



Organic Arsenical Products Task Force

Luxembourg-Pamol, Inc. • Drexel Chemical Company

April 20, 2010

Via E-Mail

Office of Environmental Information (OEI) Docket
Mail Code: 2822T
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Comments on the Draft U.S. EPA Document “Toxicological Review of Inorganic Arsenic: In Support of the Summary Information on the Integrated Risk Information System (IRIS)” (EPA/635/R-10/001); 75 Fed. Reg. 7477; Docket ID No. EPA-HQ-ORD-2010-0123

Dear Sir or Madam:

The Organic Arsenical Products Task Force (OAPTF)¹ hereby submits the appended list of materials from the scientific literature on inorganic arsenic for inclusion in the U.S. Environmental Protection Agency’s (EPA) docket maintained in support of the Summary Information on the Integrated Risk Information System (IRIS) Report (Report). We note that the appended list is not inclusive of all the literature available, and merely illustrative of the tremendous data not considered in this toxicological review. In reviewing the Report, we were disappointed to discover that “[t]he relevant literature was reviewed through December 2007” with only “a few references from 2008” included.

We briefly note the following points in connection with our submission of the additional literature:

The literature that was published since 2007 is very important to the specific issues discussed by the Report, because substantial research has been going on to address the questions raised in the 2007 Science Advisory Board (SAB) report. Thus, the state-of-the-art is

¹ The OAPTF consists of Drexel Chemical Co and Luxembourg-Pamol, Inc., both registrants of pesticide products that contain monosodium methanearsonate (MSMA).



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missing from the Report. Also, a substantial amount of literature from the period before 2007 is missing from the Report.

With arsenic science fast developing, it is wrong to make decisions in 2010 based on science from 2007, as if the relevant database were static instead of gaining in breadth and refinement. One example critical to the current review is the recent, state-of-the-art work from the laboratory of Dr. Sam Cohen, which -- contrary to EPA's assertion -- defines a mode of action (MOA) for inorganic arsenic. This information was presented during the 5-minutes public comment period at the SAB meeting on April 6, 2010.

Additionally, EPA relies heavily on the number of references collected to support each possible MOA for inorganic arsenic (Table 4.1). Regardless of whether it is good science to place such weight simply on the number of references addressing each MOA, it makes little sense to consider the proportion of references supporting each MOA unless the literature survey is complete, or nearly so. The appended list of missing references demonstrates that the literature EPA relies on falls far short of a comprehensive MOA review. Accordingly, these references should be included in the docket and considered before the draft IRIS Report is made final.

The data set from Taiwan on which EPA places great significance is outdated (data are from 1950) and has documented uncertainties related to the exposure characterization. The missing literature list we have provided shows that there are several newer studies which include more relevant and accurate information, which EPA to this point has not sufficiently considered. It is important that references discussing vital additional exposure information should be included. Meta analysis of studies from lower exposure areas should be considered, and several such studies are available in the newer literature. Moreover, such sources as occupational exposures, smoking, ultra-violet (UV) radiation, or Black Foot Disease should be taken into account when analyzing the data set from Taiwan, or any other.



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For all of the above reasons, the OAPTF requests that the references on the appended list should be included in the docket for review and consideration.

Sincerely,

A handwritten signature in blue ink that reads 'M. Eldan'.

Michal Eldan, Ph.D.

Attachment

cc: The Honorable Paul Anastas, Ph.D. (w/attachment) (via e-mail)
Anthony F. Maciorowski, Ph.D. (w/attachment) (via e-mail)
Vanessa Vu, Ph.D. (w/attachment) (via e-mail)
Steven P. Bradbury, Ph.D. (w/attachment) (via e-mail)
Peter W. Preuss, Ph.D. (w/attachment) (via e-mail)
Sue Shallal, Ph.D. (w/attachment) (via e-mail)
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