January 2025

EUROPEAN PLASTICISERS' RECOMMENDATIONS ON GROUPING APPROACH FOR THE ORTHO-PHTHALATES

We agree with the conventional grouping approach, based on OECD's 2004 phthalate categorisation into high and low molecular weight groups. In addition, in order to facilitate consistent assessment and subsequent regulatory actions to the group of ortho-phthalates in the future, European Plasticisers recommend as follows.

Data First

- All available data should be part of the assessment beyond simple structural similarity considerations, due to the complexity of toxicological effects.
- There are a substantial amount of toxicity data on the ortho-phthalates. These substances have been extensively studied and regulated for more than two decades, particularly in the EU and the US.

Strict Read-Across

- Read-across methods should apply to fill-in missing data, hence be only applied to the ortho-phthalates with data gaps.
- ECHA's read-across assessment framework (RAAF) should strictly be followed.

Our recommended approach is supported by the available toxicological data shown below:

Category	Phthalate	Total Carbon Atoms	% Primary Alcohol Backbones													Embryolethality	Teratogenic effects	Male reproductive tract: severe and irreversible	Cryptorchidism	Nipple Retention (NR) and AnoGenital Distance (AGD) - Adult	PrePutial Separation (PPS)
			C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13						
	DMP	1	■													–	–	–	–	–	
	DEP	2		■												–	–	–	–	–	
	DPP	3			■											–	–	–	–/+		
Reprotox Phthalate Esters	DIBP	4			■											+	+	+	+	+	+
	BBP	4*				■										+	+	+	+	+	+
	DBP	4				■										+	+	+	+	+	+
	DPeP	5					■									+		+	+	+	–
	DiHP	7						■	■							+	+	+	+	+	+
	DnHxP	6						■	■							+	+	+	+	+	–
	DEHP	8						■	■							+	+	+	+	+	+
	DiOP	8				■	■	■	■							–/+	–/+	+	+	+	
	711P	7-11				■	■	■	■	■	■		■			+	+				
Non-Reprotox Phthalate Esters	DnHP	7							■							–	–	–	–		
	DINP 1	9							■	■						–	–	–	–	–	
	DINP 2	9							■	■						–	–	–	–	–	
	DPHP	10							■	■						–	–	–	–	–	
	DnOP	8								■						–	–				
	79P	7-9							■	■	■					–	–	–	–		–/+
	DIDP	10								■	■					–	–	–	–	–	
	DIUP	11									■					–		–	–	–	
	DUDP	11-12										■	■			–	–	–	–	–	
	911P	9-11										■	■			–	–	–	–		–/+
	DTDP	13										■	■			–					
	DTDP	13											■	■		–	–				

A sector group of Cefic
European Chemical Industry Council - Cefic aisbl
Transparency Register n°64879142323-90

info@europeanplasticisers.eu