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Risk Assessment of Boron in a Children's Toy Product

Boron is a naturally occurring element obtained *via* diet that appears important for normal human physiology. However, evidence in laboratory animals suggests prenatal exposure to boron is associated with developmental toxicity, although there is currently a lack of evidence of these effects in humans. Recent alerts by the European Commission raised concern about toxicity associated with leaching of boron from some children's toy products. Here, we evaluated the potential risk to human health associated with exposure to boron in a children's toy and examined two relevant exposure scenarios: daily dermal exposure to the product spread across both hands (representative of intended use), and a one-time or infrequent ingestion of the entire product (considered highly unlikely due to palatability). The exposed individual of interest was a 3-year-old child based on the youngest recommended age of use; exposure parameters were based on experimental study data and US EPA sources. We received analytical chemistry results reporting concentrations of extractable boron in the toy from two different European Standard for Safety of Toys methods: an n-heptane extraction, and an acid leach test. Of note, levels of boron resulting from the n-heptane extraction were one order of magnitude greater than the acid leach test. Based on a review of the product chemistry and sample testing methods, we determined the n-heptane extraction breaks covalent bonds and essentially destroys the product; this process is inconsistent with anecdotal information provided by the toy manufacturer indicating that after accidental ingestion the product is excreted intact. Hence, results of the n-heptane extraction were not considered biologically relevant as the concentrations would not be reached under any human dermal or ingestion exposure scenarios. Based on the concentration of extractable boron resulting from the acid leach test, representative of physiological conditions in the human digestive system (*i.e.*, pH 1-1.5), the doses of boron (as boric acid) associated with the dermal and oral exposure scenarios were 0.017 mg/kg-bw/day and 0.757 mg/kg-bw, respectively. These values are lower than the dermal (196 mg/kg-bw/day) and oral (0.98 mg/kg-bw/day) exposure derived no effect levels (DNELs) of boric acid recommended by the European Chemicals Agency (ECHA). Our risk assessment indicated concentrations of extractable boron in the toy are below levels that could cause adverse health effects in children who may use the product, even on a daily basis.