

# Lead (Pb) Regulations effecting Personal Care, Toy and Pharmaceutical Products

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## Introduction

Lead is a highly toxic heavy metal that can be found in small amounts in the earth's crust. Because of its abundance, low cost, and physical properties, lead and lead compounds have been used in a wide variety of products including paint, ceramics, gasoline, cosmetics and other materials. Lead is considered a neurotoxin which accumulates in soft tissues and bone over time.

## Testing

Lead is tested by the use of wet chemistry method, atomic absorption methods or Inductively Coupled Plasma Methods. BioScreen currently performs the USP wet chemistry analysis and AA analysis for lead. BioScreen will be add the ICP instrument in 2008 and will offer that service as soon as the instrument is installed and validated.

## Regulations

### Pharmaceutical Industry

The primary regulation for the pharmaceutical industry is to meet the monograph requirements in the United States Pharmacopeia or internal client specification provided as part of a drug product approval to the Food and Drug Administration. The current USP <251> Lead chapter has a specification of 1 microgram of lead.

### Personal Care Industry

There are no clear specified limits on lead for the personal care industry. However, the United States regulations does state that cosmetics must be safe for the use by consumers. Therefore, manufacturers are responsible to assure that levels of lead in personal care products are safe. It is up to each individual company to determine the specification based on industry guidelines or other guidelines such as the Pharmaceutical Industry or Toy Industry.

### Toy Industry

The amount of lead allowed in paint or other material used in children's products is 600 parts per million (0.06%). This is cited in Code of Federal Regulations section 16 CFR 1500.

### California Proposition 65 regulations

While this only applies to products sold in California, the requirements for labeling products to meet the California Proposition 65 imposes additional requirements for products containing lead. The Maximum Allowable Dose Level (MADL) safe harbor level for lead is 0.5 µg/day of lead. If using the product exposes a person to more than this amount, the product must be labeled as stated in the regulation. For this reason, many manufacturers verify that the level of lead is below this amount. Litigation due to Prop 65 regulation also may determine what companies plan to do regarding the level of chemicals in the product.

## Discussion

Based on the regulations listed above, the manufacturer must determine which industry the product belongs to. If it is the toy industry or the pharmaceutical industry the regulations are very clear. As for the Personal Care industry the regulations are not clear and leaves the final decision to be made by the manufacturer.

BioScreen Testing Services provides this technical bulletin for informational purposes only. BioScreen recommends that the manufacturer/client consult with internal regulatory department or consult with an appropriate regulatory company to confirm the above regulatory information.

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