

SAFE GUARDS

SGS CONSUMER TESTING SERVICES

HARDLINES

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PHTHALATES RISK IN COSMETIC PRODUCTS

A number of chemicals belong to phthalate family was banned in cosmetic products in EU starting from October 2004 according to Cosmetic Directive 76/768/EEC, and the prohibition on this chemical family keeps on expanding. In the past, the commonly used phthalates include Benzyl Butyl Phthalate (BBP), Dibutyl Phthalate (DBP) and Bis(2-Ethylhexyl) Phthalate (DEHP), but these chemicals were prohibited as a cosmetics ingredient in EU at this moment. They are used as plasticizers in products such as nail polishes (to reduce cracking by making them less brittle) and hair sprays (to help avoid stiffness by allowing them to form a flexible film on the hair) and as solvents and perfume fixatives in various other products.



Due to the safety concerns of these chemical on human health, several countries (e.g. EU, ASEAN countries, China and Taiwan) have set out restriction on phthalates in cosmetic products. There is a prohibited list for phthalate, as an ingredient in cosmetics, according to the EU cosmetics directive, ASEAN cosmetics directive (ACD), China Hygienic Standard of Cosmetics and the cosmetics regulation from the Department of Health, Taiwan (Table 1).

In Nov 2008, a new regulation was passed in Taiwan banning **Di-N-Octyl Phthalate (DNOP)** as cosmetic ingredient, and it will be effective starting 1 May, 2009.

Although there is no prohibited list of phthalates in cosmetic products in the United States, under the authority of the Fair Packaging and Labeling Act (FPLA), FDA requires an ingredient declaration on the cosmetic products sold at the retail level to consumers. Consumers can tell whether some products contain phthalates by reading the ingredient declaration on the labels of such products. Manufacturers have responsibility to notify the consumers about the presence of substances which are known to cause cancer or reproductive toxicity according to California Proposition 65 as well.



According to the US Consumer Product Safety Improvement Act (CPSIA), if a cosmetic material is included in a toy set it is required to meet the requirements of the phthalates ban beginning February 10, 2009. However, cosmetics in general when not packaged with a toy, are not covered by the section 108 prohibitions and fall under the jurisdiction of the Food and Drug Administration.

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Table 1: A summary table on phthalates restriction in cosmetics for your reference:

Chemicals	CAS No.	EU, ASEAN & China ⁽¹⁾	Taiwan ⁽²⁾	US ⁽³⁾
Benzyl Butyl Phthalate (BBP)	85-68-7	Prohibited*	Prohibited	<0.1%
Bis(2-Ethylhexyl) Phthalate (DEHP)	117-81-7	Prohibited*	Prohibited	<0.1%
Dibutyl Phthalate (DBP)	84-74-2	Prohibited*	Prohibited	<0.1%
Di- <i>n</i> -Octyl Phthalate (DNOP)	117-84-0	-	Prohibited (as of 1 May 2009)	<0.1%
Diisoo nonyl phthalate (DINP)	28553-12-0	-	-	<0.1%
Diiso decyl phthalate (DIDP)	26761-40-0	-	-	<0.1%
Bis(2-Methoxyethyl) Phthalate	117-82-8	Prohibited	Prohibited	-
Di- <i>n</i> -Pentyl Phthalate	131-18-0	Prohibited	Prohibited	-
Diisopentylphthalate	605-50-5	Prohibited	Prohibited	-

Remark:

¹ 76/768/EEC for EU; ASEAN Cosmetics Directive (ACD); Hygienic Standard of Cosmetics for China;

² The Department of Health, Taiwan;

³ US Consumer Product Safety Improvement Act (CPSIA), it is only applicable for a cosmetic material which is included in a toy set. Subsection 108(a) prohibits the manufacture, import, distribution, or sale of children's toys or child care articles containing more than 0.1% of benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), or di-(2-ethylhexyl) phthalate (DEHP), beginning February 10, 2009. Subsection 108(b)(1) further prohibits, on an interim basis, the manufacture, import, distribution, or sale of "children's toys that can be placed in a child's mouth" or child care articles containing more than 0.1% of diisodecyl phthalate (DIDP), diisononyl phthalate (DINP), or di-*n*-octyl phthalate (DNOP), beginning February 10, 2009.

* Banned under the EU cosmetic Directive as CMR-substance.



If you are concerned about the presence of phthalates in your cosmetic products, SGS can help to provide you an answer. Contact us now!

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