkema Kynar®
- Arkema Orevac®
- Solvay Radel®
- Solvay Udel®
- EMS Grilamid®
- GRECO Isothane®
- MGC MX-Nylon ®
- Evonik Vestamid®
- Barium Sulfate
- Bismuth Subcarbonate
- Bismuth Oxychloride
- Bismuth Trioxide
- Tungsten
- Foster LoPro™
- Foster LoPro Clear™
- Foster ProPell™ C
- Foster PureEase™
- Foster HLS™
- Foster Nanomed™
- Foster MediBatch™

Foster Support Resources

Regulatory

- Documentation
- Compliance training
- Device Masterfiles
- FDA Submission Support

Engineering & Product Development

- Application development
- Formulation development
- Material selection
- Sampling