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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

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MEMORANDUM

SUBJECT: Poly(hexamethylenebiguanide) - Environmental Fate
Data Requirement

[This chemical is also known as
Poly(iminoimidocarbonyliminoimidocarbonyliminohexa
methylene hydrochloride)]

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6/23/94

EFGWB has completed the review of two studies (161-1: Hydrolysis; and 161-2: Photodegradation in Water) submitted by Zeneca, Inc. to support the Environmental Fate data requirements for poly(hexamethylenebiguanide). The chemical is classified as an industrial microbiocide. As submitted, these studies are unacceptable and cannot be used to satisfy the data requirements. However, the studies can be upgraded provided the registrant can adequately address the deficiencies (see attached Data Evaluation Record for details). If it is not possible to address the deficiencies, then a new hydrolysis study (161-1) must be submitted. Photodegradation in Water (161-2) data is no longer required.

3. This study is unacceptable at this time for the following reason:
 - * the analytical procedure used may have been an unacceptable method because the registrant has not presented data to demonstrate that this colorimetric method analyzes only PHMB and is free from the interference by possible PHMB degradation products; and,
 - * necessary details and data were not included in the submitted summary. The incubation vessels were not described, the method of collecting samples was not reported, and the number of replicates was not discussed. The sample containers for hydrolytic incubation were not adequately described. Volatiles were not trapped and it is unclear if the samples were properly sealed.
4. In order for this study to fulfill the hydrolysis data requirement, the registrant must submit detailed information, including detection limits, about the colorimetric analysis. If acceptable information is not available from the original study, a new study must be submitted.

Degradation - Photodegradation in Water

1. This study cannot be used to fulfill the Photodegradation in Water data requirement at this time.
2. Poly(hexamethylene-biguanide) HCl did not photodegrade in distilled water that was continuously irradiated for 28 days with an artificial light source at 25 C.
3. This study is unacceptable for the following reasons:
 - * the analytical procedure used may have been an unacceptable method because the registrant has not presented data to demonstrate that this colorimetric method determines only PHMB and is free from the interference by possible PHMB degradation products;
 - * the artificial light source used to irradiate the samples was not adequately described;
 - * the irradiation method was not provided; and,
 - * other necessary details and data were not included in the submitted summary. The incubation vessels were not described, the method of collecting samples was not reported, and the number of replicates was not discussed. The sample containers for photolytic incubation were not adequately described. Volatiles were not trapped and it is unclear if the samples were properly sealed.

4. In order for this study to fulfill the Photodegradation in Water data requirement, the registrant must submit detailed information on the following: the colorimetric analysis, including detection limits; the irradiation methods; and the light source. If acceptable information is not available from the original study, a new study must be submitted.

METHODOLOGY:

Degradation - Hydrolysis

Poly(hexamethylene-biguanide) HCl (20% w/w technical formula, ICI) was mixed, at 10 and 20 ppm, with nonsterile aqueous buffer solutions of pH 5 (0.01 M sodium acetate/0.1 M acetic acid), 7 (0.01 M sodium acetate/0.1 M acetic acid), and 9 (0.025 M sodium tetraborate borate/0.9 M acetic acid). The solutions were incubated in the dark at 25 and 45 C. Samples were collected at 0, 8, 14, 21, and 28 days for colorimetric analysis, and at 8, 15, 22, and 39 days for "polarographic analysis".

In order to analyze the sample colorimetrically, immediately after sampling, aliquots (5 mL) of the sample solutions were mixed with 10% sodium tetrahydrate and Eosin Y. The mixture was diluted to 25 mL with water, allowed to develop for 5 minutes, and analyzed for optical density using a spectrophotometer at 550 nm. Samples were compared to a standard calibration curve with optical density versus mg active ingredient.

"Polarographic analysis" was not described.

Degradation - Photodegradation in Water

Poly(hexamethylene-biguanide) HCl (20% w/w technical formula, ICI) was mixed in nonsterile distilled water at 10 ppm. Samples were continuously irradiated with artificial visible and UV light (Specroline Q-225; not further characterized) for 28 days. Samples were in polyethylene cylindrical containers that were 6 inches in diameter and were covered with a "polyethylene film which acted as a filter transparent to visible and UV light above 280 nm". The study author stated that data from the hydrolysis study served as the dark control for the photodegradation experiment.

Samples were analyzed as described above in the hydrolysis methodology section.

DATA SUMMARY:

Degradation - Hydrolysis

Poly(hexamethylene-biguanide) HCl (20% w/w technical formula), at 10 and 20 ppm, did not hydrolyze in nonsterile buffered aqueous solutions of pH 5, 7, and 9 that were incubated in the dark at 25 and

45 C (Table I). After 28 days of incubation, colorimetric analysis of the 10 ppm solution detected 10.3-10.4 ppm of poly(hexamethylene-biguanide) HCl in the solutions incubated at 25 C and 10.4-11.8 ppm in the solutions incubated at 45 C. After 28 days of incubation, colorimetric analysis of the 20 ppm solution detected 19.8-20.6 ppm in the solutions incubated at 25 C and 20.6-21.4 ppm in the solutions incubated at 45 C.

Degradation - Photodegradation in Water

Poly(hexamethylene-biguanide) HCl (20% w/w technical formula), at 10 ppm, did not photodegrade in nonsterile distilled water that was continuously irradiated with artificial light (Spectroline Q-225; light source not further described). After 28 days of continuous irradiation, colorimetric analysis detected 10.4 ppm of poly(hexamethylene-biguanide) HCl (Table III).

COMMENTS:

General

1. Colorimetric methods are often too insensitive to be adequate analytical techniques. The possibility of interferences of the color complex, particularly by poly(hexamethylene-biguanide) HCl degradates, was not addressed. While the method was summarized in the information submitted for this review, detection limits were not reported. This method was compared in the study to a "polarographic" method which was not further described.

In order for this study to be acceptable, the registrant must submit data to demonstrate that this method only analyzes PHMB and the presence of other compounds (including the possible degradation products of PHMB) does not interfere the analysis of the parent. The detection limits for this method must also provided.

2. The documents received for this review were summary documents only. The package contained a registrant summary of MRID 00030785, a 1980 review of MRID 00030785, a study authors' summary/letter regarding the Baquacil Hydrolysis/Photodegradation Study, and the colorimetric method of analyzing for poly(hexamethylene-biguanide) HCl. Necessary details and data were not included with these summary documents.
3. The solutions used in this study were not sterile; however, since the compound appears to be both hydrolytically and photolytically stable, the lack of sterility does not affect the study.
4. The methodology was incomplete. The incubation vessels were not described, the method of collecting samples was not reported, and the number of replicates was not discussed. The sample containers for hydrolytic and photolytic incubation were not adequately described. Volatiles were not trapped and it is unclear if the samples were properly sealed; the study authors noted "a slight upward trend

possibly due to evaporation". The artificial light source was not adequately described, and the intensity and wavelength distribution were not reported.

5. An "absorbance spectra" for poly(hexamethylene-biguanide) HCl at 540 nm was provided with this review. This spectra was a poor copy and the axes were not labeled. It is preferable to have an absorbance spectrum across a range of wavelengths.
6. The effectiveness of the buffers was unknown because their pH was not monitored during the course of the study.