

Lancaster Laboratories Melamine Testing Method offers greater sensitivity and specificity

LANCASTER, Pa. (November 6, 2009) - Lancaster Laboratories, part of Thermo Fisher Scientific, today announced a new method for detecting melamine in pharmaceutical products that uses LC/MS/MS to provide greater sensitivity and specificity over other techniques. Lancaster Laboratories' new method meets the Food and Drug Administration's August 2009 guidance, entitled Pharmaceutical Components at Risk for Melamine Contamination, which identifies raw materials that are considered high-risk for melamine contamination and recommends monitoring of these raw materials for the presence of melamine prior to release into production.

Melamine is used in the manufacture of a variety of products, including resin based products (countertops, glues, housewares, etc), cleaning products and industrial cleaners. Melamine has a low acute toxicity and is not readily metabolized. Cyanuric acid, which also has a low acute toxicity, is a structural analogue of melamine and is used in the manufacture of herbicides, dyes, resins and antimicrobial agents. It is also used as a stabilizer and disinfectant in swimming pools and as a component of feed grade biuret (a ruminant feed additive).

The combined presence of melamine and cyanuric acid leads to the formation of melamine cyanurate. This compound has low solubility which can lead to the formation of crystals in the kidneys, a condition known to cause renal failure, kidney toxicity and, in some subjects, death.

Two recent incidents led the FDA to assess the potential impact of melamine in pharmaceutical products. First, in 2007, numerous deaths and illnesses in both cats and dogs led investigators to discover melamine in both wheat gluten and rice protein used as a pet food thickener. This led to a mass recall of pet food products. In 2008, melamine-contaminated infant formula in China was linked to illness in more than 50,000 infants and to the deaths of at least six infants.

Founded in 1961, Lancaster Laboratories is the global leader in pharmaceutical and biopharmaceutical laboratory services, providing innovative and timely scientific solutions that enable customers to better manage the drug development process.

Visit www.lancasterlabspharm.com and discover why customers rank Lancaster Laboratories #1.