

TECHNICAL BRIEF – Summary of Phthalate Esters Listed in CPSIA, CA Proposition 65 and EU Regulations

Abbrev.	Compound Name	CAS #	M.W.	CPSIA Content (0.1 wt)	Prop65 Safe Harbor (µg/day)	# Prop65 60-Day Notices in 2015	EU Regulations
DBP	Di- <i>n</i> -butyl phthalate	84-74-2	278	Sec. 108 (a)	MADL: 8.7	23	ECHA, REACH
DnHP	Di- <i>n</i> -hexyl phthalate	84-75-3	334	Proposed ¹	MADL: 2,200 <i>o</i>	0	ECHA, REACH
BBP	Butyl benzyl phthalate	85-68-7	312	Sec. 108 (a)	MADL: 1,200 <i>o</i>	0	ECHA, REACH
DEHP	Di(2-ethylhexyl) phthalate	117-81-7	390	Sec. 108 (a)	MADL: 410 <i>o</i> ^a , 58 <i>o</i> ⁱ , 20 <i>o</i> ⁿ ; NSRL: 310	520	ECHA, REACH
DnOP	Di- <i>n</i> -octyl phthalate	117-84-0	390	Sec. 108 (b) ²	--	--	ECHA
DINP	Diisononyl phthalate	68515-48-0/28553-12-0	~418	Sec. 108 (b) ³	NSRL: 146	227	ECHA
DIDP	Diisodecyl phthalate	68515-49-1/26761-40-0	~446	Sec. 108 (b) ²	MADL: 2,200	31	ECHA
DIBP	Diisobutyl phthalate	84-69-5	278	Proposed ¹	--	--	ECHA, REACH
DnPP	Di- <i>n</i> -pentyl phthalate	131-18-0	306	Proposed ¹	--	--	ECHA
DCHP	Dicyclohexyl phthalate	84-61-7	330	Proposed ¹	--	--	--

Abbreviations / Notes

CPSIA: Consumer Product Safety Improvement Act of 2008

1: 2014 proposal to permanently ban

2: 2014 proposal to lift current ban

3: 2014 proposal to make interim ban permanent

Prop65: California Proposition 65

NOEL: No Observable Effect Level

NSRL: No Significant Risk Level for carcinogens

MADL: Maximum Allowable Dose Level for reproductive toxins

o: oral ingestion

a - adult, *i* - infant boys, *n* - neonatal infant boys

ECHA: European Chemicals Agency

REACH: Registration, Evaluation, Authorization & Restriction of Chemicals

Background - CPSC Section 108

CPSIA Section 108 (a): Permanent ban on DEHP, DBP and BBP in any amount greater than 0.1 percent for each individual phthalate in children's toy or child care article. CPSIA Section 108 (b): Interim ban on DINP, DIDP and DnOP in any amount greater than 0.1 percent for each individual phthalate in children's toy or child care article that can be placed in a child's mouth. "Statement of Policy: Testing of component Parts with respect to Section 108 of the CPSIA" published by CPSC on August 7, 2009, states that each component part that may contain phthalates is tested individually instead of the whole toy because a whole-toy result may dilute the content of a component part with very high phthalate content. Various changes to the CPSIA list of phthalates were proposed in 2014 CPSC report of *Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives*.

Background - Prop 65

In 1986, California voters approved the Safe Drinking Water and Toxic Enforcement Act of 1986, known as Proposition 65. Six phthalates are listed in Proposition 65: BBP, DEHP, DIDP, DINP, DBP and DnHP. Since the regulation relates to exposure rather than to content, the results are subject to interpretation and it's the sole responsibility of the manufacturer or business to determine whether a label or other warning is required under Proposition 65. The California Department of Justice maintains a searchable database of Prop 65 60-Day Notices.

Cal/EPA OEHHA publishes a list of No Significant Risk Levels (NSRLs) for Carcinogens and Maximum Allowable Dose Levels (MADLs) for Chemicals Causing Reproductive Toxicity. NRS� denotes the level of carcinogen exposure that would result in no more than one case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime. For developmental toxins that cause birth defects and/or other reproductive harm, the MADL is the level at which a chemical would have no observable effect assuming exposure at 1,000 times that level, i.e. 1/1000th of the NOEL. Note that intravenous (non-environmental exposure) MADL values for DEHP are not shown in the table.

Background - ECHA and REACH

Chemicals identified by ECHA as "Substance of Very High Concern" (SVHC) are proposed to be included in the candidate list for eventual inclusion in ANNEX XIV of REACH. The applicable reasons for inclusion for phthalates are: carcinogenic, mutagenic and/or toxic for reproduction. Substances included in Annex XIV of REACH are termed the "Authorization List".

Testing Services Available for Phthalates - Berkeley Analytical tests toys, childcare items, building products, consumer products and other items for phthalate esters. Berkeley Analytical is named by the CPSC as a qualified laboratory for the testing of phthalate esters in toys and childcare items. We use the CPSC method and U.S. EPA Methods 3545A and 8270D for analysis of phthalates. These methods are listed in the scope of our laboratory's ISO/IEC 17025 accreditation. Our chain-of-custody form listing the testing options can be downloaded at <http://berkeleyanalytical.com/forms>. Contact us at info@berkeleyanalytical.com or call us at 510-236-2325 for more information and to request a quotation.