

Cal/OSHA Draft Substance Summary for the December 12, 2017 HEAC Meeting

Substance name: Aluminum Metal & Insoluble Compounds

Aluminum metal and insoluble compounds are found in multiple forms and properties. Welding fume consist mostly of aluminum oxide.

USES / APPLICATIONS / OCCURRENCE / EXPOSURE

Aluminum is the third most abundant element on the planet, comprising 8.3% of the earth's crust. In nature it occurs primarily as complex silicates. Aluminum is amphoteric, forming both aluminum salts and aluminates.

Aluminum metal has thousands of uses where its light weight, and low density, is the key attraction. Aluminum metal also finds applications where corrosion resistance is a key attribute. Pure aluminum is highly malleable and ductile allowing it to be drawn into wire, rolled into sheets and films of almost any thickness and deposited onto almost any surface. Pure aluminum is a good conductor of electricity and heat. Aluminum is alloyed with many different elements giving it a wide range of properties in terms of strength, density, melting temperature and corrosion resistance. Exposures occur during mining the ore, production of aluminum by electrolytic reduction of the oxide, cold cutting, sawing, grinding; polishing the metal, welding and flame cutting. Aerosol particle size, shape, and composition is dependent on the base metal and process. **Aluminum oxide** in bulk form can be gem-quality crystal. Most aluminum oxide is used in particle form in abrasives, ceramics, catalysts, cosmetics. Exposures can occur in the handling of the material and in the use of the product.

Insoluble aluminum compounds, including oxides, hydroxides, silicates, and chlorhydroxides, are used in personal hygiene products, cosmetics, pharmaceuticals and food additives. Aluminum compounds make up the active ingredient in deodorants, antiperspirants, antacids, analgesics, and disinfectants. Aluminum compounds are used as flocculating and coagulating agents in water purification and chemical synthesis

Occupational Exposure Limits

Title 8 PEL (1989):

Alumina; see Particulates not otherwise regulated		
Aluminum, alkyls (not otherwise classified)	--	2 mg/m³ TWA
Aluminum soluble salts	--	2 mg/m³ TWA
Aluminum metal and oxide	--	
Total dust	--	10 mg/m³ TWA
Respirable fraction⁽ⁿ⁾	--	5⁽ⁿ⁾ mg/m³ TWA
Aluminum pyro powders	--	5 mg/m³ TWA
Aluminum welding fumes	--	5 mg/m³ TWA

NIOSH REL: 5 mg/m³ TWA
DFG (Germany): 4 mg/m³ TWA inhalable / 1.5 mg/m³ TWA respirable fraction
Sweden: 4 mg/m³ TWA respirable fraction / 10 mg/m³ TWA total
UK: 4 mg/m³ TWA respirable fraction / 10 mg/m³ TWA inhalable

Other recommendations

Source and date	Recommendations	Basis/source/ref(s)	Discussion and Assessment
OEHHA REL	Not listed		
Prop 65	Not listed		
NTP	No evidence		
EPA	Not assessed		
IARC	Not classified		
EU	Not Established		

Peer-reviewed journal articles used for proposed PEL

Piggot 1981

Study type/Endpoint: 90-week rat inhalation study; respiratory effects, fibrosis, cancer

Method: Animals exposed to 2.5 mg/m³ of aluminum fiber (median diameter – 3.0 microns) in inhalation chamber for 86 weeks. Study terminated at 128 weeks with interim sampling to evaluate

Results: Reaction was generally confined to the presence of groups of pigmented alveolar macrophages. Minimal aveolar epithelialization was observed but not evident after 106 weeks. No evidence of fibrosis. In a few cases fibers observed in the nasal passage were associated with slight irritation of nasal mucosa with minimal focal necrosis.

Discussion/ assessment: This single-dose study with aluminum fibers observed very little respiratory effects. The LOAEL was set at 2.5 mg/m³. The particle size was very homogeneous and considerably larger (3 microns) than welding particle fumes (< 1 µm).

Sjogren, 1985

Study Type: cross-sectional

Methods: Three welder groups (aluminum, stainless steel and railroad track) and controls were evaluated for respiratory symptoms and pulmonary effects. Median exposure to welding time for Al welders was 5 years (range: 1-24). Controls were non-welding workers. Welders and controls were matched for smoking. Symptoms were assessed by questionnaire and effects by forced vital capacity and forced expiratory volume. Total particulate welding fumes were measured gravimetrically and ranged from 0.5 to 4.5 mg/m³ (tungsten inert gas welding) and 7 – 42 mg/m³ (metal inert gas welding).

Results: Al welders reported greater frequency of bronchitis and respiratory symptoms but not significantly different from controls. Within welders, symptoms were significantly different between welders exposure to high and low levels of ozone (p =0.03). There were no significant differences in FVC and FEC between welders and controls.

Discussion/Assessment: What respiratory effects observed in the study were likely due to the particle load and ozone generated during welding,

Hänninen H 1994

Study: cross-sectional

Method: Seventeen male welders with a mean age of 37 (range 24 - 48) years and a history of four years of metal inert-gas welding on aluminum were evaluated by tests for simple reaction time, psychomotor speed, visual and spatial ability, memory tests, verbal ability, subjective mood and quantitative electroencephalography (QEEG). Urine and serum Al were determined. For 11 welders, urinary aluminum was the mean of four weekly urine samples taken during a summer vacation while for the other six subjects, the serum and urine samples were taken on the morning of the examination day. Control responses were compared to historic average values from other studies involving skilled and semiskilled chemically exposed workers and workers with slight neurotoxic exposure.

Results: The urinary-Al concentrations ranged from 0.9 to 6.1 $\mu\text{mol/L}$ (median 2.4, mean 2.8). All neurological test results fell within the average or good range of the historic values. However, correlations between the test scores and exposure parameters showed a negative association between the four memory tests and exposure to aluminum and a positive association between the variability (standard deviation) of visual reaction times and U-Al. The QEEG power parameters recorded from the frontal and frontotemporal regions of the brain correlated with the Al exposure parameters.

Discussion/Assessment: Though the numbers are small, the results in this study are consistent with other studies showing neurological decrements with urinary Al levels. Urinary Al levels were negatively correlated with age and the group was highly homogeneous so correlations between test results and urinary Al levels are convincing.

Sjogren, 1996

Study type: cross-sectional, retrospective

Methods: Comparison of symptom questionnaire response and psychological/psychomotor testing of Al-welders with self-declared non-Al welders.

Results: Al exposed workers (38, mean age = 39, mean years welding = 17.1) had urinary Al levels of 0.21 $\mu\text{mol/L}$ (0.04 - 2.5) whereas controls had levels of 0.03 $\mu\text{mol/L}$ (ND - 0.26) to controls (39, mean age = 41, mean years welding = 13.8). Information on exposure time was obtained from a questionnaire. The exposure to particles in the breathing zone of the welders was surveyed in the mid-1970s. The median exposure was 10 mg/m^3 during Al metal inert gas (MIG) welding. Al workers differed from controls in 2 of 28 questionnaire responses, 4 of 20 psychological tests and 1 EEG measure. When controls and welder groups were combined and categorized into percentiles by Al urinary levels (50th : < 0.08 $\mu\text{mol/L}$; 50th-75th: 0.08 - 0.23 $\mu\text{mol/L}$; 75th: > 0.23 $\mu\text{mol/L}$ ug/l, 75th median = 0.59 $\mu\text{mol/L}$) three response/test comparisons had a significant dose-response effect. With this grouping, the 75th percentile was significantly different from the other two groups in its response.

Discussion/Assessment: the study has limitations due to the retrospective exposure assessment and confounders (other metals in urine) but the significant dose-response relationship between urinary levels and symptoms/effects supports the role of Al as a cause in Al-exposed workers. All Al welders in this study had at least 5 years welding and the mean was 17. The study appears to have been done on the past welding experience of the workers so Al levels likely represent the accumulated body burden from past exposure.

Akila, 1999

Study type: cross-sectional

Method: A comprehensive neuropsychological examination was undertaken to assess psychomotor function, simple visual reaction time, attention related tasks, verbal and visual or visuospatial abilities as well as verbal and visual learning and memory of asymptomatic aluminum welders and a reference group of mild steel welders.

Workers (mean age = 38.4) from 12 sites were classified into three groups based on urinary aluminum

concentrations: reference (<1.0 µmol/L), low exposure (1.1–4.0 µmol/L) and high exposure (>4.1 µmol/L). The reference value for urinary aluminum in occupationally non-exposed populations was 0.6 µmol/L. Mean welding years were not reported but workers with up to 25 years welding were included.

Results: Performance on 16 cognitive tests compared between groups. Of the 16 tests conducted, 4 showed significant ($p<0.05$) exposure-response relations and group effects (high dose group).

Discussion/Assessment: The study implemented a more extensive array of cognitive tests to assess specific cognitive domains and claims results are consistent with expected neurological deficits. The study concluded that based on the tasks showing impairments, the involvement of time-limited processing in visuospatial tasks requiring working memory demands is impacted by Al.

Riihimaki, 2000

Study Type: Cross-sectional

Method: Nation-wide survey identified 10 companies that had been conducting Al welding for many years. 90 participants from 9 workplaces were administered symptom surveys (Profile of Mood States), neuropsychological tests (psychomotor, reaction time, attention, verbal/visual abilities and memory/learning) and quantitative electroencephalography (QEEG). Exposure was assessed by questionnaire and measurement of urinary Al. Controls were non-Al welding workers from within the same companies. Three exposure groups were established based on urinary Al levels: controls (range: 0.1-1.2 µmol/L) low exposure (0.3 – 5.7 µmol/L, 1-16 years welding) and high exposure (3.2 – 27.6 µmol/L, 4 – 23 years welding).

Results: In the population of aluminum MIG welders, the U-Al ranged from 0.3 to 27.6 µmol/L. Among the current mild-steel welders, the corresponding ranges were 0.04-0.19 µmol/L and 0.1-1.6 µmol/L, respectively. For 1/3 of the aluminum welders, the exposure had continued over 10 years with a maximum of 23 years. Grouping symptom responses into 4 categories: fatigue, memory/concentration differences, emotional lability and sensory/motor symptoms, significant differences ($p < 0.05$) between controls and the high exposure group were seen for the first 3 categories. The biggest difference was found in memory and concentration difficulties, and a more moderate difference was found for fatigue and emotional lability. For sleeping disturbances and sensory and motor symptoms the difference was not significant. Significant impairments of neuropsychological function between controls and the high exposed group were found in 5 of the 6 tests ($p<0.05$ for all). 12 of 21 age-adjusted correlations between urinary Al and the neuropsychological tests were significantly negatively correlated. For QEEG, diffuse EEG abnormalities were observed in 13 subjects. All of them had mild abnormalities. Five of them belonged to the low-exposure group, 8 belonged to the high-exposure group, and the exposure-related linear trend of change among the groups was significant.

Discussion/Assessment: The subjective symptom inquiry showed exposure-related increases in memory and concentration problems, fatigue, emotional disturbances indicative of mild depression, and certain sensory and motor symptoms. Overall, the complaints associated with Al exposure seemed to focus on certain core symptoms rather than being expressions of a more general distress. Association between the neuropsychological tests and Al exposure were less strong. In the visually interpreted EEG, diffuse nonspecific abnormalities were observed in the low- and high-exposure groups, whereas epileptiform abnormalities were present mainly in the high-exposure group. The threshold of aluminum body burden implying an adverse effect thus seemed to correspond to 4-6 µmol/L of Al in urine.

Bast-Pettersen, 2000

Study type: cross-sectional

Methods: Twenty aluminum welders (mean age 33), who had been exposed to Al for an average of 8.1 years (range 2-21), were tested for tremor and reaction time and screened for neuropsychiatric symptoms in a cross-sectional study. The welders' median urinary Al concentration was 1.5 µmol/L (range 0.7-4.8). Al in air, measured inside the respiratory protection, was 0.9 mg/m³ (range 0.6- 3.8). The welders were compared with twenty construction workers matched for age.

Results: Welders reported more symptoms than referents did (median 2 vs. 1; $P = 0.047$). Welders performed better on tremor test and psychomotor tests than controls. There was a statistically significant relation between longer reaction times and Al in air among welders. Also, hand steadiness in welders was inversely correlated with years welding.

Discussion/Assessment: Welders performed better on tests than controls (construction workers). This study indicates a slight exposure-related effect on the studied parameters, i.e., reaction time, steadiness of hand, and neuropsychiatric symptoms all declined with years welding. However, the results indicate that these welders were not clinically impaired in terms of steadiness of hand or reaction time compared to clinical values.

Buchta, 2003; Kiesswetter, 2009

Study type: longitudinal with matched controls – automobile welders

Method: Study of automobile welders over 4 years with assessments on 98 Al welders (Al welding years 8.8 ± 1.7) and 50 controls. Symptoms, neurobehavioral and psychomotor performance tests collected at 3 examination points (0, 2 and 4 years) were compared. Respirable dust samples and urine samples collected. Loss to enrollment over the 4-year study was 6%

Results: Median respirable dust exposure from the three sampling events were 0.8 ± 0.9 , 0.5 ± 0.3 , and 0.7 ± 0.3 mg/m^3 resulting in median urinary-Al concentrations of 0.52 ± 0.35 $\mu\text{mol}/\text{L}$, 0.48 ± 0.35 $\mu\text{mol}/\text{L}$, and 0.22 ± 0.27 $\mu\text{mol}/\text{L}$, respectively. No significant differences in the 15 psychomotor performance and other neurobehavioral tasks were seen between welders and non-welder, with the exception of simple reaction time. Reaction time increased in welders over the four year period but not in controls ($p = 0.015$). The interaction term for examination and exposure was not significant but for examination and age was significant ($P < 0.001$).

Discussion/Assessment: the exposure interval of this study is short – 4 years – and limits the study's ability to discriminate an effect of Al exposure. Regression analysis showed that urinary-Al was only a predictor of reaction time in models when all groups, not just the exposed workers, were included, suggesting Al exposure alone was not the sole cause of the effects.

Buchta, 2005; Kiesswetter, 2007

Study type: longitudinal with matched controls - truck/trailer welders.

Method: Study of automobile welders over 4 years with assessments on 44 Al welders (Al welding years 15) and 37 controls. Using same methods as Buchta, 2003, symptoms, neurobehavioral and psychomotor performance tests collected at examination points 2 years apart were compared to controls. Respirable dust samples and urine samples collected. Loss to enrollment over the 4-year study was 52%

Results: Median respirable dust exposure from the three sampling events were 5.6 mg/m^3 , 4.5 mg/m^3 and 6.8 mg/m^3 resulting in median urinary-Al concentrations of 1.34 $\mu\text{mol}/\text{L}$ and 1.61 $\mu\text{mol}/\text{L}$, and 0.95 $\mu\text{mol}/\text{L}$, respectively. Neurobehavioral symptoms declined in both groups and were not significantly different (Welders = 1.9; Controls = 1.6). No significant group differences were detected between welders and controls for psychomotor tests (steadiness, line tracing, tapping or aiming). Exposed and controls did not differ significantly for simple reaction time. The interaction between “examination and exposure” was nonsignificant ($p = 0.11$). In the cognitive tests, welders performed significantly less than controls for the Block design and forward digit span test.

Discussion/Assessment: This study was done in parallel with Buchta, 2003 with a group of truck/train welders with significantly higher Al exposure (5.6 mg/m^3 total dust). A few neurological effects were detected but not consistently as with the previous study. The authors acknowledge that the interval between examinations (2 years) and the drop in participation of the exposed welders (from 44 to 20) may not have been sufficient to detect differences of neurobehavioral trends between exposed and controls.

HEAC Health-based assessment and recommendation

Aluminum (Al) occurs in multiple physical and chemical forms with 100 unique substances with Al as a constituent listed in the Chemical Abstracts Services. Most toxicological data for Al has been obtained through oral or injection administration so it is problematic to assess inhalation effects for many Al compounds. In addition, with the development of nanotechnology, particle size has been identified as an important factor in Al toxicity but these studies are generally not designed for hazard and risk assessment. To date, no inhalation reference concentrations or risk levels for Al have been developed by USEPA, OEHHA or ATSDR.

Effects of Al on the brain are the most sensitive toxicological endpoint, however Al brain levels that are associated with neurological disease are not characterized. There are no good animal models for the cognitive and memory effects of Al seen in humans and the most informative data comes from epidemiological studies of Al urinary levels in aluminum welders and neurological deficits assessed through symptom questionnaires and cognitive testing. Al urinary levels are a function of Al air concentration and welding years but an absolute relationship between these factors and neurological effects is not known, though Al welding of >15 years seems implicated with significant neurological effects. The reviewed studies indicate that after at least 4 years of exposure at or below occupational exposure levels, marginal neurological deficits are observed in Al welders and are associated with exposure. In several of these studies, many of these deficits fall within or above the range seen in controls or populations average however given a significant dose-response has been established in several of these studies it can be concluded that Al contributed to the neurological deficits seen in the welders.

Using studies in which Al air concentration and Al welding years were recorded brackets exposure conditions from 0.5 – 5.6 mg/m³ for Al air concentrations and 4.0 – 17 years for welding years. Several of the studies overlap in this range of exposure conditions so their findings can be compared. The welders in Bast-Pettersen 2000 and Buchta 2003 experienced roughly the same exposure level (1 mg/m³) with less than 10 years welding years (8 and 8.8). Urinary Al levels are similar and both studies found an increase in simple reaction time. In the studies with longer exposure intervals (mean >15 years; Akila, 1999; Sjogren, 1996, possibly Riihimaki, 2000) there is stronger evidence for an association between Al exposure in that dose-response relationships between urinary Al levels and neurological deficit are significant. Unfortunately these longer-term studies did not measure Al air levels so it cannot be determined what level of Al exposure produced the urinary Al levels. The longitudinal studies of Al welders by Buchta 2003 and Buchta 2005 provide well-characterized exposure estimates for welders with moderate to high years welding (8 and 15) yet could only detect inconsistent neurological deficits in the welders. Unfortunately Buchta 2005 experienced a high drop in welder participation that makes the findings of that study problematic. Buchta 2003 experienced virtually no drop in participation and with multiple measures detected a significant drop in simple reaction time in welders with multiple measures over 6 years.

Given that Al accumulates in the body from chronic workplace exposure, years welding is a prime determinant of risk of acquiring neurological effects of aluminum. Using findings of the studies cited above a matrix can be prepared of years welding, urinary Al levels and total dust concentrations (for a subset of studies. All studies established some level of neurological deficit at a result of Al exposure which is to be expected as these effects are on a continuum of neurological decline that would occur in a time-dependent manner. Riihimaki, Sjogren and Akila had the cohorts with the greatest years welding and found the most number of significant impacts in welders. The Buchta studies found minimal neurological impacts but these studies were conducted with personal protective equipment (forced air ventilation in the welding helmet) and report some of the lowest urinary Al levels of the studies. Mean urinary Al levels in Buchta 2003 are comparable with Bast-Pettersen where Al air measurements were obtained inside the personal protective equipment.

Study	Years welding	Urinary Al ($\mu\text{mol/L}$, median)	Al air (mg/m³)
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Hänninen, 1994	4	2.4 (0.9 – 6.1)	
Sjogren, 1996	15	0.81 (0.04 – 2.5)	
Akila, 1999	10-23	0.46/2.25/9.98	
Bast-Pettersen, 2000	8.1	1.54 (0.7 – 4.8)	0.9
Riihimaki, 2000	10-23	0.4/1.8/7.1	
Buchta 2003	8.8	0.52/0.48/0.22	0.8/0.5/0.7
Buchta 2005	15	1.34/1.61/0.95	5.6/4.5/6.8

Recommendation: A PEL of 1.0 mg/m³ T for all forms of aluminum. This recommendation is based on urinary Al levels associated with the onset of neurological effects and the corresponding air concentrations. Air concentrations in Bast-Pettersen, 2000 and Buchta 2003 are comparable and while the studies did not observe definitive differences between welders and controls, both studies found a decline in simple reaction time in welders that indicates a neurological effect of Al. A summary of this recommendation is presented below:

CAS #	Name		mg/m ³
Various	Aluminum, alkyls (not otherwise classified)		1
1344281	[Aluminum oxides]		
	Alumina; see Particulates not otherwise regulated		1
	Aluminum metal and insoluble forms	Total	1
Various	Aluminum salts and soluble forms		1
300925	Aluminum distearate		1
7047849	Aluminum stearate		1
637127	Aluminum tristearate		1

Usage information: EPA TSCA Chemical Data Reporting (CDR), EPA Toxics Release Inventories (TRI), other sources

In 2015, there were 159 TSCA CDR records for aluminum (usage in excess of 25,000 lbs) in U.S. Of these, 9 were in California. In 2016 there were 336 TRI records for aluminum of which 15 were in California.

Measurement information

OSHA Method: OSHA ID -121, OSHA ID-109SG, OSHA ID-198SG

NIOSH Method: 7013, 7300, 7301, 7302, 7303, 7304, 7306

Estimated LOD/LOQ: each method has a different LOD/LOQ many of which can measure down to from 0.05 mg/m³ to 0.001mg/m³.

Measurement issues: Choosing the best method for the form of aluminum to be encountered.

Based on the above, there are no anticipated analytical feasibility issues with aluminum at this time.

Recommended Workplace Controls

Providing suitable control measures such as ventilation to control exposure can be accomplished using existing equipment as most systems have the ability to control to the proposed levels.

Economic Impact Analysis/Assessment

The Division has made a determination that this proposal is not anticipated to result in a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This proposal will not have any effect on the creation or elimination of California jobs nor result in the creation or elimination of existing businesses or affect the expansion of existing California businesses. The Division anticipates that any potential costs will be balanced by avoiding or minimizing the costs inherent in workers' compensation claims, lost work time, and productivity losses that would have been caused by exposure related illness of employees.

The PEL proposed is consistent with recent scientific findings, of which professional health and safety staff and consultants of these employers and others with significantly exposed employees should be aware. Many of these entities already seek to control employee exposures to substances to levels below existing PELs in the interest of business continuity and minimization of tort and workers compensation liability.

Setting a Permissible Exposure Limit for aluminum that is up-to-date and consistent with current scientific information and state policies on risk assessment will send appropriate market signals to employers with respect to the costs of illness and injury, which chemicals can impose on workers and their families, the government, and society at large. With appropriate market signals, employers may be better able to choose chemicals for use in the workplace that impose less of a burden on workers and society. There are no anticipated benefits to the state's environment.

The economic benefits from the proposed PEL will result primarily from reduced health risk among exposed workers.

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