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**CBIC Control Number**

**369045**

April 26, 2016

US EPA Office of Pollution Prevention and Toxics  
1201 Constitution Avenue, NW  
WJC East; Room 6428; Attn: Section 8(e)  
Washington, DC 20004-3302

**SUBJECT: TSCA 8(e) Notice**

Dear TSCA Section 8(e) Coordinator:

On behalf of Akzo Nobel Surface Chemistry LLC, we are reporting preliminary results of an OECD 408 90-day repeat dose study conducted on Quaternary ammonium compounds, C12-18-alkylbis (hydroxyethyl) methyl, chlorides (CAS No 70750-47-9).

The test item was administered by dietary admixtures to three groups each of ten male and ten female Wistar Han™:RccHan™: WIST Strain rats, for ninety consecutive days, at dietary concentrations of 150, 400 and 1500 ppm (Active Ingredient(A.I.)) corresponding to approximately 10, 30 and 100 mg/kg/day. A further group of ten males and ten females was fed basal laboratory diet to serve as a control.

Body weight gain was noticeably lower throughout the study for animals of either sex treated with 1500 ppm A.I. when compared to controls. Overall body weight gain was 45% lower for both males and females at this level.

Animals of either sex treated with 1500 ppm A.I. showed reduced food conversion efficiency throughout the study when compared to controls.

Males and females treated with 1500 ppm A.I. showed a statistically significant increase in total leukocyte count and neutrophils when compared to controls. The majority of individual values exceeded the background control ranges.

Females from all treatment groups showed a statistically significant reduction in mean corpuscular hemoglobin concentration when compared to controls. All individual values were within background control ranges.

At 1500 or 400 ppm A.I. females showed a statistically significant reduction in levels of hemoglobin and monocytes when compared to controls. All individual values were within the background ranges.

Females treated with 1500 ppm A.I. also showed a statistically significant reduction in mean corpuscular hemoglobin and mean corpuscular volume. The majority of individual values were within the background control ranges.

Males from all treatment groups showed a statistically significant reduction in levels of albumin and phosphorus concentration when compared to controls. All individual values were within the background control ranges.

Males treated with 1500 and 400 ppm A.I. showed a statistically significant reduction in chloride concentration when compared to controls. All individual values were within the background control ranges.



Males treated with 1500 ppm Al. showed a statistically significant reduction in albumin/globulin ratio and a statistically significant increase in levels of urea. All individual values were within the background control ranges for both parameters. Both males and females from this level showed statistically significant increases in aspartate aminotransferase and alanine aminotransferase. The majority of the individual values were above the background control ranges.

Females from all treatment groups showed a statistically significant increase in bile acids when compared to controls. The majority of the individual values were within the background control ranges.

All males and eight females treated with 1500 ppm Al. had a raised non glandular region of the stomach at necropsy.

Hypertrophy of the zona glomerulosa in the adrenal gland was present in 5/10 males and females treated with 1500 ppm Al.

Hyperplasia of the mucosa of the caecum was present in all males and 7/10 females treated with 1500 ppm Al., also inflammation was present in all males and 6/10 females

Various changes in the kidney were apparent in most males and all females treated with 1500 ppm Al. These included tubular dilation, especially in the medullary tubules, increased basophilic tubules and brown pigment deposition.

Periportal basophilia (homogenous, darker staining cells) in the liver was present in 5/10 males treated with 1500 ppm Al.

Erythrocytosis was present in the mesenteric lymph node in 6/10 males treated with 1500 ppm A.I. compared to 1/10 controls.

Changes were present in the stomach of all males and 9/10 females treated with 1500 ppm Al. The changes included ulceration, erosion and various degrees of hyperplasia, all affecting the non-glandular region.

Please contact me at (312) 544-7061 if you have any questions regarding this letter.

Sincerely,

Louette Rausch  
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BA Specialty Chemicals  
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SHIP DATE: 26APR16  
ACTWGT: 0.50 LB  
CAD: 103794831/INET3730

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TO **ATTN: SECTION 8(E)**  
**U.S. EPA - POLLUTION PRVNTN & TXCS**  
**1201 CONSTITUTION AVE NW**  
**WJC EAST BUILDING ROOM 6428**  
**WASHINGTON DC 20004**

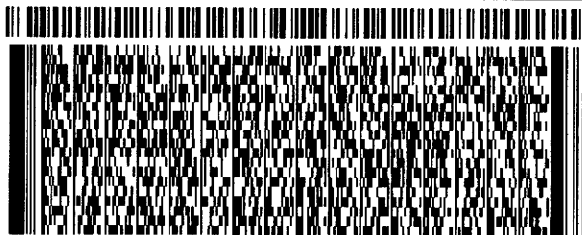
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