



EASTMAN

Eastman 168™ SG
non-phthalate plasticizer

**Sensitive grade.
Sensible choice.**

Meeting the unique needs of the medical market

Eastman 168™ SG

non-phthalate plasticizer

A sensitive grade for demanding markets

To help medical device and packaging manufacturers comply with an ever-changing and increasingly stringent regulatory environment, we offer a differentiated non-phthalate plasticizer: Eastman 168 SG.

A sensitive-grade solution designed specifically for the extensive testing and qualifications within the medical market, Eastman 168 SG is manufactured to higher purity standards—with more comprehensive testing and documentation.



For example, we subject Eastman 168 SG to the same analysis required of manufacturers, including:

- United States Pharmacopeial Convention (USP) Class VI classification
- Hemocompatibility testing according to ISO 10993-4
- Cytotoxicity testing according to ISO 10993-5
- U.S. FDA food contact compliant

Tested—Tried—Proven

Plastics are widespread in the medical industry, with a prevalence of polyvinyl chloride (PVC). Historically, phthalate plasticizers have been used to make these flexible PVC products more pliable and useful. However, customer preferences and regulatory trends are causing a technology shift to non-phthalate alternatives.

Eastman 168™ non-phthalate plasticizer has a long history of safe use; and now, Eastman 168 SG offers even higher standards for customers that need even greater assurance for specific applications, particularly flexible medical devices.

Structurally and toxicologically different

In today's regulatory language, the term "phthalate" is technically regarded to mean *ortho*-phthalate—or specifically by the U.S. Environmental Protection Agency (EPA) to mean dialkyl *ortho*-phthalate ester.¹ Eastman 168 SG is recognized as a non-phthalate because it is a terephthalate, a completely different structure from an *ortho*-phthalate.

Eastman 168 SG has a comprehensive and clean toxicological profile with studies that demonstrate it is not carcinogenic, mutagenic, or toxic to reproduction.

Toxicologically inactive, terephthalates are metabolized differently than *ortho*-phthalates. Through known metabolic pathways, *ortho*-phthalates yield long-lived monoesters that are considered biologically active. The structure of terephthalates does not allow the formation of monoesters that have been implicated in phthalate toxicology.

¹References to the meaning of phthalate by the EPA can be found in the U.S. EPA Existing Chemicals, Phthalates Action Plan, Clean Water Act, Safe Drinking Water Act, Comprehensive Environment Responsibility Compensation & Liability Act (Superfund), Office of Pollution Prevention & Toxics (TSCA and ITC).

The U.S. Consumer Product Safety Commission (CPSC) and EPA under their 2009 Chemical Action Plan view terephthalates as a phthalate alternative. The European Food Safety Authority and the U.S. FDA have cleared Eastman 168 for a variety of food contact applications. For complete regulatory information, visit EastmanPlasticizers.com.

Performance with peace of mind

Eastman 168™ SG non-phthalate plasticizer offers excellent formulation performance when compared to other medically approved plasticizers. (See Figure 1 and Table 1.)

As a result, it yields flexible PVC with excellent physical properties, such as:

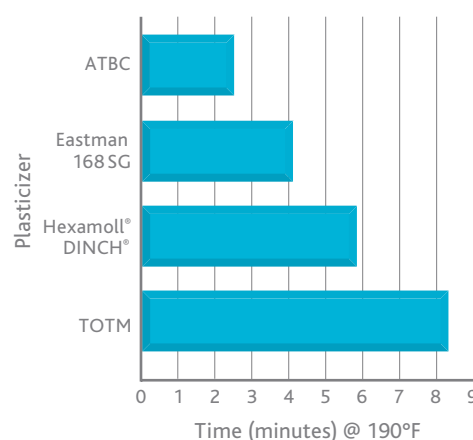
- Gamma and sterilization stability
- Migration resistance
- Color consistency
- Thermal stability
- RF and solvent welding
- Printability

These properties make it the easy replacement for traditional plasticizers without significant changes to formulations or processing conditions.

Eastman 168 SG is ideal for use in class 1 and class 2 medical applications including:

- Cannulae
- Examination gloves
- Catheters
- Films
- Connectors
- Goggles
- Cushioning products
- Inflatable splints
- Device packaging
- IV bags
- Dialysis equipment
- IV containers and components
- Drainage tubing
- Mouthpieces
- Oxygen delivery
- Seals
- Surgical wire jacketing
- Tubing
- Valves

Figure 1 PVC powder mix time*



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

Note: Shorter time is better.

Table 1 Physical properties

Plasticizer	1	2	3	4
	ATBC	Eastman 168 SG	Hexamoll® DINCH®	TOTM
Loading necessary to reach 70 Shore A hardness (phr)	61	66	65	69
Tensile strength, MPa (ASTM D412)	17.6	16.4	15.9	17.3
Elongation, % (ASTM D412)	324	308	309	316
Modulus, MPa (ASTM D412)	6.5	6.9	6.9	7.3
Tear resistance, kN/m (ASTM D624)	55.2	50.6	51.0	57.8
Brittleness temperature, °C (ASTM D746)	-36	-47	-48	-40
Fusion torque, mg	1264	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)



The Eastman 168 SG difference

- Non-phthalate classification
- Manufactured to a higher purity standard
- Cost efficient
- Advanced notification of specification changes
- Global supply continuity through multiple manufacturing sites
- Access to certification data, e.g., USP Class VI, ISO 10993, biocompatibility
- Letters of compliance
- Supported by scientifically sound testing
- Active customer auditing

Compliance has never been easier

Switching to a new plasticizer can be a challenge. Eastman makes the decision to change easier.

We understand how important patient care is to you and the regulatory trends you face. Eastman can help you in preparing for emerging regulations that might impact your patients and your business. With decades of experience and comprehensive technical support, we can help you find the safest choice—for patients and your bottom line.

For example, with its outstanding performance properties, low-temperature flexibility, extensive toxicological profile, and excellent nonmigration properties, Eastman 168 SG will pay for itself in the long run because it is a hassle-free replacement for general-purpose plasticizers like DEHP.

Simply requesting a DEHP-free plasticizer may not be good enough for your most sensitive applications. To be sure what's inside your formulated products—and what's not—specify Eastman 168 SG by name.



The results of **insight**™

For more information, visit
www.EastmanPlasticizers.com

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