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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: *Waiver Request/Data Submission*
Poly(hexamethylenebiguanide)

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The registrant, ICI America's Inc., has requested a waiver for Accumulation in Fish data requirement to support the reregistration of Poly(hexamethylenebiguanide) for the Aquatic Nonfood Industrial/Residential uses. The Accumulation in Fish is not an EFGWB data requirement and has never been an EFGWB data requirement for the above mentioned use pattern. For the current status of environmental fate data requirements for Poly(hexamethylenebiguanide), please refer to EFGWB memorandum dated Aug. 9, 1991.

The registrant has also resubmitted the following studies for review:

161-1 Hydrolysis
161-2 Photodegradation in Water
162-1 Aerobioc Soil Metabolism
163-1 Leaching/Adsorption/Desorption

A combined Hydrolysis and Photodegradation in Water study (161-1/161-2; MRID #30785) is the duplicate of the study that has been previously submitted and is currently being reviewed in the Branch. The studies on Aerobic Soil Metabolism (162-1; MRID #77932), and Leaching/Adsorption/Desorption (163-1; MRID #77931) were previously returned unreviewed because they were not legible. These studies are not required to fulfill the environmental fate data requirement and are reviewed only to provide supplemental information. The study on Aerobic Soil Metabolism was screened against the acceptance criteria and is found unacceptable due to following deficiencies:

1) The half-life of the parent was not reported.

2) Suitable analytical methods were not available for the detection of the parent or its degradates.

3) The study was not conducted in the dark.

4) The radiochemical purity of the test substance was not reported.

5) Soil Moisture was not maintained at 75% of 1/3 bar.

6) The foreign soils used in the study were not compared with domestic soils.

The above study is not needed to satisfy the environmental fate data requirements for Poly(hexamethylenebiguanide). However, the study provides supplemental information which is summarized in the following paragraph.

[^{14}C]PHMB (at rates 1, 10, and 100 Kg ai ha^{-1}) in two sandy loam soils and a loam soil at pH 6.6, 7.0, and 7.5 was rapidly adsorbed to soil with 10-20% of the applied radioactivity being evolved over a one year incubation period. Only small amounts of radioactivity (<3%) was extracted with methanol, methanol-water, acetone or 0.1 M HCl. Sodium hydroxide and 5M H_2SO_4 extracted approximately 40-50% of the radioactivity which was not identified as the parent or the degradates.

The study on Leaching/Adsorption/Desorption was screened against

the acceptance criteria and was found unacceptable due to the following deficiencies:

1) K_{ads}, K_{des}, and K_{oc} were not reported in the Batch Equilibrium study.

2) No attempt was made to identify the parent and the degradates in the aged leaching study.

3) Foreign soils were not compared with the domestic soils.

4) None of the soils had a % OM < 1%.

The above study is not needed to satisfy the environmental fate data requirements. However, the study provides supplemental information which is summarized in the following paragraphs.

[^{14}C]Poly(hexamethylenebiguanide) has an extremely low mobility as determined by thin layer chromatography. 99 % of the PHMB leached less than 2cm-32cm in calcareous loam, coarse sand, coarse sandy loam and loam soils.

In an aged soil column leaching study [^{14}C]PHMB was incubated with calcareous clay loam, coarse sand, and coarse sandy loam soils for four weeks under aerobic conditions. No radioactivity was detected in the leachate when 35 cm long soil columns were leached with 68 cm rain over a two months period. About 95% of the radioactivity remained in the top 5 cm of soil.

In batch equilibrium study [^{14}C]PHMB was rapidly adsorbed and equilibrium was reached within the first 16 hour shaking period. No K_{ads}, K_{des}, and K_{oc} were reported.