

Flow-Cast is Dangerous

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Abstract:

Flow-Cast is a functional dental impression material that flows. Flow-Cast is a durable prosthetic device that can withstand repeated use and has a number of dental applications ranging from a dental impression material to produce fixed partial, removable partial and full dentures; as a soft lining permanent material that is incorporated into the denture; denture relining; denture undercuts; denture permanent alignment and re-alignment; permanent denture borders, and as a long-term tissue treatment. This product is produced and distributed by Cassidy Dental Lab and contains dangerously high levels of the phthalate butyl benzyl phthalate (BBP), a known endocrine system disrupter, at orders of magnitude higher than the maximum allowed level of 0.1% by weight in the European Union and in children's toys and items in the United States.

Key Words:

Dental Impression Material, Dentures, Phthalates, Toxic, Banned, Dental Prosthesis, Flow-Cast, Functional Impressional Material, Cancer Causing, Carcinogenic, Cancer, Illegal, Immoral, Unethical, Endocrine Disruptors, Plastics, Health Impact, Risk Assessment.

Introduction:

It has come to this author's attention that a functional dental material sold under the name Flow-Cast contains dangerously high levels of butyl benzyl phthalate (Chemical Abstract Number: 85-68-7, IUPAC preferred name: Benzyl butyl benzene-1,2-dicarboxylate).

Flow-Cast has been produced and sold for several years by the following:

Companies:

Cassidy Dental Lab and Cassidy Dental Associates
148 College Street
Macon, Georgia 31201

Phone for Cassidy Dental Associates: (478) 746-0044
Website: Flow-Cast.supply
Phone for Flow-Cast: (478) 538-0862

The chemical composition for 100 grams of Flow-Cast solution is as follows:

90 grams Butyl benzyl phthalate (Density: 1.119 g/mL)

7 grams Propan-2-one (C. A. S. Number: 67-64-1)

3 grams Ethanol (C. A. S. Number: 64-17-5)

This solution is reacted with poly (methyl methacrylate) powder [C. A. S. Number: 9011-14-7, IUPAC preferred name: Poly (methyl 2-methylpropenoate)] to form Flow-Cast.

Flow-Cast is a durable prosthetic device that can withstand repeated use and has a number of dental applications ranging from a dental impression material to produce fixed partial, removable partial and full dentures; as a soft lining permanent material that is incorporated into the denture; denture relining; denture undercuts; denture permanent alignment and re-alignment; permanent denture borders, and as a long-term tissue treatment.

When utilized as indicated above, Flow-Cast stays in constant contact with the patient's mouth tissue and continually leaches out butyl benzyl phthalate from the polymer base. This author's research has shown that a

minimum of 120-190 µg/mg of butyl benzyl phthalate is leached out per hour at a temperature of 36.7° C (98° F).

Phthalates:

A phthalate is a dialkyl, alkyl or aryl ester of phthalic acid (1,2-Benzenedicarboxylic acid, C₈H₆O₄) reacted with a 6 to 13 carbon alcohol (i.e., long-chain fatty alcohols). Phthalic acid (C.A.S. number: 88-99-3), whose name is derived from the chemical naphthalene, is manufactured by catalytic oxidation of 2-methylbenzoic acid (C.A.S. number: 118-90-1), an aromatic carboxylic acid, and oxidation of di-methylbenzene (C.A.S. number: 1330-20-7).

Phthalates and related compounds effect plasticization of polar polymers by interaction between polar centers of the phthalate molecule (i.e., C=O carboxyl functionality group), and the positive charged areas of the phthalate's vinyl chain (ethenyl group: -CH=CH₂, methylidyne cation, CH⁺, double bonded to methylene, CH₂ where H=C is called a carbene reaction) normally located on the carbon atom of the carbon-chlorine bond.

When phthalates are added to a plastic they allow polyvinyl molecules to slide against one another. Polar carboxyl group only contributes to the phthalate's physical properties when **R** and **R'** are very small as in an ethyl or methyl groups.

It is important to note that phthalates are not chemically bonded to the plastic matrix with which they are reacted and this is why phthalates can easily leach-out of the polymer matrix, which makes them dangerous.

Common Phthalate Compounds:

Compounds	Abbreviation	Where Found	Also Known As
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Diethylhexyl phthalate	DEHP	Plasticizer	Di-2-ethylhexyl phthalate; Bis-2-ethylhexyl phthalate.
Dibutyl phthalate	DBP	Nail polishers; plasticizer; an additive to adhesives or printing inks;	Di-n-butyl phthalate, DnBP, DNBP
Diethyl phthalate	DEP	Toothbrushes; automobile parts; tools; toys; food packaging; cosmetics; insecticides; aspirin	Ethyl phthalate; Di-n-ethyl phthalate
Di-isononyl phthalate	DiNP	Plasticizer	Bis(7-methyloctyl) phthalate; DINP
Di-iso-decyl phthalate	DiDP	Plasticizer	Di(i-decyl) phthalate; diisodecyl phthalate; DIDP
Butyl benzyl phthalate	BBP	Plasticizer	Benzyl n-butyl phthalate; n-Butyl benzyl phthalate
Mono-(2-ethylhexyl) phthalate	MEHP	Vinyl tiles; food conveyor belts; carpet tile; artificial leather	tert-Butyldimethylsilyl 2-ethylhexyl phthalate

Di-isobutyl phthalate	DiBP	Plasticizer; adhesive	Di(i-butyl)phthalate; Isobutyl phthalate; di-1-butyl phthalate; DIBP
Dioctyl phthalate	DnOP	Household items and building products; food applications	Di-n-octyl phthalate, DNOP

Source: Wang and Qian, 2021

Biological Dangers of Phthalates:

Phthalates are endocrine system disruptors and have been shown to be detrimental to human health (Wang and Qian, 2021). The endocrine system is one of the most important systems of the human body. This system is the human body's hormone messenger network comprising bio-chemical feedback loops excreted by various internal glands directly into the circulatory system in order to regulate other target organs within the body. (Netter, 2002; Molina, 2023; Melmed, Koenig, Rosen, Auchus, and Goldfine, 2019; Young, 2011; Kleine and Rossmanith, 2019). The hypothalamus is the neural control center for all endocrine systems, including the pancreas and thymus and they too can act as an endocrine gland. (Netter, 2002; Molina, 2023; Melmed, Koenig, Rosen, Auchus, and Goldfine, 2019; Young, 2011; Kleine and Rossmanith, 2019).

The major endocrine glands of the human body are:

1. Pineal gland
2. Thyroid gland
3. Parathyroid gland
4. Adrenal gland
5. Pituitary gland
6. Testes
7. Ovaries

(Netter, 2002; Molina, 2023; Melmed, Koenig, Rosen, Auchus, and Goldfine, 2019; Young, 2011; Kleine and Rossmanith, 2019).

The kidneys play a role within the endocrine system by secreting hormones such as erythropoietin, which stimulates erythropoiesis (the production of red blood cells) and renin, an enzyme that controls blood pressure and regulation of aldosterone levels, a hormone which helps regulate blood pressure by managing levels of potassium and sodium in your blood; and calcitriol, which promotes intestinal absorption of calcium and the renal reabsorption of phosphate (Netter, 2002; Molina, 2023; Melmed, Koenig, Rosen, Auchus, and Goldfine, 2019; Young, 2011; Kleine and Rossmanith, 2019).

The first step after exposure to a phthalate is metabolism which involves hydrolyzation which occurs after absorption into a cell. The next step conjugation to form the hydrophilic glucuronide conjugate (Wang and Qian, 2021).

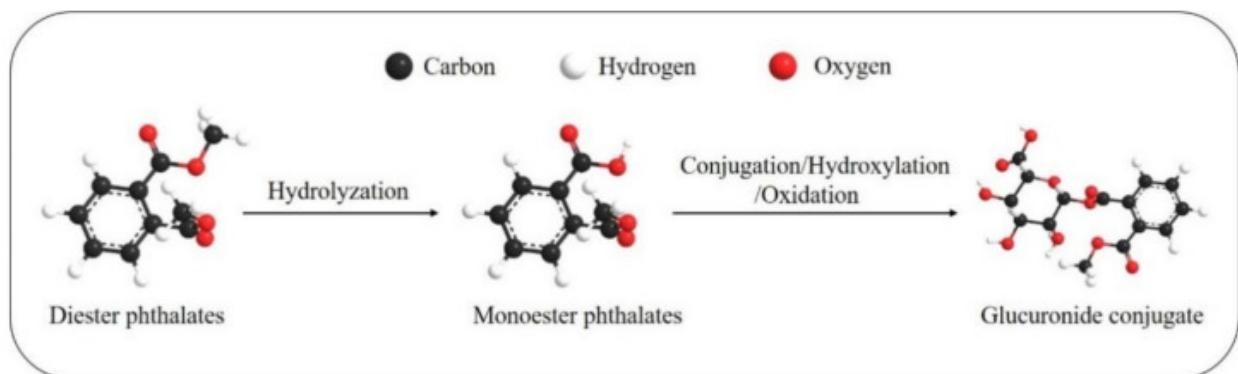
Glucuronidation which is often, for example, involved in drug metabolism occurs mainly in the liver, but the enzyme responsible for its catalysis, UDP-glucuronyltransferase, has been found in all major human organs including the brain, thymus, adrenal gland, spleen, kidneys and intestines (Ohno and Nakajin, 2009; Bock and Köhle, 2005).

The hydrophilic glucuronide conjugate is catalyzed by the enzyme uridine 5'-diphosphoglucuronyl transferase (Frederiksen, Skakkebaek and Andersson, 2007).

H. M. Koch, H. M. Bolt, R. Preuss and J. Angerer in 2005 showed that phthalates are not all metabolized in the same manner, and that the type of phthalate determines its toxicological fate in the human body. They found that short-branched phthalates (e.g., benzyl butyl phthalate, BBP; di-butyl phthalate, DBP; di-cyclohexyl phthalate, DCHP and di-ethyl phthalate, DEP) are often hydrolyzed to a mono-ester phthalate and then excreted in the urine. Long-branched phthalates [e.g., di-(2-ethylhexyl phthalate, DEHP)].

undergo several bio-transformations (e.g., hydroxylation and oxidation) before being excreted in urine and feces as a phase 2 conjugated compound.

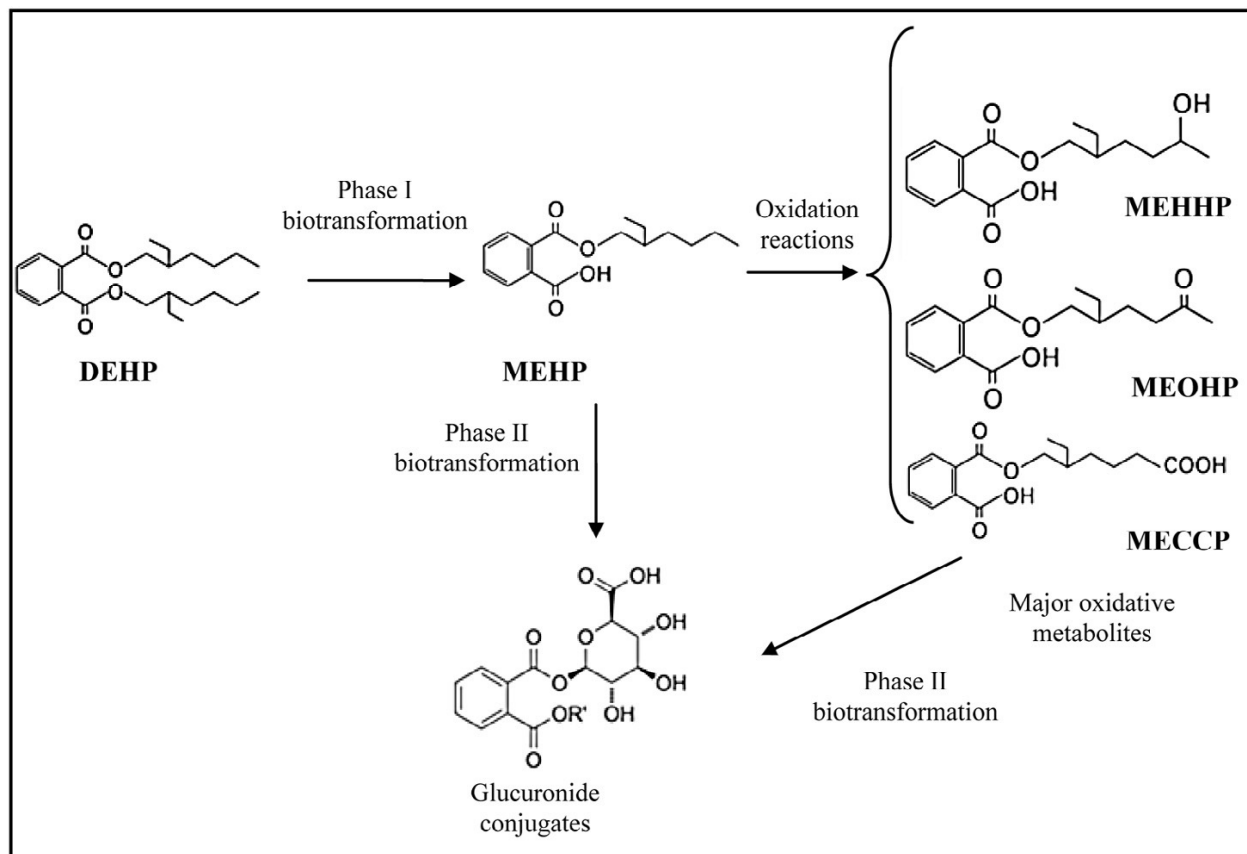
Metabolic Pathways for Phthalates (Wang & Qian, 2021)



In 2016 A. R. Kumar and P. Sivaperumal found that the complex branched chains of di (2-ethylhexyl phthalate (DEHP) is often hydrolyzed to mono (2-ethylhexyl) phthalate (MEHP), mono (2-ethyl-5-hydroxyhexyl) phthalate, mono (2-ethyl-5-oxohexyl) phthalate, mono (2-ethyl-5-carboxypentyl) phthalate (MECPP), mono (2-carboxymethylhexyl) phthalate (MCMHP) or other metabolites.

Metabolism of Long-Chain Phthalates (DEHP)

A. R. Kumar and P. Sivaperumal, 2016



Restrictions on Phthalates:

Many countries have imposed strict restrictions on the use of high-risk phthalates, such as BBP, DEHP, DBP, DiNP, DiBP, DnOP and DiDP. A few examples are:

United States:

All products containing BBP, DBP and DEHP at levels > 0.1% by weight are banned in children's products. DiDP, DnOP and DiNP containing m > 0.1 weight percent are banned in products that can be placed in a child's mouth or childcare items (Consumer Product Safety Improvement Act of 2008 (CPSIA). Public Law 110–314. 14 August 2008. [(accessed on 4 June 2023)]; Available online: <https://www.congress.gov/110/plaws/publ314/PLAW-110publ314.pdf>.

See Also:

<https://www.p65warnings.ca.gov> › fact-sheets › butyl-benzyl-phthalate-bbp

- US Department of Health and Human Services (HHS)
National Toxicology Program (NTP)
 - [NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Butyl Benzyl Phthalate \(BBP\)\(link is external\)](#).
- Centers for Disease Control and Prevention (CDC)
 - [“Benzylbutyl Phthalate” in Biomonitoring Summary. Phthalates Overview\(link is external\)](#).

European Union:

BBP, DBP, DEHP and DiBP are fully banned in all PVC and plasticized toys and all childcare items. DiDP, DnOP and DiNP are banned completely for any products that can be placed in a child's mouth (EUR-Lex EU Phthalates Directive 2005/84/EC. 14 December 2005. [(accessed on 4 June 2023)]; Available online: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32005L0084>; Commission Regulation (EU) 2018/2005 Official Journal of the European Union. 17 December 2018. [(accessed on 4 June 2023)]; Available online: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R2005&from=EN>.

ECHA E.U. European Chemicals Agency (2022):

“The phthalates DEHP, DBP, DIBP and BBP are chemicals added to plastics to increase flexibility, transparency, durability, and longevity. They are toxic for reproduction and interfere with human hormonal system.”

GUIDELINES on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties, SCHEER, https://health.ec.europa.eu/system/files/2020-10/scheer_o_015_0.pdf.

2023 EU Restrictions on Phthalates in Medical Products:

SCIENTIFIC COMMITTEE ON HEALTH, ENVIRONMENTAL AND EMERGING RISKS (**SCHEER**) Directorate-General for Health and Food and Safety: https://health.ec.europa.eu/system/files/2020-10/scheer_o_015_0.pdf.

SCHEER approved this mandate by written procedure on March 20, 2023.

Japan:

DEHP is completely banned in food-handling gloves, while DEHP and DiNP is fully banned in all toys (Mutsuga, Wakui, Kawamura, and Maitani, 2002).

China (National Standards of the People's Republic of China):

BBP, DNP, DEHP, DiBP, DnOP, DNP and 10 other phthalates are restricted in food and food containers. DEHP in medical transfusion bags and equipment is restricted to less than 10 mg/mL. BBP, DBP and DEHP in all childcare items cannot exceed 0.1 weight percent (Wang and Qian, 2021).

Australia:

Children's plastic products containing or having a component containing more than 1% by weight of DEHP are banned (Product Safety Australia DEHP in Children's Plastic Items. Australian Competition & Consumer Commission. n.d. [(accessed on 4 June 2023)]; Available online: <https://www.productsafety.gov.au/bans/dehp-in-childrens-plastic-items>).

Conclusion:

Phthalates have been repeatedly proven to have detrimental health effects and are easily leached into food and water and leached from other products applied directly to the human body; with ingestion, dermal and inhalation being the most important phthalate exposure routes (Wang, Leung, Chu, and Wong 2018).

An especially dangerous phthalate, which is banned in Europe and for children's toys and items in the United States, in amounts of 0.1 weight percent or greater, is butyl benzyl phthalate (Chemical Abstract Number: 85-68-7) IUPAC preferred name: Benzyl butyl benzene-1,2-dicarboxylate. BBP is a known endocrine system disrupter.

This phthalate is commonly known as BBP and Flow-Cast solution contains 90 grams of this dangerous phthalate per 100 grams, which when mixed with the polymer component as directed forms Flow-Cast which contains far more BBP than is allowed by law in many other countries.

What makes this dangerous is that Flow-Cast sits in the patient's mouth for 12 hours or more per day, leaching out the BBP second by second.

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