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Why Eastman 168 is a non-phthalate plasticizer

A regulatory memo

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Contents

Why Eastman 168 is a non-phthalate plasticizer

A detailed view of existing scientific literature and environmental, food, drug, cosmetics, and consumer protection laws demonstrates that Eastman 168™ non-phthalate plasticizer is not a "phthalate ester" and is not subject to the same restrictions as those compounds.

Science

1. The term "phthalate" is generally taken in chemistry to mean *ortho*-phthalate.
2. Terephthalates are not derived from phthalic acid as are all *ortho*-phthalates.
3. Terephthalates are structurally different from *ortho*-phthalates.
4. Terephthalates are toxicologically different from *ortho*-phthalates.
5. A senior EPA toxicologist has stated that terephthalates are "not biologically active" and have zero potential for reproductive effects.
6. The terephthalate structure does not allow the formation of the stable monoester moiety that is implicated in phthalate toxicology.

Regulation

1. The U.S. EPA Phthalates Action Plan has consistently specified phthalate to mean *ortho*-phthalate under major environmental laws including
   - Clean Water Act
   - Safe Drinking Water Act
   - Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund)
   - Toxic Substances Control Act (TSCA) and the Interagency Testing Committee (ITC) through the Office of Pollution Prevention and Toxics
2. Consumer Product Safety Improvement Act (CPSIA) does not classify Eastman 168™ non-phthalate plasticizer as a phthalate and, in fact, the CPSC CHAP is reviewing it as a phthalate alternative.
3. Regulation of phthalates under California's Proposition 65 and the California Environmental Contaminant Biomonitoring Program (CECBP) includes several *ortho*-phthalates but no terephthalates.
4. Eleven states in the U.S. have enacted or proposed phthalate legislation specific to *ortho*-phthalates.
5. EU Competent Authorities specify phthalate to mean *ortho*-phthalate including SCENIHR, Danish EPA, and Dutch Food Safety Agency.
6. Australia's NICNAS carefully distinguishes terephthalates from phthalates.
7. Numerous competent authorities and private organizations have reviewed terephthalates as viable alternatives in their phthalate-alternative assessments.

The formal chemical name for Eastman 168™ non-phthalate plasticizer is 1,4-benzenedicarboxylic acid, di(2-ethylhexyl) ester. The Chemical Abstracts Service Registry Number (CASRN) is 6422-86-2. Informally, this compound has been referred to as dioctyl terephthalate (DOTP) or di(2-ethylhexyl) terephthalate (DEHT). Because phthalate is a part of these common names for Eastman 168, it can be confused with the distinct class of phthalate esters that has been the target of recent regulatory efforts.

The following detailed review of existing environmental, food, drug, cosmetics, and consumer protection laws demonstrates that Eastman 168™ non-phthalate plasticizer is not recognized as a phthalate ester within the scope of these laws and should not be subject to the same restrictions. In fact, several phthalate replacement assessments performed by competent authorities and other private organizations have included DEHT as an alternative and found it to be a very good replacement for phthalates in products on the market today.

The term phthalate in chemistry generally refers to *ortho*-phthalate esters, and common scientific usage distinguishes terephthalate esters from phthalate esters.

Two molecules, each composed of the same number and kind of elements (e.g., carbon, oxygen, and hydrogen atoms) but assembled into different structures, are called isomers. For benzenedicarboxylic acid esters, there are three (3) distinct isomers known as *ortho*-phthalates, *meta*-phthalates, and *para*-phthalates. More commonly, these isomers are referred to as phthalates, isophthalates, and terephthalates, respectively. These compounds are the esters derived from the corresponding phthalic acid, isophthalic acid, or terephthalic acid. Eastman 168™ non-phthalate plasticizer is an ester of terephthalic acid. All of the regulated phthalates are derived from phthalic acid. Table 1 summarizes the synonyms for the three distinct benzenedicarboxylic acid isomers and their respective esters.

A review of leading chemical dictionaries, scientific review papers, and other scientific literature indicates that scientists use the term phthalate or phthalate ester to refer to the specific *ortho*-phthalate ester class of the isomers. For example, a text published by CRC Press states

> Phthalate esters or phthalic acid esters (PAEs) are terms used interchangeably to describe the esters of *ortho*-phthalic acid. . . .While PAEs refer to the *ortho*- form of benzenedicarboxylic acid, *meta*- and *para*- forms occur and are termed isophthalate and terephthalate esters. They have some similarities and many differences in properties as well as end uses, toxicology, and so forth.[1]

Therefore, common scientific usage distinguishes terephthalates such as Eastman 168™ non-phthalate plasticizer from phthalate esters.

Table 1 Synonyms for phthalic acid and phthalate ester isomers

	1,2-isomer	1,3-isomer	1,4-isomer
Acid	1,2-benzenedicarboxylic acid	1,3-benzenedicarboxylic acid	1,4-benzenedicarboxylic acid
	phthalic acid	isophthalic acid	terephthalic acid
	ortho-phthalic acid	*meta*-phthalic acid	*para*-phthalic acid
	o-phthalic acid	*m*-phthalic acid	*p*-phthalic acid
Ester	1,2-benzenedicarboxylic acid, diester	1,3-benzenedicarboxylic acid, diester	1,4-benzenedicarboxylic acid, diester
	phthalate ester	isophthalate ester	terephthalate ester
	ortho-phthalate ester	*meta*-phthalate ester	*para*-phthalate ester
	o-phthalate ester	*m*-phthalate ester	*p*-phthalate ester

U.S. EPA Guidance uses the term phthalate esters to refer to *ortho*-phthalate esters; terephthalates are treated as a separate class.

The Environmental Protection Agency (EPA) is responsible for implementing and enforcing the laws that protect the quality of air, water, and soil in the U.S. In assessing the effect of phthalates and phthalate esters on human health and the environment, the Agency has generated a wealth of toxicological information. Encompassing programs across all environmental media, this information consistently demonstrates that the agency defines phthalates to be *ortho*-phthalates and distinguishes them from the isophthalates and terephthalates. Representative language can be found in the Clean Water Act (CWA), Safe Drinking Water Act (SDWA), and the "Superfund" Act (CERCLA).

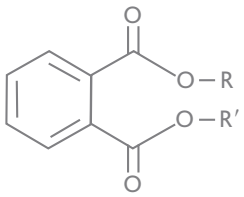
Use of phthalate esters under the Toxic Substances Control Act

The Office of Pollution Prevention and Toxics (OPPT), originally known as the Office of Toxic Substances (OTS), regulates the manufacture and import of chemical substances under the Toxic Substances Control Act (TSCA). The Interagency Testing Committee (ITC) within the OPPT is responsible for recommending chemicals for testing. Several documents issued by the ITC indicate that the understanding within OPPT is that phthalate esters refer to *ortho*-phthalate esters and exclude terephthalates such as Eastman 168™ non-phthalate plasticizer.

In a 1977 report, the ITC recommended the testing of the category of alkyl phthalates which the ITC defined as all high-production (e.g., 10 million lb/yr or greater) alkyl esters of 1,2-benzenedicarboxylic acid (orthophthalic acid).[2] Thus, the term phthalate is equated with *ortho*-phthalate.

Categorization of substances tested under the TSCA Section 4 testing program provides convincing evidence that the Agency classifies phthalates as *ortho*-phthalates and distinguishes them from bis(2-ethylhexyl)terephthalate (i.e., the chemical marketed as Eastman 168™ non-phthalate plasticizer). The directory lists alkyl phthalates and a separate entry for bis(2-ethylhexyl)terephthalate.[3] Following the link for alkyl phthalates takes the viewer to a page titled "Alkyl Phthalates and Benzyl Butyl Phthalate."[4] Benzyl butyl phthalate (BBP) is not an alkyl phthalate but is an *ortho*-phthalate. Appendix A to this page lists 14 *ortho*-phthalate compounds and no isophthalates or terephthalates.[5] For bis(2-ethylhexyl) terephthalate, the Agency provides a separate Web page. This organization demonstrates that OPPT segregates terephthalates from a large family of *ortho*-phthalate substances.

The Agency re-emphasized this distinction in the "Phthalates Action Plan,"[6] (Action Plan) released in late 2009. In the Action Plan, the Agency states Dialkyl *ortho*-phthalates **(or phthalate esters)** have the general chemical structure shown here:



(R, R′ groups can be linear, branched, or linear/branched or cyclic ring)

(emphasis added). This statement makes it very clear that the EPA defines the 1,2-benzenedicarboxylic acid as the phthalate esters. Under the Action Plan, the Agency then identifies eight (8) 1,2-benzenedicarboxylic acids for a thorough scientific review and possible regulation. In the Design for the Environment (DfE) Program portion of this Action Plan, the Partnership on Alternatives to Certain Phthalates, Eastman 168 (DEHT) is included as one of 96 possible alternatives to be evaluated.[7]

United States Consumer Product Safety Improvement Act (CPSIA) of 2008

The Consumer Product Safety Act (CPSA) was substantially amended by the Consumer Product Safety Improvement Act (CPSIA) of 2008 that includes restrictions on lead and phthalates in consumer products intended for children.[8] Section 108 of the CPSIA prohibits the sale of children's toys or child care articles that contain more than 0.1% of specific phthalates, namely DEHP, DBP, and BBP. Pending review, the CPSIA also imposed an interim ban on DINP, DIDP, and DnOP. While neither the Act nor the Commission[9] defines phthalates, all six banned substances are *ortho*-phthalates and suggest that the Commission's use of the term parallels that of the EPA.

Eastman 168™ non-phthalate plasticizer is not banned by the CPSA

Under the amended CPSA, Eastman 168™ non-phthalate plasticizer is not subject to either the permanent or the interim bans and can be used in children's toys and child care articles in compliance with the Act. Complementing the phthalate bans, the Commission must also study the effects on children's health of all phthalates and phthalate alternatives used in children's toys and child care articles. In contrast to phthalates, the term "phthalate alternative" is defined as "any common substitute to a phthalate, alternative material to a phthalate, or alternative plasticizer."[10] Eastman 168 is a terephthalate plasticizer that is offered as a replacement for the six *ortho*-phthalates banned from use in toys and children's articles. As a result, Eastman 168 is included by the Consumer Products Safety Commission (CPSC) as a phthalate alternative. Due to the raw materials used in its manufacture, Eastman 168 contains trace amounts of *ortho*-phthalates with a total concentration several times lower than the CPSIA limit of 0.1%. In summary, Eastman 168 is a phthalate alternative that can be used in the manufacture of toys and children's articles that comply with the CPSIA.

State regulation of phthalates

A number of states have introduced legislation similar to the CPSIA and restrict the use of certain phthalates in consumer products or environmental media.[11] All of these acts regulate *ortho*-phthalates only; the use of terephthalates is not prohibited by any state legislation currently proposed or in effect.

California's Proposition 65

California's Safe Drinking Water and Toxic Enforcement Act of 1986, better known as "Proposition 65," is intended to advise California citizens about the presence of chemicals that may cause cancer, birth defects, or reproductive harm. Towards accomplishing that goal, the state publishes a list of chemicals known by the state of California to cause cancer, birth defects, or other reproductive harm. Currently, the Proposition 65 list contains over 800 substances including six (6) phthalates.[12] No terephthalate or isophthalate compounds are listed or nominated for listing under Proposition 65.

The California Environmental Contaminant Biomonitoring Program (CECBP) list of Priority Chemicals for biomonitoring includes eight (8) chemicals from the class of phthalates. All eight phthalates are *ortho*-phthalates; no terephthalates or isophthalates are included on the list of Priority Chemicals or list of Designated Chemicals from which it is drawn.[13]

Regulation of phthalates in the European Union

Commission Decision 1999/815/EC and Directives 2005/84/EC

Since 1999, the EU has prohibited the use of six (6) *ortho*-phthalates in toys and child care articles to concentrations not to exceed 0.1%.[14] In 2005, EU Directive 2005/84/EC made the ban permanent for all six (6) phthalates and broadened the ban for DEHP, DBP, and BBP to toys and child care articles intended for children of any age.[15] For the phthalates DINP, DIDP, and DnOP, the Directive banned their use in toys and child care articles that can be placed in the mouth.

European Food Safety Authority (EFSA) Opinion and European Commission Plastics Regulation 10/2011

EFSA's Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food adopted a favorable opinion on January 31, 2008, for use of Eastman 168™ non-phthalate plasticizer with materials coming into contact with a wide variety of foodstuffs. Consequently, Eastman 168 was placed on a positive list of additives effective January 1, 2010.[16] The opinion was accepted by the European Commission and Eastman 168 (FCM substance number 798) is now compliant with the positive list of additives in the Plastics Regulation 10/2011 which regulates the components and additives of plastics allowed to contact food. According to the listing, Eastman 168 may be used in PVC formulations as well as other materials and articles with exposures up to the maximum specific migration limit (SML) of 60 mg/kg in food.[17]

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

In the framework of REACH, substances suspected of presenting profound risks to human health can be nominated for authorization which is a process that prescribes the specific uses for a substance.[18] Such "substances of very high concern" (SVHC) may include carcinogens, mutagens, and reproductive toxins (CMRs); persistent, bioaccumulative, and toxic substances (PBTs); very persistent and very bioaccumulative (vPvB) substances; or substances for which scientific evidence suggests a probable serious effect on humans or the environment (e.g., endocrine disruptors). Currently, there are 11 *ortho*-phthalates on the SVHC list, including DEHP, BBP, and DBP, and several more *ortho*-phthalates nominated to the Community Rolling Action Plan (CoRAP) list for further evaluation as possible SVHCs. Four *ortho*-phthalates have begun the authorization process with outright bans in many applications probable starting February 2015.[19] If any uses are authorized, use of these substances will only be permitted for specific purposes for time-limited periods. No isophthalates nor terephthalates are on the SVHC or CoRAP lists, or recommended for authorization.

Danish EPA phthalates ban

In 2012 the Danish EPA introduced a plan to implement a ban in 2013 on four *ortho*-phthalates (DEHP, DBP, BBP, and DIBP) in all consumer goods. The ban was delayed until December 2015 due to competition concerns. This was the first proposed outright ban on *ortho*-phthalates anywhere outside the toy and child care articles markets and was ahead of the REACH timelines. The ban will effectively negate many or all authorized uses under REACH in Denmark.[20]

The Danish EPA is a worldwide leader in the regulation of *ortho*-phthalates, and they have written and commissioned several reports on their strategy and plans for the future. In every document, only *ortho*-phthalates are named as targets for replacement. In every document, terephthalates are named as non-phthalate alternatives as possible replacements for the targeted *ortho*-phthalates.[21, 22, 23]

The Dutch RIVM has risk-assessed DEHT and other alternatives as replacements for phthalates in children's and adult's toys, lending yet another authoritative voice to the fact that terephthalates are distinct from phthalates.[24, 25]

SCENIHR Report on DEHP in medical devices

This report, by the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR), was an evaluation of the health risks associated with exposure to the *ortho*-phthalate DEHP in medical devices.[26] Included in the report was an evaluation of possible non-phthalate alternatives which included DEHT. Once again DEHT was shown to be a safe and viable alternative. This report is being updated and should publish in June 2014 with updated data and assessments.

Australian risk assessment recognizes phthalate esters as *ortho*-phthalates

Prompted by concerns over the health effects of phthalate ester plasticizers, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in Australia published risk assessments on 24 phthalates and dimethyl terephthalate in 2007.[27] These risk assessments were based on reviews of published literature and information obtained from the industry through a data call in. In the Phthalate Hazard Compendium on the 24 phthalates, NICNAS states

> Structurally, phthalate esters are characterized by a diester structure consisting of a benzenedicarboxylic acid headgroup linked to two ester side chains. However, there are three isomeric forms of benzenedicarboxylic acid esters: *ortho*-phthalates, *meta*-phthalates, and *para*-phthalates, also known as phthalates, isophthalates, and terephthalates, respectively. Generally, the term phthalate ester is used to identify the *ortho* structural configuration (i.e., based on 1,2-benzenedicarboxylic acid). . . . All of the phthalate esters included for review in the compendium are esters of 1,2-benzenedicarboxylic acid. The use of the terms "phthalates" or "phthalate esters" in this compendium follows the common usage and refers to phthalates of this *ortho* configuration.

The language from the NICNAS compendium is clear and emphasizes the widely held position that phthalate esters only encompass the *ortho*-phthalates.

Latin American countries ban the use of *ortho*-phthalates in toys and child care products

In September 2007, Brazil's National Institute of Technology, Normalisation and Industrial Quality (INMETRO) established a ban on toys containing more than trace levels of phthalates. Similar to EU Directive 2005/84/EC, INMETRO Administrative Rule 369 prohibited DEHP, BBP, and DBP at concentrations exceeding 0.1% in all toys. For toys intended for children under three years of age that can be placed in the mouth, Rule 369 also prohibits DINP, DIDP, and DnOP at concentrations exceeding 0.1%.[28]

In neighboring Argentina, the Argentine Ministry of Health passed Resolution 583/2008 which restricted the use of the same six (6) phthalates in toys and child care products.[29] The resolution prohibits the manufacture, import, export, or sale of toys or child care articles with DEHP, BBP, and DBP at concentrations exceeding 0.1%. For the subset of toys and child care articles that can be placed in the mouth, the resolution also prohibits DIDP, DINP, and DnOP at concentrations exceeding 0.1%. In contrast to Brazil's ban, the Argentine ban on DIDP, DINP, and DnOP applies to all toys that can be placed in the mouth regardless of the intended age of use.

Mercosur, a Latin America trade group, and ANVISA, the Brazilian authority in charge of food contact approvals, have jointly decided to adopt the European Plastics Regulation (10/2011) list of approved substances in plastics.[30] In 2014, Eastman 168 will therefore be approved throughout Latin America for food contact applications with the same approval as it already enjoys in Europe.

Independent alternatives assessments

Eastman 168 (or DEHT) has been evaluated in a number of independent chemical hazard assessments as one possible alternative to *ortho*-phthalates in applications such as wire and cable (replacing DINP and DIDP),[31] in toys and child care articles (replacing DEHP, BBP, and DBP),[32] in textile print applications (replacing DEHP, BBP, and DBP),[33] and in electronics cables in computers (replacing DEHP, BBP, DBP, and DIBP).[34] DEHT consistently rates as one of the best alternatives available to replace restricted phthalates using hazard- and risk-based assessments.

Eastman 168 non-phthalate plasticizer toxicology profile is distinct from *ortho*-phthalate ester toxicology profile

Distinguishing Eastman 168™ non-phthalate plasticizer from *ortho*-phthalates is also supported by its toxicological profile. In animals, the metabolism of Eastman 168 yields a chemically distinct profile of metabolites that produce biological effects that differ significantly from those seen following exposure to *ortho*-phthalates.

In contrast to Eastman 168™ non-phthalate plasticizer, the metabolism of *ortho*-phthalates yields a monoester which is stabilized by the presence of the adjacent carboxylic acid group and the resulting persistence of this metabolite is believed to be responsible for *ortho*-phthalate toxicity. Metabolism of Eastman 168 does not lead to the significant formation of the monoester, and therefore, Eastman 168 does not produce the toxicities seen following exposure to *ortho*-phthalates.

In animal studies, Eastman 168™ non-phthalate plasticizer administered by mouth shows no overt or organ-specific toxicity in animals receiving doses as high as 1% of the daily diet for 90 days (approximately 617 mg/kg/day). Similarly, Eastman

168 has shown no evidence of developmental or reproductive toxicity in studies specifically intended to evaluate such toxicity (e.g., a two-generation reproductive toxicity study).

Genotoxicity tests for Eastman 168 showed no evidence of mutagenicity. A 2-year carcinogenicity study conducted on Eastman 168 in laboratory animals showed no evidence of tumor formation.

In aquatic toxicity studies designed to identify potential environmental effects, Eastman 168™ non-phthalate plasticizer did not exhibit any deleterious effects at concentrations up to its solubility limit.

Based on fundamental chemical and biological processes, Eastman 168™ non-phthalate plasticizer can be distinguished from *ortho*-phthalates. Moreover, it is generally accepted that the terms phthalates or phthalate esters refer to the *ortho*-phthalates only and not the isophthalates or terephthalates.

Conclusion

Information developed within the scientific community and within the U.S. EPA strongly supports the conclusion that Eastman 168™ non-phthalate plasticizer is not included in the regulated class "phthalate esters," a distinct class of chemicals regulated by a number of regulatory agencies throughout the world.

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[6]USEPA, Phthalates Action Plan (December 30, 2009). The Action Plan can be found at http://www.epa.gov/opptintr/existingchemicals/pubs/actionplans/phthalates.html (accessed August 30, 2010).

[7]EPA Design for the Environment (DfE) Alternatives to Certain Phthalates Partnership, http://www.epa.gov/oppt/dfe/pubs/projects/phthalates/ as viewed on 9 April 2014.

[8] The CPSIA can be found at http://www.cpsc.gov/about/cpsia/cpsia.html.

[9]The Consumer Products Safety Commission (CPSC) is responsible for enforcing the CPSA.

[10]CPSIA Section 108(e)(1).

[11]CT, HI, IN, MS, MO, NJ, NM, NY, OR, PA, and WI have proposed or enacted legislation that limits or bans phthalates in consumer products, children's products or environmental media (e.g., water).

[12] The list can be found at http://www.oehha.org/prop65/prop65_list/Newlist.html.

[13]The CECBP's Scientific Guidance Panel publishes the list of Designated Chemicals which includes those chemicals included in the Centers for Disease Control and Prevention's National Biomonitoring Program, as well as additional chemicals meeting certain criteria. The list of Priority Chemicals is a subset of the Designated Chemicals and represents the chemicals that are priorities for biomonitoring in California. Both lists can be found at http://www.oehha.org/multimedia/biomon/chemselect.html.

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[15]Directive 2005/84/EC.

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[27]NICNAS is the Australian agency responsible for the regulation of industrial chemicals for the protection of human health. A June 2008 summary of the assessments titled "Phthalates hazard compendium: A summary of physicochemical and human health hazard data for 24 *ortho*-phthalate chemicals" can be found at http://www.nicnas.gov.au/Publications/CAR/Other/Phthalate%20Hazard%20Compendium.pdf (accessed May 23, 2009).

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[29]Resolution 583/2008 was passed in June 2008. However, Resolution 1107/2008 postponed the effective date until March 2009.

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[31]Green Chemistry and Commerce Council (GC3) Report on Chemical Hazard Assessments of Alternative Plasticizers for Wire & Cable Applications, http://greenchemistryandcommerce.org/documents/PilotProjectFullReportOct2-final_000.pdf, as viewed on 9 April 2014.

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