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Rev. 07/10/02

Lead and compounds (inorganic) [illegible]

[illegible] assessment information [illegible] after a comprehensive review of chronic [illegible] of U.S. EPA scientists from several Program Offices. [illegible] Sections I and II represent a consensus reached in the review [illegible] other sections contain U.S. EPA information which is specific [illegible] EPA program and has been subject to review procedures prescribed [illegible] Program Office. The regulatory actions in Section IV may not be based [illegible] most current risk assessment, or may be based on a document, but [illegible] risk assessment, and may take into account factors other than [illegible] (e.g., treatment technology). When considering the use of regulatory [illegible] data for a particular situation, note the date of the regulatory [illegible] date of the most recent risk assessment relating to that action, and [illegible] technological factors were considered. Background information and explan-

ations of the methods used to derive the values given in IRIS are provided [illegible] the five Background Documents in Service Code

5, which correspond to Sections

More?...(Yes or No) --I through V of the chemical files.

STATUS OF DATA FOR Lead and compounds (inorganic)

File On-line 03/01/88

Category (section)	Status	Last Revised
Oral RfD Assessment (I.A.)	message only	
Inhalation RfD Assessment (I.B.)	no data	
Carcinogenicity Assessment (II.)	on-line	06/01/89
Drinking Water Health Advisories (III.A.)	no data	
U.S. EPA Regulatory Actions (IV.)	on-line	06/01/89

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More?...(Yes or No) --

I. CHRONIC HEALTH HAZARD ASSESSMENT FOR NONCARCINOGENIC EFFECTS

Substance Name -- Lead and compounds (inorganic)
CASRN -- 7439-92-1

II.A. REFERENCE DOSE FOR CHRONIC ORAL EXPOSURE (RfDo)

A great deal of information on the health effects of lead has been obtained through decades of medical observation and scientific research.

criteria by the Agency's Office of Health and Environmental Assessment [illegible] in support of regulatory decision-making by the Office of [illegible] and Standards (OAQPS) and by the Office of Drinking Water (ODW). [illegible] comparison to most other environmental toxicants, the degree of [illegible] about the health effects of lead is quite low. It appears that some [illegible] effects, particularly changes in the levels of certain blood enzymes [illegible] aspects of children's neurobehavioral development, may occur at [illegible] levels so low as to be essentially without a threshold. The Agency's [illegible]

More?...(Yes or No) --Group discussed inorganic lead (and lead [illegible] [illegible]) and considered it inappropriate to develop an RfD for [illegible] lead. For additional information, interested parties are referred to [illegible] Air Quality Criteria for Lead (EPA-600/8-83/028a-cF) in the following Agency scientists:

[illegible] Michael Davis / OHEA -- (919)541-4162 / FTS 629-4162

Jeff [illegible] / OAQPS -- (919)541-5282 / FTS 629-5282

Gregory Helms / ODW -- (202)475-8049 / FTS 475-8049

William Marcus / ODW -- (202)475-7580/ FTS 475-7580

------<<< Lead and compounds (inorganic) >>>------

__I.B. REFERENCE DOSE FOR CHRONIC INHALATION EXPOSURE (RfDi)

More?...(Yes or No) --
Not available at this time

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_II. CARCINOGENICITY ASSESSMENT FOR LIFETIME EXPOSURE

Substance Name -- Lead and compounds (inorganic)
CASRN -- 7439-92-1
Last Revised -- 06/01/89

Section II provides information on three aspects of the carcinogenic risk assessment for the agent in question; the U.S. EPA classification, and quantitative estimates of risk from oral exposure and from inhalation exposure. The classification reflects a weight-of-evidence judgment of the likelihood that the agent is a human carcinogen. The quantitative risk estimates are presented in three ways. The slope factor is the result of application of a low-dose extrapolation procedure and is presented as the risk per mg/kg/day. The unit risk is the quantitative estimate in terms of either risk per ug/L

More?...(Yes or No) --

drinking water or risk per ug/cu.m air breathed. The third form in which risk is presented is a drinking water or air concentration providing cancer risks of 1 in 10,000, 1 in 100,000 or 1 in 1,000,000. Background Document 2 (Service Code 5) provides details on the rationale and methods used to [illegible] the carcinogenicity values found in IRIS. Users are referred to Section [illegible] information on long-term toxic effects other than carcinogenicity.

<<< Lead and compounds (inorganic) >>>

II.A.1. WEIGHT-OF-EVIDENCE CLASSIFICATION

Classification -- B2; probable human carcinogen

Basis -- Sufficient animal evidence. Ten rat bioassays and one mouse bioassay have shown statistically significant increases in renal tumors with oral and subcutaneous exposure to several soluble lead salts. Animal studies provide reproducible results in several laboratories, in multiple rat strains with some evidence of multiple tumor sites. Short term studies show that lead affects gene expression. Human evidence is inadequate.

More?...(Yes or No) --

((Lead and compounds (inorganic)))

II.A.2. HUMAN CARCINOGENICITY DATA

Inadequate. There are four epidemiologic studies in occupational cohorts exposed to lead and lead compounds. Two studies (Dingwall-Fordyce and Lewis 1983, Nelson et al., 1982) did not find any association between exposure to lead and cancer mortality. Selevan et al. (1985) in their retrospective cohort mortality study of primary lead smelter workers found a slight decrease in the total cancer mortality (SMR=95). Apparent excesses were observed for respiratory cancer (SMR=111, obs=41, p>0.05) and kidney cancer (SMR=204, obs=6, p>0.05). Cooper and Gaffey (1975) and Cooper (1985 update) in their cohort mortality study of battery plant workers and lead smelter workers found statistically significant excesses for total cancer mortality (SMR=113, obs=344), stomach cancer (SMR=168, obs=34) and lung cancer (SMR=124, obs=109) in battery plant workers. Although similar excesses were observed in smelter workers, they were not statistically significant. Cooper and Gaffey (1975) felt it was possible that individual subjects were monitored primarily on the basis of obvious signs of lead exposure, while others who show no symptoms of lead poisoning would not be monitored.

More?...(Yes or No) --

All of the available studies lacked quantitative exposure information, as well as information on the possible contribution of smoking. All studies also had exposures to other metals such as arsenic, cadmium and zinc for which no adjustment was done. The cancer excesses observed in the lung and stomach were relatively small (<200). There was no consistency of site among the various studies, and no study showed any dose-response relationship. Thus, the available human evidence is considered to be inadequate to refute or demonstrate potential carcinogenicity for humans from lead exposure.

(((Lead and compounds (inorganic))))

II.A.3. ANIMAL CARCINOGENICITY DATA

Sufficient. The carcinogenic potential of lead salts, primarily phosphates and acetates, administered by the oral route, diet or by injection has been demonstrated in rats and mice by more than 10 investigators. The most characteristic cancer response is bilateral renal carcinoma. Rats given lead acetate or subacetate orally have developed gliomas, and lead subacetate also produced lung adenomas in mice after i.p. adminstration. Most of these investigations found a carcinogenic response only at the highest dose. The lead compounds tested in animals are almost all soluble salts. Metallic lead, lead oxide and lead tetraalkyls have not been tested adequately. Studies with

More?...(Yes or No) --inhalation exposure have not been located in the literat

[illegible] in dietary concentrations to fifty rats/sex/treatment [illegible] two years. The [illegible] control rats of each sex received the basal [illegible] diet. In a second two-year feeding study, twenty rats per [illegible] were [illegible] diets containing 0, 1000 and 2000 ppm lead as lead acetate. No renal [illegible] were reported in the control groups or in treated animals if either sex receiving 10-100 ppm. Male rats fed 300, 1000 and 2000 ppm lead acetate [illegible] an increased renal tumor incidence of 5/50, 10/30 and 16/20, while [illegible] females in the 2000 ppm developed renal tumors.

The Kizer et al. (1973) study is limited by the lack of experimental details. The possibility of environmental contamination from lead in the [illegible] in drinking water was not mentioned. The strains of rats used were not specified in the study, but the Health Effects Assessment for Lead (U.S. EPA, 1984) indicated the rats were Wistar strain. The weight gain at 1000 and [illegible] ppm was reported to be depressed, but details were not given.

Kasprzak et al. (1985), in investigating the interaction of dietary calcium on lead carcinogenicity, fed a diet with 1% lead subacetate (8500 [illegible] ppm) to male Sprague-Dawley rats for 79 weeks. Of the rats surviving (29/30)

More?...(Yes or No) --in this treatment group beyond 38 weeks, 44.8% had renal adenocarcinomas; the remaining nine had adenomas. Bilateral tumors were noted. No renal tumors were noted among the controls.

As part of a study to determine interactions between sodium nitrite, ethyl urea and lead, male Sprague-Dawley rats were given lead acetate in their drinking water for 76 weeks (Koller et al., 1986). The concentration of lead was 2600 ppm. No kidney tumors were detected among the 10 control rats. Thirteen of 16 (81%) lead-treated rats had renal tubular carcinoma, with three tumors detected at 72 weeks and the remainder detected at the termination of the study.

Van Esch and Kroes (1969) fed basic lead acetate at 0, 0.1% and 1.0% in the diet to twenty five Swiss mice/sex/treatment group for two years. No renal tumors developed in the control group, but 6/25 male mice of 0.1% basic lead acetate group had renal tumors (adenomas and carcinomas combined). In the 1.0% group, one female had a renal tumor. The authors felt that the low incidence in the 1.0% group was due to early mortality.

Hamsters given lead subacetate at 0.5% and 1% in the diet had no significant renal tumor response (Van Esch et al., 1969).

More?...(Yes or No) --

<<< Lead and compounds (inorganic) >>>

___II.A.4. SUPPORTING DATA FOR CARCINOGENICITY

Lead acetate induces cell transformation in Syrian hamster embryo cells (DiPaolo et al., 1978) as well as enhances the incidence of simian adenovirus induction. Lead oxide showed similar enhanced adenovirus induction (Casto et al., 1979).

Under certain conditions lead compounds are capable of inducing chromosomal aberrations in vivo and in tissue cultures. Grandjean et al. (1983) showed a relationship between SCE and lead exposure in exposed workers. Lead has been shown, in a number of DNA structure and function assays, to affect the molecular processes associated with the regulation of gene expression (U.S. EPA, 1986).

II.B. QUANTITATIVE ESTIMATE OF CARCINOGENIC RISK FROM ORAL EXPOSURE

More?...(Yes or No) -- Not available.

Quantifying lead's cancer risk involves many uncertainties. Some of these may be unique to lead. Age, health, nutritional state, body burden, and exposure duration influence the absorption, release, and excretion of lead. It is also felt that current knowledge of lead pharmacokinetics indicates an estimate derived by standard procedures would not truly describe the potential risk. Thus, the Carcinogen Assessment Group recommends that a numerical estimate not be used.

II.C. QUANTITATIVE ESTIMATE OF CARCINOGENIC RISK FROM INHALATION EXPOSURE

Not available.

More?...(Yes or No) --__II.D. EPA DOCUMENTATION, REVIEW, AND CONTACTS (CARCI
(((Lead and compounds (inorganic))))

__II.D.1. EPA DOCUMENTATION

U.S. EPA. 1984. Health Effects Assessment for Lead. Prepared by the Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH, for the Office of Emergency and Remedial Response, Washington, DC. EPA/540/1-86/055. NTIS PB85-163996/AS.

U.S. EPA. 1986. Air Quality Criteria Document for Lead. Volumes III, IV. Prepared by the Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Research Triangle Park, NC, for the Office of Air Quality Planning and Standards. EPA-600/8-83/028dF.

U.S. EPA. 1987. Preliminary review of the carcinogenic potential of lead associated with oral exposure. Prepared by the Office of Health and Environmental Assessment, Carcinogenic Assessment Group, Washington DC, for the Office of Drinking Water, Office of Solid Waste and the Office of Emergency and Remedial Response (Superfund). OHEA-C-267. Internal Review Draft.

More?...(Yes or No) --

Anderson, E.L., and the Carcinogenic Assessment Group. 1983. Quantitative approaches in use to assess cancer risk. Risk Analysis. 3: 277-295.

Azar, A., H.J. Trochimowicz and M.E. Maxfield. 1973. Review of lead studies in animals carried out at Haskell Laboratory - Two year feeding study and response to hemorrhage study. In: Barth D., A. Berlin, R. Engel, P. Recht and J. Smeets, eds. Environmental health aspects of lead: proceedings international symposium; October 1972; Amsterdam, The Netherlands. Luxembourg: Commission of the European Communities, pp. 199-208.

Casto, B.C., J. Meyers and J.A. DiPaolo. 1979. Enhancement of viral transformation for evaluation of the carcinogenic or mutagenic potential of inorganic metal salts. Cancer Res. 39: 193-198.

Cooper, W.C. 1985. Mortality among employees of lead battery plants and lead producing plants, 1947-1980. Scand. J. Work Environ. Health. [illegible]

Cooper, W.C. and W.R. Gaffey. 1975. Mortality of lead workers. [illegible] Proceedings of the 1974 Conference on Standards of Occupational Lead [illegible] J.F. Cole, Ed., February, 1974. Washington, DC. J. Occup. Med. [illegible]

Dingwall-Fordyce, I. and R.E. Lane. 1963. A follow-up study of lead w[illegible]

[illegible] (Yes or No) --Br. J. Ind. Med. 20: 313-315.

DiPaolo, J.A., R.L. Nelson and B.C. Casto. 1978. In vitro neoplastic transformation of Syrian hamster cells by lead acetate and its relevance [illegible] environmental carcinogenesis. Br. J. Cancer. 38: 452-455.

Grandjean, [illegible], H.C. Wulf and E. Niebuhr. 1983. Sister chromatid exchange response to variations in occupational lead exposure. Environ. Res. [illegible]: 199-204.

Kasprzak, K.S., K.L. Hoover and L.A. Poirier. 1985. Effects of dietary calcium acetate on lead subacetate carcinogenicity in kidneys of male Sprague Dawley rats. Carcinogenesis. 6(2): 279-282.

Koller, L.D., N.I. Kerkvliet and J.H. Exon. 1986. Neoplasia induced in male rats fed lead acetate, ethyl urea and sodium nitrate. Toxicol. Pathol. 13: 50-57.

Nelson, D.J., L. Kiremidjian-Schumacher and G. Stotzky. 1982. Effects of cadmium, lead, and zinc on macrophage-mediated cytotoxicity toward tumor cells. Environ. Res. 28: 154-163.

More?...(Yes or No) --Selevan, S.G., P.J. Landrigan, F.B. Stern and J.-[illegible] lead smelter workers. Am. J. Epidemiol. 122: 673-683.

Van Esch, G.J. and R. Kroes. 1969. The induction of renal tumors by feeding of basic lead acetate to mice and hamsters. Br. J. Cancer. 23: 283-271.

<<< Lead and compounds (inorganic) >>>

___II.D.2. REVIEW (CARCINOGENICITY ASSESSMENT)

The review of the carcinogenic potential of lead associated with oral exposure has received Agency review.

The 1986 Air Quality Criteria Document for Lead has received Agency and External Review.

Agency Work Group Review: 05/04/88

Verification Date: 05/04/88

More?...(Yes or No) --

___II.D.3. U.S. EPA CONTACTS (CARCINOGENICITY ASSESSMENT)

William Pepelko / ORD -- (202)382-5898 / FTS 382-5898

James Cogliano / ORD -- (202)382-5898 / FTS 382-5898

___III. HEALTH HAZARD ASSESSMENTS FOR VARIED EXPOSURE DURATIONS

Substance Name -- Lead and compounds (inorganic)
CASRN -- 7439-92-1

Not available at this time

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More?...(Yes or No) --_IV. U.S. EPA REGULATORY ACTIONS

Substance Name -- Lead and compounds (inorganic)
CASRN -- 7439-92-1
Last Revised -- 06/01/89

EPA risk assessments may be updated as new data are published and as assessment methodologies evolve. Regulatory actions are frequently not updated at the same time. Compare the dates for the regulatory actions in this section with the verification dates for the risk assessments in sections I and II, as this may explain inconsistencies. Also note that some regulatory actions consider factors not related to health risk, such as technical or economic feasibility. Such considerations are indicated for each action. In addition, not all of the regulatory actions listed in this section involve enforceable federal standards. Please direct any questions you may have concerning these regulatory actions to the U.S. EPA contact listed for that particular action. Users are strongly urged to read the background information on each regulatory action in Background Document 4 in Service Code 3.

<<< Lead and compounds (inorganic) >>>

More?...(Yes or No) --__IV.A. CLEAN AIR ACT (CAA)

___IV.A.1. NATIONAL AMBIENT AIR QUALITY STANDARD (NAAQS)

Considers technological or economic feasibility? -- No

Discussion -- Under Section 109 of the CAA, EPA has set a primary (health-based) NAAQS for lead of 1.5 ug/cu.m, calendar quarter average not to be exceeded (43 FR 41258, 10/05/78). The secondary (welfare-based) NAAQS is identical to the primary standard. EPA is currently reviewing these standards to determine if changes are warranted.

Reference -- 40 CFR 50.12

U.S. EPA Contact -- Air Quality Management Division / OAQPS / (919)541-5656 / FTS 629-5656

------<<< Lead and compounds (inorganic) >>>------

More?...(Yes or No) --

__IV.B. SAFE DRINKING WATER ACT (SDWA)

___IV.B. . MAXIMUM CONTAMINANT LEVEL GOAL (MCLG) for Drinking Water

value (status) -- 0.02 mg/L (Proposed, 1985)

Considers technological or economic feasibility? -- NO

Discussion -- Neurological effects of lead in infants and adverse effec associated with blood lead levels of 15 ug/dL are the basis for this MCLG. Using a conversion factor of 6.25 to convert from blood lead concentrations to drinking water lead concentrations and an uncertainty factor of 3, an MCLG of 0.02 mg/L for lead was derived.

Reference -- 50 FR 46936 Part IV (11/13/85)

EPA Contact -- Criteria and Standards Division, ODW / (202)382-7571 / FTS 382-7571; or Drinking Water Hotline / (800)426-4791

<<< Lead and compounds (inorganic) >>>

More?...(Yes or No) --___IV.B.2. MAXIMUM CONTAMINANT LEVEL (MCL) for Drinking Water

value (status) -- 0.05 mg/L (Interim, 1980)

Considers technological or economic feasibility? -- YES

Discussion -- As an interim measure the U.S. EPA is using the value previously derived by the Public Health Service.

Reference -- 45 FR 57332 (08/27/80)

EPA Contact -- Criteria and Standards Division, ODW / (202)382-7571 / FTS 382-7571; or Drinking Water Hotline / (800)426-4791

------<<< Lead and compounds (inorganic) >>>------

__IV.C. CLEAN WATER ACT (CWA)

___IV.C.1. AMBIENT WATER QUALITY CRITERIA, Human Health

More?...(Yes or No) --

Water and Fish Consumption -- 5.0E+1 ug/L

Fish Consumption Only -- None

Considers technological or economic feasibility? -- NO

Discussion -- The criterion was set at the existing drinking water standard in 1980.

Reference -- 45 FR 79318 (11/28/80)

EPA Contact -- Criteria and Standards Division, OWRS (202)475-7315 / FTS 475-7315

<<< Lead and compounds (inorganic) >>>

___IV.C.2. AMBIENT WATER QUALITY CRITERIA, Aquatic Organisms

Acute -- 3.1E+1 ug/L 1-hour average

More?...(Yes or No) -- Chronic -- 3.3E+0 ug/L 4-day average

Marine:

Acute -- 1.40E+2 ug/L (1-hour average)
Chronic -- 5.6E+0 ug/L (4-day average)

Considers technological or economic feasibility? -- NO

Discussion -- The toxicity of this compound in freshwater is hardness dependent. The values given are for a hardness of 100 mg/L CaCO3. For a complete discussion, see the referenced notice.

Reference -- 50 FR 30784 (07/29/85)

EPA Contact -- Criteria and Standards Division, OWRS
(202)475-7315 / FTS 475-7315

------(((Lead and compounds (inorganic))))------

More?...(Yes or No) --__IV.D. FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE

No data available

------(((Lead and compounds (inorganic))))------

__IV.E. TOXIC SUBSTANCES CONTROL ACT (TSCA)

No data available

------(((Lead and compounds (inorganic))))------

__IV.F. RESOURCE CONSERVATION AND RECOVERY ACT (RCRA)

___IV.F.1. RCRA APPENDIX IX, for Ground Water Monitoring

Status -- Listed

More?...(Yes or No) --

Reference -- 52 FR 25942 (07/09/87)

EPA Contact -- Jerry Garman / OSW / (202)382-4658 / FTS 382-4658

------(((Lead and compounds (inorganic))))------

__IV.G. SUPERFUND (CERCLA)

___IV.G.1. REPORTABLE QUANTITY (RQ) for Release into the Environment

Value status -- 1 pound (Statutory, 1987)

Considers technological or economic feasibility? -- NO

Discussion -- The statutory 1-pound RQ for lead is retained pending assessment of its potential carcinogenicity and may be adjusted in a future notice of proposed rulemaking when the evaluation of available data is completed. Lead was evaluated for chronic toxicity, but was not ranked

Final...(Yes or No) --toxicity because of insufficient data.

Reference -- 52 FR 8140 (03/16/87)

EPA Contact -- RCRA Superfund Hotline
(800)424-9346 / (202)382-3000 / FTS 382-3000

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_V. SUPPLEMENTARY DATA

Substance Name -- Lead and compounds (inorganic)
CASRN -- 7439-92-1

Not available at this time

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More?...(Yes or No) --
_VI. BIBLIOGRAPHY

Substance Name -- Lead and compounds (inorganic)
CASRN -- 7439-92-1

Not available at this time

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SYNONYMS

7439-92-1
Lead
Lead and compounds
plumbum

More?...(Yes or No) --

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