



Maine Department of Environmental Protection

Department Rule Chapter 887

*Designation of Arsenic as a Priority Chemical and
Regulation of Arsenic in Children's Products*

Basis Statement

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INTRODUCTION

The objective of Maine Law *Toxic Chemicals in Children's Products*, Title 38 M.R.S.A. §§1691 - 1699-B, is to reduce exposure of children and other vulnerable populations to chemicals of high concern by substitution of safer alternatives when feasible, as set forth in the Legislature's Declaration of Policy under 38 M.R.S.A. §1692. To accomplish this, the law provides the Department of Environmental Protection ("Department") the regulatory authority to collect information on chemical use and, if applicable, prohibit the sale of children's products containing priority chemicals when safer alternatives are available.

The law requires that a substance meet certain criteria to be designated a priority chemical, and that the Department provide its findings in support of such a designation. This document sets forth such findings of fact supporting the designation of arsenic as a priority chemical, and is intended to serve as the Basis Statement for the designating rule, Chapter 887, *Designation of Arsenic as a Priority Chemical and Regulation of Arsenic in Children's Products*. Department rule Chapter 880, *Regulation of Chemical Use in Children's Products*, establishes routine technical rulemaking as the process by which the Department will designate priority chemicals.

Although arsenic is found widely in the environment, in foods, and in tobacco, the exposure of children to arsenic through the products they use has been of recent interest at both the state and federal levels.

However, a significant lack of information in the public domain regarding arsenic's specific use in children's products, leaves considerable data gaps limiting the Department's ability to determine potential exposure risk to Maine's children. Therefore, a reporting requirement for certain categories of products is needed in order to determine where arsenic may be present in children's products currently available for sale in the State of Maine. Through this rulemaking, the Department designates arsenic and arsenic compounds (registered Chemical Abstract Service name 7440-38-2 as specified on Maine's Chemicals of High Concern list) as a priority chemical in accordance with 38 M.R.S.A. §1694 and establishes a reporting requirement for manufacturers offering certain children's products for sale in the State of Maine.

I. ARSENIC BACKGROUND INFORMATION

Naturally occurring in the earth's crust, arsenic is emitted into the environment as a result of volcanic activity and industrial processes. When found in the environment combined with other elements such as oxygen, chlorine, and sulfur, this type of compound is referred to as inorganic arsenic. Arsenic combined with carbon and hydrogen is referred to as organic arsenic. (ATSDR 2007)

Used commercially for centuries, arsenic and arsenic compound uses include pharmaceuticals, wood preservatives, agricultural chemicals, glass-making, and electronics. Arsenic and arsenic compounds are used in the manufacture of pigments, leather preservatives, pyrotechnics, dyes and soaps, and are also used as antifouling agents in paints. (IARC 2012). Although the majority of commercially available arsenic has historically been used as a wood preservative, this use has declined since 2004, after a voluntary ban on chromated copper arsenate in residential applications became effective at the end of 2003. Since that time the consumption of arsenic for wood preservation has declined from 90% prior to 2004, to 50% in 2007. (USGS 2008, IARC 2012)

Measurable amounts of arsenic have been detected in children's products which are not electronic nor made of wood material and is suspected to be within a pigment or plastic component of such items.

Health Concerns

Strong, credible scientific evidence leading to exposure concerns includes the classification of arsenic and inorganic arsenic as a *known human carcinogen* by the U.S. Department of Health and Human Services, National Toxicology Program ("NTP") and the International Agency for the Research of Cancer ("IARC"). The U.S. Environmental Protection Agency's Integrated Risk Information System ("IRIS") has also classified inorganic arsenic as a known human carcinogen (IRIS 1998).

The NTP Report on Carcinogens Listing Criteria describes this classification as, "*Known To Be Human Carcinogen: There is sufficient evidence of carcinogenicity from studies in humans, which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer.*" This classification, reported in the NTP's 12th Congressional Report on Carcinogens (2011), represents the strongest possible level of confidence in a carcinogenicity rating.

Additionally, the International Agency for the Research of Cancer has placed arsenic into its highest cancer toxicity classification, *carcinogenic to humans* (Group 1) (IARC Monographs, Volumes 58 (1993) and 100C (2012)), described by the IARC Monographs Preamble as, Section B., Scientific Review and Evaluation, subsection (6)(d) Overall Evaluation as, "Group 1: The agent is *carcinogenic to humans*. This category is used when there is *sufficient evidence of*

carcinogenicity in humans. Exceptionally, an agent may be placed in this category when evidence of carcinogenicity in humans is less than *sufficient* but there is *sufficient evidence of carcinogenicity* in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity.”

The predominant exposure source for the general population is through the ingestion of arsenic contaminated food or water. Arsenic exposure can negatively impact the gastrointestinal, liver, neurological, dermal, and respiratory systems. Long term exposure is believed to cause a pattern of changes to the dermal layer such as skin hyperpigmentation and warts, as well as an increased risk of skin, bladder, and lung cancers. According to the ATSDR 2007 *Toxicological Review on Arsenic*, the exposure level which produces the above mentioned skin changes is estimated to be above 100 micrograms of arsenic per cubic meter ($\mu\text{g}/\text{m}^3$) for a brief exposure. This same report describes longer exposure at lower concentrations leading to not only skin effects, but also to circulatory and peripheral nervous disorders. Fewer exposures of concern are the result of inhalation of arsenic from ambient air. (IARC 2012). Most importantly is the ability of inhaled inorganic arsenic to increase the risk of lung cancer (ATSDR 2007).

II. STATUTORY PREREQUISITES FOR PRIORITY DESIGNATION

To be included on Maine’s list of Chemicals of High Concern (“CHC”), a chemical must have strong, credible scientific evidence classifying it as a reproductive or developmental toxicant, endocrine disruptor, or human carcinogen. Arsenic meets this requirement after having received the highest possible rating of carcinogenicity by two of the world’s leading cancer research centers (IARC 2012 and NTP 2011) as a *known human carcinogen*, as well as the U.S. EPA IRIS classification of inorganic arsenic also as a *known human carcinogen*.

Title 38 M.R.S.A. § 1694 states that the, “commissioner may designate a chemical of high concern as a priority chemical if the commissioner finds, in concurrence with the Department of Health and Human Services, Maine Center for Disease Control and Prevention:

- A. The chemical has been found through biomonitoring to be present in human blood, including umbilical cord blood, breast milk, urine or other bodily tissues or fluids;
- B. The chemical has been found through sampling and analysis to be present in household dust, indoor air or drinking water, or elsewhere in the home environment; or
- C. The chemical is present in a consumer product used or present in the home.”

The statute authorizes the Commissioner to designate chemicals that meet one or more of these criteria as priority chemicals by the adoption of routine technical rules. Arsenic meets all three criteria.

A. Priority Designation Biomonitoring Criteria

As noted in Maine Center for Disease Control and Prevention supporting documents for Chemicals of High Concern (July 2012), six different biomonitoring studies have found arsenic to be present in human urine, blood, including umbilical cord blood, or human breast milk. In addition, urine samples from a representative population of the United States, collected through the National Health and Nutrition Examination Survey (“NHANES”), from the year 2003 through 2010, found detectable levels of inorganic arsenic metabolite DMA (ME-CDC 2013).

B. Priority Designation Presence in the Home Environment Criteria

As noted in Maine Center for Disease Control and Prevention supporting documents for Chemicals of High Concern (July 2012), five different indoor air and/or dust studies found arsenic present in the home environment, including household dust and drinking water.

C. Priority Designation Presence in Consumer Products Used or Present in the Home

Arsenic has been measured in consumer products including children’s toys, clothing, jewelry and shoes. The Danish Environmental Protection Ministry Consumer Product Survey No. 23, found that clothing made of 100% viscose contained detectible levels of arsenic. This report suggests that the mouthing or chewing of textiles by children may result in the oral intake of arsenic, and may be cause for exposure concerns. The report specifies that chewing on 20 grams of a textile per day could result in a daily intake which exceeds an amount acceptable by European standards. (DEPA 2003).

The U.S. Federal Consumer Product Safety Improvement Act (“CPSIA”) of 2008, set 25 parts per million (“ppm”) as the maximum amount of soluble arsenic allowed in the surface coating of children’s products subject to the law (CPSIA 2008). Although federal law limits the amount of arsenic that may be present in certain products, available information indicates its use continues.

As of October 2013, some manufacturers reported to the Washington State Department of Ecology (“WDOE”) arsenic is either present as a contaminant or had been intentionally added to 62 children’s products, as defined by Washington rule Chapter 173-334 WAC. Reported information describes arsenic’s use as a pigment, stabilizer, preservative, reinforcement, and to impart certain physical characteristics. Some of the product categories reported include: child safety seats, shoes, occasion supplies, clothing, jewelry, toys and games, and craft supplies.

Sufficient information exists to support a finding that arsenic is present in consumer products in the home, in addition to naturally occurring arsenic.

III. PURPOSE OF PRIORITY DESIGNATION

The most current data confirming the presence of arsenic in commonly used children's products has been acquired through the Washington State Department of Ecology reporting requirement and is limited in scope. The Department now seeks to gain insight into the current use of arsenic in children's products sold within the State of Maine to analyze whether additional regulatory management would be appropriate.

Comprehensive information about arsenic content and use in children's products sold in Maine is not currently known. By law, Maine must first obtain this information in order to evaluate the need for further action. For several years arsenic has been known to cause cancer, but limited information suggests it is still used in products in such a way that could cause children to be exposed. Federal law limits the amount that can be present in some products, but does not inform consumers or the Department, in a state where exposures to naturally occurring arsenic are high.

Designating arsenic as a priority chemical within the Safer Chemicals Program will require disclosure on how and where arsenic is intentionally added to certain categories of consumer products. This information regarding the use of arsenic in manufacturing processes and products available to the Maine consumer will provide the Department with more details regarding its use than has been gleaned from any current public source, and will serve to shape a more complete analysis than can be accomplished in the absence of such a reporting requirement.

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