

201-14641



NCIC HPV
Sent by: Mary-Beth
Weaver

08/04/2003 09:27 AM

To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Revised HPV Document for 107-19-7



EJ Rauckman <erauckman@charter.net> on 08/01/2003 11:31:07 PM

To: oppt.ncic@epamail.epa.gov
cc: Christopher Bradlee <bradlec@basf-corp.com>, Jane Vergnes <JVergnes@ispcorp.com>

Subject: Revised HPV Document for 107-19-7

Hi,

On behalf of the BPPB Consortium, I am submitting the revised Test Plan and Robust Summaries for the HPV submission of Propargyl Alcohol (CASNO 107-19-7). The Test Plan, Robust Summaries and Cover Letter are attached as PDF documents. The cover letter addresses EPA's comments on the plan and summaries in a point-by-point reply.

Please contact me by email or phone if you have any difficulty with this transmission or have any questions.

Best regards,

Elmer Rauckman, PhD DABT

618-539-5280

rauckman@toxicsolutions.com



Cov Let.pdf



107-19-7 Rev Test Plan.pdf



107-19-7 Rev RS.pdf

2003 AUG -4 AM 11:27

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NCIC HPV
Sent by: Mary-Beth
Weaver

08/04/2003 02:08 PM

To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Correction to Revised HPV Document for 107-19-7

To: oppt.ncic@epamail.epa.gov
cc: Christopher Bradlee <bradlec@basf-corp.com>, Jane Vergnes <JVergnes@ispcorp.com>
Subject: Correction to Revised HPV Document for 107-19-7

Hi,

There was a minor error on the cover letter, could you please replace it with this corrected version?

Thanks in advance

Elmer Rauckman

-----Original Message-----

From: EJ Rauckman [mailto:erauckman@charter.net]
Sent: Friday, August 01, 2003 10:31 PM
To: oppt.ncic@epa.gov
Cc: Christopher Bradlee; Jane Vergnes
Subject: Revised HPV Document for 107-19-7

Hi,

On behalf of the BPPB Consortium, I am submitting the revised Test Plan and Robust Summaries for the HPV submission of Propargyl Alcohol (CASNO 107-19-7). The Test Plan, Robust Summaries and Cover Letter are attached as PDF documents. The cover letter addresses EPA's comments on the plan and summaries in a point-by-point reply.

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Best regards,

Elmer Rauckman, PhD DABT

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rauckman@toxicsolutions.com



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201-14641

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1 August 2003

Ms. Marianne L. Horinko
US Environmental Protection Agency
1200 Pennsylvania Ave., N. W.
Washington, DC 20460

Re: Revision of Propargyl Alcohol (CASNO 107-19-7) Documents
Via Electronic Submission to Oppt.ncic@epa.gov

Registered with EPA as:
BPPB Consortium, **Registration Number**

Dear Acting Administrator Horinko;

On behalf of the BPPB Consortium, Toxicology and Regulatory Affairs is hereby responding to the U.S. EPA's letter dated June 3, 2003 posted on Chem-RTK HPV Challenge Web site on June 6, 2003 for the Test Plan and robust summaries on Propargyl Alcohol (107-19-7). The U.S. EPA's comments can be broadly grouped into two categories; testing related comments and comments pertaining to information in the Test Plan or robust summaries. The following are responses to the U.S. EPA's comments/questions based on these two groups:

Testing Related Issues

U.S. EPA Comment (1): The submitter indicates that adequate data for this endpoint (biodegradation) are available. EPA disagrees. The submitter needs to submit the appropriate data in robust summary format for EPA to determine data adequacy or conduct a ready biodegradation study using the OECD TG 301 series.

BPPB Response (1): To address this endpoint the five studies referenced by the EPA were considered (Dore et al 1975; Dow Chem 1986; Petrolite 1986; Loehr 1989; CERIJ 2003), and sufficient information was obtained from some of these studies to adequately address the biodegradation endpoint. The Test Plan and robust summary for biodegradation were updated to reflect this new information.

U.S. EPA Comment (2): EPA recommends acute toxicity testing for invertebrates and algae using mean measured concentrations.

BPPB Response (2): Testing for algae and invertebrates using mean measured concentrations will be conducted according to OECD Guidelines 201 and 202, respectively.

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Test Plan and Robust Summaries

U.S. EPA Comment (3): EPA identified a reference supporting a water solubility of 1,000 g/L. (Yalkowsky and Dannenfelser, 1992). The submitter should consider adding this to the robust summary.

BPPB Response (3): The reference was reviewed and the data were added to the robust summaries.

U.S. EPA Comment (4): A robust summary for a 90-day NTP inhalation study in rats did not completely describe the exposure protocol (number of exposure hours per day per week).

BPPB Response (4): The number of exposure hours per week was added to the robust summary; however, the number of hours per day was not available. Typically, these studies are conducted by NTP at 6 hrs per day.

U.S. EPA Comment (5): A robust summary for a negative reverse mutation assay in five strains of *Salmonella typhimurium* lacked a full reference citation and information on GLP status of the study.

BPPB Response (5): The full reference citation and information on GLP status of the study was added to the robust summary.

The Test Plan and robust summaries have been revised to incorporate the changes noted above. The BPPB Consortium will initiate testing in accordance with the Revised Test Plan. Final robust summaries that cover the results of this revised testing will be prepared and submitted to the U.S. EPA. Please contact me at (618) 539-5280 if you have any questions or comments.

Sincerely,

Elmer Rauckman, PhD, DABT
Consulting Toxicologist

Attachments:

Testing Plan 107-19-7-Rev Test Plan.pdf
Robust Summaries 107-19-7-Rev RS.pdf

References:

CERIJ. Chemicals Evaluation and Research Institute, Japan web page at http://www.cerij.or.jp/ceri_en/index_e4.shtml (June 13, 2003).

Dore M, Brunet N, Legube B. 1975. Participation of Various Organic Compounds in the Evaluation of Global Pollution Criteria. Trib Cebedeau 28:3-11.

Dow Chem 1986. Summary of Environmental Data for Propargyl Alcohol with Cover Letter Dated 04/10/86. US EPA/OPTS Public OTS0510180/868600028.

Loehr RC. Treatability Potential for EPA Listed Hazardous Wastes in Soil. USEPA. Robert S. Kerr Environ Res Lab ADA, OK EPA/600/2-89/011(1989).

Petrolite 1986. Biochemical Oxygen Demand of AK-14 (Mixture containing Propargyl alcohol) with Cover Letter Dated 05/06/96. US EPA/OPTS Public OTS0510365/878216437.