



HIGH MOLECULAR WEIGHT PHTHALATES: AN OVERVIEW OF THE TSCA RISK EVALUATION PROCESS

November 21, 2019

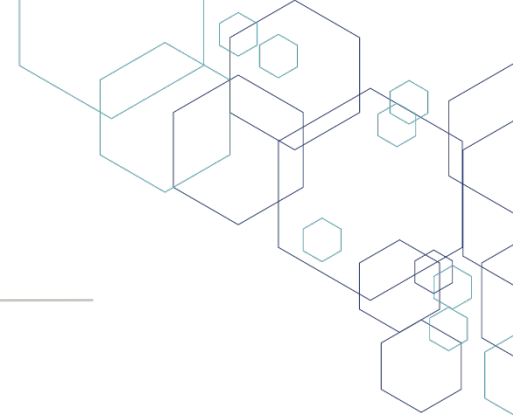
Agenda

Introduction to Phthalates

Uses

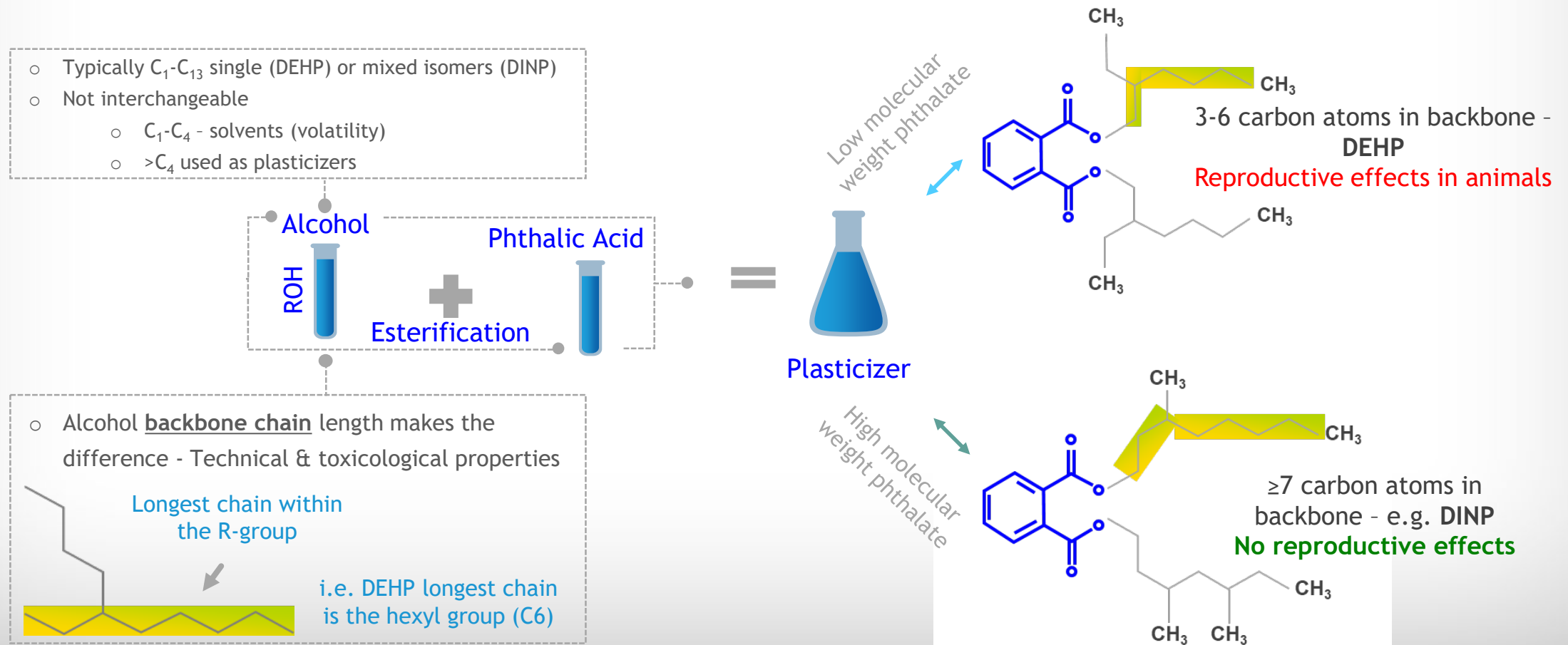
State of the Science and Regulatory Reviews

Risk Evaluations under TSCA



Why then would we treat all phthalates as if they were the same?

- Term “phthalate” represents a family of structurally similar substances
- Differentiated into low and high molecular weight categories



HIGH PHTHALATES

Make Many Products You Use Every Day Possible

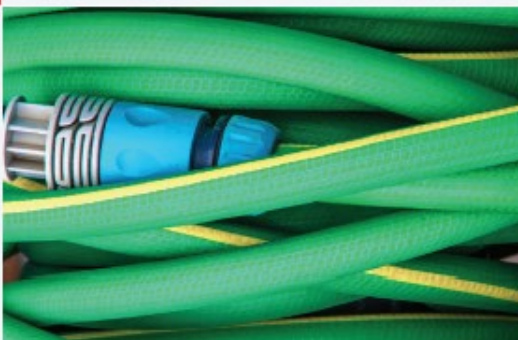
High phthalates, such as DINP and DIDP, make a wide variety of products that Americans and people around the world use every day possible. These chemical building blocks have been reviewed and determined safe to use in all of these consumer products:

High phthalates are used in PVC insulation for electrical wiring that connects and supports our electronic devices, including TVs and computers, imparting many benefits, including low temperature flexibility, heat resistance, and electrical resistivity.



Many of the components of your car interior are made possible through the use of high phthalates. They are used for upholstery and interior finishes because of their durability, UV resistance, and ability to withstand extreme temperatures.

High phthalates impart flexibility to hoses (and soft handles for garden tools) that are used in household and business applications.



High phthalates also make possible the interior flooring, wall coverings, roofing membranes and pool liners that are in millions of households, by providing excellent durability, longevity, and weather resistance.



High phthalates make coated textiles that are used to make your clothing and luggage more durable and water resistant.

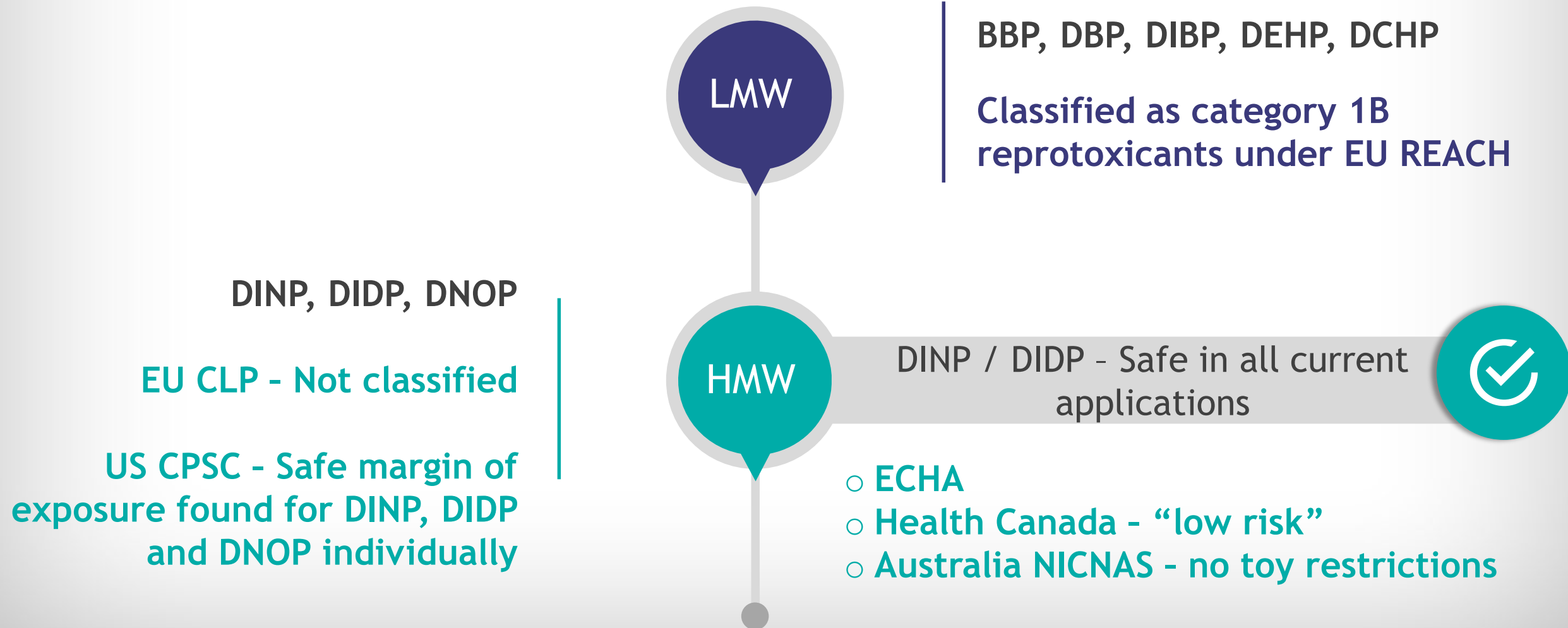
High phthalates are used in a multitude of products that demand long-lasting wear and durability, including sporting equipment, footwear, shower curtains, PVC gloves and non-animal leather for high-end furniture.



High phthalates are approved by several food safety regulatory agencies, including the US FDA and EU's EFSA, for use in some food contact products, such as conveyor belts used in food processing.

For more information, visit <https://phthalates.americanchemistry.com/>
A detailed safety evaluation can be found here: <https://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715>

Structural differences in the 5 EPA high priority phthalates are reflected in existing regulatory determinations




DINP & DIDP toy restrictions are precautionary and do not reflect a credible health risk



Toy restrictions are precautionary
- 2017 risk assessment concludes
no concern for use in toys

Canada

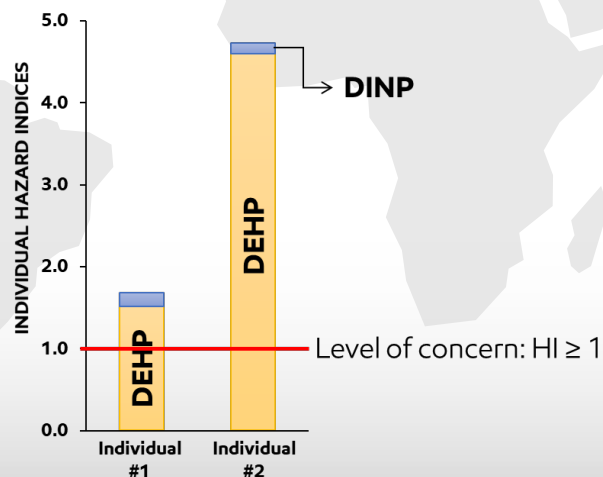
US

- DIDP no longer restricted in toys 
- DINP restriction based on questionable cumulative risk assessment



Toy restrictions based on spongiosis
hepatitis lesions found only in aging
rats and teleost fish.

EU



Australia

No toy restrictions
based on lack of risk 

The safety of DINP & DIDP has been reviewed extensively over the past 20 years

2017 - “low risk of harm...”



Canada

US

2001 - “no demonstrated health risk” from use of DINP in toys



2003 - “minimal and negligible concern” for reproductive / developmental toxicity of DINP & DIDP



2017 - toy and childcare restrictions on DIDP lifted - “risks of use are low”



2003 - “there is at present no need for further information and/or testing for risk reduction measures beyond those which are being applied already”



2014 - “no unacceptable risk has been characterized for the uses of DINP and DIDP in articles other than toys and childcare articles which can be placed in the mouth”



2018 - no basis to classify DINP for reproductive / developmental effects



2012 & 2015 - No health concern from exposure of children to DINP & DIDP in toys and childcare articles even at the highest exposure scenario considered



Australia

Risk Evaluation: *Statutory Requirements*

- EPA must establish by rule a process for risk evaluation
 - Determine if a chemical presents an unreasonable risk of injury to health or the environment **under conditions of use**
 - Without consideration of cost or other non-risk factors
 - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- This process must be completed within 3 - 3.5 years
- For each risk evaluation completed, EPA must designate a new high-priority chemical (the culmination of the prioritization process)
- By December of 2019, EPA must have 20 chemicals designated as high-priority and undergoing risk evaluation
 - Additional risk evaluations may come from **manufacturer requests**

Prioritization

- EPA will conduct a risk-based screening of all active chemicals from the inventory to identify those in need of a full evaluation
- If more information is needed, EPA can request additional testing and data



Low Priority Chemicals:

- Remain in use without further action
- Can be reprioritized based on new information at any time

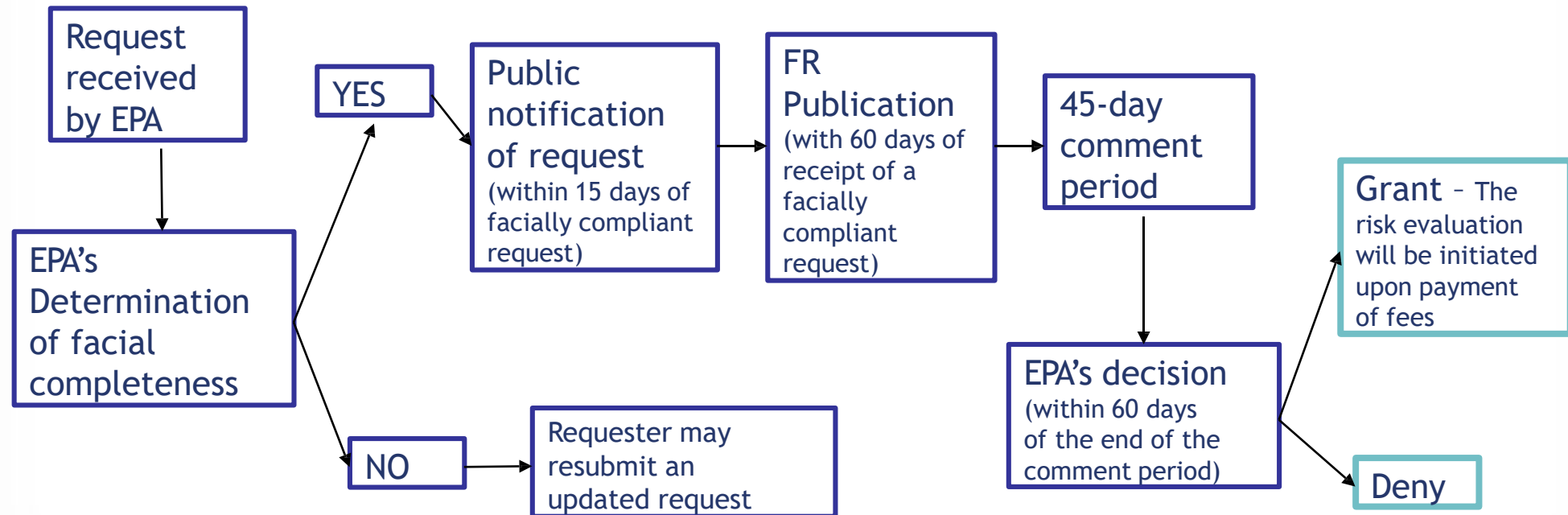


High Priority Chemicals:

- Require a risk evaluation
- First 10 must be from TSCA Work Plan
- For each risk evaluation completed, EPA must designate a new high priority chemical

Manufacturer Requests

Conditions of use - Manufacturers may request a risk evaluation for only uses of interest. EPA will identify other conditions of use that warrant inclusion in the risk evaluation.



Risk Evaluation

High Priority chemicals will undergo a full evaluation of *hazards, uses, exposure*, to determine *risk*

Risk Evaluations must:

- Be based solely on health & environmental information
- Consider a chemical's conditions of use
- Consider risks to vulnerable groups
- Rely on the best available and weight of scientific evidence



*EPA can again request more information & data if needed.

[Do you know the difference between hazard & risk?](#)

More Resources

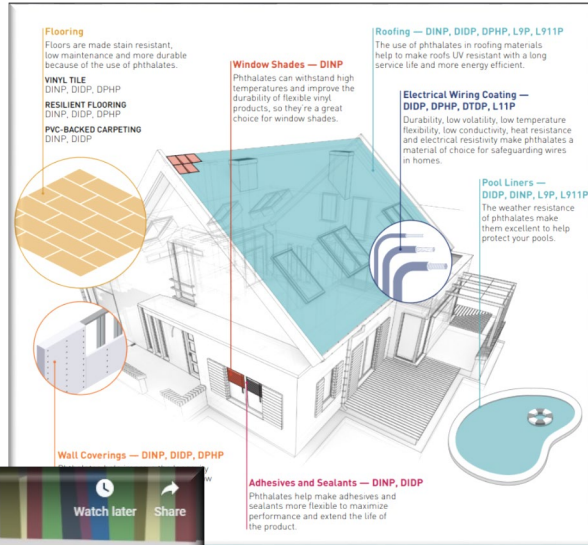
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What are high phthalates?



SAFETY IN FOOD PACKAGING: UNWRAPPING THE FACTS ON DI-ISONONYL PHTHALATE (DINP) AND DI-ISODECYL PHTHALATE (DIDP)

Risk – What is the probability of harm occurring?

EUROPEAN FOOD
SAFETY AUTHORITY
(EFSA) (2019)

Exposures¹ for high consumers (95th percentile), covering all European population groups (all countries, all surveys, all age groups), are far below the Tolerable Daily Intakes (TDI) set for phthalates authorized for use in food contact materials.

Upholstery and Interior Finishes — DIDP, L9P, L9-11P

For upholstery and interior finishes, high phthalates are an excellent choice because of their durability, stain resistance and ability to withstand extreme temperatures.

Interior PVC Skins — DIDP, L9P, L11P

High phthalates' ability to resist degradation and withstand high temperatures helps to protect interior surfaces like dashboards and shift boot covers.

Synthetic Lubricants and Engine Oils — DIDP, DTDP

The temperatures reached by synthetic lubricants and engine oils means it's vital for them to be made with materials that can withstand extremely high temperatures, like phthalates.

Wire and Cable — DINP, DIDP, L11P, DTDP

PVC insulation for wire and cable and wire harnesses made with high phthalates provides durability, low volatility, low temperature flexibility, low conductivity, heat resistance and

Sealants — DINP

PVC and acrylic plastisol sealants made with high phthalates are used in wheel wells, underbody coatings and paint to maximize performance and extend the life of the product through the

Windows — DINP, DIDP

The ability of high phthalates to withstand difficult weather conditions and prevent corrosion make them an excellent choice to help windows fit on the vehicle and stay in place.

- Urethane glass bonding adhesives (window glazing)
 - DINP, DIDP
- PVC window encapsulation
 - DIDP

Doors — DINP, L9P

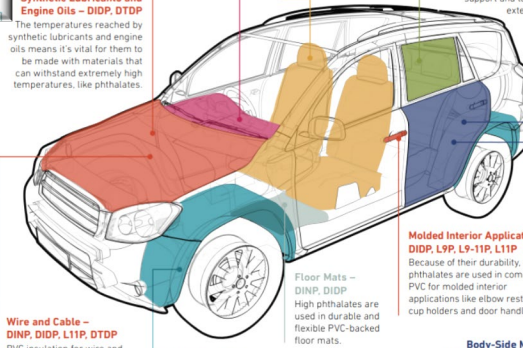
Urethane expandable foams, made with high phthalates, are added to car doors for structural support and to decrease exterior noise.

Molded Interior Applications — DIDP, L9P, L9-11P, L11P

Because of their durability, high phthalates are used in compounded PVC for molded interior applications like elbow rests, cup holders and door handles.

Body-Side Molding — DIDP, L9-11P, L11P, DTDP

The exterior of a vehicle is exposed to constant sunlight and varied weather conditions, so PVC molding made with high phthalates provides UV resistance and the ability to withstand



...te that the levels of these seven [DINP and DIDP] in Australian foods ...o appreciable health risks have ...ustralian population."
...cluded that exposures to most ...e food packaging are low and

<https://phthalates.americanchemistry.com/>

<https://www.chemicalsafetyfacts.org/phthalates/>

<https://www.mindthescience.org/chemicals-in-products/phthalates>



For more information please visit www.phthalates.org

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Questions?