

**Suppliers going  
DEHP-free, it's easier  
than you think...**

Dr. Dan Bolton  
Eastman Chemical Company  
June 21, 2013

# Agenda



- Introduction
- Current plasticizer usage
- Phthalates review
- Regulatory and toxicology information
- DEHP-free plasticizer options in the market
- Summary

# Who we are

- A global specialty chemicals company headquartered in Kingsport, Tennessee
- Approximately 13,500 employees and over 42 manufacturing sites around the globe
- A company dedicated to environmental stewardship, social responsibility and economic growth
- 2012 and 2013 ENERGY STAR® Partner of the Year
- Combined 2012 pro forma revenue of approximately \$9.1 billion



**EASTMAN**

# Our manufacturing locations

**EASTMAN**



- ★ Corporate headquarters
- Eastman Manufacturing

Anniston, AL	Dietenheim, Germany	Jefferson, PA	Longview, TX	Nienburg, Germany	Texas City, TX
Antwerp, Belgium	Dresden, Germany	Jurong Island, Singapore	Madison, WI	Santo Toribio, Mexico	Trenton, MI
Canoga Park, CA	Franklin, VA	Kashima, Japan	Martinsville, VA	São Paulo Mauá, Brazil	Ulsan, Korea
Chestertown, MD	Ghent, Belgium	★ Kingsport, TN	Middelburg, The Netherlands	Sauget, IL	Uruapan, Mexico
Chicago, IL	Hsinchu, Taiwan	Kohtla-Järve, Estonia	Monongahela, PA	Sete, France	Workington, UK
Chocolate Bayou, TX	Indianapolis, IN	Kuantan, Malaysia	Nanjing, China	Springfield, MA	Wuhan, China
Columbia, SC	Itupeva, Brazil	Lemoyné, AL	Newport, Wales	Suzhou, China	Zibo, China

# Eastman is a market leader

**2/3** of our sales revenue is from product lines in **leading market** positions

## Additives & Functional Products



#1

- Cellulosic polymers
- Insoluble sulfurs
- Aldehyde derivatives / ketones

## Adhesives & Plasticizers



#1 or #2

- Non-phthalate plasticizers
- Hydrocarbon resins

## Advanced Materials



#1

- Copolyester
- PVB sheet
- Branded window film
- Cellulosic polymers

## Fibers



#1 or #2

- Acetate tow
- Acetate yarn

## Specialty Fluids & Intermediates



#1 or #2

- Oxo alcohols in Americas
- Heat transfer and aviation hydraulic fluids

# North America's largest producer of non-phthalate plasticizers

- With the broadest range of general purpose and specialty plasticizers in the industry, supplying numerous markets:
  - Medical Bags
  - Medical Tubing
  - Flooring
  - Food Packaging
  - Wall-Covering
  - Calendered Film and Sheet
  - Adhesives, Caulks, Sealants
  - Resilient Flooring
  - PVC Plasticsols
  - Automotive Underbody Coatings



# Plasticizers are used in many different applications

## Building and construction

- Resilient flooring
- Carpet tiles
- VCT
- Cove base
- Adhesives



## Medical

- Infusion bags
- Tubing
- Gloves
- Catheters
- And more..

## Food Contact

- Food wrap
- Caps and closures
- Conveyor belts



## Commercial

- Toys
- Household items
- Upholstery
- Adhesives



# Plasticizer Usage in Hospitals





# Eras for IV Therapy

Pre – 1930's



1930's – 1950's



Nurse examines a pair of blood transfusion bottles at Baxter Lab., Glenview, Ill

Post – 1950's



# Development of Bags for IV Therapy

- Developed by Carl Walter and W.P. Murphy – Formed Fenwal with partner T. Legare Fenn
- Originally for blood storage – extended to other IV therapies
- Replaced breakable glass bottles
- Allowed for whole blood separation
- New material to replace natural rubber tubing
- Increased shelf-life of stored blood

What Material did Dr. Walter Choose???

PVC!!

# Why PVC?

- Commercially available
- Toughness
- Chemical resistance
- Flexibility
  - Hardness can “tuned” post polymerization
  - More plasticizer – soft materials
  - Less plasticizer – harder material
- Weldability
  - Solvent and Rf
- Permeability
  - O<sub>2</sub> and CO<sub>2</sub> transport – longer blood life



# Elephant in the room – PVC Facts

## Pros

- Low memory for tubing
- Chemically inert
- Can be recycled into other useful products – [video example](#)
- Positive LCA
  - Long lifetime
  - Produced from renewable resources

## Cons

- Dioxin formation during incineration

# Dioxin Formation During Incineration

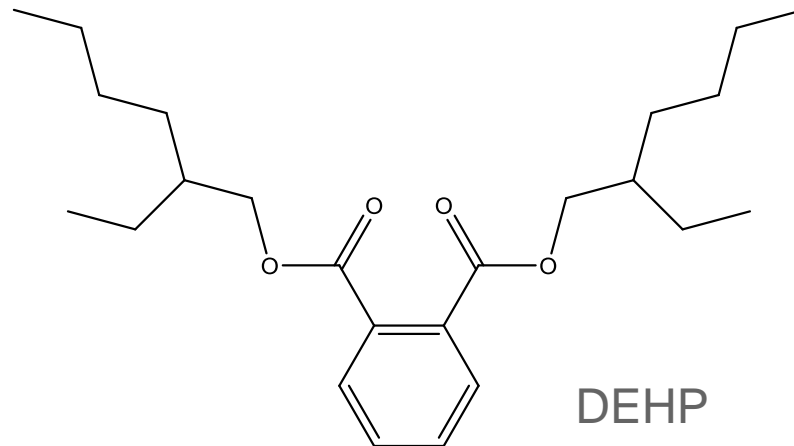
- “Dioxin” represents ~227 different compounds
  - Varying toxicities
- California dioxin emission limits – 10ng/kg of waste
- European dioxin emission limits – 0.1ng TEQ/m<sup>3</sup>
  - TEQ = Toxic Equivalent
- Dioxin formation can be dramatically reduced by\*:
  - Temperature
  - Air flow
  - Carbon monoxide reduction
  - Oxygen control
- Chlorine content\*
  - Can be organic or inorganic (*i.e.* newspaper and NaCl)

\*Shibamoto *et.al.* *Rev Environ Contam Toxicol.* 2007; 190:1-41



# Plasticizers in Medical Devices

- Plasticizers soften PVC



- Non-covalently bonded – added after polymerization
- Allows for property control
  - Rigid pipe
  - Medical tubing

# Eastman Plasticizers ca. 1950



Dimethyl Phthalate  
 •  
 Diethyl Phthalate  
 •  
 Dibutyl Phthalate  
 •  
 Di-(2 Ethyl Butyl) Phthalate  
 •  
 Dioctyl Phthalate (DOP)  
 •  
 Di-(Nerthoxy Ethyl) Phthalate  
 •  
 Triacetin  
 •  
 Tributyrin

**FOR LOW COLOR**  
**FOR STABILITY**  
**FOR DEPENDABLE PERFORMANCE**

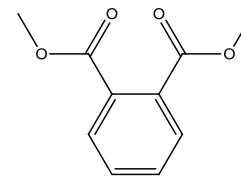
## Eastman Plasticizers

We will be pleased to send you copies of our bulletin, "PLASTICIZERS," containing specifications, properties, and typical uses of all EASTMAN Plasticizers.

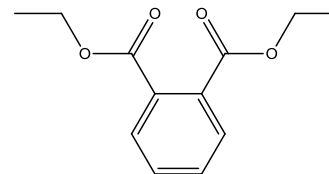
**TENNESSEE EASTMAN CORPORATION**  
 Subsidiary of Eastman Kodak Company  
**KINGSPORT, TENNESSEE**

SALES REPRESENTATIVES: New York—10 E. 40 St.; Cleveland—Terminal Tower Bldg.; Chicago—369 N. Michigan Ave.; West Coast: Wilson & Geo. Mayer & Co.; San Francisco—333 Montgomery St.; Los Angeles—4800 District Bldg.; Portland—320 S.W. Sixth Ave.; Seattle—1020 Fourth Ave., 5th.

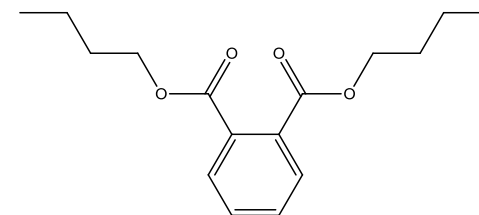
**EASTMAN INDUSTRIAL CHEMICALS**



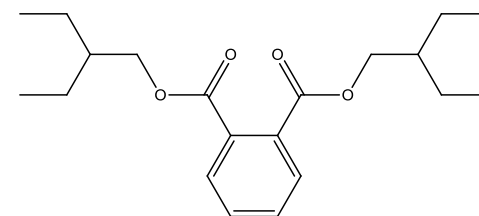
DMP



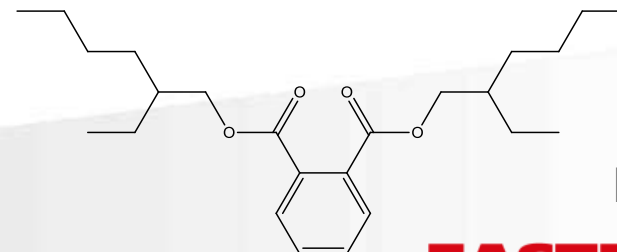
DEP



DBP



DEBP



DEHP

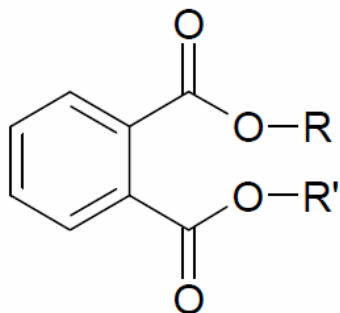
**EASTMAN**

# “Phthalate” means “*ortho*-Phthalate”

US EPA document, Phthalates Action Plan, 12/30/09:

## III. Scope of Review

Dialkyl *ortho*-phthalates (or phthalate esters) have the general chemical structure shown below:



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

US CPSC (Consumer Product Safety Commission)\*:

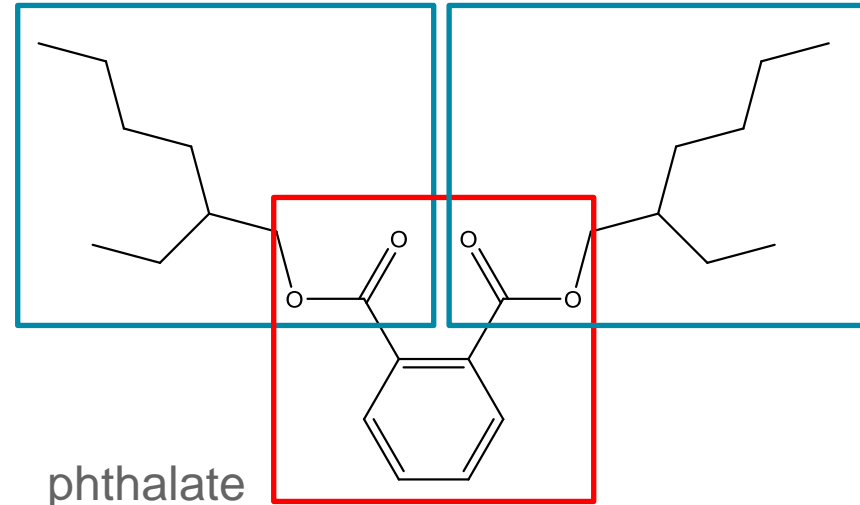
“Because “phthalate” is part of one of the common names for DEHT, it can be confused with “phthalate esters” the common name for the class of compounds known as dialkyl *ortho*-phthalates (*o*-DAPs), discussed above. While *ortho*-phthalates contain two adjacent ring substitutions, *para*-phthalates, such as DEHT, have substitutions occupying positions 1 and 4 (located “across from” each other on the ring). Therefore, **DEHT is not an *o*-DAP chemical, and thus is not subject to specific U.S. EPA or CPSC regulations aimed as (*sic*) these compounds.**”

\*Review of Exposure and Toxicity Data for Phthalate Substitutes, Michael A. Babich, Ph.D., US CPSC, Jan. 15, 2010, page 57.

# What is DEHP?

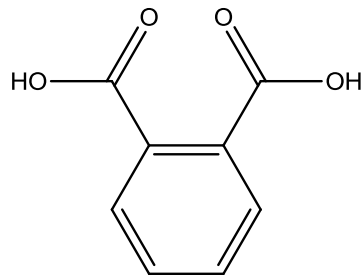
- Di (2-ethylhexyl) phthalate

“2-ethylhexyl”

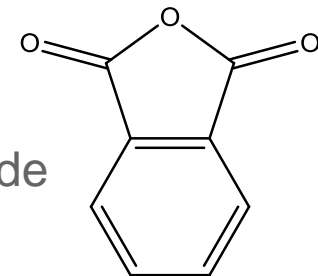


- What are *o*-phthalates?

- Compounds generated from phthalic acid/anhydride



*o*-phthalic acid



phthalic anhydride

- Why all the hub bub??

# Why focus on non-phthalates?

## ■ Regulatory pressures

- CPSC
- CHAP – Chronic Hazard Advisory Panel
- California Prop 65
- Other regions
  - REACH - Registration, Evaluation, Authorization and Restriction of Chemical substances
  - SCENIHR - Scientific Committee on Emerging and Newly Identified Health Risks
  - CoRAP - Community Rolling Action Plan
  - Danish Bans

## ■ NGOs

- EPP
- USGBC - LEED

## ■ Consumer awareness

- DfE
- GreenScreen
- Practice Greenhealth



# US and EU Plasticizer Regulatory Timeline

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Eastman plasticizers have cleared many regulatory hurdles and continue to do so

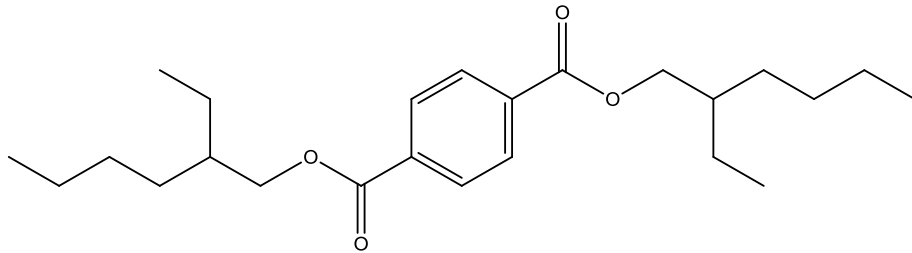




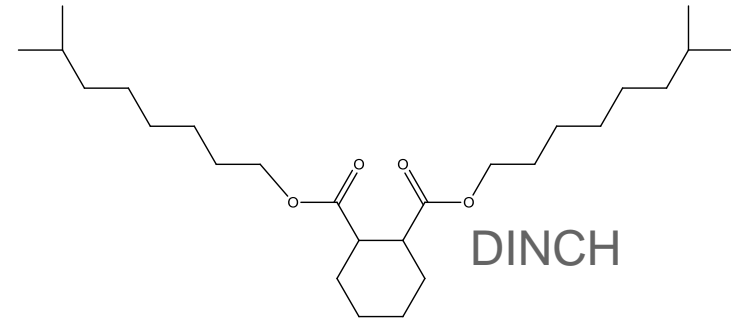
# Results of regulation

- CPSC – Regulated in toys
- Prop 65 – Requires label
  - Plasticizers affected – BBP, DEHP, DIDP, DBP, DnHP
- REACh – Requires authorization and disclosure
  - C6-C8 phthalates - branched
  - C7-C11 phthalates – branched and linear
  - DEHP
  - Lower MW phthalates – DBP, BBP, etc
- FDA – U.S. FDA food contact compliant
- EPA – May limit use by SNURs (Significant New Use Rule) or limiting production

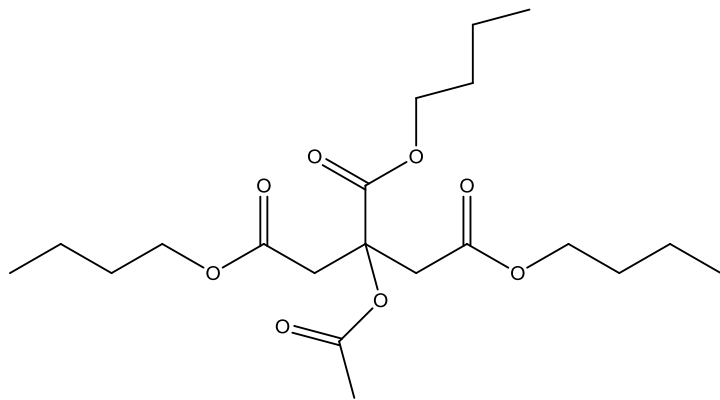
# What alternatives to DEHP are Available?



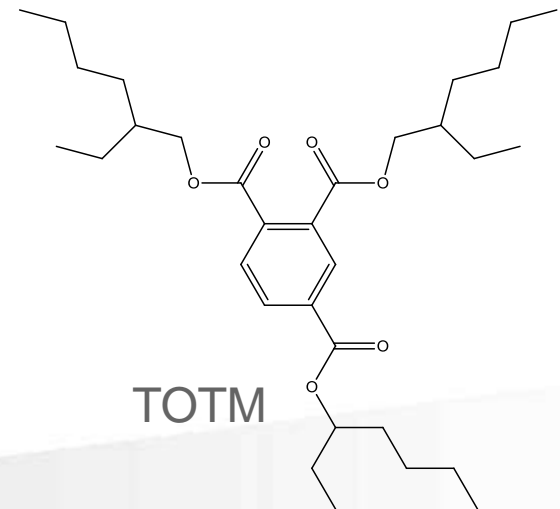
Eastman 168™ SG non-phthalate plasticizer  
(DOTP or DEHT)



DINCH



ATBC



TOTM

# SCENIHR Report: The Safety of Medical Devices containing DEHP-Plasticized PVC or Other Plasticizers

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks)

The cancer and mutagenicity effects and maternal toxicity of plasticizers.

Plasticizer	Repeated dose toxicity, NOAEL, mg/kg bw/day (higher numbers are better)	Genotoxicity	Carcinogenicity	Maternal toxicity, mg/kg bw/day
DEHP	29 (male rat)	Negative	LOAEL 320 (male rat)	LOAEL 750 (rat)
ATBC	100	Negative	Negative	NOAEL 100 (rat)
BTHC	250	Negative	Negative	NOAEL
DINCH	107	Negative	Negative	NOAEL
TOTM	100	Negative	No data	NOAEL
DOTP	500-700	Negative	Negative	NOAEL

It can be concluded that DEHP is causing the most severe reproductive effects in animal studies evaluating toxicity. TOTM is also causing reproductive toxicity, but in doses more than 20 times higher. TOTM could not be evaluated for all endpoints due to lack of data.

# SCENIHR Report: The Safety of Medical Devices containing DEHP-Plasticized PVC or Other Plasticizers

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks)

NOAEL of DEHP compared with some alternative plasticizers.

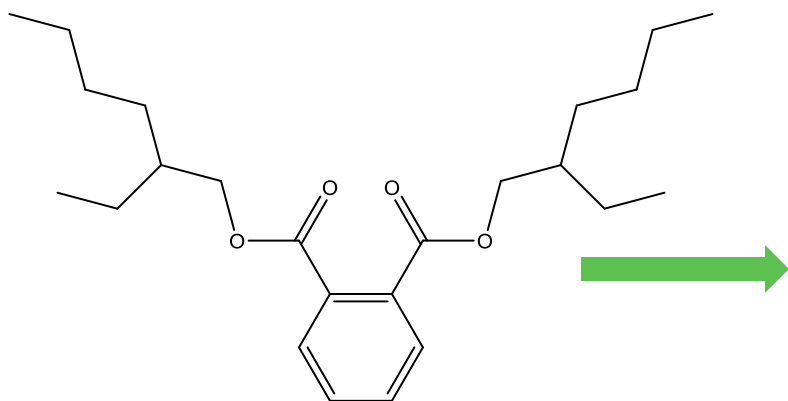
The critical endpoint is shown to indicate that for some of the chemicals it is different from reproductive effects.

Plasticizer	NOAEL mg/kg bw (higher numbers are better)	Reproductive Toxicity	Critical Endpoint	Exposure Range (neonates) micrograms/kg bw/day
DEHP	29 (male rat)	Yes	Reproduction	42-1780
ATBC	100	No data	Decreased body weight	
BTHC	250	No	Liver weight	
DINCH	107	No	Kidney	
TOTM	100	Yes	Reproduction	
DOTP	500-700	No	Developmental	

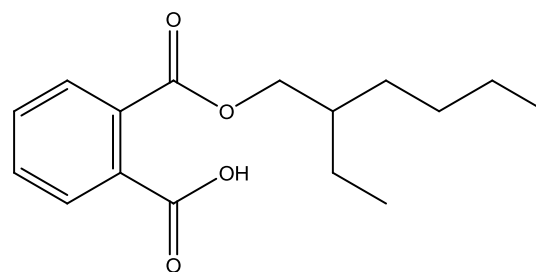
# Reasons for Phthalate Regulations

## - Metabolism

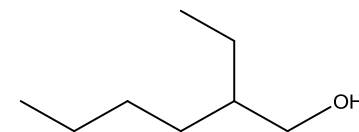
DEHP



DEHP - monoester



2-EH



- Hydrolysis allows for stabilized mono-ester
- Mono-ester and oxidation metabolites of *ortho*-phthalates are believed to have biological activity

# Non-Phthalate Plasticizers

Comparable properties to DEHP

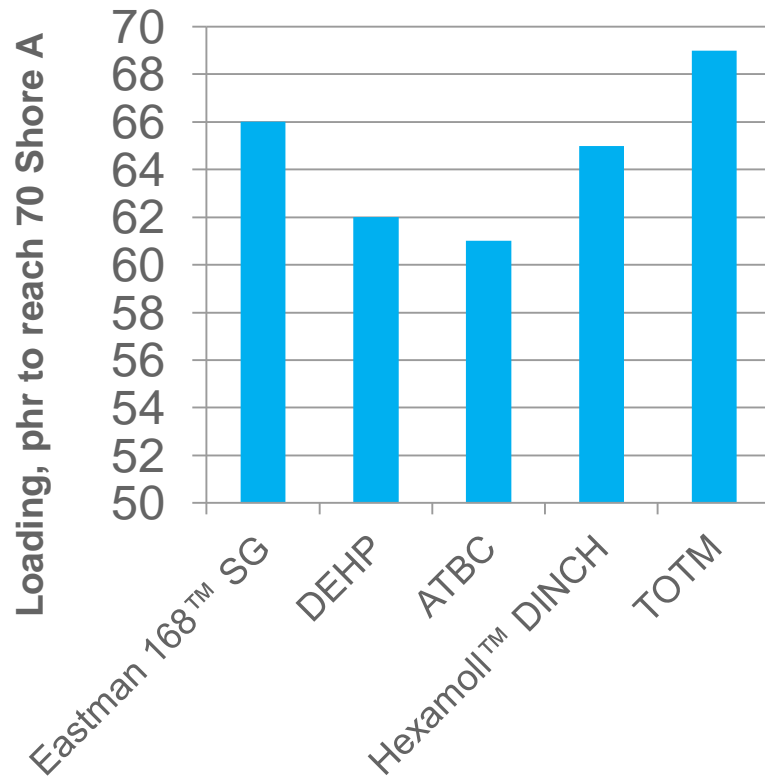
Plasticizer	DEHP	Eastman 168™ SG	Hexamoll™ DINCH	TOTM	ATBC
Loading necessary to reach 70 Shore A hardness (phr)	62	66	65	69	61
Tensile strength, Mpa (ASTM D412)	16.8	16.4	15.9	17.3	17.6
Elongation, % (ASTM D412)	311	308	309	316	324
Modulus, Mpa (ASTM D412)	6.8	6.9	6.9	7.3	6.5
Tear resistance, kN/m (ASTM D642)	53.8	50.6	51.0	57.8	55.2
Brittleness temperature, °C (ASTM D746)	-41	-47	-48	-40	-36
Fusion torque, mg	1368	980	850	1130	1264



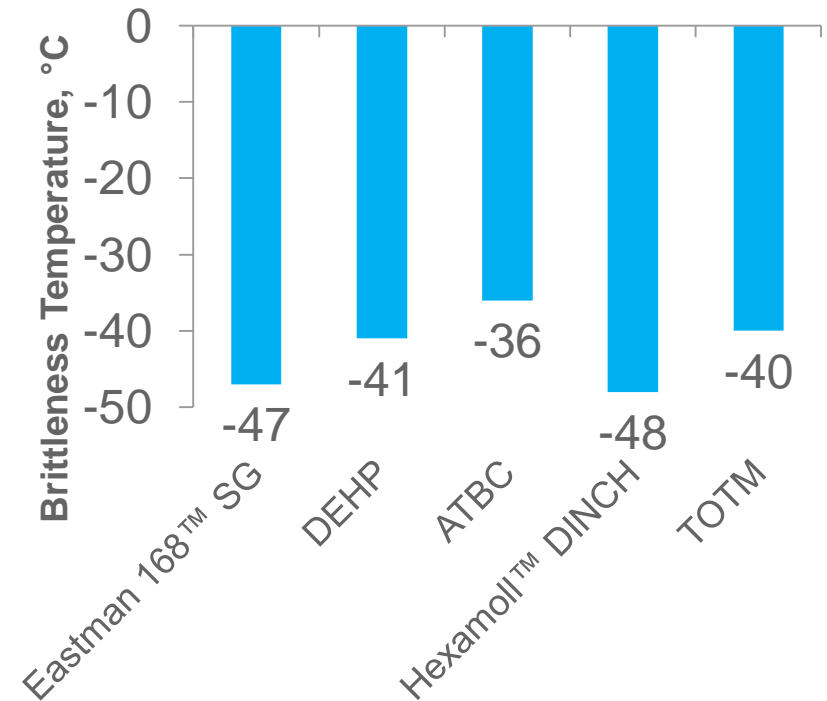


# Physical property comparisons

## Hardness/Efficiency

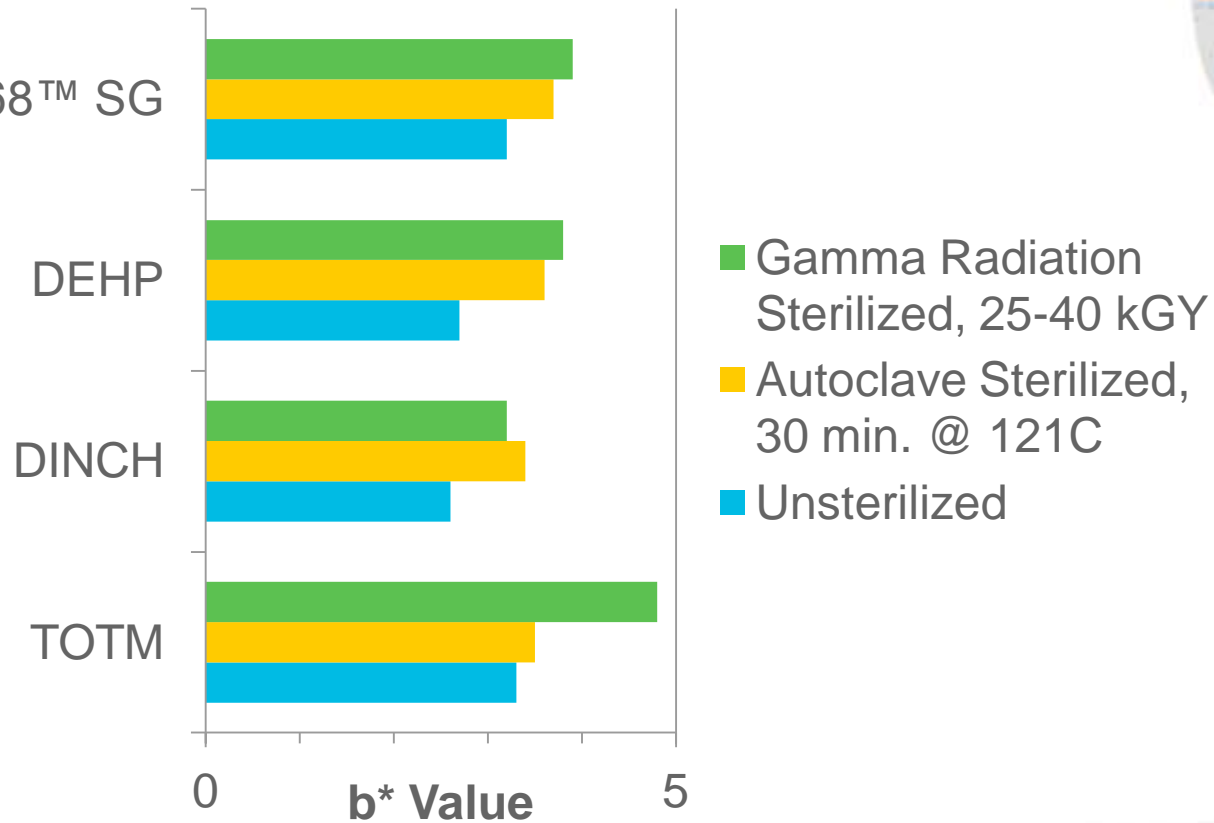


## Plasticizer Brittleness Temperature



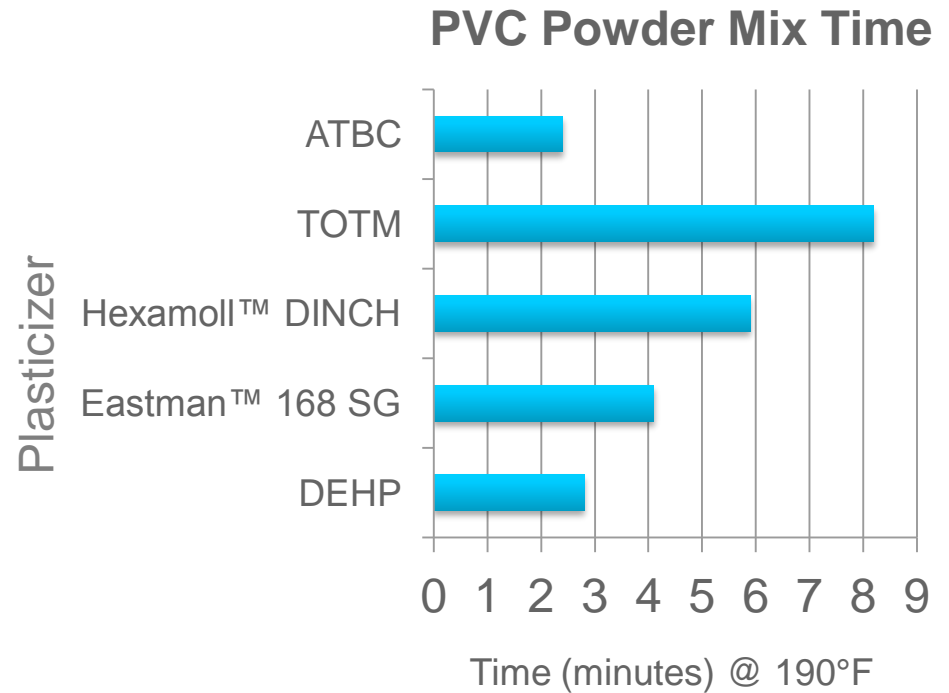
# Sterilization Stability

Eastman 168™ SG



Target hardness =  
71 Shore A

# Processing



Longer processing times = \$\$\$

# So what does the data mean?

	DEHP	Eastman 168™ SG	DINCH	TOTM	ATBC
Performance	0	0	0	0	0
Efficiency	0	0/-	0/-	--	+
Availability	0	0	0	0	-
Price	0	0	-	--	--
Toxicity data	-	++	-	-	0

**Eastman 168™ SG is the best choice.**



# Eastman 168™ SG plasticizer

**EASTMAN**

**Extensive health & safety testing:** Not a carcinogen or mutagen, shows no reproductive toxicity and has a clean & comprehensive toxicological profile

## List of Mammalian Toxicity Studies

- Acute Toxicity
  - Oral LD50 (rat, mouse)
  - Dermal LD50 (guinea pig)
  - Skin Irritation (guinea pig)
  - Skin Irritation (human)
  - Repeated Skin Irritation (guinea pig)
  - Eye Irritation (rabbit)
  - Skin Sensitization (guinea pig)
  - Skin Sensitization (human)
- Carcinogenicity Potential
  - Two-year bioassay (rats)
- Dermal Absorption (*in vitro*)
- Genotoxicity
  - Mutagenicity Bacterial (Ames)
  - Mutagenicity Mammalian (CHO-HGPRT)
  - Chromosomal Aberration (Mammalian CHO cells)
- Repeated Exposure Toxicity
  - Oral study (10 days)
  - Oral study (21 days)
  - Oral study (90 days)
  - Inhalation study (10 days)
  - Intravenous study (28 days)
- Metabolism (*in vitro* and *in vivo*)
- Developmental /Reproductive Toxicity
  - Oral study (2-generation, rat)
  - Oral study (developmental, rat)
  - Oral study (developmental, mouse)
  - Estrogenicity potential (Uterotrophic)

# Eastman 168™ SG is recognized for sensitive applications

- U.S. Pharmacopeial Convention (USP) Class VI certification
- Hemocompatibility testing according to ISO 10993-4
- Cytotoxicity testing according to ISO 10993-5
- U.S. FDA Food Contact Notification (FCN) for a variety of food contact applications
- Used extensively in the toy market
  - Replacement for phthalates banned under CPSIA (Consumer Product Safety Improvement Act)
- Considered to be a non-phthalate
  - Phthalate Esters Panel of American Chemistry Council
  - U.S. EPA
  - U.S. Consumer Product Safety Commission (CPSC)

# Summary

- Flexible PVC is used in many applications
  - Medical - over 50 years
  - Sterilization stability
  - Low memory
  - Cost
- Made possible through plasticizers
  - Flexibility
- Moving away from DEHP is easier than you think **with Eastman 168 SG**
  - Clean toxicological profile, supported by 3<sup>rd</sup> party testing
  - Similar performance and cost compared to DEHP
  - Hassle-free replacement
- All you have to do is..
  - Learn about what goes into the products in your facility
  - Don't just ask for any DEHP replacement, **specify Eastman 168 SG!**
  - Hospitals and GPO's have the power to influence what goes into their products



Questions?

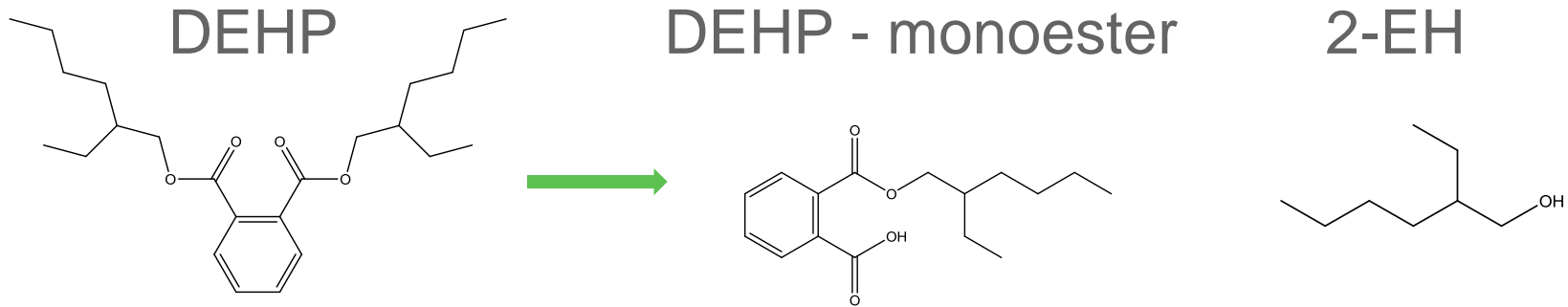




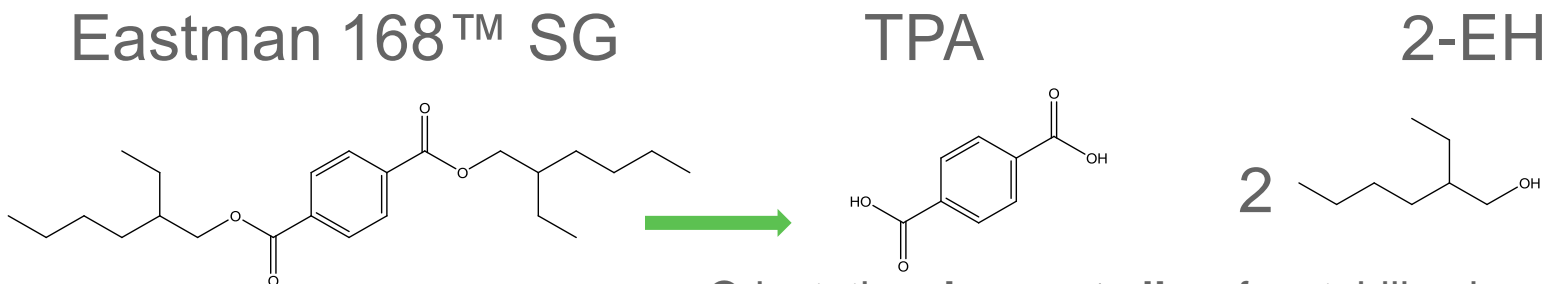
# Backup

# Reasons for phthalate regulations

## - Metabolism



- Hydrolysis **allows** for stabilized mono-ester
- Mono-ester & oxidation metabolites of *ortho*-phthalates are believed to have biological activity



- para*-Orientation **does not allow** for stabilized mono-ester
- Quickly and completely metabolized back to starting materials
- Starting materials are not known to be biologically active

# Infusion Therapy Timeline

- 1854 – 1884 – Transfusion of milk for the treatment of Cholera – Saline was discovered to be more beneficial
- 1876 – Ringer's solution introduced
- 1914 – First use of citrated blood for transfusions
- 1932 – First blood bank established – Cook County, Chicago, Ill
- 1950 – Plastic bag developed – Carl Walter
- 1951 – Blood separator developed

# Eastman plasticizer portfolio today

General Purpose Non-phthalates	General Purpose Plasticizers	Specialty PZs
Products		
<ul style="list-style-type: none"> <li>• Eastman 168™ non-phthalate plasticizer</li> <li>• Eastman 168™ SG non-phthalate plasticizer</li> <li>• Eastman™ DOA</li> <li>• Eastman™ DOM</li> <li>• Eastman™ TOTM</li> <li>• Eastman™ TEG-2EH</li> <li>• Eastman™ 425</li> </ul>	<ul style="list-style-type: none"> <li>• DEHP</li> </ul>	<ul style="list-style-type: none"> <li>• Benzoflex™ Plasticizers</li> <li>• Admex™ Polymerics</li> <li>• Eastman™ TXIB</li> <li>• Eastman™ Triacetin</li> </ul>
Markets		
<ul style="list-style-type: none"> <li>• Flooring</li> <li>• Medical Tubing</li> <li>• Food Packaging</li> <li>• Wall-Covering</li> <li>• Calendered Film and Sheet</li> </ul>	<ul style="list-style-type: none"> <li>• Medical Bags</li> <li>• Medical Tubing</li> </ul>	<ul style="list-style-type: none"> <li>• Adhesives, Caulks, Sealants</li> <li>• Resilient Flooring</li> <li>• PVC Plastisols</li> <li>• Automotive Underbody Coatings</li> </ul>