

**Department of Defense Comments on the
The National Toxicology Program (NTP)/
Report on Carcinogens (RoC) Request for Public Comments on the RoC Expert Panel's Recommendation on Listing Status for
Cobalt-Tungsten Carbide Powders and Hard Metals in the 12th RoC and the Scientific Justification for the Recommendation**

Comments submitted by: Office of the Secretary of Defense Chemical and Material Risk Management Directorate

Organization: Department of Defense

Date Submitted: 4 March 2009

*Comment categories: Science or methods (S); Editorial, grammar/spelling, clarifications needed (E); or Other (O). Also please indicate if Major i.e. affects the outcome, conclusions or implementation of the assessment.

Comment No.	Section	Page & Paragraph (enter "Global" if report section-wide)	Comment	Suggested Action, Revision and References (if necessary)	Category*
1		Global	<p>We neither agree nor disagree with the recommendations of the External Peer Panel to list Cobalt-Tungsten-Carbide as <i>“reasonably anticipated to be a human carcinogen”</i> in the NTP ROC Criterion 1:</p> <p><i>“There is limited evidence of carcinogenicity from studies in humans [*], which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded”</i></p> <p>We are aware that differences exist in the scientific interpretation of historical occupational studies data due to potential confounding and limitations of these studies in regard to lack of quantitative biomonitoring data, timeframe under consideration, where historical information may be lacking, and therefore assumed, etc.</p> <p>Both the National Toxicology (NTP) Program Background Document and the Expert Peer</p>	<p>No biological fluid monitoring data is available in the French occupational worker studies to confirm quantitative dose/response. At present, biological monitoring can provide measurements of cobalt or tungsten in urine, blood, tissues, or exhaled breath, which would provide more quantitative measures of human exposure to cobalt tungsten carbide hard metals.</p> <p>We believe taking advantage of opportunities to confirm the causal relationship with quantitative data from occupational worker studies using biological fluid monitoring to better define dose response would be beneficial.</p>	

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			<p>Reviewers' comments recognize that there are limitations in the occupational studies of French hard metal workers lung cancer cited in the NTP Background document (human studies) and lack of animal data evaluating lung cancer.</p> <p>However, we believe that there are opportunities to reduce the uncertainty of the data from the French and Swedish occupational studies. For example the data are too weak for positive causal interpretation.</p> <p>As cited on the NTP Background document, tungsten and cobalt were measured in airborne particulates in Fallon, reportedly due to a cobalt-tungsten hard metal manufacturing facility. This appears to be an opportunity to confirm the link of exposure to hard metal and development of lung cancer.</p>		