

**CHEMICAL MEETING THE CRITERIA FOR LISTING AS CAUSING  
CANCER VIA THE AUTHORITATIVE BODIES MECHANISM:  
METAM POTASSIUM**

**PACKAGE 34b**

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Reproductive and Cancer Hazard Assessment Branch  
Office of Environmental Health Hazard Assessment  
California Environmental Protection Agency

Metam potassium meets the criteria for listing as known to the State to cause cancer under the authoritative bodies mechanism of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code Section 25249.5 *et seq.*), more commonly known as Proposition 65. The regulatory requirements for listing by this mechanism are set forth in Title 27, California Code of Regulations, section 25306<sup>1</sup>. These regulations include the criteria for evaluating the documentation and scientific findings by the authoritative body that the Office of Environmental Health Hazard Assessment (OEHHA) uses to determine whether listing under Proposition 65 is required.

The U.S. Environmental Protection Agency (U.S. EPA) is one of five institutions that have been identified as an authoritative body for identification of chemicals as causing cancer for the purposes of Proposition 65 (Section 25306(l)). U.S. EPA has identified metam potassium as causing cancer. OEHHA has determined that this chemical is “formally identified” as causing cancer as required by Section 25306(d). Metam potassium is the subject of reports published by U.S. EPA that conclude that the chemical causes cancer. Also, U.S. EPA documents specifically and accurately identify the chemical. Each of these documents meet one or more of the criteria in Section 25306(d)(2).

OEHHA also finds that the criteria for “as causing cancer” in Section 25306(e) have been satisfied for metam potassium. In making this determination, OEHHA relied upon the discussions of data by U.S. EPA in making its finding that metam potassium causes cancer. A brief discussion of the relevant carcinogenesis studies providing the scientific evidence supporting U.S. EPA’s finding is presented below. The statement in bold reflects data and conclusions that satisfy the criteria for the sufficiency of evidence of carcinogenicity in Section 25306(e). The full citations for the U.S. EPA documents can be found at the end of this report.

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<sup>1</sup> All further references are to sections of Title 27 of the California Code of Regulations unless otherwise indicated.

**Chemical Meeting the Criteria for Listing as Known to the State to Cause  
Cancer**

<b>Chemical</b>	<b>CAS No.</b>	<b>Chemical Use</b>	<b>Reference</b>
Metam Potassium (Potassium N-methyldithiocarbamate)	137-41-7	Dithiocarbamate soil fumigant used for producing lettuce, potatoes, onions, tomatoes, and watermelon.	U.S. EPA (1995; 2005; 2007; 2009a)

Metam potassium [Potassium N-methyldithiocarbamate] (CAS No. 137-41-7)

**Increased incidence of malignant tumors in male and female mice.**

In 2005 and 2007 memoranda, U.S. EPA states: “Unless further qualified or specified, use of the term ‘metam sodium’ should be assumed to also include ‘metam potassium.’” The U.S. EPA (1995) classified metam sodium (sodium N-methyldithiocarbamate, the sodium salt of N-methyldithiocarbamate) as a probable human carcinogen (Group B2) in 1995, and reaffirmed this classification in the 2005 and 2007 memoranda (U.S. EPA, 2005; 2007). In its 2009 evaluation of the carcinogenic potential of metam sodium, the U.S. EPA classified it as “likely to be carcinogenic to humans” (U.S. EPA, 2009a). This was based on “a treatment-related increase in malignant angiosarcomas in both male and female mice, which exceeded both the range and means of historical controls in both sexes, and had a high incidence in males (up to 52%)” (U.S. EPA, 2009a). Thus, by reference metam potassium is also classified as “likely to be carcinogenic to humans” by the U.S. EPA. U.S. EPA identified methyldithiocarbamate salts (metam sodium, metam potassium) in its 2008 Reregistration Eligibility Decision (RED) document and in its 2009 Amended RED for these chemicals (U.S. EPA, 2008; 2009b).

Metham sodium (metam sodium) was listed as causing cancer under Proposition 65 in 1998. Based on U.S. EPA 2005, 2007, and 2009 memoranda, metam potassium meets the criteria for listing as causing cancer under Proposition 65. The relevant cancer bioassays are described below.

Metam sodium was administered to male and female CD-1 mice in drinking water for two years. Angiosarcomas were observed in both males and females, with liver and spleen being the primary targets. In male mice, there were statistically significant increases in angiosarcoma of the liver (1/52, 8/52, 5/55, and 10/52 [ $p < 0.01$ ] for control, low-, mid- and high-dose animals, respectively),

spleen (6/53, 3/53, 10/55, and 21/53 [ $p < 0.01$ ]) and bone marrow [femur] (3/53, 3/53, 8/55, and 15/53 [ $p < 0.01$ ]). The combined incidence of angiosarcoma (at all sites) in male mice was 7/52, 12/52, 12/55, and 27/52 [ $p < 0.01$ ]. In female mice, the incidence of angiosarcoma of the spleen was significantly increased in mid- and high-dose animals compared to controls (0/55, 2/55, 4/47 [ $p < 0.05$ ], and 5/52 [ $p < 0.05$ ]). The incidence of angiosarcoma of the liver was also increased (0/54, 0/55, 1/47, and 4/52) although the increase was of borderline significance ( $p = 0.055$ ). A significant increasing trend [ $p < 0.01$ ] was observed in the combined incidence of angiosarcoma (at all sites) in female mice (4/54, 2/55, 6/47, and 10/52).

## **REFERENCES**

U.S. Environmental Protection Agency (U.S. EPA, 1995). *Memorandum: Carcinogenicity Peer Review of Metam Sodium*. Office of Prevention, Pesticides and Toxic Substances. May 1, 1995.

U.S. Environmental Protection Agency (U.S. EPA, 2005). *Memorandum: Metam Sodium: Revised HED Human Health Risk Assessment for Phase 3: DP Barcode: D318051, Metam Sodium PC Code: 039003, MITC PC Code: 068103*. Health Effects Division. Office of Pesticide Programs. June 13, 2005.

U.S. Environmental Protection Agency (U.S. EPA, 2007). *Memorandum: Metam Sodium: Phase 5 Revised Chapter of the Reregistration Eligibility Decision Document (RED); DP Barcode: D337533, Metam Sodium PC Code: 039003; Metam Potassium PC Code: 039002, MITC PC Code: 068103*. Health Effects Division. Office of Pesticide Programs. April 12, 2007.

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U.S. Environmental Protection Agency (2009a). *Metam Sodium: Second Report of the Cancer Assessment Review Committee (Final)*. Office of Prevention, Pesticides and Toxic Substances. May 14, 2009.

U.S. Environmental Protection Agency (2009b). *Amended Reregistration Eligibility Decision (RED) for the Methylthiocarbamate Salts (Metam-sodium, Metam-potassium) and Methyl Isothiocyanate (MITC)*. Prevention, Pesticides and Toxic Substances. May 2009.