JuanB Perez/DC/USEPA/US

11/19/2007 12:08 PM

To NCIC HPV@EPA

cc

bcc

Subject EPA comments on the 2-Propanone, Reaction Products with Phenol HPV Challenge Submission

2007 NOV 20 AM 9:29

201-16653

"Dimond, Stephen S (SABIC Innovative Plastics)" <Stephen.Dimond@sabic-ip.com>

11/17/2007 03:11 AM

To NCIC OPPT@EPA, Rtk Chem@EPA, Ralph Northrop/DC/USEPA/US@EPA

cc Mark Townsend/DC/USEPA/US@EPA, "John P. Van Miller" <jvanmiller@toxregserv.com>

Subject RE: EPA comments on the 2-Propanone, Reaction Products with Phenol HPV Challenge Submission

HPV Coordinator and Dr. Northrop,

General Electric Plastics has been sold to Saudi Basic Industries Corporation and the business is now called SABIC Innovative Plastics. We (SABIC Innovative Plastics) are still committed to sponsoring 2-Propanone, Reactions Products with Phenol in the HPV program.

Attached are two documents. The first is a letter responding to EPA's comments (posted on the ChemRTK HPV Challenge Program Web site September 20, 2007) on the Test Plan for 2-Propanone, Reactions Products with Phenol. The second document is our Revised Test Plan for this chemical, which addresses EPA's comments and proposes additional testing. As stated in the letter, we request a rapid response to our Revised Test Plan for this material as initiation of testing awaits further reponse from EPA.

If you have any questions, please contact me at 603-860-5056.

Regards,

Stephen S. Dimond, Ph.D.
SABIC Innovative Plastics
Senior Toxicologist

One Plastics Avenue
Pittsfield, MA 01201
T: 603-860-5056 (office and mobile)
F: 866-261-8345

E: stephen.dimond@sabic-ip.com
www.sabic-ip.com

-----Original Message-----
From: Northrop.Ralph@epamail.epa.gov
[mailto:Northrop.Ralph@epamail.epa.gov]
Sent: Friday, September 14, 2007 2:02 PM
To: Dimond, Stephen S (SABIC Innovative Plastics)
Cc: Townsend.Mark@epamail.epa.gov
Subject: EPA comments on the 2-Propanone, Reaction Products with Phenol HPV Challenge Submission

Dear Mr. Dimond :

Attached please find EPA's comments on the 2-Propanone, Reaction Products with Phenol submission to the Chemical RTK Challenge Program from Mark Townsend, Chief of OPPT's HPV Chemicals Branch. This item will also be sent to you in hard copy and will be posted on the Chemical RTK website.

(See attached file: SN406 BPA Tars 091407.doc)

Ralph C. Northrop, Ph.D.
OPPT/RAD/HPVCB

202-564-7666

BPA Tars Transmittal Letter Revised Test Plan 11-16-07.pdf

BPA Tars 72162-28-8 REVISED Test Plan Final (3).pdf

SABIC
Innovative
Plastics

201-16653

2007 NOV 20 AM 11:20

November 16, 2007

HPV Coordinator
US Environmental Protection Agency
PO Box 1473
Merrifield, VA 22116

Attn: Chemical Right-to-Know Program, AR-201

RE: Revised Test Plan for 2-Propanone, Reaction Products with Phenol (CAS RN 72162-28-8)

This letter is in response to the EPA Office of Pollution Prevention and Toxics preliminary comments, provided by Mark W. Townsend and posted September 20, 2007 on the ChemRTK HPV Challenge Program Web site, to our Test Plan for 2-propanone, reaction products with phenol (CAS No. 72162-28-8), hereafter referred to as BPA-Tars. Please note that this submission was originally made under the auspices of General Electric Plastics. The General Electric Plastics business including all of its HPV commitments was recently sold to Saudi Basic Industries Corporation and renamed SABIC Innovative Plastics. My address and contact information remains the same. SABIC Innovative Plastics is committed to the successful completion of the HPV program for BPA-Tars.

Our reply to the EPA comments is provided below and a Revised Test Plan for BPA-Tars accompanies this letter. To address EPA's comments, we have included additional proposed testing and rationale. As noted in the Revised Test Plan, there are a number of technical issues regarding any (additional) testing of BPA-Tars due to the nature of the substance. Specifically, BPA-Tars is a variable mixture of components used in the production of BPA, which is principally burned as a fuel. The Revised Test Plan addresses these technical issues, but it should be noted that specific decisions will need to be made based on results of preliminary tests.

If there are details that need to be further discussed upon review of this Revised Test Plan, we respectfully request a meeting with the Agency (either in person or via conference call) to ensure understanding and agreement of the additions to the Revised Test Plan.

ONE PLASTICS AVENUE, PITTSFIELD, MA 01201 TEL: 603-860-5056 FAX: 866-261-8345
E-MAIL: stephen.dimond@sabic-ip.com WEBSITE: www.sabic-ip.com

SABIC
Innovative
Plastics™

سابك
sabic

SABIC Innovative Plastics would like to initiate the proposed testing as soon as possible, but will await a response from the Agency. Therefore, we would appreciate a rapid response to the Revised Test Plan.

We thank you for your assistance.

Regards,

Stephen S. Dimond

DN: cn=Stephen S. Dimond, c=US,
o=SABIC Innovative Plastics,
email=stephen.dimond@sabic-ip.com
Date: 2007.11.17 02:24:16 -05'00'

Stephen S. Dimond, Ph.D.
Senior Toxicologist

Enclosure

Cc: G. Porta
M. Townsend (e-mail at Townsend.Mark@epamail.epa.gov)
R. Northrop (e-mail at Northrop.Ralph@epamail.epa.gov)

ONE PLASTICS AVENUE, PITTSFIELD, MA 01201 TEL: 603-860-5056 FAX: 866-261-8345
E-MAIL: stephen.dimond@sabic-ip.com WEBSITE: www.sabic-ip.com

SABIC
Innovative
Plastics

201-16653

2007 NOV 20 AM 9:26

The following repeats EPA's comments with our responses in Blue Text:

EPA has conducted a preliminary review of this submission and has reached the following conclusions:

(1) EPA agrees that bisphenol A is a major component of the sponsored substance. However, the submitter has not demonstrated that it will be absorbed significantly better than the other components or that it is the most toxic compound present, and thus adequately characterizes the sponsored substance.

The Test Plan has been revised to include additional endpoints to adequately characterize the toxicologic properties of the substance and support bridging to data for BPA.

(2) For the human health endpoints, the other identified components in the mixture are expected to be bioavailable, and they possess functional groups that could induce toxicity different from that induced by bisphenol A. The submitter has not provided sufficient information to support using bisphenol A data to fully assess these endpoints and allow characterization of the toxicity of the sponsored substance.

We continue to believe that our proposed approach of evaluating the mutagenicity of BPA-Tars provided for an evaluation of potential differences in biological activity compared to the main component, BPA. We believe the components of BPA-Tars are structurally similar and do not contain functional groups of concern. However, we propose to conduct, based on EPA's comments, a reproductive/developmental toxicity screen (OECD 421) in addition to the mutagenicity studies previously proposed, that will adequately characterize the toxicity of this mixture. We further believe that based on the use pattern, the potential human exposure to BPA-Tars is minimal and restricted to accidental events. Therefore, to limit the use of additional experimental animals, we suggest that the OECD 421 and the mutagenicity studies serve to "bridge" from BPA-Tars to the extensive database for BPA. Since the database indicates that BPA has only toxicity at high doses in adult animals (liver and kidney effects) and the only consistent effect on offspring is reduced perinatal body weight, we believe that the OECD 421 study, with the addition of evaluation of liver and kidney weights and histopathology, will show similar toxicity for BPA-Tars as for BPA.

(3) For the ecotoxicity testing needs, EPA agrees with the proposal to base the testing on the determination of water solubility of the mixture components. However, EPA disagrees that any additional test data would need to be provided only for the fish toxicity endpoint: the submitter would need to provide measured data for all acute ecotoxicity endpoints (fish, invertebrate, algae). In addition, if acute tests are indicated, EPA recommends a chronic daphnia test also be performed on the sponsored substance because the calculated Log kow values for significant mixture components other than bisphenol A are > 4.2. All tests need to be performed using measured concentrations.

As noted in the original Test Plan, a determination of the water solubility of BPA-Tars will be attempted. However, because of the nature of the substance (mixture), the OECD Guideline for water solubility is not directly applicable. We anticipate that this determination, and any subsequent aquatic testing, will require a modified procedure, likely using the concept of Water Accommodated Fraction (WAF). Other HPV Test Plans (for example, the Heavy Fuel Oils) have used this approach for aquatic testing. Various methods of analysis have been employed that include selection of one or a few "representative peaks" or

ONE PLASTICS AVENUE, PITTSFIELD, MA 01201 TEL: 603-860-5056 FAX: 866-261-8345
E-MAIL: stephen.dimond@sabic-ip.com WEBSITE: www.sabic-ip.com

using total peak area to quantify. Of course, these procedures provide only a determination of what is actually solubilized in the water. A similar approach will be required for BPA-Tars.

Aquatic toxicity studies in fish, invertebrates, and algae are proposed in the Revised Test Plan. If the measured water solubility is > 1 ppb, the acute toxicity study with *Daphnia magna* will be performed. If the water solubility is < 1 ppb, the chronic daphnia study is proposed.

ONE PLASTICS AVENUE, PITTSFIELD, MA 01201 TEL: 603-860-5056 FAX: 866-261-8345
E-MAIL: stephen.dimond@sabic-ip.com WEBSITE: www.sabic-ip.com