

## **Phthalates Statement**

9th February 2020

### **What are Phthalates?**

Phthalates or esters of phthalic acid are mainly used as plasticizers (substances added to plastics to increase their flexibility, transparency, durability, and longevity).<sup>1</sup> They are manufactured by reacting phthalic anhydride with alcohols with differing molecular weights ranging from methanol and ethanol (C1/C2) up to tridecyl alcohol (C13), either as a straight chain or with some branching. Phthalates are used widely in polyvinyl chloride (PVC) which is further used to make products such as plastic packaging films and sheets, garden hoses, inflatable toys, blood-storage containers, medical tubing, and some children's toys.<sup>2</sup> Phthalates are also used in detergents, lubricating oils, pharmaceuticals, and personal care cosmetics, such as nail polish, hair sprays, aftershave lotions, soaps, shampoos, perfumes, and other fragrance preparations.<sup>3</sup>

### **Health effects of Phthalates**

In general, phthalates do not persist in the outdoor environment due to biodegradation, photodegradation, and anaerobic degradation but several literature reviews have been written and Governmental committees have been set up to study the health risks associated to phthalate exposure. A host of adverse effects ranging from endocrinal, reproductive, and neurological systems disruption, prenatal risks and carcinogenic implications have all been linked to exposure to phthalates.<sup>4-9</sup>

In August 2008, the United States Congress passed the Consumer Product Safety Improvement Act (CPSIA) wherein it was stated that "it shall be unlawful for any person to manufacture for sale, offer for sale, distribute in commerce, or import into the United States any children's toy or child care article that contains concentrations of more than 0.1 percent of' DEHP [Bis(2-ethylhexyl) phthalate], DBP (Dibutyl phthalate), or BBP (Benzylbutyl phthalate). Further provisions stated that "it shall be unlawful for any person to manufacture for sale, offer for sale, distribute in commerce, or into the United States any children's toy that can be placed in a child's mouth or child care article that contains concentrations of more than 0.1 percent of" DINP (Diisononyl phthalate), DIDP (Diisodecyl phthalate),

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DnOP (Di-n-octyl phthalate).<sup>10</sup> In December 2013, phthalates were added to the list of chemicals known to cause cancer for purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).<sup>11</sup>

Additionally, the use of some phthalates has been restricted in the ELI for use in children's toys since 1999.<sup>12</sup> In 2008-09 38P, DEHP, DISP (Diisobutyl phthalate) and DBP were added to the Candidate list of Substances for Authorisation under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations and added to the Authorisation list, Annex XIV, in 2012. This meant that from February 2015 these phthalates are not allowed to be produced in the ELI without authorisation but may still be Imported in consumer products.<sup>13</sup>

In 2010-2011, the Australian Government announced a permanent ban of children's products containing more than of DEHP.<sup>14</sup>

China's National Safety Technical Code for Toys (GB 6675) was modified in 2013 to set a 0.1% by mass concentration limit for DBP, BBP, DEHP (Diethylhexyl phthalate, DNOP, DINP and DIDP (Diisodecyl phthalate) in toys for children.<sup>15</sup>

## **FLEXCUBE**

Our mission as an organization is to provide the best packaging system combined with rigorous manufacturing standards. Our products are based on Polyethylene - a polymer that does not require the use of phthalates at any point in the manufacturing cycle. However, to reassure our customers, we conduct different purity tests on all the components that make up our product prior to assembly.

Based on those tests we can make the following statements:

1. Semi Volatile Organic Content Analysis by GC-MS established that the phthalate level was found to be less than the limit of quantitation<sup>16</sup> and less than the established NOAEL (No-observed- Adverse-Effect-Level) stated in Kamrin's review.<sup>9</sup>
2. The materials used in the manufacture of our product contain only ingredients that meet the current requirements of the LIS Food and Drug Administration (FDA) for use under regulations 175.105, 175.300, 176.170, 176.180, 177.1520, 177.1550, 177.2600 and 178.3570 for articles coming into repeated contacted with food.<sup>17</sup>

The results of such rigorous testing have helped us assert to the best of our ability that the FLEXCUBE range of products are phthalate free<sup>9,16</sup> and adhere strictly to the standards of the LIS FDA.<sup>17</sup>

If you require more information on this topic, please contact the company.

A handwritten signature in black ink, appearing to read 'Peter Henry', with a horizontal line extending to the right.

Peter Henry

Director – Engineering

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## References

1. J. Autian, 'Toxicity and health threats of phthalate esters: review of the literature', *Environmental Health Perspectives* 4 (1973) 3—26.
2. O\_G\_ Hansen, 'PVC and phthalates in medical devices: a never ending story', *Medical Device Technologies* 17 (2006) 16-18.
3. <http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm12825.htm>
4. M. Wit-tassek, H.M. Koch, J. Angerer, T. Bruning, 'Assessing exposure to phthalates- The Human biomonitoring approach', *Molecular Nutrition and Food Research* 55 (2011) 7-31.
5. J. Hogberg, A. Hanberg, M. Berglund, S. Skerfving, M. Remberger, A.M. Calafat, A.F. Filipsson, Jansson, N. Johansson, M. Appelgren, H. Hakansson, 'Phthalate Diesters and Their Metabolites in Human Breast Milk, Blood or Serum, and Urine as Biomarkers of Exposure in Vulnerable Populations', *Environmental Health Perspectives* 116 (2008) 334-339.
6. M. Matsumoto, M. Hirata-Koizumi, M. Ema, 'Potential adverse effects of phthalic acid esters on human health: A review of recent studies on reproduction', *Regulatory Toxicology and Pharmacology* 50 (2008) 37-49.
7. U. Heudoff, V\_ Mersch-Sundermann, J. Angerer, 'Phthalates: Toxicology and exposure', *International Journal of Hygiene and Environmental Health* 210 (2007) 623-634.
8. J. A. Tickner, T. Schettler, T\_ Guidotti, M. McCaw, M. Rossi, 'Health risks by use of Di-2-ethylhexyl phthalate (DEHP) in PVC medical devices A critical review', *American Journal of Industrial Medicine* 39 (2001) 100-111.
9. MA Kamrin, 'Phthalate Risks, Phthalate Regulation, and Public Health: A Review', *Journal of Toxicology and Environmental Health-part a-critical Reviews* 12 (2009) 157-174.
10. <https://www.govtrack.us/congress/bills/110/hr4040/text>
11. <http://oehha.ca.org/proposition-65/cnrn/chemivcl-located-effective-december-20-2013-unknown-state-california-cause-cancer>
12. [http://europa.eu/rapid/press-release\\_IP-99-829](http://europa.eu/rapid/press-release_IP-99-829)
13. <https://goo.gl/kmigsk>
14. <http://www.legislation.gov.au/Details/F2010L03282>
15. [https://www.bureaveritas.com/home/about-us/our-business/cps/whats-new/bulletins/china\\_toy\\_safety\\_standard\\_updateLOQ](https://www.bureaveritas.com/home/about-us/our-business/cps/whats-new/bulletins/china_toy_safety_standard_updateLOQ)
16. O\_ MacDougall, W. Crummett, "Guidelines for data acquisition and data quality evaluation in environmental chemistry", *Analytical Chemistry* 52 (1980) 2242—2249
17. <https://goo.gl/pXUdEe>