



# Selected lead-based pigments: Human health tier II assessment

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## Chemicals in this assessment

Chemical Name in the Inventory	CAS Number
<b>Lead oxide phosphonate (Pb<sub>3</sub>O<sub>2</sub>(HPO<sub>3</sub>)), hemihydrate</b>	1344-40-7
<b>Lead oxide phosphonate (Pb<sub>3</sub>O<sub>2</sub>(HPO<sub>3</sub>))</b>	12141-20-7
<b>Lead oxide sulfate (Pb<sub>4</sub>O<sub>3</sub>(SO<sub>4</sub>))</b>	12202-17-4
<b>Sulfuric acid, lead(2+) salt (1:1)</b>	7446-14-2
<b>Phosphoric acid, lead(2+) salt (2:3)</b>	7446-27-7
<b>Silicic acid (H<sub>2</sub>SiO<sub>3</sub>), lead(2+) salt (1:1)</b>	10099-76-0
<b>Molybdic acid (H<sub>2</sub>MoO<sub>4</sub>), lead(2+) salt (1:1)</b>	10190-55-3
<b>Silicic acid, lead salt</b>	11120-22-2
<b>Lead tin oxide (PbSnO<sub>3</sub>)</b>	12036-31-6
<b>Lead oxide sulfate (Pb<sub>2</sub>O(SO<sub>4</sub>))</b>	12036-76-9

Chemical Name in the Inventory	CAS Number
<b>Lead titanium oxide (PbTiO<sub>3</sub>)</b>	12060-00-3
<b>Lead oxide sulfate (Pb<sub>5</sub>O<sub>4</sub>(SO<sub>4</sub>))</b>	12065-90-6
<b>Phosphonic acid, lead(2+) salt (1:1)</b>	13453-65-1
<b>Diphosphoric acid, lead(2+) salt (1:2)</b>	13453-66-2
<b>Boric acid (HBO<sub>2</sub>), lead(2+) salt</b>	14720-53-7
<b>Phosphonic acid, lead(2+) salt (2:1)</b>	15521-60-5
<b>Sulfuric acid, lead salt</b>	15739-80-7
<b>Phosphonic acid, lead salt</b>	16038-76-9
<b>Phosphonic acid, lead(2+) salt</b>	24824-71-3
<b>Sulfuric acid, lead salt, tetrabasic</b>	52732-72-6

## Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

For more detail on this program please visit: [www.nicnas.gov.au](http://www.nicnas.gov.au)

### Disclaimer

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## ACRONYMS & ABBREVIATIONS

## Grouping Rationale

This group of 20 chemical compounds consists of selected lead-based pigments based on a range of oxyanions. These compounds have been included in this group due to the expectation that the group has related end uses and their low water solubilities. The lead compounds with an unspecified oxidation state will predominantly contain lead in the +2 oxidation state. While the individual oxyanions may vary in toxicological properties, in each case the lead cation is expected to dominate the toxicological profile. Information outlined in the Organisation for Economic Co-operation and Development's (OECD) guideline on Grouping of Chemicals (OECD, 2007) provided guidance on the grouping of these chemicals based on physico-chemical or toxicological criteria.

## Import, Manufacture and Use

### Australian

The following lead compounds have Australian industrial uses reported under previous mandatory (NICNAS) and/or voluntary calls for information:

***Tribasic lead sulfate* (CAS No. 12202-17-4), *lead molybdate* (CAS No. 10190-55-3) and *lead sulfate* (CAS No. 7446-14-2)** have one or more of the following reported uses:

Domestic use including:

- in paints and inks.

Commercial uses including:

- in the manufacture of glass and ceramics; and
- in plastics.

Site-limited use including:

- as a stabiliser.

The total volume introduced into Australia for ***tribasic lead sulfate* (CAS No. 12202-17-4)** and ***lead sulfate* (CAS No. 7446-14-2)**, reported under previous mandatory and/or voluntary calls for information, was below 1000 tonnes.

For the remaining members of the group, no specific Australian use, import or manufacturing information has been identified.

## International

For this group, the following international use has been identified through the US Environmental Protection Agency's (EPA) Aggregated Computer Toxicology Resource (ACToR) via eChemPortal:

Site-limited use including:

- in metallurgy, e.g. bearing materials, brass, aluminium and steel used in the automotive industry.

The following individual lead compounds have international uses identified from European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; and eChemPortal: The Finnish Environment Institute; the US EPA's ACToR; and the US National Library of Medicine's Hazardous Substances Data Bank (HSDB):

***Tribasic lead sulfate (CAS No. 12202-17-4), lead sulfate (CAS No. 7446-14-2), tetrabasic lead sulfate (CAS No. 12065-90-6), lead titanate (CAS No. 12060-00-3), dibasic lead phosphite (CAS No. 12141-20-7), lead phosphite (CAS No. 7446-27-7), lead silicate (CAS No. 10099-76-0), lead sulfate (CAS No: 15739-80-7), and lead borate (CAS No. 14720-53-7)*** have one or more of the following uses:

Domestic use including:

- paints, lacquers and varnishes, e.g. quick dry oil varnishes;
- in colouring agents/dyes, e.g. used as a replacement for white lead as pigment; and
- in water proofing paints.

***Tribasic lead sulfate (CAS No. 12202-17-4), lead sulfate (CAS No. 7446-14-2), tetrabasic lead sulfate (CAS No. 12065-90-6), lead titanate (CAS No. 12060-00-3), lead molybdate (CAS No. 10190-55-3), dibasic lead phosphite (CAS No. 12141-20-7), dibasic lead phosphite (CAS No. 1344-40-7), lead stannate (CAS No. 12036-31-6), lead silicate (CAS No. 10099-76-0) and lead sulfate (CAS No: 15739-80-7), dibasic lead sulfate (CAS No. 12036-76-9), and lead borate (CAS No. 14720-53-7)*** have one or more of the following uses:

Commercial use including:

- manufacture of lead acid storage batteries;
- in lithography;
- in the weighting of fabrics in the textile industry;
- in lubricants;
- in adhesives and binding agents;
- in construction materials;
- as process regulators;
- in the manufacture of other non-metallic mineral products, e.g. plasters, cement, ceramics; and
- used with other metals including silver in galvoplasty for the placement of electrically-conducting coatings on glass, pottery, chinaware and porcelain.

Site-limited use including:

- as a stabiliser;
- in the manufacture of rubber and plastic products; and
- as reactants in the manufacture of laboratory chemicals.

## Restrictions

### Australian

Lead and lead compounds are listed in the Poisons Standard (the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) (SUSMP, 2012) in:

#### **Appendix I, Uniform Paint Standard**

Lead compounds are not permitted to be used in domestic or industrial paints at > 0.1 %.

The proportion of a substance for the purposes of this Schedule is calculated as a percentage of the element present in the non-volatile content of the paint.

#### **Appendix C**

Lead compounds in paints, tinters, inks or ink additives except in preparations containing  $\leq 0.1$  % of lead calculated on the non-volatile content of the paint, tinter, ink or ink additive.

Appendix C substances, other than those included in the Schedule 9, are considered of such danger to health as to warrant prohibition of sale, supply and use. These substances are poisons prohibited from sale, supply or use because of their known potential for harm to human and/or animal health.

#### **Schedule 6**

Lead compounds unless specified in Appendix C or:

- when included in Schedule 4 or 5;
- in paints, tinters, inks or ink additives;
- in preparations for cosmetic use containing 100 mg/kg or less of lead;
- in pencil cores, finger colours, showcard colours, pastels, crayons, poster paints/colours or coloured chalks containing 100 mg/kg or less of lead; or
- in ceramic glazes when labelled with the warning statement: *CAUTION - Harmful if swallowed. Do not use on surfaces which contact food or drink.* Written in letters not less than 1.5 mm in height.

Schedule 6 substances are considered to have moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

#### **Schedule 5**

Lead compounds in preparations for use as hair cosmetics, unless specified in Appendix C.

Schedule 5 substances are considered to have low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

In addition, under the *Customs (Prohibited Imports) Regulations 1956*, the importation of cosmetic products containing more than 250 mg/kg (0.025 % w/w) of lead or lead compounds (calculated as lead), except products containing more than 250 mg/kg

of lead acetate designed for use in hair treatments, is prohibited

unless written permission is granted by the Minister (Australian Government, 2013).

## International

The risk of exposure to lead and lead compounds has been recognised internationally, which has resulted in broad restrictions regarding occupational and public exposure.

### **Cosmetics**

Lead compounds appear on the following:

- Health Canada List of Prohibited and Restricted Cosmetic Ingredients ("Hotlist").
- The EU Cosmetic Directive 76/768/EEC Annex II: List of Substances which must not form part of the Composition of Cosmetic Products.
- The New Zealand Cosmetic Products Group Standard - Schedule 4: Components Cosmetic Products Must Not Contain.
- The Thailand Cosmetic Act - Prohibited Substances.

## Existing Worker Health and Safety Controls

### Hazard Classification

The compound **lead phosphate (CAS No. 7446-27-7)** is classified as hazardous with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

Repr. Cat. 1; R61 (Reproductive toxicity - may cause harm to the unborn child).

Repr. Cat. 3; R62 (Reproductive toxicity - possible risk of impaired fertility).

Xn; R33 (Danger of cumulative effects).

Xn; R48/22 (Harmful: danger of serious damage to health by prolonged exposure if swallowed).

The remaining members of this group are not individually listed in the HSIS and therefore, by default, are covered by the generic 'lead and lead compounds' classification as hazardous with the following risk phrases for human health:

Repr. Cat. 1; R61 (Reproductive toxicity - may cause harm to the unborn child).

Repr. Cat. 3; R62 (Reproductive toxicity - possible risk of impaired fertility).

Xn; R20/R22 (Harmful by inhalation and if swallowed).

Xn; R33 (Danger of cumulative effects).

### Exposure Standards

#### Australian

Lead, inorganic dusts and fumes (as lead) have the following exposure standards reported in HSIS (Safe Work Australia). These exposure standards apply to the lead compounds in this assessment:

Time Weighted Average (TWA): 0.15 mg/m<sup>3</sup> for lead compounds (as lead).

Short-Term Exposure Limits (STEL): No specific exposure standards are available.

## International

For lead compounds in general the following exposure limits were identified:

TWA: 0.20 mg/m<sup>3</sup> [Thailand, USA (Idaho)]

TWA: 0.15 mg/m<sup>3</sup> [Argentina, Canada (Northwest Territories, Yukon), Egypt, European Union, Gibraltar, Hungary, India, Luxembourg, Malta, Mexico, Philippines, Serbia, Singapore, Slovak Republic, Turkey]

TWA: 0.12 mg/m<sup>3</sup> [Chile]

TWA: 0.10 mg/m<sup>3</sup> [Austria, Maximum Allowable Concentration (MAK), New Zealand, Republic of South Africa, Sweden, Switzerland MAK]

TWA: 0.05 mg/m<sup>3</sup> [Bulgaria, Canada (Alberta, British Columbia, Nova Scotia, Ontario, Prince Edward Island, Saskatchewan), China, Italy, Malaysia, Nicaragua, Peru, Poland, USA (California, Hawaii, Michigan, North Carolina, Oregon, Washington, Wyoming)]

TWA: 0.005 mg/m<sup>3</sup> [Latvia]

STEL: 0.80 mg/m<sup>3</sup> [Switzerland MAK]

STEL: 0.60 mg/m<sup>3</sup> [Hungary]

STEL: 0.45 mg/m<sup>3</sup> [Argentina, Canada (Northwest Territories, Yukon), Egypt]

STEL: 0.40 mg/m<sup>3</sup> [Austria MAK]

STEL: 0.15 mg/m<sup>3</sup> [Canada (Saskatchewan)]

STEL: 0.01 mg/m<sup>3</sup> [Latvia]

## Health Hazard Information

### Toxicokinetics

Inorganic lead compounds can be absorbed orally, dermally or via inhalation (NICNAS, 2007).

When ingested, the absorption of inorganic lead compounds in the human gastrointestinal tract is influenced by different factors, the most significant being age. Children (up to the age of eight) are estimated to absorb up to 50 % of the lead dose they ingest while adults would absorb up to 10 % of the dose they ingest. This route of absorption can be dependent on solubility and particle size with smaller particles being absorbed more readily than larger ones. In addition, results from rodent feeding studies indicate that water-insoluble lead compounds (lead oxide and carbonate) are bioavailable following ingestion (LDAI, 2008).

In an oral repeat dose toxicity study, rats were dosed with 0, 200, 500 or 1000 ppm lead acetate and tested for four, eight or 12 weeks. The blood lead (PbB) level range was 40 - 100 µg/dL and the kidney lead levels were highest at four weeks. For all test groups the urinary lead excretion was highest at four weeks then decreased with continued exposure to lead (REACH).

If inhaled, the size of lead compound particles can dictate the site of deposition and rate of absorption (NICNAS, 2007).

Absorption via the dermal route has shown to be the least efficient (NICNAS, 2007). Less than 0.3 % of lead from lead acetate in cosmetics was absorbed dermally in human male volunteers over a 12 hour period. When lead nitrate was applied to the skin, 30 % of the dose was absorbed. It is not known if the absorption was systemic or confined to the layers of the skin.

The current lead compounds have low water solubility but are considered bioavailable (LDAI, 2008) as the small amount that can be absorbed from any route by dosing may be sufficient to lead to chronic effects.

Lead stored in bone can be released into the blood after exposure has ceased. Within bone, distribution is not uniform and lead accumulates in areas that are undergoing active calcification at the time of exposure (NICNAS, 2007). Inorganic lead is distributed in the body independently of the source compound and route of exposure. The spatial distribution of lead in bone is similar between children and adults, although adults generally have a higher concentration. When in the blood, 99 % of lead is bound to proteins within erythrocytes (NICNAS, 2007).

Mobilisation of lead from bone increases during pregnancy when maternal bone is catabolised to produce the foetal skeleton. It has been shown that up to 80 % of lead in human cord blood comes from maternal bone stores and can be transferred into the foetal skeleton during its formation.

The PbB level is a reflection of recent exposure and does not capture the more significant impact and slower elimination kinetics of the chemical in bone (ASTDR, 2007). The accumulation of lead in bone is considered a biomarker for long-term exposure over a lifetime. As a result, the affinity of lead for bone would

suggest that lead levels in bone, rather than lead levels in blood, provide more relevant predictive information for some health effects associated with long term exposure.

## Acute Toxicity

### Oral

The majority of the members of this group are not listed in HSIS, and therefore, by default, are covered by the generic 'lead and lead compounds' hazard classification with the risk phrase 'Harmful if swallowed' (Xn; R22) (Safe Work Australia). The one member of this group with individual classification, **lead phosphate (CAS No. 7446-27-7)**, is not classified for acute toxicity.

The available data do not support classification for acute toxicity for some of the lead mixed oxides in this group, as presented below.

Some lead pigments demonstrated low acute toxicity in animal tests following oral exposure. The rat oral median lethal doses (LD50s) for **dibasic lead phosphite (CAS No: 12141-20-7)**, and **tetrabasic lead sulfate (CAS No: 12065-90-6)** are reported to be > 2000 mg/kg bw for male and female rats (REACH). **Lead silicate (CAS No. 11120-22-2)**, **dibasic lead sulfate (CAS No. 12036-76-9)** and **tribasic lead sulfate (CAS No. 12202-17-4)** are reported to be > 5000 mg/kg bw for male and female rats (REACH). No clinical signs were reported. The high LD50 values are presumed to be due to the low solubility of these chemicals.

**Lead phosphate (CAS No: 7446-27-7)**, **lead sulfate (CAS No: 7446-14-2)**, **lead dibasic phosphite (CAS No: 1344-40-7)**, **lead stannate (CAS No: 12036-31-6)**, **lead titanate (CAS No: 12060-00-3)**, **dilead pyrophosphate (CAS No: 13453-66-2)**, **lead molybdate (CAS No: 10190-55-3)**, **lead silicate (CAS No: 11120-22-2)**, **lead sulfate (CAS No. 15739-80-7)** and **tetrabasic lead sulfate (CAS No. 52732-72-6)** are reported to have similar solubility to the other lead compounds in this group (Holleman AF, Wiberg E & Wiberg N, 2001; Windholz M et al, 1983), therefore, they are not expected to exhibit greater toxicity than these compounds via the oral route (i.e. is expected to have a similar oral LD50 of > 2000 mg/kg bw).

There is insufficient information available on the acute oral toxicity of the following lead compounds. In the absence of suitable data, the hazard classification with the risk phrase 'Harmful if swallowed' (Xn; R22) for generic 'lead and lead compounds' (Safe Work Australia) will apply to the following lead compounds.

Lead phosphite (CAS No. 13453-65-1)

Phosphonic acid, lead(2+) salt (2:1) (CAS No. 15521-60-5)

Lead phosphite (CAS No. 16038-76-9)



Lead phosphite (CAS No. 24824-71-3)

Lead borate (CAS No. 14720-53-7)

## Dermal

The chemicals in this group are not expected to be acutely toxic via dermal exposure. **Tribasic lead sulfate (CAS No. 12202-17-4)** and **dibasic lead phosphite (CAS No. 12141-20-7)** were reported to exhibit low acute toxicity in animal tests as evidenced by reported LD50 values in rats of >2000 mg/kg bw (LDAI, 2008).

## Inhalation

The majority of the members of this group are not individually listed in HSIS and therefore, by default, are covered by the generic 'lead and lead compounds' hazard classification with the risk phrase 'Harmful by inhalation' (Xn; R20) in HSIS (Safe Work Australia). The one member of this group with individual classification, **lead phosphate (CAS No. 7446-27-7)**, is not classified for acute toxicity. The available data do not support classification for acute toxicity for the lead mixed oxides in this group, as presented below.

Lead oxide is reported to be of low toxicity via inhalation; the rat median lethal concentration (LC50) was reported to be >5 mg/L (REACH). The pulmonary deposition patterns and water solubility of several chemicals in this group (**dibasic lead sulfate (12036-76-9)**, **tribasic lead sulfate (12202-17-4)**, **tetrabasic lead sulfate (12065-90-6)** and **dibasic lead phosphite (12141-20-7)**) are reported to be similar to lead oxide (LDAI, 2008). Therefore, these lead compounds are unlikely to cause acutely toxic effects via inhalation.

There is insufficient information available on the acute inhalation toxicity of the following lead compounds. In the absence of suitable data, the hazard classification with the risk phrase 'Harmful by inhalation' (Xn; R20) for generic 'lead and lead compounds' (Safe Work Australia) will apply to these lead compounds.

Lead sulfate (CAS No: 7446-14-2)

Lead sulfate (CAS No. 15739-80-7)

Lead sulfate, basic (CAS No 12036-76-9)

Lead silicate (CAS No 10099-76-0)

Lead silicate (CAS No. 11120-22-2)

Lead molybdate (CAS No: 10190-55-3)

Lead stannate (CAS No: 12036-31-6)

Lead titanate (CAS No: 12060-00-3)

Dilead pyrophosphate (CAS No: 13453-66-2)

Lead borate (CAS No. 14720-53-7)

Phosphonic acid, lead(2+) salt (2:1) (CAS No. 15521-60-5)

Lead phosphite (CAS No. 13453-65-1)

Lead phosphite (CAS No. 16038-76-9)

Lead phosphite (CAS No. 24824-71-3)

## Observation in humans

In this section, route specific data are not provided but exposure is reported in terms of absorbed dose. The concentration of lead in the blood is the most commonly reported value. However, lead in bone, hair and teeth are also reported in the literature.

### *Adult Exposure*

The majority of the data have been collected from accidental or intentional exposure via ingestion or inhalation, and there are rich data regarding the dose-effect in humans (NICNAS, 2007; ATSDR, 2007). Exposure can cause encephalopathy (the signs of which include: hyperirritability, ataxia, convulsions, stupor and coma) in

addition to gastrointestinal effects such as colic (displayed as: abdominal pain, constipation, cramps, nausea, vomiting, anorexia and weight loss) (ATSDR, 2007; WHO, 1995). It was recorded that signs of acute toxicity were observed in adults with a PbB level ranging from 50 - 300 µg/dL. However, that is challenged in a more

recent study that only noted signs of encephalopathy in adults with PbB levels greater than 460 µg/dL (NICNAS, 2007; ATSDR, 2007).

Colic is indicative of gastrointestinal impact and is typically displayed as an early effect of exposure to lead (NICNAS, 2007; ATSDR, 2007). Colic has been noted in individuals exposed to high levels of lead and can be evident as a result of occupational exposure where workers generally register PbB levels between 100 – 200 µg/dL. However, symptoms have been reported by workers with PbB levels between 40 – 60 µg/dL.

Exposure to lead has been reported to cause proximal renal tubular damage (NICNAS, 2007).

### *Paediatric Exposure*

Data were compiled from a paediatric population regarding the dose-response after acute exposure to lead. Signs of encephalopathy were noted in children with PbB levels between 90 – 800 µg/dL. The mean value reported for PbB levels related to death (327 µg/dL) is similar to that noted for encephalopathy (330 µg/dL). Gastrointestinal effects (abdominal pain, constipation, cramps, nausea, vomiting, anorexia and weight loss) were reported at PbB levels between 60 – 450 µg/dL. Data collected from additional reports indicate that acute encephalopathy was noted in children with PbB levels of 80 – 100 µg/dL and infants at PbB levels of 74.5 µg/dL (NICNAS, 2007).

In paediatric populations, acute colic has also been reported as an effect of poisoning associated with exposure to lead and is noted to occur when the PbB level is greater than or equal to 60 µg/dL (NICNAS, 2007; ATSDR, 2007). In addition, it has been reported that exposure to lead can inhibit the formation of the haem-containing

protein cytochrome P450 (NICNAS, 2007).

## **Corrosion / Irritation**

### **Skin Irritation**

In general, lead compounds are not considered irritating to the skin (REACH). No effects were reported in skin irritation assays in rabbits citing OECD Test Guideline (TG) 404 using **dibasic lead phosphite (CAS No. 12141-20-7)**.

### **Eye Irritation**

In general lead compounds were not reported to be irritating to eyes or having caused serious eye damage (REACH). In an eye irritation assay (OECD TG 405) in rabbits (New Zealand White) using **dibasic lead phosphite (CAS No. 12141-20-7)**, all symptoms reported were fully reversible within seven days.

### **Observation in humans**

No studies were located that recorded skin or eye irritation in humans as a result of exposure to lead compounds.

## Sensitisation

### Skin Sensitisation

Several lead compounds were reported to be non-sensitisers (REACH). It was reported that the compounds gave negative results for skin sensitisation in guinea pigs when tested according to OECD TG 406 using **dibasic lead phosphite (CAS No. 12141-20-7)**.

### Observation in humans

Although altered immune parameters were described in occupational and paediatric groups that were exposed to lead, there were no reports of skin or respiratory sensitisation to lead in humans (ATSDR, 2007).

## Repeated Dose Toxicity

### Oral

**Lead phosphate (CAS No. 7446-27-7)** is listed in HSIS with the hazard classification and risk phrases 'Danger or cumulative effects' (Xn; R33) and 'Harmful: Danger of serious damage to health by prolonged exposure if swallowed' (Xn; R48/22). The remaining lead compounds in this group are not individually listed in HSIS, and therefore, by default, are covered by the generic 'lead and lead compounds' hazard classification with the risk phrase 'Danger of cumulative effects' (Xn; R33) in HSIS (Safe Work Australia). While no data are available for the chemicals in this group, data available from animals studies on other lead compounds, and observations in humans, support these classifications and are presented in the following sections.

A lowest observed adverse effect level (LOAEL) of 200 ppm (corresponding to PbB levels of 40–60 µg/dL) was derived for lead acetate from a repeated dose toxicity study in Sprague Dawley (SD) rats following the guidelines set out in a US EPA chronic feeding study (REACH). Lead acetate was administered in drinking water (which was freely accessible [*ad libitum*]) to males rats (18 animals/dose group) at 0, 200, 500 or 1000 ppm per day for four, eight or 12 weeks. Decreased body weight and increased kidney weight as a percentage of body weight were reported at all dose ranges following four weeks exposure.

### Dermal

While no data are available for the lead compounds in this group, no significant adverse effects were reported following repeated dermal exposure to several other lead compounds (REACH).

In a report available on repeat dose toxicity during dermal exposure, rats were exposed to lead acetate, lead oleate, lead arsenate or tetraethyl lead for 24 hours. The test groups had lead compounds applied either directly to the skin or to skin that had been mechanically injured. Dermal absorption of lead was shown to occur in both test groups. However, comparatively greater absorption of lead was reported in the groups where the skin had been mechanically injured.

### Inhalation

While no data are available for the chemicals in this group, no significant adverse effects were reported following repeated inhalation exposure to lead nitrate (REACH).

Aerosolised lead nitrate was administered to mice (Swiss Webster) via inhalation at 2.5 mg/m<sup>3</sup> per day for 14 or 28 days. It was determined, considering total retention of the inhaled lead, that each mouse received a dose of 80 µg/day of lead.

A statistically significant reduction in the relative size of the spleen and thymus in both test groups was reported when compared with the control group. Increased lung weight was noted in both test groups and an increase in lead concentration was reported

in the liver, lung and kidney; although the 28 day group was noted to show a greater concentration. There were no apparent differences in body weight and food consumption noted for either test group.

## Observation in humans

Lead has multiple modes of action in biological systems; as a result, any system or organ in the body can potentially be affected by lead exposure. For the purposes of this report, the effects of lead toxicity on the most sensitive target organs have been identified and summarised (NICNAS, 2007; ASTDR, 2007).

### *Neurological Effects*

Lead encephalopathy is considered the most severe neurological effect of lead exposure in adults. Occupational lead exposure has also been linked to neurotoxicity and studies have shown that the following signs and symptoms have been noted in those recorded to have PbB levels of between 40 – 120 µg/dL: malaise, forgetfulness, irritability, lethargy, headache, fatigue, impotence, decreased libido, dizziness, weakness, paraesthesia, visual motor coordination impairment, cognitive performance impairment, decreased reaction time, mood and coping ability as well as affecting memory.

### *Haematological Effects*

Lead exposure impacts the haematological system by inhibiting haem synthesis and decreasing the lifespan of erythrocytes, which results in the onset of microcytic and hypochromic anaemia (NICNAS, 2007). It has been estimated that the PbB threshold for a decrease in haemoglobin to be seen in occupationally exposed adults is 50 µg/dL. For children the threshold is estimated to be PbB 40 µg/dL.

### *Cardiovascular Effects*

Studies investigating the effect of PbB on blood pressure in humans are not conclusive (NICNAS, 2007; ASTDR, 2007). The cardiovascular endpoint of concern for humans when exposed to low levels of lead is an increase in systemic blood pressure. Longitudinal occupational studies investigating the possible relationship

between low level lead exposure and blood pressure have been undertaken, with mixed results. Subsequently, based on the available literature, it is suggested that a relationship between low level exposure to lead and increased systemic blood pressure cannot be determined (NICNAS, 2007).

### *Renal Effects*

Nephrotoxicity associated with lead is characterised by proximal tubular nephropathy, glomerular sclerosis and interstitial fibrosis. The deterioration in renal function is characterised by enzymuria, proteinuria and an impaired ability to transport organic anions and glucose, in addition to a decreased glomerular filtration rate. Studies summarised in ATSDR (2007) indicate that an increase in nephrotoxicity is proportional to an increase in PbB levels. Effects on glomerular filtration are reported at or below 20 µg/dL, enzymuria and proteinuria are reported at equal to or greater than 30 µg/dL and severe deficits in function and pathological changes are reported in association with PbB levels  $\geq$  50 µg/dL.

## Genotoxicity

In general, lead compounds are considered genotoxic to mammalian cells.

The genotoxic effects of lead were reviewed and presented by the ATSDR (2007). The majority of the in vitro point mutation tests in bacteria were negative, while mammalian clastogenicity tests were generally positive.

It was reported that in bacterial reverse mutation assays, lead was negative both with and without metabolic activation (REACH). However, in vitro chromosomal aberration tests using Chinese hamster ovary (CHO) cells and human lymphocytes were positive without metabolic activation. An in vivo micronucleus assay using human peripheral lymphocytes (from those working with lead compounds) was positive below the maximum tolerated dose.

## Carcinogenicity

A review conducted by the International Agency for Research on Cancer (IARC) in 1980, which was updated in 1987 and again in 2006, indicated that there was sufficient evidence in experimental animals for the carcinogenicity of inorganic lead compounds, that there is limited evidence in humans for the carcinogenicity of inorganic lead compounds and that there is inadequate evidence in experimental animals for the carcinogenicity of lead oxide (IARC 1980; IARC, 1987; IARC 2006). The review resulted in the IARC classification of inorganic lead compounds as 'Probably carcinogenic to humans' (Group 2A).

A subsequent review by the International Lead Association (LDAI, 2008) concluded that lead oxide exhibits high bioavailability as evidenced by animal feeding studies and when tested in vitro via gastric simulation systems. There is consistent evidence from studies in rodents that soluble lead compounds or those that are considered bioavailable are carcinogenic in animals; notably, reproducible renal tumours in male rats following administration of high levels of lead via food or water.

This evidence is sufficient to classify the chemicals in this group as potential carcinogens.

## Reproductive and Developmental Toxicity

**Lead phosphate (CAS No. 7446-27-7)** is listed in HSIS with the hazard classification and risk phrases 'Possible risk of impaired fertility' (R62) and 'May cause harm to the unborn child' (R61). The remaining lead compounds in this group are not listed in HSIS, and therefore, by default, are covered by the generic 'lead and lead compounds' hazard classification with the risk phrases 'Possible risk of impaired fertility' (R62) and 'May cause harm to the unborn child' (R61) in HSIS (Safe Work Australia). While no data are available for the lead compounds in this group, the available data on other lead compounds support these classifications.

In a reproductive and developmental toxicity screening test in SD rats, lead acetate was administered via drinking water to nine females at 0.6 % weight per volume (w/v) (equivalent to 502 mg/kg bw/day) at gestation days 5–21 (Ronis et al, 1996; LDAI, 2008). A stillbirth rate of 19 % was recorded in the test group compared with a 2 % rate noted in the control group. The dams and offspring had PbB levels >200 µg/dL.

In a subsequent reproductive and developmental toxicity screening test in SD rats, lead acetate was administered via drinking water to 10 females at 0.05 % w/v, eight females at 0.15 % w/v and nine females at 0.45% w/v, during gestation days 5–21 (Ronis et al, 1998). Stillbirth rates of 3(±3), 10(±6) and 28(±8) % were recorded for increasing dose groups respectively. This was compared with a 4(±3) % rate noted in the control group. At birth, the male pups had PbB levels of 40(±1), 83(±8) and 120(±120) µg/dL for increasing dose groups respectively, while the female pups had PbB levels of 42(±7), 67(±16) and 197(±82) µg/dL. A developmental LOAEL of 0.05 % (equivalent to 42 mg/kg bw/day) was reported for this study (LDAI, 2008).

With respect to lead borate (CAS No. 14720-53-7), reproductive and developmental end points were the most sensitive effects in animals following exposure to boron (boric acid). Boric acid (CAS No: 10043-35-3) is classified as a hazardous, Category 2 substance toxic to reproduction, with the risk phrases 'May impair fertility' (T; R60) and 'May cause harm to the unborn child' (T; R61) in HSIS (Safe Work Australia) (NICNAS). However, due to the low boron content of the chemical, the reproductive effects of the chemical due to its borate content are likely to occur only at doses where lead toxicity is extreme.

### **Reproductive toxicity observations in humans**

Recent studies have investigated the effect of lead exposure in occupational groups and general populations living near industrial plants. Although the evidence reported is predominantly qualitative and dose-effect relationships have largely not been established (NICNAS, 2007; WHO, 1995), it has been suggested that moderately high PbB levels in humans could result in spontaneous abortion, pre-term delivery, alterations in sperm and decreased male fertility (ASTDR, 2007).

### **Developmental toxicity observations in humans**

Data pertaining to low level exposure to lead contributing to developmental toxicity in infants and young children were recently reviewed. Consensus exists between the reports, which suggest that PbB levels in humans >10 µg/dL can affect paediatric intellectual development (ASTDR, 2007; Donovan, J, 1996).

In addition, data regarding the effects on children of higher levels of lead exposure were reviewed. Although neurobehavioural deficits were reported in children with PbB levels <10 µg/dL, there is uncertainty attached to these estimates of reported effects (ASTDR, 2007). Even so, the US Centers for Disease Control and Prevention (CDC) has a reference level of 5 µg/dL, above which it is recommended that public health action be initiated (CDC).

## Risk Characterisation

### Critical Health Effects

The acute toxicity of the chemicals in this group is limited by their low water solubility. However, they are considered bioavailable with respect to long term effects. The critical health effects for risk characterisation include systemic long-term effects (carcinogenicity, mutagenicity, reproductive toxicity and developmental toxicity). The lead compounds may also cause harmful effects following repeated exposure and harmful systemic effects following a single exposure via oral and inhalation routes.

### Public Risk Characterisation

The restrictions on the use of lead and lead compounds in products available to the public in Australia are listed in the Poisons Standard (SUSMP, 2012). These restrictions will prevent risks from domestic use of these compounds.

Historical use of lead compounds in surface coatings suggests that the potential for the public to be exposed, through flaking paint and during home renovation, still exists. While it is possible that the public will be exposed to lead or lead compounds, the risk can be managed by following appropriate guidelines.

### Occupational Risk Characterisation

Given the critical health effects, the risk to workers from these chemicals is considered high if adequate control measures to minimise occupational exposure to the chemical are not implemented. The chemicals should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU) at a workplace (such as an employer) has adequate information to determine appropriate controls.

### NICNAS Recommendation

Current risk management measures are considered adequate for the protection of public and workers' health and safety, provided that all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory. No further assessment is required.

### Regulatory Control

#### Public Health

Current restrictions control the use of lead and lead compounds in cosmetics, paint, tinters, inks or ink additives, which effectively reduces the risk of public exposure.

The availability and permissible lead content in products, such as paint, are regulated in terms of availability and concentration (SUSMP, 2012). Products that historically contained lead or lead compounds still pose an exposure risk to the public due to their existence in the public domain.

The National Health and Medical Research Council (NHMRC) of Australia has published recommendations regarding how the public can manage exposure to lead by mitigating the risk (NHMRC, 2009). Methods for the safe approach to painting a house (when there is a likelihood of lead paint having been used previously) have

been published by the Department of Sustainability, Environment, Water, Population and Communities.

## Work Health and Safety

The health risk to workers from these chemicals is controlled when correct classification and labelling are considered, and adequate control measures to minimise occupational exposure and protective clothing are implemented. Safe Work Australia (SWA) encourages working safely with lead and promotes the *National*

*Code of Practice for the Control and Safe Use of Inorganic Lead at Work [NOHSC: 2015 (1994)]* and the *National Standard for the Control of Inorganic Lead at Work [NOHSC:1012 (1994)]*. These Codes of Practice, in addition to the *Model Work Health and Safety Regulations, 2011* are available from the SWA website.

The chemicals in this group are recommended for classification and labelling under the current Approved Criteria and adopted Globally Harmonized System of Classification (GHS) and Labelling of Chemicals as below. This does not consider classification of physical hazards and environmental hazards.

Classification for acute oral toxicity (Xn; R22) applies only to the following chemicals:

Phosphonic acid, lead(2+) salt (1:1) (CAS No. 13453-65-1)

Phosphonic acid, lead(2+) salt (2:1) (CAS No. 15521-60-5)

Phosphonic acid, lead salt (CAS No. 16038-76-9)

Phosphonic acid, lead(2+) salt (CAS No. 24824-71-3)

Boric acid (HBO<sub>2</sub>), lead(2+) salt (CAS No. 14720-53-7)

Classification for acute inhalation toxicity (Xn; R20) applies only to the following chemicals:

Phosphonic acid, lead(2+) salt (1:1) (CAS No. 13453-65-1)

Phosphonic acid, lead(2+) salt (2:1) (CAS No. 15521-60-5)

Phosphonic acid, lead salt (CAS No. 16038-76-9)

Phosphonic acid, lead(2+) salt (CAS No. 24824-71-3)

Boric acid (HBO<sub>2</sub>), lead(2+) salt (CAS No. 14720-53-7)

Sulfuric acid, lead(2+) salt (1:1) (CAS No: 7446-14-2)

Sulfuric acid, lead salt (CAS No. 15739-80-7)

Lead oxide sulfate (Pb<sub>2</sub>O(SO<sub>4</sub>)) (CAS No 12036-76-9)

Silicic acid (H<sub>2</sub>SiO<sub>3</sub>), lead(2+) salt (1:1) (CAS No 10099-76-0)

Silicic acid, lead salt (CAS No. 11120-22-2)

Molybdic acid (H<sub>2</sub>MoO<sub>4</sub>), lead(2+) salt (1:1) (CAS No: 10190-55-3)

Lead tin oxide (PbSnO<sub>3</sub>) (CAS No: 12036-31-6)

Lead titanium oxide (PbTiO<sub>3</sub>) (CAS No: 12060-00-3)

Diphosphoric acid, lead(2+) salt (1:2) (CAS No: 13453-66-2)

Classification for repeat dose toxicity (Xn; R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed) applies only to lead phosphate (CAS No 7446-27-7) (see Existing Work Health and Safety Controls).

Classifications for repeat dose toxicity, genotoxicity, carcinogenicity, and reproductive and developmental toxicity apply to all chemicals in this group assessment.

If empirical data become available for any member of the group indicating that a lower (or higher) classification is appropriate for the specific chemical, this may be used to amend the default classification for the chemical.

Hazard	Approved Criteria (HSIS) <sup>a</sup>	GHS Classification (HCIS) <sup>b</sup>
Acute Toxicity	Harmful if swallowed (Xn; R22)* Harmful by inhalation (Xn; R20)*	Harmful if swallowed - Cat. 4 (H302)* Harmful if inhaled - Cat. 4 (H332)*
Repeat Dose Toxicity	Danger of cumulative effects (R33)* Harmful: danger of serious damage to health by prolonged exposure if swallowed (Xn; R48/22)*	May cause damage to organs through prolonged or repeated exposure - Cat. 2 (H373)*
Genotoxicity	Muta. Cat 3 - Possible risk of irreversible effects (Xn; R68)	Suspected of causing genetic defects - Cat. 2 (H341)
Carcinogenicity	Carc. Cat 3 - Limited evidence of a carcinogenic effect (Xn; R40)	Suspected of causing cancer - Cat. 2 (H351)
Reproductive and Developmental Toxicity	Repro. Cat 1 - May cause harm to the unborn child (T; R61)* Repro. Cat 3 - Possible risk of impaired fertility (Xn; R62)*	May damage the unborn child. Suspected of damaging fertility - Cat. 1A (H360Df)*

<sup>a</sup> Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

<sup>b</sup> Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

\* Existing Hazard Classification. No change recommended to this classification

## Advice for consumers

Products containing the chemicals listed in this report should be used according to label instructions.

## Advice for industry

- Control measures to minimise the risk from exposure to the chemicals should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using hazardous chemicals depend on the physical form and the manner in which the chemicals are used. Examples of control measures which may minimise the risk include, but are not limited to:
  - using closed systems or isolating operations;
  - using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
  - health monitoring for any worker who is at risk of exposure to the chemical if valid techniques are available to monitor the effect on the worker's health;
  - air monitoring to ensure control measures in place are working effectively and continue to do so;
  - minimising manual processes and work tasks through automating processes;



- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing Risks of Hazardous Chemicals in the Workplace—Code of Practice* available on the Safe Work Australia website.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other

approved standards.

### ***Obligations under workplace health and safety legislation***

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of the chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of Safety Data Sheets for Hazardous Chemicals— Code of Practice* and *Labelling of Workplace Hazardous Chemicals—Code of Practice*, respectively. These codes of

practice are available from the Safe Work Australia website.

A review of the physical hazards of the chemical has not been undertaken as part of this assessment.

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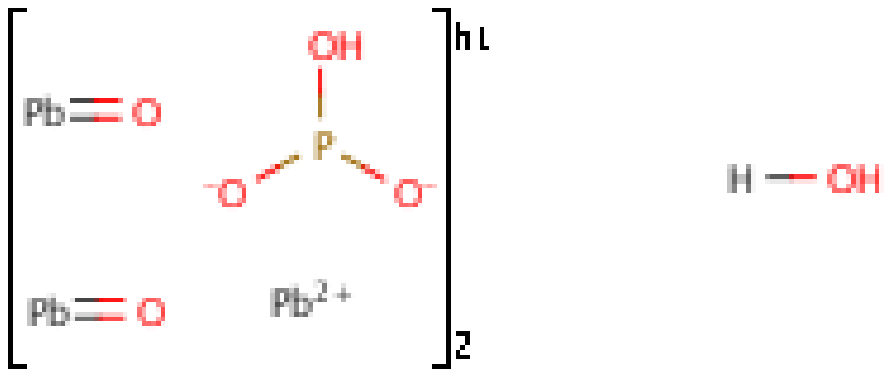
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Last Update 26 October 2018

## Chemical Identities

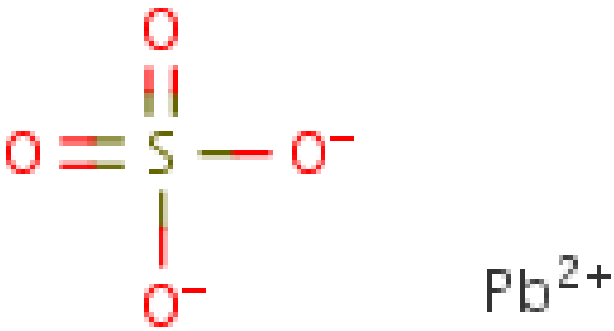
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CAS Number	1344-40-7
Structural Formula	
Molecular Formula	H <sub>2</sub> O.2HO <sub>5</sub> PPb <sub>3</sub>
Molecular Weight	1485.17

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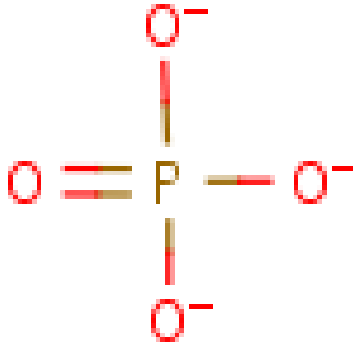
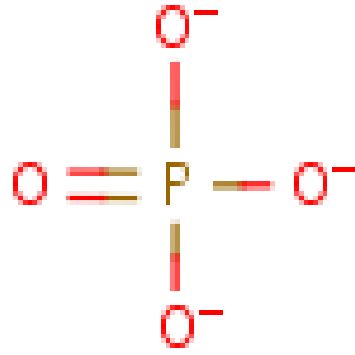
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Molecular Weight	733.58

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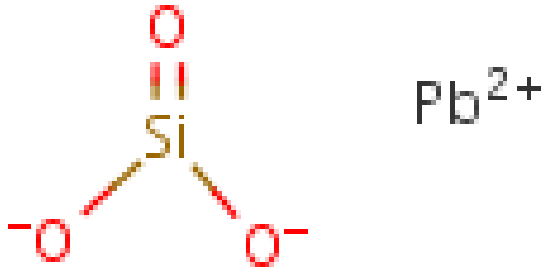
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CAS Number	7446-27-7
Structural Formula	



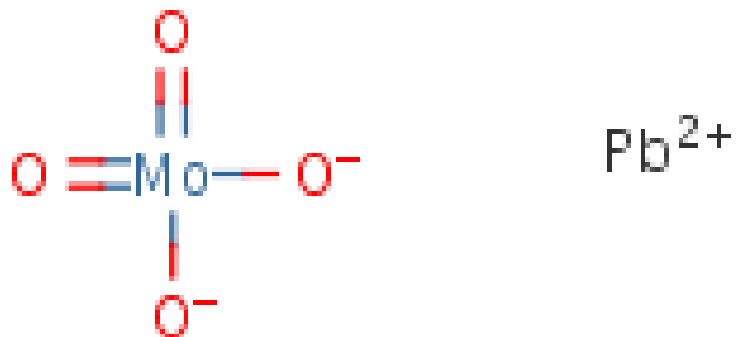
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Molecular Formula	H <sub>2</sub> O <sub>3</sub> Si.Pb
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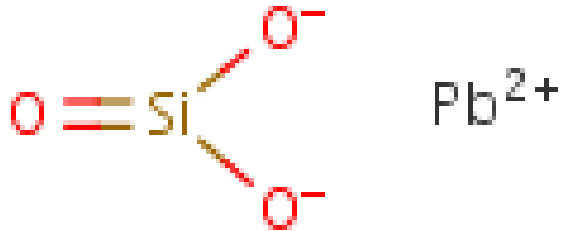
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Structural Formula	



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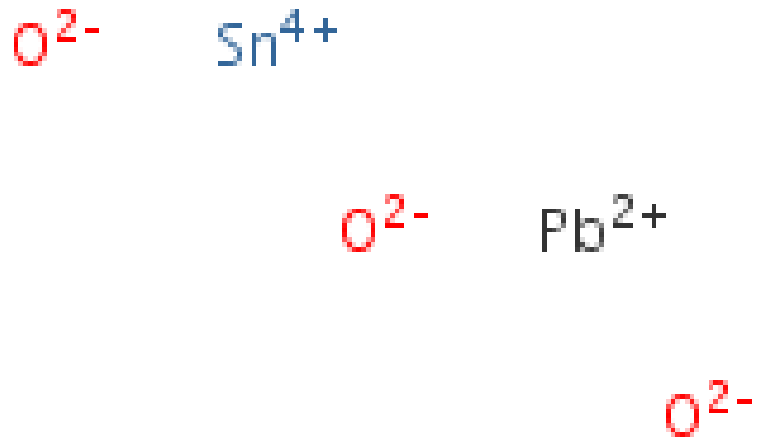
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Structural Formula	





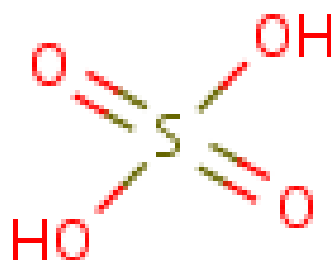
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CAS Number	12036-31-6
Structural Formula	



Molecular Formula	O.Pb.Sn
Molecular Weight	373-91

Chemical Name in the Inventory and Synonyms	<b>Lead oxide sulfate (Pb<sub>2</sub>O(SO<sub>4</sub>))</b> Lead sulphate, basic
CAS Number	12036-76-9
Structural Formula	



Molecular Formula	O4S.O.Pb
Molecular Weight	321.28

Chemical Name in the Inventory and Synonyms	<b>Lead titanium oxide (PbTiO3)</b> Lead titanate Titanic acid, lead salt Lead titanium trioxide Lead (II) titanate Metatitanic acid lead(II) salt
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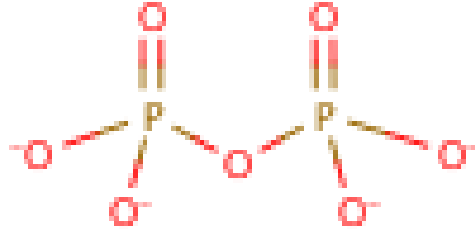
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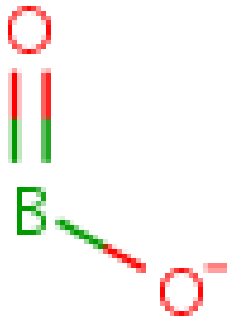
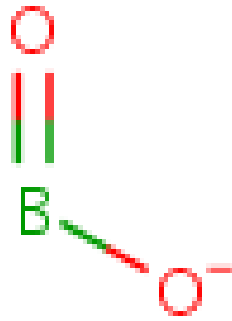
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Molecular Weight	

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Structural Formula	



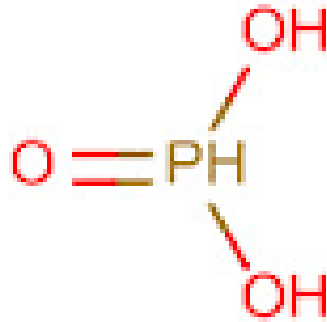
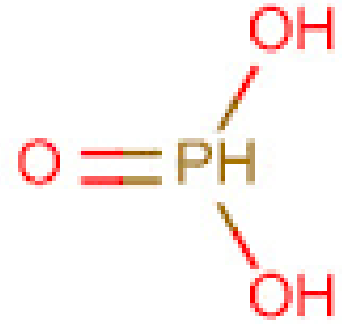
Molecular Formula	H4O7P2.2Pb
Molecular Weight	588.34

Chemical Name in the Inventory and Synonyms	<b>Boric acid (HBO<sub>2</sub>), lead(2+) salt</b> lead borate lead metaborate
CAS Number	14720-53-7
Structural Formula	



Molecular Formula	BHO2.1/2Pb
Molecular Weight	292.82

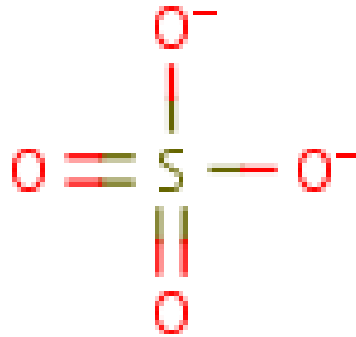
Chemical Name in the Inventory and Synonyms	<b>Phosphonic acid, lead(2+) salt (2:1)</b>
CAS Number	15521-60-5
Structural Formula	



Molecular Formula	H3O3P.1/2Pb
Molecular Weight	

Chemical Name in the Inventory and Synonyms	<b>Sulfuric acid, lead salt</b> Sulfuric acid, lead salt (1:?) Sulfuric acid, lead salt (1:?) Sulphuric acid, lead salt Lead sulfate
CAS Number	15739-80-7
Structural Formula	

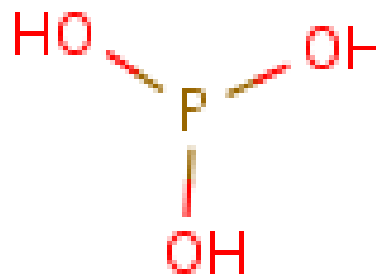




Molecular Formula	H <sub>2</sub> O <sub>4</sub> S.xPb
Molecular Weight	303.26

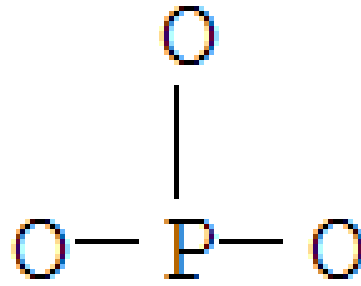
Chemical Name in the Inventory and Synonyms	<b>Phosphonic acid, lead salt</b> Lead phosphite Phosphonic acid, lead salt (1:?)
CAS Number	16038-76-9
Structural Formula	

Pb  
(v0)



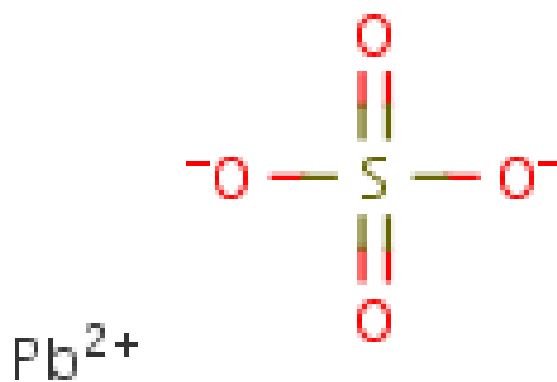
Molecular Formula	H3O3P.xPb
Molecular Weight	289.20

Chemical Name in the Inventory and Synonyms	<b>Phosphonic acid, lead(2+) salt</b> Lead phosphite
CAS Number	24824-71-3
Structural Formula	



Molecular Formula	H3O3P.xPb
Molecular Weight	733.58

Chemical Name in the Inventory and Synonyms	<b>Sulfuric acid, lead salt, tetrabasic</b> Lead sulfate, tetrabasic Sulfuric acid, lead salt, tetrabasic Tetrabasic lead sulfate
CAS Number	52732-72-6
Structural Formula	



Molecular Formula	Unspecified
Molecular Weight	303.26

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