# Lead (CAS No. 7439-92-1) and Lead Compounds\*

Reasonably anticipated to be human carcinogens First Listed in the Eleventh Report on Carcinogens (2004)

## Introduction

The compounds lead phosphate and lead acetate were first listed in the *Second Annual Report on Carcinogens* as *reasonably anticipated to be human carcinogens*. This listing of lead and lead compounds supersedes the previous listing of lead phosphate and lead acetate in the Report on Carcinogens and applies to lead and all lead compounds.

## Carcinogenicity

Lead and lead compounds are reasonably anticipated to be human carcinogens based on limited evidence from studies in humans and sufficient evidence from studies in experimental animals. Lead exposure has been associated with increased risk of lung, stomach, and bladder cancer in diverse human populations (Fu and Boffetta 1995, Steenland and Boffetta 2000, NTP 2003). The strongest epidemiological evidence is for lung and stomach cancer, which are consistently but weakly associated with occupations and industries entailing lead exposure and with indices of individual lead exposure, including job history and biological monitoring of occupationally exposed and general populations. However, most studies of lead exposure and cancer reviewed had limitations, including poor exposure assessment and failure to control for confounders (other factors that could increase the risk of cancer, including lifestyle factors and concurrent occupational exposure to other carcinogens) and did not demonstrate relationships between the amount of exposure (concentration or duration, for example) and the magnitude of cancer risk. The crude exposure measures used in most studies, such as treating whole plants or occupations as having uniform exposure, may have limited the magnitude of risk estimates, most of which were modest. Evidence from epidemiological studies thus is compatible with small increases in risk for cancer of the lung or stomach; however, this evidence must be weighed against the potential for confounding by coexposures such as smoking, arsenic, or diet.

In studies with laboratory animals, carcinogenicity has been observed for both soluble (lead acetate and lead subacetate) and insoluble (lead phosphate, lead chromate) inorganic lead compounds as well as for tetraethyl lead (an organic lead compound). These studies show that lead causes cancer in rats and/or mice, by multiple routes of exposure including oral, injection, and in offspring exposed via the placenta or lactation. Although kidney tumors (including adenomas, carcinomas, and adenocarcinomas) were most frequently associated with lead exposure, tumors of the brain, hematopoietic system, and lung were reported in some studies (IARC 1980, 1987). Lead subacetate administered in the diet caused benign (adenoma) and malignant (carcinoma or adenocarcinoma) kidney tumors in both sexes of mice and rats, and brain tumors (gliomas) in rats; whereas intraperitoneal injection caused lung adenomas in mice. Lead acetate given in the diet or in drinking water caused kidney tumors (adenoma and carcinoma) in rats and increased the incidences of viral-induced lymphocytic leukemia in mice. In another study, pregnant mice were given lead acetate in the drinking water from gestation day 12 to four weeks postpartum. A dose-related increase in proliferative lesions of the kidneys (including atypical hyperplasia, adenoma, and adenocarcinoma) were observed in the offspring (Waalkes et al. 1995). Rats exposed to lead phosphate by subcutaneous injection or subcutaneous injection followed by intraperitoneal injection developed kidney tumors (adenoma or carcinoma). Rats exposed to lead chromates by subcutaneous injection developed injection-site sarcomas; whereas administration of lead chromates by intramuscular injection caused renalcell carcinomas (IARC 1990). It should be noted that since lead chromate

is also a hexavalent chromium compound, it is also included in that listing (see Chromium, Hexavalent Compounds). Tetraethyl lead administered by subcutaneous injection caused lymphoma in female mice. Exposure to lead naphthenate, lead carbonate, lead arsenate, lead nitrate, and metallic lead (as lead powder) did not significantly increase tumor incidences in experimental animals (IARC 1980).

Exposure of rodents to lead compounds also has been shown to increase the incidence or accelerate the appearance of kidney tumors induced by other carcinogens (e.g., *N*-ethyl-*N*-hydroxyethylnitrosamine and *N*-(4'-fluoro-4-biphenyl)acetamide). Increased incidences of malignant kidney and liver tumors were reported in rats fed diets containing lead subacetate and 2-acetylaminofluorene compared to groups fed lead subacetate or 2-acetylaminofluorene alone (IARC 1980, 1987).

## Additional Information Relevant to Carcinogenicity

In studies of humans occupationally exposed to lead, there is evidence to suggest that lead damages chromosomes or DNA. In most studies, lead caused micronucleus formation, chromosomal aberrations, and DNA damage (ATSDR 1999, NTP 2003), but studies on sister chromatid exchange gave conflicting results. Genetic studies on humans environmentally exposed to lead also gave conflicting results. Lead did not cause mutations in bacteria, and results from test systems using mammalian cells were conflicting. Lead caused chromosomal aberrations (changes in chromosome structure or number) in most studies in plants or mammals, both in vitro (in cell cultures) and in vivo (following exposure of the living organism). It caused DNA damage or fragmentation in mammals in vivo and in cell-free systems (in the presence of hydrogen peroxide); mammalian in vitro studies gave conflicting results. Lead also inhibited the activity of DNA and RNA polymerase in cell-free systems and in mammalian cell cultures. Conflicting results were observed for sister chromatid exchange and micronucleus formation in mammalian test systems (in vitro and in vivo).

Absorption of lead is affected by age, the chemical form of the lead, and minerals in the diet (e.g., iron, calcium, and zinc) (ATSDR 1999). Gastrointestinal absorption of lead is greater in children than in adults (Hammad *et al.* 1996). Once absorbed, lead is distributed to blood plasma, the nervous system, and soft tissues. It subsequently is redistributed and accumulates in bone; approximately 75% to 90% of the lead body burden is found in bones and teeth.

The mechanisms by which lead causes cancer are not understood. Lead compounds do not appear to cause genetic damage directly, but may do so through several indirect mechanisms, including inhibition of DNA synthesis and repair, oxidative damage, and interaction with DNA-binding proteins and tumor-suppressor proteins (NTP 2003).

### Properties

Elemental lead is an odorless, silver-bluish white metal that is insoluble in water. It is soft, highly malleable, ductile, and a relatively poor conductor of electricity. Lead is resistant to corrosion but tarnishes upon exposure to air. Its melting point is 327°C, and its boiling point is 1,740°C. Lead exists in the valence states of +2 and +4 and has four naturally occurring isotopes: <sup>204</sup>Pb, <sup>206</sup>Pb, <sup>207</sup>Pb, and <sup>208</sup>Pb. Inorganic lead compounds usually consist of lead in the divalent state (+2), and the chemistry of divalent lead is similar to that of Group 2 metals (beryllium, magnesium, calcium, strontium, and barium) (Budavari *et al.* 1996, Lide and Frederikse 1998, HSDB 2003).

Lead compounds may be divided between those compounds that are relatively soluble in water and those that are relatively insoluble in water. Compounds are considered soluble or insoluble based on the following criteria: (1) If a solubility constant ( $K_{sp}$ ) is available, a compound with a value greater than or equal to the  $K_{sp}$  for lead chloride (1 × 10<sup>-4</sup>) is considered soluble. (2) If a  $K_{sp}$  is not available, a compound

is considered soluble if more than 2 g of the compound dissolves in 100 mL of water. (3) If no numeric solubility data are available, the compounds are considered soluble or insoluble based on a general rule of solubility of chemical species, as outlined in McQuarrie and Rock (1984).

Lead acetate, lead acetate trihydrate, lead chloride, lead nitrate, and lead subacetate are the major soluble lead compounds. Lead acetate exists as colorless or white crystals, granules, or powders. It has a melting point of 280°C, a specific gravity of 3.25 and is soluble in glycerol and slightly soluble in ethanol. Lead acetate trihydrate occurs as white crystals with a melting point of 75°C and a boiling point of 280°C. It has a specific gravity of 2.55 and is slightly soluble in ethanol and acetone. Lead chloride exists as a white crystalline powder. It has a melting point of 501°C and a boiling point of 950°C. The compound has a specific gravity of 5.85 and is insoluble in ethanol. Lead nitrate occurs as colorless or white crystals with a melting point of 470°C. It has a specific gravity of 4.53 and is insoluble in nitric acid. Lead subacetate is a white heavy powder with a melting point of 75°C, decomposes before it reaches its boiling point, and is soluble in ethanol (ChemFinder 2003, HSDB 2003).

Seventeen inorganic lead compounds are considered the major insoluble compounds. Lead arsenate, lead azide, lead bromide, lead fluoride, lead phosphate, lead stearate, lead sulfate, and lead thiocyanate occur as white powder, crystals, or needles. Lead carbonate occurs as colorless rhombic crystals while lead fluoborate occurs as a colorless crystalline powder. Lead chromate, lead iodide, lead naphthenate, lead oxide, and lead styphnate occur as yellow to reddish-yellow powder, crystals, or paste. Lead sulfide occurs as metallic black cubic crystals while lead tetraoxide is a bright-red heavy powder. While all of this group of lead compounds is considered to be insoluble in water, lead arsenate, lead fluoride, and lead phosphate are soluble in nitric acid, and lead arsenate, lead carbonate, lead oxide, lead phosphate, lead sulfate, and lead thiocyanate are soluble in potassium hydroxide or other alkali. Lead bromide, lead iodide, lead oxide, lead phosphate, and lead sulfate are insoluble in alcohol while lead fluoborate decomposes in alcohol. Lead tetraoxide is soluble in hydrochloric and acetic acids and insoluble in ethanol. The reported melting points of these compounds range from 100°C (lead naphthenate) to 1,170°C (lead sulfate). All of these compounds have high reported boiling points (ranging up to 1,470°C); however, lead carbonate decomposes before it boils, and lead azide explodes at 350°C. Most of these compounds have high specific gravities with values ranging from 6.2 (lead sulfate) to 9.53 (lead oxide). A few compounds have lower specific gravities, such as lead naphthenate (1.15), lead fluoborate (1.75), and lead thiocyanate (3.82) (ChemFinder 2003, HSDB 2003).

Tetraethyl lead and tetramethyl lead are insoluble organic lead compounds. They both exist as colorless liquids and are soluble in benzene, ethanol, and diethyl ether. Tetraethyl lead has a melting point of -136.8°C, a boiling point of 200°C, a specific gravity of 1.659, and a log octanol-water partition coefficient of 4.15. Tetramethyl lead has a melting point of -27.5°C, a boiling point of 110°C, a specific gravity of 1.995, and a log octanol-water partition coefficent of 2.97 (ChemFinder 2003, HSDB 2003).

### Use

In worldwide metal use, lead ranks behind only iron, copper, aluminum, and zinc (Howe 1981). Its largest use is in lead-acid storage batteries for motor vehicles and general industry. Lead metal also is commonly used for ammunition, cable covering, piping, brass and bronze, bearing metals for machinery, and sheet lead (ATSDR 1999).

All of the major soluble lead compounds have industrial uses. Lead acetate is used as a water repellant, for mildew protection, and as a mordant for cotton dyes. Lead acetate trihydrate is used in varnishes, chrome pigments, and as an analytical reagent, while lead chloride is used in asbestos clutch or brake linings, as a catalyst, and as a flame retardant. Lead nitrate is used in the manufacture of matches and explosives, as a heat stabilizer in nylon, and as a coating on paper for photothermography. Lead subacetate is used in sugar analysis and for clarifying solutions of organic substances (HSDB 2003).

The insoluble lead compounds also have a variety of uses. Lead azide and lead styphnate are both used in munitions manufacture. Lead carbonate, lead fluoride, lead fluoborate, and lead naphthenate are used as catalysts, with additional uses in the electronic and optical industries (lead fluoride), in coatings for thermographic copying (lead carbonate), as a curing agent for epoxy resins (lead fluoborate), and as a varnish drier (lead naphthenate). Lead phosphate and lead stearate are both used as stabilizers in the plastics industry, while lead iodide and lead sulfate are used in photography, as well as in thermoelectric materials (lead iodide) and with zinc in galvanic batteries (lead sulfate). Lead oxide and lead sulfide are used in ceramics and as a vulcanizing agent in rubber and plastics (lead oxide) and as a humidity sensor in rockets (lead sulfide). Lead chromate is used as a pigment in paints, rubber, and plastics; lead tetraoxide is used in plasters, ointments, glazes, and varnishes; and lead thiocyanate is used in the manufacture of safety matches and cartridges. Lead arsenate was formerly used as an insecticide and herbicide, but no current uses were located.

Organic lead (including tetraethyllead and tetramethyllead) was widely used in the United States as an anti-knock additive in motor vehicle fuels until the U.S. Environmental Protection Agency initated a phase-out of leaded gasoline in the early 1970s. By 1988 the total lead used in gasoline had been reduced to 1% of the 1970 level, and in 1996, the use of lead in fuel for on-road motor vehicles was totally banned. Organic lead still is permitted for use in gasoline in the United States for aircraft and in fuels for racing vehicles and for non-road vehicles, such as farm machinery, marine vessels, construction equipment, and recreational vehicles (Smith 2000). Despite the legislated end to use of lead as a gasoline additive and reductions in some other uses of lead, overall U.S. lead consumption is growing, mainly because of increased production of lead-acid batteries (ATSDR 1999).

## Production

Lead is refined from mined ore, which occurs most frequently in the form of lead sulfide, also known as galena (Howe 1981). As of 2000, 19 mines, employing approximately 1,000 workers, produced the vast majority of lead in the United States (Smith 2000). Mined lead ore is crushed and ground, and a lead concentrate is formed by separation of the various minerals. The lead concentrate is shipped to a primary smelter for refining. At the smelter, lead concentrates are sintered, roasted, and refined into lead metal that is 99.99% pure. In 2001, two primary lead smelter-refineries were operating in the United States, employing approximately 400 people (Smith 2002b). Secondary smelters recycle scrap lead, mainly from used lead-acid batteries (Howe 1981). As of 2001, 26 secondary lead smelters were operating in the United States, employing approximately 1,600 workers (Smith 2002a). In 2001, the United States produced 1,375,000 metric tons (3.0 billion pounds), used 1,687,000 metric tons (3.7 billion pounds), and recycled 1,099,000 metric tons (2.4 billion pounds) of lead (LDA 2002).

Lead acetate was first produced in the United States in 1944; however, very little production information was available. Three companies reported production of an undisclosed amount of lead acetate in 1977 (IARC 1980). Reported production volumes were estimated at more than 6,810 kg (15,000 lb) in 1978 and more than 2,270 kg (5,000 lb) in 1982 (HSDB 2003). U.S. imports were 113 kg (250 lb) in 1978 and 39,300 kg (87,000 lb) in 1982 (IARC 1980, HSDB 2003). Lead carbonate has been produced commercially in the United States since the 1600s; in 1976, U.S. production was 1.48 million kilograms (3.3 million pounds), with imports in 1978 of 178,000 kg (392,000 lb) (IARC 1980). Exports for lead carbonate in 2002 were 779,071 kg (1.7 million pounds) (ITA 2003a). Commercial production of lead naphthenate in the United States was first reported in 1944. In 1969, production of lead naphthenate was 8.2 million kilograms (18.1 million pounds), with production dropping to 2.2 million kilograms (4.9 million pounds) in 1977 (IARC 1980). Lead nitrate was first commercially produced in the United States in 1943, and imports of 480,000 kg (1.06 million pounds) were reported in 1978 (IARC 1980). U.S. production of lead oxide in 1976 was 120 million kilograms (260 million pounds), with imports at 20 million kilograms (44 million pounds) (IARC 1980). Imports of lead oxides in 2002 totalled 3.9 million kilograms (8.6 million pounds), and 1.7 million kilograms (3.7 million pounds) were exported (ITA 2003b). Commercial production of lead subacetate was first reported in the United States in 1947 (IARC 1980); no production data are available. U.S. production of lead tetraoxide in 1976 was reported at 18 million kilograms (39.7 million pounds), with imports at 800,000 kg (1.8 million pounds) in 1976 and 1 million kilograms (2.2 million pounds) in 1979. In 1977, approximately 1 to 15 million kilograms (2.2 to 33 milion pounds) were exported (IARC 1980).

Tetraethyl lead was first produced commercially in the United States in 1923, with 266 million kilograms (590 million pounds) produced in 1964; production dropped in 1977 to 148 million kilograms (330 million pounds). Imports of tetraethyl lead in 1978 were 17,000 kg (37,500 lb) (IARC 1980). Commercial production of tetramethyl lead in the United States began in 1960, with 54 million kilograms (119 million pounds) produced in 1977 and 13,800 kg (30,400 lb) imported in 1974 (IARC 1980).

### **Exposure**

Environmental exposure to lead results in its absorption into the body via inhalation (with approximately 30% to 50% of the inhaled dose absorbed into the bloodstream), via ingestion (with approximately 8% to 15% of the ingested dose absorbed into the bloodstream) and, to a limited extent, through the skin. Lead is released to the environment from both natural and anthropogenic sources; however, most exposure occurs as a result of anthropogenic sources (e.g., mining, smelting, industrial uses). Lead exists in different inorganic and organic forms which affect its environmental fate and transport and bioavailability, but regardless of the form, lead is not degraded and remains available for exposure. In the mid 1980s, combustion of leaded gasoline contributed about 90% of all anthropogenic lead emissions but decreased sharply through the late 1990s due to the phase out of leaded gasoline (ATSDR 1999, EPA 2003). More than 90% of the lead compounds released from the combustion of leaded gasoline were inorganic lead halides (e.g., lead bromochloride) while less than 10% were organic lead alkyls (e.g., tetraethyl lead). Tetraalkyl lead compounds once contributed about 5% to 10% of the total particulate lead present in the atmosphere but are no longer present in significant quantities. Industrial processes, particularly lead smelters, are now the primary source of lead emissions and accounted for more than 78% of emissions in 2001 (EPA 2003).

Concentrations of lead in the air in the United States declined by 97% between 1976 and 1995 and by 57% between 1993 and 2002 (ATSDR 1999, EPA 2003). Ambient concentrations are highly variable but may exceed 10  $\mu$ g/m<sup>3</sup> near industrial sources such as smelters (ATSDR 1999). A 1991 survey of lead levels in U.S. urban air found a maximum quarterly mean concentration of approximately 0.08  $\mu$ g/m<sup>3</sup>. Lead concentrations typically are lower in rural areas. In 1995, the estimated U.S. mean air lead concentration was 0.04  $\mu$ g/m<sup>3</sup> (EPA 1996). The estimated daily average intake of lead by inhalation in 1991 was 2  $\mu$ g for an adult living in a U.S. urban setting and was significantly lower than estimates from the early 1980s (ATSDR 1999).

Lead concentrations in U.S. drinking water generally are below 5  $\mu$ g/L. Lead also is found in food, cigarette smoke, and alcoholic beverages. Levels in food have declined since the elimination of lead-soldered food cans between 1979 and 1989 (ATSDR 1999). In 1990, the estimated daily intake of lead from consumption of food, water, and beverages was approximately 4  $\mu$ g for children 2 years of age and younger, 6 to 9  $\mu$ g for children aged 14 to 16, 6 to 9  $\mu$ g for adults aged 25 to 30, and 2 to 8  $\mu$ g for adults aged 60 to 65. For young children, the most common source of environmental lead exposure is direct ingestion of paint chips and lead-laden dusts and soils released from aging painted surfaces. These sources can contribute an additional daily intake of 5  $\mu$ g for a toddler engaging in normal hand-to-mouth activity (CDC 1997, Lanphear *et al.* 1998).

The most common route of occupational exposure to lead is inhalation of lead fumes or lead-laden dusts in air and absorption of lead through the respiratory system. Lead also may be ingested and absorbed via the gastrointestinal tract (Bress and Bidanset 1991, Stauber *et al.* 1994). The National Institute for Occupational Safety and Health has estimated that 1,378,000 Americans potentially are occupationally exposed to some form of lead (NIOSH 1990).

Many occupations have the potential for high exposure to lead (Fu and Boffetta 1995, ATSDR 1999). Occupations having frequent high exposure to lead include battery-production worker, battery-recycling worker, foundry worker, lead chemical worker, lead smelter and refinery worker, leaded-glass worker, pigment worker, and radiator-repair worker. Occupations with a moderate frequency of high exposure include firing-range instructor, house renovator, lead miner, newspaper printer, plastics worker, rubber worker, and steel welder or cutter. Occupations with a low frequency of high exposure include automobilerepair worker, cable-production worker, construction worker, demolition worker, firing-range participant, flame-solder worker, plumber or pipe fitter, pottery-glaze producer, ship-repair worker, and stained-glass producer. Among U.S. industries identified by the Occupational Safety and Health Administration as having significant airborne lead, the mean concentration ranged from 165  $\mu$ g/m<sup>3</sup> (at secondary smelters) to 200 µg/m<sup>3</sup> (at storage-battery plants and brass, bronze, and copper foundries) (Froines et al. 1990).

According to EPA's Toxics Release Inventory (TRI), more than 22 million pounds (10 million kilograms) of lead and 428 million pounds (194 million kilograms) of lead compounds were released on- and offsite in 2001 (TRI01 2003). More than 4,000 reports were filed for both lead and lead compounds in 2001.

## Regulations

## CPSC

- Furniture articles for consumer use that bear paint with lead at levels greater than 0.06% of the total weight of the solid or dried paint film are banned
- Metal-cored candlewicks containing more than 0.06 percent lead by weight in the metal, and candles with such wicks, have been banned
- Paint or any other surface coating materials for consumer use may not contain lead at levels greater than 0.06%
- Toys and other items for child use that bear paint with lead at levels greater than 0.06% of the total weight of the solid or dried paint film are banned

### DOT

Lead, numerous specific lead compounds, and lead compounds not otherwise specified are all considered hazardous materials and requirements have been prescribed for shipping papers, package marking, labeling, and transport vehicle placarding for the shipment and transportation of these hazardous materials

Numerous lead compounds are considered marine pollutants and requirements have been prescribed for marking the packaging and transport vehicles containing these materials

#### EPA Clean Air Act

- Mobile Source Air Toxics: Lead Compounds listed as a Mobile Source Air Toxic for which regulations are to be developed
- NAAQS: National primary and secondary ambient air quality standard = 1.5 µg/m<sup>3</sup> (lead and lead compounds)
- NESHAP: Lead Compounds listed as a Hazardous Air Pollutant (HAP)
- NSPS: Manufacture of tetraethyl lead, tetramethyl lead, and tetra (methyl-ethyl) lead is

subject to provisions for the control of Volatile Organic Compound (VOC) emissions Prevention of Accidental Release: Threshold Quantity (TQ) = 10,000 lb (tetramethyl lead) Urban Air Toxics Strategy: Lead Compounds identified as one of 33 HAPs that present the greatest threat to public health in urban areas

Gasoline shall not be sold for use in motor vehicles, as defined by the Clean Air Act, which contains lead additives or contains lead at a concentration greater than 0.05 grams/gallon

#### Clean Water Act

Biosolids Rule: Ceiling concentration of total lead for land application = 840 mg/kg Effluent Guidelines: Listed as a Toxic Pollutant (lead and lead compounds)

Comprehensive Environmental Response, Compensation, and Liability Act

Reportable Quantity (RQ) = 10 lb (lead, lead acetate, lead chloride, lead fluoborate, lead fluoride, lead iodide, lead nitrate, lead phosphate, lead stearate, lead subacetate, lead sulfate, lead sulfide, lead thiocyanate & tetraethyl lead); 1 lb (lead arsenate) Emergency Planning and Community Right-To-Know Act

Toxics Release Inventory: Lead and lead compounds are listed substances subject to reporting requirements

Federal Insecticide, Fungicide, and Rodenticide Act

Registrations for most non-wood preservative uses of inorganic arsenicals, including lead arsenate, have been cancelled

Resource Conservation and Recovery Act

- Characteristic Toxic Hazardous Waste: TCLP Threshold = 5.0 mg/L
- Listed Hazardous Waste: Waste codes in which listing is based wholly or partly on lead or lead compounds F035, F037, F038, K002, K003, K005, K046, K048, K049, K051, K052, K061, K062, K064, K069, K086, K100, P110, U144, U145, U146

Listed as a Hazardous Constituent of Waste

Safe Drinking Water Act

Treatment Technique, Action Level = 0.015 mg/L (lead)

Numerous requirements have been established to reduce exposure to lead in drinking water due to lead leaching from lead pipes and lead fittings

Toxic Substances Control Act

- A seller must disclose to the purchaser of a home any known lead-based paint hazard where a lead hazard is defined, in part, as lead concentrations exceeding 40 µg/ft<sup>2</sup> on floors or 250 µg/ft<sup>2</sup> on interior window sills (dust-lead); 400 ppm (soil in play area) or 1,200 ppm (bare soil in rest of yard)
- Lead-Based Paint Poisoning Prevention Regulations stipulate that paint used in home renovations shall not contain lead at levels greater than 1.0 mg/cm<sup>2</sup> or 0.5% by weight

#### FDA

- A permanent and conspicuous warning statement shall be applied, e.g., embossed on ornamental or decorative ceramicware that contains lead that leaches in excess of levels permitted for ceramic foodware stating that the vessel is not for food use and may be harmful if used for such.
- A number of food ingredients that are Generally Recognized As Safe (GRAS) are permitted for use in foods for human consumption providing maximum lead levels do not exceed concentrations which range from 0.1-10 ppm
- Action levels for lead in ceramic flatware, hollowware, cups, mugs and pitchers range from 0.5-3.0 ug/mL of leach solution.
- Lead acetate-containing hair coloring must provide warning labels and may be safely used in cosmetics intended for coloring hair on the scalp if lead levels do not exceed 0.6% (weight to volume)

Lead solder may not be used in food cans.

Lead specification limits in various color additives range from 5-70 ppm

Maximum permissible level of lead in bottled water = 0.005 mg/L

- Select food additives are permitted for use in animal feed with maximum lead levels ranging from 10-30 ppm
- Lead specification limits in various food additives range from 0.1 to 50 ppm (select items as specified by the regulation); from 0.5 to 2 mg/kg (select items as specified by the regulation); or up to a maximum of 0.002% (select item as specificed by regulation)

Select vitamin preparations are permitted for use in animal feed with lead levels not to exceed 10 ppm

Some drug substances and excipients have limits for heavy metals (including lead), generally 10 or 20 ppm. These limits are given in the U.S. Pharmacopeia.

#### HUD

A seller must disclose to the purchaser the presence of any lead-based paint in a home for sale, provide an EPA pamphlet on the health effects of lead, provide records on leadbased paint used in home, and provide a 10-day period to conduct a home inspection

#### **OSHA**

Permissible Exposure Limit (PEL) = 0.050 mg/m<sup>3</sup> (metallic lead, inorganic lead compounds, organic lead compounds called "soaps")

"Comprehensive Standards" for occupational exposure to lead have been developed

## Guidelines ACGIH

Threshold Limit Value - Time-Weighted Average Limit (TLV-TWA) = 0.05 mg/m<sup>3</sup> (lead, inorganic lead compounds, lead chromate); 0.15 mg/m<sup>3</sup> (lead arsenate, tetramethyl lead); 0.1 mg/m<sup>3</sup> (tetraethyl lead)

### CPSC

- Requests manufacturers to eliminate the use of lead that may be accessible to children from products used in or around households, schools, or in recreation
- Recommends that, before purchasing products for resale, importers, distributors, and retailers obtain assurances from manufacturers that those products do not contain lead that may be accessible to children

#### NIOSH

Immediately Dangerous to Life and Health (IDLH) =  $100 \text{ mg/m}^3$  (as metallic lead)

Recommended Exposure Limit (REL) = 0.050 mg/m<sup>3</sup> (metallic lead, lead oxides, and lead salts (including organic salts such as lead soaps but excluding lead arsenate))

\*No separate CAS registry number is assigned to lead compounds.

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