(19) NPCA. National Paint and Coatings Association, Toxic Substances Task Force. Coatings polymers—general properties and uses. Washington, DC: NPCA. 1981.

(20) NPCA. National Paint and Coatings Association. 2-Phenoxyethanol as a coalescing agent in the manufacture of latex paint. Report. Washington, DC. NPCA. 1983.

(21) OSHA. Occupational Safety and Health Administration, U.S. Department of Labor. Spray finishing operations. (29 CFR 1910.94). 1981.

(22) OSHA. Occupational Safety and Health Administration, U.S. Department of Labor. Occupational exposure to ethylene oxide; proposed rule. (48 FR 17284). 1983.

(23) RIFM. Research Institute for Fragrance Materials, Inc. beta-phenoxyethyl alcohol. Monograph. Englewood Cliffs, NJ: RIFM. 1983.

(24) Rohm and Hass Company. Information package on 2-phenoxyethanol (CAS No. 122-99-66) for submittal to the ITC. Government and Regulatory Affairs Department, Independence Mall West, Philadelphia, PA 19105. 1982.

(25) USEPA. Twelfth Report of the Interagency Testing Committee: Receipt of the report and requests for comments regarding priority list chemicals. Federal Register June 1, 1983 (48 FR 24443). 1983.

VI. Public Record

The EPA has established a public record of this testing decision (docket number OPTS-42057). This record includes:

(1) Federal Register notice designating 2-PE to the priority list and comments received thereon.

(2) Communications before industry testing proposal consisting of letters, contact reports of telephone conversations, meeting summaries.

(3) Testing proposals and protocols.

(4) Published and unpublished data, including the references cited above.

(5) Nonconfidential summaries of market data.

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays, in Rm. E-107 401 M St., SW., Washington, DC 20460. The Agency will supplement this record periodically with additional relevant information received. (Sec. 4, 90 Stat. 2003; 15 U.S.C. 2601).

Dated: May 14, 1984.

William D. Ruckelshaus,

Administrator.

[FR Doc. 84-13565 Filed 5-18-84; 8:45 am]

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[OPTS-42058; TSH-FRL 2571-5]

Calcium, Cobalt, and Lead Naphthenates; Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice is EPA's response to the Interagency Testing Committee's (ITC's) recommendation that EPA consider chemical fate, health effects, and environmental effect testing of calcium, cobalt, and lead naphthenates under section 4(a) of the Toxic Substances Control Act (TSCA). EPA is not initiating rulemaking under section 4(a) to require such testing at this time. The Agency has determined that data being developed in ongoing testing, in conjunction with available health effects information, should provide sufficient information to reasonably determine or predict the risks of those health effects recommended for testing by the ITC for each of the three metal naphthenates. At present, EPA does not believe that there is a sufficient basis to find that these substances may present an unreasonable risk to the environment nor that there is or may be substantial environmental release, and therefore does not plan to seek testing for chemical fate or environmental effects.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Pesticides and Toxic Substances, Rm. E-543, Environmental Protection Agency, 401 M St. SW., Washington, D.C. (554-1404), 20460, Toll Free: (800-424-9065). In Washington, D.C., Outside the U.S.A., (Operator—202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is not initiating rulemaking at this time under section 4(a) to require chemical fate, health effects, or environmental effects testing of calcium, cobalt, and lead naphthenates as designated by the ITC in its Twelfth Report.

I. Introduction

Section 4(a) of the Toxic Substances Control Act (TSCA) or the Act (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) authorizes EPA to promulgate regulations which require manufacturers and processors to test chemical substances and mixtures. Data developed through these test programs are used by EPA in assessing the risks that the tested chemicals may present to health and the environment. Section 4(e) of TSCA established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for the promulgation of testing rules under section 4(a) of the Act. The ITC may designate up to 50 of its recommendations at any one time for priority consideration by EPA. EPA is required to respond within 12 months of the date of designation, either by initiating rulemaking under section 4(a) or by publishing in the Federal Register reasons for not doing so.

On May 11, 1983, the ITC designated the three metal naphthenates for priority consideration in its Twelfth Report published in the Federal Register of June 1, 1983 (48 FR 24443). The Committee recommended that these substances be considered for testing for the following: (1) Chemical fate, abiotic/biotic persistence including dissociation, and chemical transport including soil mobility; (2) health effects, specifically carcinogenicity, mutagenicity, teratogenicity, toxicokinetics and reproductive effects; and (3) ecological effects (depending on the results of chemical fate tests), specifically acute toxicity to fish and aquatic invertebrates, toxicity to plants, and bioconcentration.

The ITC's testing recommendations for the designated substances were based on: (1) Potential release to the aquatic environment because of the amount produced and a wide variety of uses; (2) consumer and worker exposure from use in paints, varnishes and printing inks; (3) potential for health effects due to known toxic properties of calcium, cobalt, and lead salts; and (4) insufficient information to properly characterize the overall toxicological properties of the naphthenate salts of these three metals.

In evaluating the ITC's testing recommendations for the three metal naphthenates, EPA considered all relevant information, including the following: (1) Information presented in the ITC's Twelfth Report; (2) publicly available production volume, use, and exposure information for each of the three metal naphthenates; (3) other published and unpublished data available to the Agency, including data submitted under TSCA sections 8 (a) and (d); and (4) material relating to various ongoing testing programs. Based on its evaluation, as discussed in Units II and III, EPA is not initiating rulemaking at this time under section 4(a) of TSCA to require the testing recommended by the ITC for the three metal naphthenates. (See Units II.D and III of this Notice for the Agency's findings in this regard.)

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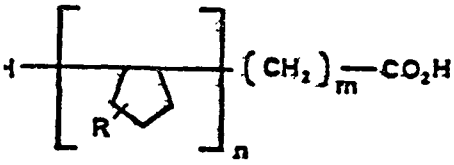
II. Assessment of Production, Use, Exposure, and Release

A. Production

These three metal naphthenates belong to a general group of metal soaps. Metal soaps are salts or complexes of metals with lipophilic carboxylic acides. the lipophilic acid moieties make the metal soaps insoluble in water and soluble in nonpolar organic solvents. Thus, metal soaps provide a mechanism of introducing the reactivity of the metals into media to which their inorganic salts normally would not have access.

The specific chemical nature of the lipophilic carboxylate is generally not important and several different types of lipophilic carboxylic acids have been used to make various metal soaps, all of which have similar chemical properties, uses, and exposure potentials. In the cases of calcium, cobalt and lead naphthenates, the lipophilic moiety, i.e., naphthenic acid, is a mixture of compounds primarily defined by the methods used to isolate the acid, via refining, from curde petroleum (Refs. 1 and 2). Naphthenic acides used to make metal soaps can be characterized by the general formula



where n may range from 0 to 5 and m is greater than 1. R is usually a small aliphatic group such as a methyl group. No information on the specific physical/chemical properties of the naphthenic acid or the metal naphthenates was found. However, EPA notes that because they are natural organic components of crude petroleum and because of their insolubility in water and solubility in organic solvents (Ref. 51), they should exhibit a high octanol/water partition coefficient.

Metal naphthenates are generally manufactured in mineral spirits by reaction of either free metal, metal oxide, or metal hydrate with naphthenic acid. The reaction is described as continuing to completion wherein there is no loss of naphthenates to the environment. As a result of production methods, metal naphthenates doe not exist commercially as a pure chemical substance, but instead are available only in a petroleum-based solvent or a mineral spirit solution [Ref. 3].

EPA has determined through available information that in 1982 domestic manufacturers batch-produced approximately 500,000, 1–2,000,000 and 4,000,000 pounds of calcium, cobalt and lead naphthenates, respectively. Only calcium naphthenate has been imported into the United States over the past several years, and in 1982 the volume was approximately 1.2 million pounds, all of which was and continues to be consumed as an additive in marine diesel engine fuels (Ref. 4).

B. Use

Like other metal soaps, the use of naphthenic acid to make a metal soap product and the choices of metal naphthenate for a specific task are probably determined as much by cost, availability, and habit, as by function. Excluding the calcium naphthenate used in marine diesel oils, the predominant uses of these metal naphthenates appear to be as paint driers, and to a lesser extent, ink driers. EPA has found from several sources that the amount of calcium, cobalt, and lead naphthenate in paints is typically less than one percent of the formulation and in a few specialty uses, as high as 5 to 10 percent of calcium and cobalt naphthenates (Refs. 5 through 8). For printing inks, the amount of these substances typically used in a formulation is also much less than one percent (Refs. 5 and 9). Most of the drier used in the printing ink industry have shifted away from naphthenates to tallates or linoleates, thus the use of calcium and cobalt naphthenate driers is described as representing a relatively small portion of the 1.8 million pounds of driers currently used by the ink industry. The use of lead driers has been mostly discontinued (Ref. 10). The estimated current consumption of the metal naphthenates in paint and ink drier uses, however, accounts for a substantial portion of their total production volumes, i.e., over 90 percent for calcium naphthenate, about 50 percent for cobalt naphthenate, and perhaps 30 percent for lead naphthenate (Ref. 11).

As the paint drier market specifically for lead naphthenate has declined, lubricants have become the principal market for this chemical, now accounting for as much as 70 percent of its overall consumption (Ref. 6). Lead naphthenate is used in sulfur-treated fatty acid lubricants intended for extreme-pressure situations and as an anti-corrosion agent (Ref. 1 and 12). Lubricants and greases containing lead naphthenate, at concentrations typically ranging from 1 to 7.5 percent, are used primarily in non-automotive, heavy industrial uses [Ref. 7 13 through 16]. In comparison with substitute organic acids such as oleates, tallates, and stearates, lead naphthenate continues to be the best grease and lubricant additive for some extreme-pressure applications (Ref. 16).

Minor use of cobalt naphthenates, which account for a very small portion of the total production volume, include humidity-resistant urethane adhesives. Cobalt naphthenate has also been reported to be used as a catalyst in the plastics industry (Ref. 6).

In general, production and use of the metal naphthenates has been continually declining at a fluctuating rate, averaging about 15 percent annually over the last several years (Refs. 17 and 18). This is occurring for the following reasons: (1) naphthenic acid metal soap driers are being replaced by cheaper synthetic acides; (2) a sharp disruption of supply in 1979 as a result of recessionary economic conditions encouraged its replacement; and (3) the future availability of naphthenic acid is not assured. Over the long term, market demand favors the use of solventless paints and will probably further reduce the market for naphthenate metal driers in the future.

C. Human Exposure

In assessing the potential for human exposure to these chemical substances EPA considered several routes of potential exposure: absorption and leaching from paints, release incidental to lubricant and grease formulation and use, and exposure during manufacture. EPA's analyses of these paths and its conclusions for human exposure are presented below.

1. *Exposure associated with paints.* Potential for exposure to the metal napthenates may exist from the use of oil-based paints and coatings which contain these chemcials. For some time, quick-cleaning solventless paints (i.e., water-based or latex) have been successfully marketed for general consumer uses (Ref. 19); such paints do not contain naphthenate soaps. In addition, lead soaps have not been used in domestic paints intended for household use (Ref.20) because the permissible lead content imposed by the U.S. Consumer Product Safety Commission was reduced to 0.06 percent by weight in 1978 (Ref. 21). Even where permitted for use, lead soaps generally have been replaced by calcium and zirconium soaps (Ref. 22). Therefore, some potential for general consumer exposure to calcium and cobalt metal naphthenates in oil based-paints does appear to exist. The potential for consumer exposure to lead naphthenates in paints, though may be less because of its regulations.

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EPA expects that exposure to oil-based paints containing these three metal naphthenates will occur most frequently with professional painters, who would be most likely to use these products in specific exterior and industrial applications. Both occupational and consumer exposure to the metal naphthenates in paints may occur through several possible routes: (a) Dermal absorption from paint films on the skin, (b) inhalation of respirable particles or aerosols, (c) ingestion of dried flakes.

a. With respect to the dermal route of human exposure, some information is available which indicates that absorption of metals from paints is a viable mens of uptake. One study showed tht when a test-paint product containing enhanced levels of lead naphthenate (i.e., 1.2 and 6 percent in the test paint vs. 0.42 percent in the base paint) was applied to occluded rabbit skin (10 consecutive days for 6 hours per day) blood lead levels were increased. The authors described a dose-response relationship in which the dermal absorption of lead was approximately 1.5 times greater in the 6 percent group than in the group treated with paint containing 1.2 percent lead naphthenate. The study showed that the blood lead levels peaked at about day 5, and once exposure was terminated, leveled off and decreased with time. The results also showed that blood lead levels never exceed 40 μg/100 ml blood (the limit established by the Occupational Safety and Health Administration as a workplace standard for lead in humans) in those animals exposed to the 1.2 percent level and rarely exceeded it in those exposed to 6 percent lead naphthenate paint (Ref. 23).

The Agency believes that this study may be applicable to uptake of cobalt and calcium metals from wet paint films as well. In general, however, EPA believes that drying of paint films on skin surfaces will render the metal less mobile, and the the lower levels of metal naphthenates in typical paint formulations will further limit the potential for exposure to the metals.

b. Spraying paints containing the three metal naphthenates may also result in potential inhalation exposures. EPA believes that a potential for inhalation exposure exists only with aerosol sprays because the metal naphthenates have not been found to volatilize (Refs. 24 and 25). EPA believes this route of exposure can be controlled by painters utilizing protective masks. However, one study shows that automobile workers, including painters, had blood lead levels that were higher than an unexposed control group (Ref. 26). EPA believes that this finding may be a result in part of other forms of lead present in this type of work environment as well as lead naphthenates, which was also the conclusion of the author.

c. A very limited potential for exposures to the metal naphthenates leaching from ingested dried paint and coatings may also exist. However, EPA expects this would occur only under the most unusual circumstances, and that under such circumstances the small amount of metal or metal naphthenates available for absorption would further reduce this exposure potential.

2. *Exposure associated with lubricants and greases.* EPA believes there exists potential human exposure to calcium and lead naphthenates due to their use in lubricants and greases. The use of lead naphthenate in domestic automotive oils and greases (Refs. 13, 14 and 15) generally is limited to gear lubricants and greases where its extreme pressure properties are needed (Ref. 15). Lead naphthenate lubricants also have application in heavy industrial machinery where the lubricants are frequently pneumatically distributed to the points of application at determined intervals (Ref. 13). Thus, EPA believes that human exposures to lead naphthenate, as a result of its use in lubricants and greases, as well as calcium natphthenate, are primarily occupational, dermal exposures. Three groups of workers are believed to be potentially exposed: workers in grease and lubricant manufacuring or formulating plants, workers in application plants, and maintenance workers (especially mechanics).

Several studies of occupational exposure of mechanics have demonstrated that lead naphthenate in oils and grease may be the most likely potential source of exposure to this compound (Refs. 26, 27 28 and 29). EPA has information that shows that exposures to greases and lubricants containing lead naphthenate of typical concentrations may lead to absorption of measurable amounts of lead. For example, human subjects who were dermally exposed to a gear oil containing 1.35 percent lead by weight (or approximately 4.5 percent lead naphthenate) twice daily for 4 weeks showed widely fluctuating though increased blood and urine lead concentrations during application, though no obvious pattern was evident among subjects (Ref. 30). The study does demonstrate lead absorption and excretion from a lead naphthenate-containing oil. The study also shows that lead from lead naphthenate, when absorbed through the skin, is in part excreted via the kidneys in urine. In fact, the kidney was found to be the organ with the highest lead concentrations when rats were exposed to lead acetate or lead naphthenate by cuaneous or subcutaneous pathways (Ref. 31). In percutaneous applications of leaded greases on test rabbits (Ref. 32), blood lead values were slightly higher in animals receiving repeated applications when compared to controls. Urinary lead levels were noticeably higher in treated animals and were proportional to the concentration of lead in the lubricants used. Tissue levels (i.e., liver, kidney, bone and brain) of lead were described by the authors as having failed to provide convincing evidence of lead absorption, although a strong suggestion was noted.

A second study, using a 0.24M lead naphthenate solution (ether:ethanol (1:3)) and exposing rats both by dermal application and subcutaneous injection to 500 μl for 5 applications over an 8-day period, showed that animals sacrificed 2 days after the last exposure had increased lead uptake and organ distribution when compared to controls. The study showed that dermally exposed animals had (a) levels of lead in the brain and spleen that were nearly identical to those found in control animals, (b) a 2-fold increase of lead in the liver, and (c) a 4-fold increase of lead in muscle and kidney tissues. Animals given subcutaneous injections of lead naphthenate showed a significantly different distribution of lead; i.e., brain, kidney, liver, spleen and muscle lead levels were approximately 2- 23- 11- 6- and 8- fold greater than controls (Ref. 31).

EPA believes that the results of the dermal application study, described above, are more relevant to the route of exposure to metal naphthenates in occupational situations than those results of the injection studies. They may further indicate that uptake through the skin may be limited, leading to the lower lead tissue levels which were found in the dermal application study. The increased tissue-lead levels found with the subcutaneous injection route may indicate that the body is forced to assimilate all of the available lead compound.

EPA also believes that, in a similar fashion, calcium or calcium naphthenate absorption into the body may take place due to the exposure of calcium naphthenate-containing lubricants and greases.

3. *Exposure during manufacture.* As noted above, the metal naphthenates are, in general, manufactured in mineral

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spirits by reaction of either the free metal (e.g., Co), or its oxide (e.g., CaO or PbO) or hydrate (e.g., $Co[OH]_2$) or $Ca[OH]_2$) with naphthenic acid in a closed reactor. During production the naphthenic acid and mineral spirits are charged through feed lines directly from closed storage tanks; the solids (i.e., metal, metal oxides, or metal hydrates) are introduced by means of screw or bucket feeders equipped with dust collectors. Engineering controls are described by the manufacturers as satisfactory to comply with the OSHA standards currently regulating the handling of the raw materials, lead compounds, and the product's base solvent. Worker exposure to the naphthenates is limited in duration, occurring only at sampling, filter changing, and drumming operations (Ref. 3).

The numbers of workers involved in the manufacture of the metal naphthenates is also limited. Currently there are fewer than 100 workers involved in the manufacture of all Ca, Co, and Pb naphthenates in the United States (Ref. 3). In a typical chemical plant, the number of chemical operators immediately involved with the manufacturing operations is two persons per shift. Because these products are usually prepared separately, these same operators prepare all of the soaps in successive batches (Ref. 3).

4. *Conclusion for human exposure.* Though low volatility, low end-use concentrations, and specialized production limit the potential for workplace exposure to the metal naphthenates, the Agency concludes that these factors do not preclude the potential for worker exposure during manufacture and use. Consequently, EPA believes that there may be a low potential for worker exposure to these chemicals, and that it exists principally through dermal exposures to products containing these chemicals.

A presentation of the available health effects information is given in Unit III.

D. Environmental Release

EPA has determined from the available information received in response to the ITC's recommendations that virtually none of these metal naphthenates is lost to the environment during production and that generated wastes from production are disposed of as hazardous wastes due to flammability of the base solvent medium or, in the case of lead naphthenate, because of the lead content. In the case of cobalt naphthenate production, the high cost of the starting materials (i.e., cobalt oxide, etc.) dictates the recycling of cobalt-containing wastes (Ref. 24).

Because of the negligible release during manufacture and the limited uses and the use specifications of these metal naphthenates in paints, lubricants, and greases, EPA believes that spills, leaks, and leaching of the compounds from dried paint films represent the only potential sources of release to the environment. The Agency, therefore, believes that the metal napthenates may reasonably be anticipated not to enter the environment in substantial quantities.

In the aquatic environment, the fate of low concentrations of these complexes may also reasonably be predicted. Because the rate of exchange of water molecules acting as ligands to dissolved metal ions with water is believed to be determined primarily by the nature of the metal (Ref. 33) and related to the metal naphthenate concentration in solution, EPA believes that it can reasonably expect exchange of these metals between naphthenate and hydronium ions to be rapid, and the resulting hydrolysis/dissociation of low concentrations of the metal naphthenates in water to be rapid as well. Additionally, EPA further believes one effect of the dissociation of low concentrations of the metal naphthenate complex in solution will be a variation in the apparent octanol/water partition coefficient as a function of the concentration of the compound. When concentrated in solution, most of the quantity will retain its chemical structural integrity; more of it, however, will tend to partition when the compound is diluted in solution, thereby dissociating into its ions. Consequently, EPA believes the environmental concentrations will be so low that hydrolysis will inevitably occur and the expected high octanol/water partition coefficient will be irrelevant.

Because the metal naphthenates are each a mixture of compounds, no specific octanol/water partition coefficient can be calculated. But, because of their low water solubility and high solubility in organic solvents, the coefficient should be high. Therefore, they may be expected to adsorb onto the organic components of soils, as well as bioconcentrate when in sufficiently high concentrations, which favor non-dissociation.

Also, because these metal naphthenates are high molecular weight complexes, volatility is presumably negligible and there should be little, if any, release to the atmosphere during production, processing or use.

III. Health Effects

The ITC recommended health effects testing for these three metal naphthenates on the basis of known toxicities of the metals, or some complex forms of these metals, and its conclusion that sufficient evidence did not exist to characterize their overall toxicological properties. Although the toxicities of lead, cobalt and calcium are well characterized, there is a paucity of information on these metals complexed with naphthenic acid. However, the available health effects studies on these metal naphthenates are briefly detailed below.

A. Calcium Naphthenate

The oral LD_{50} value in rats for calcium naphthenate is reported as greater than 6.0 g/kg (Ref. 34), thus suggesting that calcium naphthenate has low, if any, acute toxicity.

The results of short-term in vitro tests suggest that calcium naphthenate also has low, if any, mutagenic potential. Mutagenic activity was investigated in *Escherichia coli, Salmonella typhimurium,* and liquid cultures of the yeast, *Saccharomyces cerevisiae* (Ref. 35). Assays were performed both with and without S9 activation. In addition, rat liver cells were incubated in monolayer slide culture for 24 hours in culture medium containing the test substance; cells in metaphase were analyzed for structural chromosome aberrations (Ref. 35). The National Cancer Institute has also performed Ames/*Salmonella typhimurim* tests and reported that calcium naphthenate was not found to be mutagenic (Ref. 36). The *Salmonella* strains included TA 1535, TA 1537 TA 1538, TA 98, and TA 100, tested both without and with S9 activation. The results of these assays indicate that calcium naphthenate does not induce reverse mutations in bacteria, gene conversions in yeast, or chromosomal damage in rat liver cells under the test conditions.

Shell Oil Company reported that there are two on-going health effects studies sponsored by Shell International Chemical Company (Ref. 35). One is a 2-year "carcinogenicity" study in which female mice are treated twice weekly by painting a calcium naphthenate-containing product on shorn skin. The study was initiated in August, 1983. The second study is a reproductive effects study in which male rabbits were treated by painting a calcium naphthenate-containing product on shorn dorsal skin for 10 weeks (total of 50 doses), and were then mated with virgin females. The males' reproductive tracts are being examined by histopathology and females examined for number of corpora lutea, resorption sites, live and dead fetuses. The live

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portion of the study was completed in August 1983; the data will become available during the fall of 1984. Protocols for both studies are available in the docket for this action.

EPA has found no data which address the teratogenicity or toxicokinetics of calcium naphthenate.

B. Cobalt Naphthenate

The acute oral toxicity (LD_{50}) of cobalt naphthenate (6 percent cobalt) in rats was reported to be 3.9 g/kg (Refs. 34 and 37), with a range of 3.5 g/kg to 4.4 g/kg. More recently, the acute oral toxicity (LD_{50}) for male and female rats was determined to be 2.8 g/kg (Ref. 38), with a range of 2.5 g/kg to 3.1 g/kg. Signs of toxicity included reduced appetite, reduced activity, weakness, collapse, and death. Gross pathological examination revealed slight lung congestion, liver discoloration, and acute gastrointestinal inflammation. The 24-hour acute, dermal-minimal-lethal dose for male and female rabbits was determined to be greater than 1.26 g/kg and less than 2.0 g/kg (Ref. 38).

Cobalt naphthenate was reported to be carcinogenic under the poorly described conditions of test in rabbits (Refs. 39 and 40) and mice (Ref. 41). A group of 12 rabbits each received a solution of 0.2 µl of cobalt naphthenate (containing 1 percent metallic cobalt in an unspecified solvent) 2–4 times per week. Six of these animals received the compound intramusclarly at three different sites, three animals received it intravascularly, two received it intrapleurally, and one received it intrahepatically. The animals were killed at various time periods ranging from 3 to 6 months, presumably, immediately after dosing was initiated. Nine of twelve animals developed cancerous growths at the injection site; the other three animals died. No controls were reported for the experiments, and the compound was not administered with relevance to normal portals of entry.

In a separate but continued portion of this study, cellular changes taking place during progression of tumor development in mice after treatment with cobalt naphthenate was investigated (Ref. 41). A group of 30 mice each received an intramuscular injection (0.02 µl) of the compound (containing 1 percent metallic cobalt in an unspecified solvent) daily for an unspecified period of time; some animals were killed weekly for gross and microscopic examinations. Eight of thirty animals examined developed tumors in cross-striated muscles.

Although tumors were observed at the injection site in rabbit and mouse studies employing cobalt naphthenate (Refs. 39 through 41), EPA concludes that this finding is not indicative of an oncogenic response. EPA also finds that the lack of adequate controls in these studies also precludes an evaluation of whether the induction of neoplasia is attributable to trauma, the solvent, a combination of trauma and solvent or cobalt naphthenate itself. Because the compound was not administered with relevance to normal portals of exposures, because tumors were observed only at the injection site, because it was given in an unspecified solvent, and because no controls were included and the duration of dosing was poorly specified, the Agency concludes that the induction of neoplasia cannot be attributed directly to cobalt naphthenate per se, as suggested by the ITC, and does not clearly suggest that cobalt naphthenate is an oncogen.

Cobalt naphthenate was also tested for mutagenicity using the Ames *Salmonella typhimurium* assay and was found to be negative (Ref. 36). Five dose levels were tested in triplicate using two liver S9 systems (rat and hamster) induced with Aroclor 1254 and without activation. Five tester strains (TA 1535, TA 1537 TA 1538, TA 98, and TA 100) of *Salmonella typhimurium* were used.

At this time the National Cancer Institute Chemical Selection Work Group has nominated cobalt naphthenate, with a moderate to high priority, for testing in the National Toxicology Program (NTP) bioassay testing system (Ref. 42). NTP will begin its study design process for cobalt naphthenate testing shortly and has plans to also test cobalt sulfate, from an earlier recommendation, in their bioassay system as well. EPA also has learned of an ongoing tracheal intubation cobalt (II) oxide 24-month carcinogenicity study in Sprague-Dawley rats being conducted by Bayer AG in West Germany (Ref. 43). Results of this study will be added to the record for this action when received.

On October 31, 1983, the Chemical Manufacturers Association (CMA) Naphthenate Metal Soap Program Panel (the Panel) submitted to EPA a preliminary protocol (Ref. 44) designed to determine whether cobalt is absorbed into the blood of rats after repeated dermal applications of a cobalt naphthenate-containing paint product. The study is also designed such that significant increases in blood-cobalt levels will trigger further metal analyses in tissue(s) determined by EPA to be the target organ(s). The Panel's study protocol is available in the public record for this notice.

C. Lead Naphthenate

Several studies are available on the absorption of lead applied to the skin or ingested as lead naphthenate, and the distribution and excretion of that lead. Studies with animals and humans have shown that lead penetrates into the body when lead naphthenate and products containing the chemical are applied to the skin. There is no direct evidence that the internal lead is in the form of lead naphthenate, but the tissue/organ distribution of lead in the experiments is different from the result obtained when lead acetate is used (Refs. 25 and 29). The biochemical effect (i.e., depression of ALA-D activity) also appears to be greater with lead naphthenate than with lead acetate (Ref. 31). The oral LD_{50} value for lead naphthenate in rats is 5.1 g/kg (Ref. 34). The intraperitoneal LD_{50} value in rats is 0.52 g/kg (Ref. 34). By both routes of administration, gastrointestinal disturbances were observed.

Rats treated orally with 20 doses of lead naphthenate (0.2 µl of a solution containing 1 percent lead) over a period of 30 days did not develop any toxic effects. Body weight, gross appearance, and functions were similar to those of controls. There were no mortalities, and there were no differences in lead content of the liver or histopathology. There was, however, a 3-fold increase in mean lead content of hair over that of controls (1.0 µg/g hair vs 0.295 µg/g hair for controls) (Ref. 34).

Lead naphthenate in the diet (100 ppm lead) and paint containing lead naphthenate (190 ppm lead) fed to male rats for 12 weeks caused no toxic effects (Ref. 45). Growth and food intake were normal, and there were no changes in bone or blood histology.

Lead naphthenate appears to be more toxic when administered to rats subcutaneously in comparison to application on the skin. In two studies rats were treated with lead naphthenate at two concentration levels by these two routes for 2–10 weeks (Refs. 31 and 46). Toxic effects were noticed only in subcutaneously treated animals. Industrial gear oil, grease, and gear lubricants containing lead naphthenate applied to the skin of rabbits did not cause any unusual macroscopic, microscopic, or functional changes (Refs. 30 and 32).

Lead acetate and other lead compounds have not been found to be mutagenic (Refs. 47 and 48). Lead naphthenate was not mutagenic in recent NTP Ames *Salmonella typhimurium* assays (Ref. 36). Five strains of *S. typhimurium* (TA 1535, TA

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1537, TA 1538, TA 98 and TA 100) were studied, and they were tested with and without metabolic activation by Aroclor 1254-induced liver enzyme systems.

The carcinogenicity of an engine oil additive and its components (including lead naphthenate) was studied in mice (Refs. 49 and 50). In a pilot study, the clipped dorsal skin of mice was painted with the whole additive, the base oil used to make the additive (a Venezuelan crude oil), a 20 percent solution of the additive concentrate in benzene, or a 20 percent solution of lead naphthenate in benzene. The mice were painted twice weekly for 12 months and observed for a total of 569 days. The incidence for skin tumors for the lead naphthenate or the other engine oil additive components was 11 percent (7 of 59). No controls were mentioned.

In a more detailed report of the carcinogenicity study, the tumors were more thoroughly characterized and organs other than the skin were examined. The authors did not discuss any controls, but they stated: "Neither the whole additive formulation nor the lead naphthenate fraction produced any significant carcinogenic response in mouse skin." Skin papillomata were observed in only 2 mice (4 percent) following skin painting with lead naphthenate, while only a single papilloma developed in mice treated with the whole additive formulation (additive concentrate). However, skin painting with the lead naphthenate fraction induced marked kidney damage, and tubular adenomata were observed in 4 mice while one had a renal carcinoma (Ref. 50).

EPA believes that the carcinogenicity study of an engine oil and its components (Refs. 49 and 50) does not show that lead naphthenate produces skin tumors when applied to the skin.

In a study of human subjects exposed to dermal application of gear oil containing lead naphthenate (Ref. 30), the authors noted that the subjects showed no significant deviations from expected values of objective medical findings (e.g., blood pressure, reflexes, tremor, pulse), and there was no evidence of any physiologic change due to inorganic lead absorption, although lead content in blood and urine were increased. All clinical chemistry values obtained before and after application of the oil were within expected limits. Normal liver and kidney functions were indicated by these tests. Urinary analysis data were normal, including normal coproporphyrin values. Blood did not show any stippling of red cells.

Given the extensive toxicity data base for lead and the limited data for lead naphthenate, the CMA Panel recognized the need to perform additional testing for lead naphthenate in order to be able to correlate these test results with available lead toxicity data. On October 31, 1983, the CMA Panel submitted a preliminary protocol (Ref. 44) to EPA designed to determine whether lead is absorbed into the blood of rats after repeated dermal applications of a lead naphthenate-containing grease product. As with cobalt naphthenate, the study is designed to trigger tissue residue analyses if blood-lead levels are significantly increased. The protocol for this study is available for review in the public record for this notice.

IV Summary of Decision Not To Initiate Rulemaking

A. Health Effects

EPA believes that there is no basis for requiring health effects testing of these metal naphthenates under TSCA section 4(a)(1)(A) at this time because there is no sound evidence that indicates that these compounds themselves may cause any of the health effects identified by the ITC. The Agency also has found no information that indicates that napthenic acid may present an unreasonable risk to human health. EPA believes that any health effects caused by absorption of the constituent metals contained in these naphthenates can be reasonably predicted from current knowledge of the metals' effects once information about such absorption is available. Industry is conducting testing that should allow EPA to judge the degree to which exposure to typical products containing the naphthenates results in absorption of the metals. The Agency believes, as explained below, that the testing being conducted by industry will permit EPA to determine whether observed effects of these naphthenate salts can be explained by the known toxic effects for the constituent metals, or whether further health effects testing of the metal naphthenates themselves is necessary.

In regard to TSCA section 4(a)(1)(B), the Agency believes that the naphthenates' production volumes are declining, their uses are limited and specialized and are declining in consumer products, and they are used in low concentrations in most products incorporating them. In deciding what testing is appropriate, EPA noted that there is uncertainty as to the extent to which the metal naphthenates are absorbed through the skin and where they may be deposited throughout the body. EPA believes the answers to these questions, as well as to the concern for uptake from available commercial products, should be provided by the industry-sponsored dermal absorption studies now being conducted on cobalt and lead naphthenates.

Furthermore, the Agency believes that because calcium is toxicologically innocuous in moderate amounts, that moderate amounts of both calcium and cobalt are necessary elements for normal human growth and development, and that anticipated exposures to calcium and cobalt naphthenate may lead to minor uptake and distribution of these metals, extensive toxicological testing is not warranted at this time. EPA also believes that the toxicity data base on the three constituent metals is quite extensive and that if toxicity were to be demonstrated through testing of cobalt or lead naphthenate, the toxicity observed would likely be that of the metal. EPA believes that the ongoing testing including the dermal uptake studies, will provide valuable information to evaluate the role of the constituent metals in determining the metal naphthenates' toxicity and should permit the correlation of dermal exposure and metal uptake from the naphthenates. EPA also believes the ongoing testing, especially that of the Shell International Company and the NTP will provide information relative to predicting the toxic effects of napthenic acid. If the testing supports the Agency's belief, the available data base on the metals, as well as the being developed for some of the metal naphthenates, is expected to be sufficient to reasonably predict the health effects of exposure to the metal naphthenates. If the Agency's belief is not borne out by the ongoing testing, further studies may be necessary. Nevertheless, without the results from the ongoing work, the Agency believes that it would be premature to require additional testing.

As part of its commitment to conduct the dermal exposure and metal uptake testing, the industry has agreed that if further health effects testing is scientifically warranted they will perform such testing.

If based on its evaluation of the data generated by the industry test program, EPA concludes that further health effects testing of one or more of the metal naphthenates is necessary, and should industry not agree to promptly initiate such testing, EPA will reconsider the need to propose a test rule under TSCA section 4(a) to require that testing.

For these reasons, EPA has decided not to initiate rulemaking to require testing of these metal naphthenates at this time.

HeinOnline -- 49 Fed. Reg. 21416 1984

B. Chemical Fate and Ecological Effects

From the analysis presented in Unit II. D. above, EPA believes the environmental release of all three metal naphthenates from production is not substantial because of the production processes currently being employed by the manufacturers. Environmental release of all three metal naphthenates during normal use in paints is also not believed to be substantial because of their limited application in oil-based paints and coatings, and because movement of these chemicals out of a dried paint matrix is believed to be insignificant. Releases of lead or calcium naphthenates from industrial specialty lubricants and greases may occur; however, EPA believes they are an insignificant source of environmental contamination by either the metal or the metal naphthenate itself. EPA has also determined that the most likely route of environmental exposure to the designated metal naphthenates is through uncontrolled spills and leakages of greases and paints. However, it is unlikely that substantial amounts of these materials would be released to the environment through such events. Therefore, EPA finds that while there is a limited potential for environmental release, this release is not likely to be in substantial quantities and is not likely to result in substantial environmental concentrations of the three metal naphthenates. EPA also believes that the gradual replacement of naphthenic acids with other more readily available organic acids further reduces the likelihood of environmental risks caused by spills, leaks, or leaching of these metal naphthenates. Accordingly, EPA finds no basis to require chemical fate or ecological effects testing at this time based upon production and release. Furthermore, no data were found which showed that these metal naphthenates may cause any environmental effects. For these reasons too, EPA has decided not to require chemical fate or ecological effects testing of any of these metal naphthenates at this time.

C. Interactive Process and Availability of Test Data

Test data from all study programs described above will became part of the administrative record for this notice and will be available for review as noted above. EPA and the CMA Panel agree that they will meet to discuss the results of the CMA Panel's absorption studies and that EPA reserves the reight to require the analyses of tissues it deems necessary for assessing the health effects of cobalt and lead naphthenate.

The CMA Panel anticipates starting their absorption studies by the time this notice is published and submitting a final report to the record within 3 months of the completion of the animal experiments. The CMA Panel has also agreed to the following stipulations:

1. To furnish EPA with the names and addresses of the Laboratories conducting the tests described above as soon as they are available. The specific test being performed by each laboratory shall be indicated.

2. To adhere to the TSCA Good Laboratory Practice Standards adopted by EPA on November 29, 1983 (48 FR 53922).

3. To permit laboratory inspections and data audits by the EPA or FDA in accordance with authority and procedures outlined in TSCA section 11. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and that the studies are being conducted according to TSCA Good Laboratory Practices.

4. That all raw data, documentation, records, protocols, specimens, and reports generated as a result of a study and required to be retained by TSCA Good Laboratory Practice Standards will be retained for a period of 10 years after completion of a study and made available to EPA during an inspection, or submitted to EPA if requested by EPA.

5. Finally, failure to conduct the testing according to the specified protocol(s) or failure to follow Good Laboratory Practices as indicated above may invalidate the tests. In such cases, a data gap may still exist and the Agency may decide to require testing through a rule.

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HeinOnline -- 49 Fed. Reg. 21417 1984

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VI. Public Record

The EPA has established a public record for this testing decision docket number [OPTS-42058]. The record includes the following information:

(1) Federal Register notice designating calcium, cobalt, and lead naphthenates to the Priority List and all public comments received thereon.

(2) Communications consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Published and unpublished data.

The record, containing the basic information considered by the Agency in developing this decision, is available for inspection from 8:00 a.m. to 4:00 p.m., Monday through Friday, except legal holidays, in Rm. E-107, 401 M St., SW., Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, Pub. L. 94-469, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: May 14, 1984.

William D. Ruckelshaus,

Administrator.

[FR Doc. 84-13360 Filed 5-18-84; 8:45 am]

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[WH-FRL-2591-7]

Draft General National Pollutant Discharge Elimination System (NPDES) Permit for Log Transfer Facilities in the State of Alaska; Change in Comment Period

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of extension of public comment period.

SUMMARY: The Regional Administrator of Region 10 is today giving notice that the public comment period for the draft general National Pollutant Discharge Elimination System (NPDES) permit for log transfer facilities in the State of Alaska is extended until June 5, 1984. The proposed permit was previously noticed at 49 FR 6788 (February 23, 1984) and 49 FR 11875 (March 28, 1984). EPA is taking this action in response to requests made by several individuals commenting in writing and at the public hearing. EPA is seeking additional comments on the proposed effluent limitations and Best Management Practices (BMPs) in the permit and information on small businesses potentially impacted by the permit. Information submitted during the original comment period, at the public hearing held on April 27 1984, and in response to this notice will be

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