Citroflex™ B-6 Plasticizer

a phthalate-free solution for flexible PVC
medical bag storage and transfusion systems

aurorium™

the Citroflex™ B-6 plasticizer advantage

- ✔ a truly phthalate-free plasticizer
- ✔ approved by the European Pharmacopoeia
- ✔ proven, field tested solution for 20+ years
- ✔ excellent low-temperature flexibility
- ✔ clean toxicological profile as documented in SCENIHR Report, Revision February 2016

do not just specify a DEHP-free plasticizer for blood storage applications

ask for Citroflex B-6
a proven plasticizer in medical PVC

When it comes to plastics for medical devices, softness, flexibility, and patient safety are the key attributes. Whether ensuring optimum patient comfort for the tubing that interacts with the body or providing safe storage and transportation of blood and its components, plasticizers play a crucial role.

Aurorium's Citroflex B-6 phthalate-free plasticizer offers excellent performance in medical PVC plastics formulations. With a clean toxicological profile, Citroflex B-6 presents a proven, field-tested alternative to traditional DEHP plasticizers.

As an easy, drop-in replacement for DEHP, Citroflex B-6 assures PVC compounders of production continuity with minimal formulation or process adjustment. This empowers compounders to provide medical bag manufacturers with regulatory-compliant products having identical or improved performance.

making medical bags more sustainable

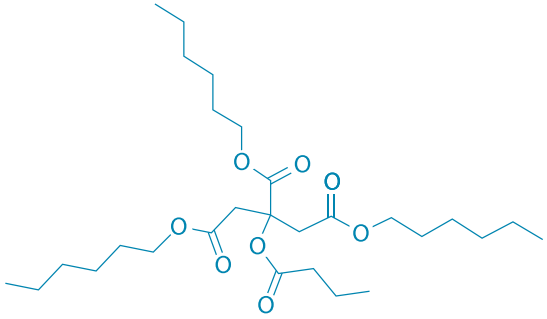
Offering high performing products that do not compromise on sustainability is a focus for Aurorium.

Citroflex B-6, another example of our commitment to help our customers reach their sustainability goals, is partially derived from bio-based raw materials and has been demonstrated to be biodegraded by microorganisms in soil.

chemistry and performance

Citroflex™ B-6 Plasticizer is Butyryl Trihexyl Citrate (BTHC)

- a butyrylated ester derived from the reaction of bio-sourced citric acid with hexanol
- low viscosity, colorless liquid, nearly insoluble in water



excellent alternative to DEHP

PVC films plasticized with Citroflex B-6 demonstrate superior benefits when compared to those plasticized with DEHP:

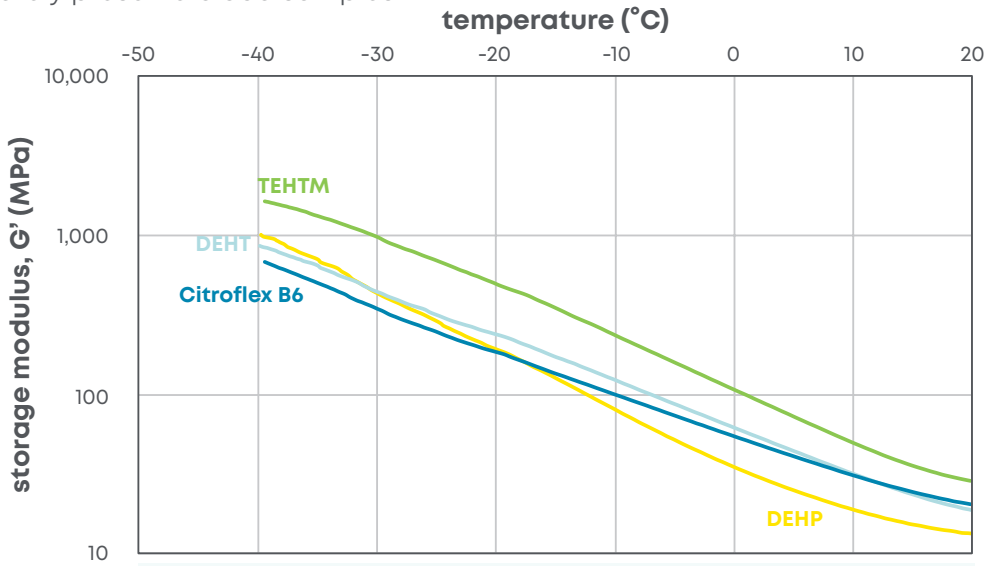
- identical or improved physical properties
- reduced brittle point temperature
- significantly less volatile loss
- lower soapy water extraction

		Citroflex B-6	DEHP
Hardness	Shore A	81	79
Tensile Strength	psi	2924	2748
Ultimate Elongation	%	427	395
100% Modulus	psi	1362	1368
Brittle Point	°C	-33.5	-24.5
Volatile loss (air)	%	1.7	4.8
Volatile loss (A/C)	%	1.4	3.4
Soapy water extraction	%	2.2	2.7

Representative data for Medical Grade PVC films prepared using 50 phr plasticizer, 2.5 phr stabilizer, and 0.25 phr lubricant

superior low-temperature flexibility

Compared to other plasticizers approved by the European Pharmacopoeia, PVC films plasticized with Citroflex B-6 maintain a lower G' modulus at sub-freezing temperatures, indicating better flexibility at the low storage temperatures required to safely preserve blood samples.



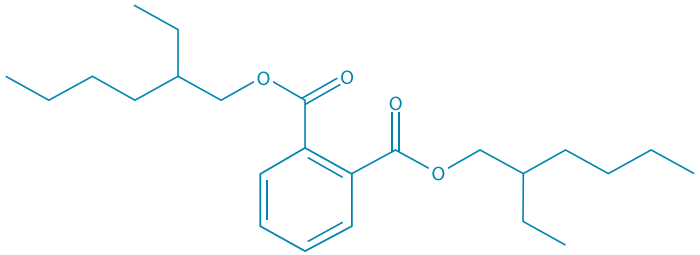
Dynamic rheology temperature ramp data for PVC films prepared using 70 phr plasticizer, 2.5 phr stabilizer, and 0.25 phr lubricant

why all the fuss about about phthalates

Phthalates are a family of man-made chemical compounds which became commercially available in the 1920's to be used in the manufacture of plastics, solvents, and personal care products. They are colorless, odorless, oily liquids which do not evaporate easily nor become chemically bound.

Various studies have been conducted to investigate the relationship between exposure of children to phthalates and increased prevalence of autistic traits, obesity, ADHD, and other developmental disorders.

Unlike several other plasticizers advertised as DEHP alternatives that claim to be free of "ortho-phthalates", Citroflex B-6 does not contain any phthalates.



Though questions about the safety of DEHP in medical bag systems have been raised since the early 1970s, it wasn't until nearly thirty years later that DEHP was labeled as a reproductive toxin, and the search for alternatives intensified, driving nearly complete replacement by other plasticizers. However, the basic DEHP-PVC combination of blood storage disposables continues to be in use today despite these concerns.

With the recent changes in MDR published in May 2021, as well as Amendment Annex XIV per ECHA REACH mandates, use of DEHP will require authorization based on risk assessment, therefore complicating and prolonging the paths to product commercialization.

Medical PVC compounders and blood transfusion product brand owners are now preparing for next-generation products, fast-tracking the development of alternative, phthalate-free technologies. Completely phthalate-free Citroflex B-6 helps ensure compliance with the ever-changing regulatory landscape.

frequently asked questions

What is the chemistry behind Citroflex™ B-6 Plasticizer?
Citroflex B-6 (CAS 82469-79-2) is n-butyryltri-n-hexyl citrate or Butyryl Trihexyl Citrate, commonly known as BTHC. It is a butyrylated ester derived from the reaction of citric acid with hexanol.

I have been making medical grade PVC with DEHP plasticizer for years. Why should I look for an alternative?
DEHP plasticizer has long been the primary choice for flexible PVC-based medical applications. However, due to its classification as a reproductive toxin, it has undergone increased scrutiny by regulatory and medical authorities and is no longer a preferred plasticizer in blood transfusion products. Thanks to Aurorium's forward-looking innovation, Citroflex B-6 is readily available as a drop-in replacement.

Do I need to change my processes to accommodate a new plasticizer?
We understand switching plasticizer may seem like a big task. Citroflex B-6, however, can be seamlessly integrated into your existing polymer compounding process as it is a drop-in replacement for other plasticizers and can be used with little or no reformulation.

Is Citroflex B-6 compatible with existing sterilization methods?
Citroflex B-6 is compatible with EtO and gamma radiation, which are sterilization methods commonly used in medical bag manufacturing.

Where is Citroflex B-6 manufactured?
Citroflex B-6 is manufactured in Greensboro, North Carolina, U.S.A. and ships worldwide. Backed by our robust quality and manufacturing practices, our customers can rest easy about the supply-security and quality of the plasticizer.

Is Citroflex B-6 safer than DEHP?
DEHP has been classified as a carcinogen and reproductive toxin, and is categorized as an endocrine disruptor. Citroflex B-6 is not classified as a carcinogen, reproductive toxin, or endocrine disruptor, and is a proven alternative to DEHP.

What is an endocrine disruptor?
Endocrine disruptors are natural or human-made chemicals that may mimic or interfere with the body's natural production of hormones, known as the endocrine system. Phthalates are known to be endocrine disruptors. Based on ECHA (REACH). DEHP has been classified as a reproductive toxin. DEHP is currently listed as a REACH Substance of very high concern (SVHC) and is on the Proposition 65 list because it can cause cancer and birth defects or other reproductive harm.

Many DEHP alternatives that claim to be free of ortho-phthalates. What makes Citroflex B-6 preferable to other plasticizers?
Unlike many other "non-phthalate" plasticizers that contain terephthalates, Citroflex B-6 is 100% phthalate-free, and is a tested, tried and proven solution in field-use by the world's leading blood and cell therapy companies for more than 20 years.

Is Citroflex B-6 a viable alternative as the industry approaches a DEHP sunsetting date as mandated by REACH?
Yes, BTHC is listed in European Pharmacopoeia as a safe plasticizer and approved alternative to DEHP for medical products. Citroflex B-6 enables brand owners to comply with various regulatory mandates, including EU 2017/745 Medical Device Regulation, REACH Regulations, and RoHS EU Directive 2015/863 (RoHS 3).

Still have questions? Ask us at ask@aurorium.com

history of Citroflex™ B-6

The history of Citroflex B-6 is rooted in foward-looking innovation. Patented in the 1980s, Citroflex B-6 continues to be produced at Aurorium's Greensboro, North Carolina USA site, in a plant named after one of its inventors.

At a time when discussions of carcinogenic and toxicity implications of the leading plasticizer in medical bag applications were not at the forefront of the industry, Aurorium envisioned an improved plasticizer that could provide superior test results in biological studies while allowing easy processing via conventional extrusion and calendering techniques.

With a 20+ year history of successfully proven and field-tested usage in blood storage and transfusion systems, today Citroflex B-6 is used by the world's leading medical bag manufacturers.

Industry participants preparing to comply with the roadmaps of REACH and other regulatory bodies, Citroflex B-6 offers a clear, established pathway to phthalate-free PVC products for blood transfusion and other critical medical applications.

a world of possibilities

We believe in the power of possibility; through specialty ingredients and performance-enhancing materials, **Aurorium** makes it possible for companies around the world to create life-improving products that make the world a better place.

industries we impact

The partner for global manufacturers looking to solve the problems of tomorrow; **Aurorium** is your partner in possibility. Together, we have the power to build a better world for everyone; a world where anything and everything is possible. Key industries Aurorium serves include personal & home care, healthcare, mobility, infrastructure, and paper & packaging.

healthcare

Aurorium is your partner for a better future; focused on providing solutions that enhance drug delivery, feature biocompatibility for optimized performance, and support human health

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