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August 2, 2002

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2002 AUG 29 AM 10:07

Attention: TSCA Section 8(e) Coordinator

Re: Pyrolysis C5 – OECD 422 Study in Rats by Inhalation Exposure

Dear Madam or Sir:

The American Chemistry Council Olefins Panel submits this letter on behalf of certain of its members (listed below) pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA) to inform EPA of preliminary histopathology results from a OECD 422 study that was conducted for Pyrolysis C5 in rats. The Panel has not made a determination as to whether a significant risk of injury to health or the environment is actually presented by the preliminary findings.

Pyrolysis C5 was tested pursuant to the Olefins Panel's testing plan for the C5 non-Cyclics Category under the High Production Volume Chemical Challenge Program.¹ The Pyrolysis C5 stream is a hydrocarbon distillate fraction separated from pyrolysis gasoline that consists primarily of C5 dienes and other C5 hydrocarbons and low levels of higher boiling C4 hydrocarbons and volatile C6 hydrocarbons. CAS Registry numbers that are used by Panel members to identify pyrolysis C5 streams include: 68476-55-1 (Hydrocarbons, C5-rich), 68476-43-7 (Hydrocarbons, C4-6, C5 rich), 68527-19-5 (Hydrocarbon, C1-4, debutanizer fraction), 68603-00-9 (Distillates, petroleum, thermal cracked naphtha and gas oil) and 68956-55-8 (Hydrocarbons, C5-unsatd.).

¹ The test plan is available at <http://www.epa.gov/chemrtk/olefins/olefintp.pdf>.



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The preliminary histopathology results of the 422 study were reported in a laboratory study update memorandum (attached) that described the findings for all (12/sex/group) control and high dose (1000 ppm) animals and a few low (100 ppm) and mid dose (300 ppm) animals that exhibited gross lesions at necropsy. A summary of the histopathology results follow:

Liver

Centrilobular hepatocyte hypertrophy, minimal in degree, was detected in 8 and 4 high dose males and females, respectively. This finding correlates with the slightly higher bodyweight adjusted liver weights seen in high dose male and female rats.

Kidneys

Cortical tubules with hyaline droplets, moderate to marked in degree, were detected in all male high dose rats. This finding correlates with the increased adjusted group mean kidney weights seen in high dose males. These changes were not observed in the high dose females or control groups.

An increased degree of cortical tubular basophilia was detected in male rats. Marginal increases in basophilic/dilated cortical tubules was detected in 3 high dose male rats. Cortical scarring (minimal) and medullary tubular basophilia was detected in 4 and 2 high dose male rats, respectively.

No similar findings were seen in female rats to account for the increased kidney weight seen in high dose females. A minor finding of a focus of basophilic/dilated cortical tubules was seen in the kidneys of two high dose females.

A final report is not available at this time but will be forwarded when received from the laboratory.

Letters were submitted earlier this year by three Panel members pursuant to Section 8(e) of TSCA, describing preliminary results from the dose range finding study that was conducted for this OECD 422 study. These letters were submitted by Equistar Chemicals, LP on April 26, 2002 (8EHQ-02-15137), The Dow Chemical Company on May 2, 2002 (8EH number not available) and Chevron Phillips Chemical Company on May 3, 2002 (8EHQ number not available).

The following members of the Panel produce one or more of the streams included in the C5 non-Cyclics Category and are sponsors of the testing for the category: BP Amoco Chemical Company, Chevron Phillips Chemical Company LP, The Dow Chemical Company, Equistar Chemicals, LP, ExxonMobil Chemical Company, The Goodyear Tire & Rubber Company, Huntsman Corporation, NOVA Chemicals Inc., and Shell Chemical Company LP.

If you have any questions, please call Elizabeth Moran, Manager of the Olefins Panel, at 301 924 2006, write her at the address given at the bottom of the first page of this letter, or e-mail her at Elizabeth_Moran@americanchemistry.com.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Courtney M. Price". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Courtney M. Price
Vice President, CHEMSTAR

cc: Richard H. Hefter (MC 7403)

ABCDE

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PRELIMINARY HISTOPATHOLOGY REPORT

Treatment-related changes

Liver

Centrilobular hepatocyte hypertrophy, minimal in degree was detected in High dose males and females. This finding correlates with the slightly higher bodyweight adjusted liver weights seen in High dose male and female rats.

Group		Male				Female			
		Control	Low	Inter	High	Control	Low	Inter	High
Hepatocyte hypertrophy –									
Centrilobular	Minimal	0	-	-	8	0	-	-	4
	Total	0	-	-	8	0	-	-	4
Number examined		12	0	0	12	12	0	0	12

Kidneys

Cortical tubules with hyaline droplets, moderate to marked in degree were detected in all male High dose rats. This finding correlates with the increased adjusted group mean kidney weights seen in High dose Males.

An increased degree of cortical tubular basophilia with marginal increases in basophilic/dilated cortical tubules, cortical scarring and medullary tubular basophilia was detected in High dose male rats.

No similar findings were seen in female rats to account for the increased kidney weight seen in High dose females. A focus of basophilic/dilated cortical tubules was seen in the kidneys of two High dose females. This minor finding on its own was not considered to be of toxicological importance.

Group		Male				Female			
		Control	Low	Inter	High	Control	Low	Inter	High
Cortical tubules with hyaline droplets									
	Minimal	0	2	0	0	0	0	-	0
	Slight	0	1	0	0	0	0	-	0
	Moderate	0	0	4	4	0	0	-	0
	Marked	0	0	0	8	0	0	-	0
	Total	0	3	4	12	0	0	-	0
Cortical tubular basophilia									
	Minimal	11	1	1	8	3	1	-	3
	Slight	0	1	3	4	0	0	-	0
	Total	11	2	4	12	3	1	-	3
Basophilic/dilated cortical tubules									
	Minimal	0	0	0	3	0	0	-	2
	Total	0	0	0	3	0	0	-	2
Cortical scarring									
	Minimal	2	1	2	4	0	0	-	0
		2	1	2	4	0	0	-	0
Medullary tubular basophilia									
	Minimal	0	0	0	2	0	0	-	0
		0	0	0	2	0	0	-	0
Number examined		12	3	4	12	12	1	0	12

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