



## Key Notes - Acetone

**Source: Voluntary Children's Chemical Evaluation Program (VCCEP) 65 Fed. Reg. 81,700**

Acetone is unusual among commercial chemicals, in that it is a normal by-product of fatty acid metabolism and is naturally present throughout the human body at measurable levels.

Physiological concentrations increase as energy requirements increase (e.g., during exercise, dieting or pregnancy).

Acetone occurs naturally in a wide variety of foods such as onions, grapes, cauliflower, tomatoes, milk, cheese, beans, and peas (SIDS, 1999). The levels of acetone in the milk of healthy cows range from 0 to 0.2 millimoles (0 to 11.6 mg/l). Thus, all people have acetone exposure via natural sources in the diet.

Acetone is used in a variety of general medical applications and is also listed as a component in food additives and food packaging.

- EPA EPCRA Delisting (1995). EPA removed acetone from the list of "toxic chemicals" maintained under Section 313 of the Emergency Planning and Community Right to Know Act (EPCRA). In making that decision, EPA conducted an extensive review of the available toxicity data on acetone and found that acetone "exhibits acute toxicity only at levels that greatly exceed releases and resultant exposures," and further that acetone "exhibits low toxicity in chronic studies."
- Genotoxicity. Acetone has been tested in more than two dozen *in vitro* and *in vivo* assays. These studies indicate that acetone is not genotoxic.
- Carcinogenicity. EPA in 1995 concluded, "There is currently no evidence to suggest a concern for carcinogenicity." (EPCRA Review, described in Section 3.3). NTP scientists have recommended against chronic toxicity/carcinogenicity testing of acetone because "the prechronic studies only demonstrated a very mild toxic response at very high doses in rodents."
- Neurotoxicity and Developmental Neurotoxicity. The neurotoxic potential of both acetone and isopropanol, the metabolic precursor of acetone, have been extensively studied. These studies demonstrate that although exposure to high doses of acetone may cause transient central nervous system effects, acetone is not a neurotoxicant. A guideline developmental neurotoxicity study has been conducted with isopropanol, and no developmental neurotoxic effects were identified, even at the highest dose tested. (SIAR, pp. 1, 25, 31).
- Environmental. When the EPA exempted acetone from regulation as a volatile organic compound (VOC) in 1995, EPA stated that this exemption would "contribute to the achievement of several important environmental goals and would support EPA's pollution prevention efforts." 60 Fed. Reg. 31,634 (June 16, 1995). EPA noted that acetone could be used "as a substitute for several compounds that are listed as hazardous air pollutants (HAP) under section 112 of the [Clean Air] Act."

**Source: National Institutes of Health / National Institute of Arthritis and Musculoskeletal and Skin Diseases - SBIR No. 5R42AR44435**

- Skin Drying and Irritation

Applying straight acetone to skin is typically associated with removal of skin lipids which results in dryness and irritation. Dryness and irritation have not been observed with Skincerity. Using a standard testing protocol for Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products, 1999, from the Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Skincerity was found to be non-irritating to the skin of human subjects. Skincerity is non-irritating because of the presence of the polymers that comprise the coating. Rather than drying out the skin like acetone, the coating provides a physical barrier to water loss, so that more water is retained in the outermost layer of the skin.

#### Summary

The larger issue is with chronic occupational exposure to solvents -- not any personal use of acetone. Potential health issues associated with acetone are related to exposure at extremely high levels over long periods of time.

