

Eastman 168™ non-phthalate plasticizer . . . *the science of safety and innovation in medical devices*

Tested . . . Tried . . . Proven

Eastman recognizes customers' needs for plasticizer alternatives when it comes to PVC-based medical devices. Eastman 168™ non-phthalate plasticizer is the solution that has a long history of safe use and is backed by an extensive toxicological profile that demonstrates its suitability in sensitive applications, particularly flexible medical devices.

Studies demonstrate that Eastman 168™ non-phthalate plasticizer

- Is **not** a carcinogen or mutagen
- Shows **no** reproductive toxicity
- Is proven to have a clean and comprehensive toxicological profile

The alternative to phthalate plasticizers

Eastman 168 is a non-phthalate plasticizer that provides easy replacement from traditional plasticizers without significant changes to formulations or processing conditions. This and the safety profile of Eastman 168, make it ideal for use in medical applications including

- Tubing
- Films
- IV bags
- Gloves
- Inhalation masks

Performance characteristics

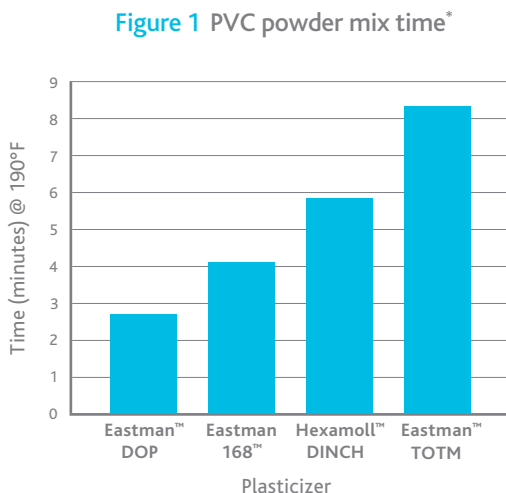
Eastman 168™ non-phthalate plasticizer offers excellent formulation performance when compared with common *ortho*-phthalates and non-*ortho*-phthalates (see Figure 1 and Table 1).

- Processing characteristics similar to DEHP and Eastman™ TOTM
- Excellent gamma stability
- Consistent color
- Excellent thermal stability

Regulatory evidence

A detailed review of existing science, toxicology, and consumer protection laws demonstrates that Eastman 168™ non-phthalate plasticizer is recognized as a non-phthalate plasticizer alternative. Eastman 168 has also received regulatory clearance by various governmental bodies around the world including

- The U.S. EPA 2009 Chemical Action Plan lists Eastman 168™ non-phthalate plasticizer as a phthalate alternative.
- The U.S. Consumer Product Safety Commission (CPSC) is reviewing Eastman 168 as a phthalate alternative.
- The Dutch Food and Consumer Product Safety Authority (Voedsel en Waren Autoriteit, VWA) has performed a risk assessment on Eastman 168 as a phthalate alternative for use in toys.¹



*Based on ASTM D2396, using the plasticizer levels stated in Table 1.

Table 1 Physical properties

Plasticizer	1 Eastman™ DOP	2 Eastman 168™	3 Hexamoll™ DINCH	4 Eastman™ TOTM
Loading necessary to reach 70 Shore A hardness (phr)	62	66	65	69
Tensile strength, MPa (ASTM D412)	16.8	16.4	15.9	17.3
Elongation, % (ASTM D412)	311	308	309	316
Modulus, MPa (ASTM D412)	6.8	6.9	6.9	7.3
Tear resistance, kN/m (ASTM D624)	53.8	50.6	51.0	57.8
Brittleness temperature, °C (ASTM D746)	-41	-47	-48	-40
Fusion torque, mg	1368	980	850	1130

Base formulation in addition to plasticizer (phr): OxyVinyls 500F PVC (100), ESO (5), calcium stearate (0.15), zinc stearate (0.2), stearic acid (0.2)

¹For more detailed regulatory information, refer to the Product Regulatory Information Sheet for Eastman 168™ non-phthalate plasticizer located at www.EastmanPlasticizers.com.

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Material Safety Data Sheets providing safety precautions that should be observed when handling and storing Eastman products are available online or by request. You should obtain and review the available material safety information before handling any of these products. If any materials mentioned are not Eastman products, appropriate industrial hygiene and other safety precautions recommended by their manufacturers should be observed.

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intraaortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

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