28 JUN 1979

ICI Americas, Inc.
Wilmington, DE 19897

Attention: Judith A. Gleave

Gentlemen:

Subject: Baquacil
EPA File Symbol 10182-RO
Application of May 16, 1978

The review of this product by the Environmental Fate Branch and by the Ecological Effects Branch has been completed.

The following is a review of the environment chemistry data submitted for this product.

1. Hydrolysis

No hydrolysis study submitted per se with this submission. Samples of Baquacil placed into deionized water at pH 5,7, and 9 that were kept in the dark at room temperature (controls for photolysis experiment) indicate that after 20 days 9% hydrolysis occurred at pH 9,16% at pH 5, and 22% at pH 7.0. Regression analysis indicate that corresponding half-lives are calculated as 32, 28 and 59 days respectively. No attempt was made to identify the hydrolysis products and a material balance was not submitted. EFB speculates that hexamethylene diamine and reaction of the end group (cyano) to give guanyl urea may be potential hydrolysis products. It can be assumed that indoor swimming (principal use area) have temperatures above STP and the hydrolysis reaction may increase. This combined with swimming pools (and aquatic systems being the principal reaction sites) lends that a hydrolysis study is needed and the data above submitted can not be used to substitute for a hydrolysis study. This study does not fulfill the data requirement and can not be used to support proposed uses of Baquacil, where this data is required.

2. Photolysis

Solutions of Baquacil (in deionized water) subject to sunlight showed a loss of activity with time; at pH 5, 23% was lost after 20 days; at pH 7.0, 28% was lost; and at pH 9.0, 29% was lost. Controls (pH 7.0) kept in the dark lost 5.9%. No photodegradation occurred after 60 days of exposed Baquacil to artificial light (flourescent). Solutions exposed to mercury pressure lamp (filtered through pyrex) were degradated in five hrs. from 10.4 to 6.6 ug/g and to 0.7 ug/g in 100 hrs. River water containing Baquacil 10.7 ug/g (pH 5.0) was degraded by 83% after 20 days; 76% at pH 7.0, and 100% at pH 8.0. Controls kept in the dark degraded 5.3-8.7%. Author claims microbial degradation is important; however, the rate of degradation in deionized water (in the dark) is the same or less than river water (kept in the dark), which indicates hydrolysis and not microbial attack. This is further substantiated by the activated sludge and soil metabolism studies. Photoproducts were not indentified, although the photoproduct is still polymeric in nature (modification of biguanide group?--based on no eosin color reaction). Hexamethylene diamine is not indicated to occur. Light spectrums submitted indicate UV is partially responsible for the photogradation, although a gap from the 600-700 nm range occurs from the artificial source. The crystallising dishes (were Baquacil solution were placed) were covered with polythene and stored in glasshouses during exposure. What effect this may have is unknown and will have to be clarified before it can be used to support proposed uses of Baquacil.

3. Soil metabolism

After one year only 10-20% of the activity was recovered in etholamine traps for sandy loam (pH 7.0), sandy loam (pH 6.6), and loam soil treated with 1, 10, and 100 kg/ha. Over 50% is bound and of the 50% , 33-40% appears to be polymeric in nature. No attempt was made to identify the extractable metabolites and it was assumed that the activity

in the etholamine traps was 14_{CO2}. Table referenced as to anaerobic soil degradation did not appear to be anaerobic degradation data (by title). The temperature of incubation was not given. Anaerobic soil degradation was not a data requirement outline in the 10/17/73 meeting between ICI and EFB and the deficiencies will not have to be addressed for this use, but may for future uses that require this data. Clarification of above points needs to be resolved before this data can be used to support this proposed use.

4. Activated sludge metabolism

Results indicate that Baquacil is resistant to microbial attack and that at concentrations of 40 mg/l and higher the sludge process is affected such that respiration is inhibited, pH changes to a basic nature (5.5-6.0 to 7.5-8.0) which lends to nitrification inhibition, and suspended solids accumulation. From 10-23% of the material may be discharged into the receiving aquatic environment, (over 25 days) or 1% per day depending on the concentrations of suspended solids (based on adsorption isotherms submitted). No effect is observed on anaerobic sludge digestion from 56-250 mg/l concentration of Baquacil. This is an acceptable activated sludge metabolism study and can be used to support proposed uses of Baquacil.

5. Leaching

The mobility of parent Baquacil determined by TLC analysis indicated very low mobility in calcareuous clay loam, coarse sand, coarse sandy loam and loam soils. In these soils 90-95% of the parent material remained in the top 5 cm of the soil. Some volatilization appears to have occurred during incubation. Soil columns incubated aerobically or anaerobically for four months resulted in 90-95% of the material remaining in the top 5 cm of the soil column. No activity was detected in the leachage. This is an acceptable leaching study and fulfill the data requirement and can be used to support proposed uses of Baquacil.

6. Adsorption

Baquacil adsorbs to sandy loam (pH 6.6), sandy loam (pH 8.0), calcareuous clay loam and coarse sand readily, with equilibrium reached in 1-4 days. Adsorption values at day one were 851, 880, 803, and 540 respectively. These values increased with time and at day seven were 1824, 705, 629, and 816, with a notable exception calcareuous clay loam

which decreased with time. No corresponding desorption values were reported. The leaching study, soil metabolism, and activated sludge study lend to the fact that Baquacil is strongly adsorbed and desorption would not be rapid. The meeting of 10/17/73 did not indicate that adsorption was a requirement for this use. It has been used to support the registration of this chemical (in that sense is acceptable for this use) and if other uses are proposed that have this requirement, desortion values may be required.

7. Ancillary (rat metabolism)

Dosages of 100 ppm Baquacil resulted in c. 90-95% of the compound excreted in the faeces, c. 6% in the urine, 0.6% in the bile and 0.2% in the expired air. Only 20% of the material could be extracted from the faeces and chromatographed similar to Baquacil itself. Dietary exposure resulted in residues in fat (depuration half-life of four weeks) of 1.2 ppm, live (0.8 ppm), kidney (0.1 ppm), and none in the brain. Identification of components in the urine indicate that there are two oligomers of Baquacil with two cyanoguanidine end groups plus 3,3' -dicyano-1, 1-hexamethylenediguanide and 1-(6-aminohexyl)-3-cyanoguanidine. Indications are that the faecal polymer-related material is not metobolized by the gut microorganisms.

Note: Chromatography of this chemical indicated that there were at least ten components of Baquacil and that some are mobile and some are immobile. The mobile ones apparently are excreted in the urine and it may be plausible that the immobile components-fractions are the adsorbed components in soil, activated sludge, etc., with the mobile ones being discharged, desorbed, or extracted from soil or activated sludge.

This is an ancillary study and was reviewed in that context.

8. Recommendations

The fate of this chemical in the environment has not been discerned.

a. The following study is required for this use and was not submitted with this submission (data gap).

(1) Hydrolysis

b. The following studies submitted have deficiencies and/or require clarification.

(1) Soil metabolism, Accession No. 234289, Vol. 6 of 7., Section C. Appendix No. C-26, page 1027. Preliminary laboratory studies of the degradation of ^{14}C-Banquacil in soil.

(a) degradates/metabolites extracted will have to be identified.

(b) temperature of the study was not given.

(c) Figure 2 is claimed to be anaerobic degradation data, however, the title does not indicate this (i.e. is the table correctly identified). Anaeorbic soil degradation is not a requirement for this use and this comment is for the applicant's own information.

(d) these deficiencies/clarifications do not have to be addressed if the applicant attaches a statement to the label such as, "Do not discharge into lake, streams, or ponds."

(2) Photolysis, Accession No. 234289, Vol. 6 of 7., Section C. Appendix No. C-27, page 1055. Preliminary study of the photodegradation in water of Baquacil.

(a) degradative products greater than 10% of applied material will have to be identified.

(b) material balance will have to be submitted.

(c) what effect does the polythene covering on crystallizing dishes have on the photodegradation of Baquacil.

(d) what effect to photolysis does storing the samples in glass houses have (other than simulate indoor pool conditions) to outdoor treated pools.

(e) degradation rates for deionized water (kept in the dark), are less or the same as river water (kept in the dark), which indicates hydrolysis and not microbial attack when compared to photodegradation of Baquacil in river water. Could this photodegradation be mitigated by organic matter in the water?

(f) these deficiencies/clarifications do not have to be addressed if the applicant attaches a statement to the label such as, "Do not discharge into lakes, streams, or ponds."

c. Baquacil is a mixture of three different chemicals, are all three subject to the same rate of degradation in water, soil, and photolysis in water?

The following is a review of the fish and wildlife data submitted for this product.

1. The following studies are not adequate to support registration of Baquacil for the reasons listed.

a. Acute toxicity of Vantocil 1B, mix No. 1857, to bluegill (lepomis macrochirus) and the water flea (Daphnia magna) dated June, 1977, is unacceptable because

Both studies tested the formulated product; tests on the technical material is required for registration. If tests on the formulated product is necessary it may be used.

b. Determination of the acute toxicity to rainbow trout of Vantocil IB in freshwater, February, 1975, by Brixham Laboratory, ICI, LTD. BL/B/1631. Study is unacceptable for the following reasons:

(1) Study tested the formulated product.

(2) Using the ET_{50} to determine LC_{50} is not an acceptable method. If the dose-response data is available to determine a 96-hr. LC_{50} value, the study will be reevaluated and may be used if an LC_{50} value for the formulated product is necessary.

2. Prior to registration of the product the following basic studies must be supplied or referenced for each active ingredient of the product.

a. Avian subacute dietary LC_{50} studies for both wild waterfowl (preferably mallard duck) and upland game bird (preferably bobwhite quail or ring-necked pheasant).

b. Avian acute oral LD_{50} for one of the species tested in (1) above.

c. Fish acute 96-hour LC_{50} studies for one species of warmwater (preferably bluegill sunfish) and for one species of coldwater (preferably rainbow trout) fish.

d. An aquatic invertebrate acute 48-hour LC_{50} study (preferably for Daphnia magna).

Sincerely,

AEC

A.E. Castillo
Product Manager (32)
Disinfectants Branch
Registration Division (TS-767)

TS-767:A.E. Castillo/wcf:TSB224:TX10:#49926:Raven:479-2018:66/13/79
REVISED: TX-767:CASTILLO/wcf:vfd/palJune 15, 1979