11-24-92

DATA EVALUATION RECORD

STUDY IDENTIFICATION:

Sabat, M., and C. C. Yu. 1992. SAN 582 H: Photodegradation Study on Soil. Performed by Metabolism/Pharmacokinetics Section of Sandoz Agro, Inc., Des Plaines, Illinois. MRID No. 422662-08.

TYPE OF STUDY: Photolysis on Soil (161-3)

REVIEWED BY:

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CONCLUSIONS:

1. EFGWB concludes that the submitted study is acceptable and satisfies the data requirement for a soil photolysis study.

2. Based on the results of the study SAN 582 H photodegraded with a reported half-life of 5.3±0.3 days (photodegradation rate of 0.131±0.01 day^{-1}). This corresponds to a half-life of 7.8 days and a photodegradation rate of 0.089 day^{-1} based on sunlight irradiance data in spring at 40°N latitude.

3. The material balance ranged from 93.7% (day 9) to 101.0% (day 0) of applied radioactivity in the irradiated samples and 101.1% in the dark controls.

4. By day 9 parent SAN 582 H (25.1%) and ten other radioactive bands in the ethyl acetate extractable portion were identified by TLC analysis. These bands ranged from 0.8 to 5.4% of applied radioactivity and further identification by TLC cochromatography, HPLC cochromatography, and MS analysis identified band 3 (5.4% of applied) as M9 (the external ring cyclization product of SAN 582 H), band 4 (2.6% at day 9) as M11 (the hydroxylation product of SAN 582 H), and band 5 (2.1% at day 9) as M7 with trace amounts of M20 present. The other bands were not identified.

In the methanol water extract eleven radioactive bands were found by TLC analysis. Further identification (HPLC cochromatography, MS analysis) showed band 1 as parent SAN 582 H (1.9% at day 9) and band 5 as M11 (2.1% at day 9). Attempts to identify the other bands (2, 3, 4, 6-10, and 11) ranging from 0.4 to 5.0% of applied radiocarbon at day 9 were not successful.

5. It was reported that SAN 582 H degraded by light in at least five different pathways (See #2 of Discussion, and Fig. 25).

MATERIALS AND METHODS:

One hundred grams of air dried Kenyon loam soil (28% sand, 46% silt, and 26% clay; organic content 3.2%; CEC 26.2 meq/100g; and pH 7.4) was fortified with 50 mg of ^{14}C-SAN 582 H (specific activity 50.5 mCi/mmol, radiochemical purity 98%) in methanol and thoroughly mixed. After evaporation of the solvent at room temperature, two 10 g portions of the treated soil were taken, wrapped with aluminum foil and kept at 25^{0}C to serve as dark controls. The remaining soil was placed in a 12 inch diameter glass dish equipped with two air hose connectors located on opposite sides. The photolysis dish was equipped with a cooling water jacket to maintain the soil at 25^{0}C. The dish was covered with a quartz glass plate and the volatile products during photolysis were collected in series with silica gel, ethylene glycol, and sodium hydroxide traps. A vacuum pump was attached to the exit of the NaOH trap to draw air through the wash bottle containing distilled water, the glass dish containing the soil, the silica gel trap, the ethylene glycol trap, and the NaOH trap. The glass dish was exposed to a 2500 watt xenon lamp containing borosilicate filters to filter out light below 290 nm. The average light intensity reaching the soil surface was 3.1x10^{6}W-hour/m^{2} which was 1.47 times greater than the sunlight intensity at noon in spring at 40^{0}N latitude. Soil irradiation was conducted non-stop on a twenty-four hour per day basis. It appears that samples (10 g of irradiated soil) were taken on days 0, 2, 6, and 9 after dosing (information extracted from Table III of results). Silica gel, ethylene glycol and NaOH traps were changed at each sampling interval.

At each sampling period triplicate 0.2 g of the soil was subjected to combustion analysis. Duplicate 4 g of each sample was twice extracted with methanol and these extracts were radioassayed and a portion used for TLC analysis.

The residual soil was twice extracted with methanol/water (1:1). The slurry was centrifuged and the liquid portions radioassayed. The residual soil was twice homogenized with 0.5 NaOh and centrifuged. The solid was radioassayed by combustion analysis to determine the amount of unextractable radiocarbon. The combined NaOH extracts were treated with concentrated HCl to pH 1, and the precipitate (Humic acid fraction) was collected by centrifugation. The precipitate was dissolved in 0.5 N NaOH for radioassay. The supernatant (fulvic acid) was also radioassayed.

Parent SAN 582 H and photodegradation products were separated on precoated silica gel plates with fluorescent indicator using two solvent systems: A, chloroform/acetic acid (90:10, v/v); and B, toluene/ethyl acetate (50:50, v/v). Identification of the major products was performed by HPLC and GC-MS analysis followed by comparison with the synthesized model compounds when needed.

REPORTED RESULTS:

1. SAN 582 H photodegraded at a rate of 0.131 ± 0.01 day^{-1} with a reported half-life of 5.3 ± 0.3 days. This corresponds to a half-life of 7.8 days and a photodegradation rate of 0.089 day^{-1} based on sunlight irradiance data in spring at 40^{0}N latitude (Fig. 1).

2. The material balance ranged from 93.7% (day 9) to 101.0% (day 0) of applied radioactivity in the irradiated samples and 101.1% in the dark control (Table III).

3. The ethyl acetate extractable radiocarbon decreased steadily (Table III). By day 9 only 46% of the radiocarbon was extractable with ethyl acetate (95% on day 0). By day 9 the ethyl acetate extractables contained 25.1% parent SAN 582 H and ten other radioactive bands ranging from 0.8 to 5.4% as identified by TLC analysis. Further identification was performed by TLC cochromatography, HPLC cochromatography, and MS analysis (Table III). Band 3 (5.4% at day 9) was identified as M9, the external ring cyclization product of SAN 582 H. Band 4 (2.6% at day 9) was identified as M11, the hydroxylation product of SAN 582 H. Band 5 (2.1% at day 9) was mostly M7, with trace amounts of M20 present.

The secondary methanol/water extraction radiocarbon was 8.6% at day 2 and increased to 14.0% by day 9. In the methanol/water extract eleven radioactive bands were found by TLC analysis. Further identification by HPLC cochromatography and MS analysis identified band 1 as parent SAN 582 H (1.9% at day 9) and band 5 as M11 (2.1% at day 9). Attempts to identify the other bands (2, 3, 4, 6-10, and 11) ranging from 0.4 to 5.0% of radiocarbon at day 9 were not successful. Fulvic acid ranged from 3.8% at day 0 to 10.1% at day 9. Humic acid ranged from 1.8% at day 0 to 15.1% at day 9. SAN 582 H also mineralized to CO_2 (5.8% by day 9).

4. SAN 582 H was reportedly degraded by light in at least five different pathways (Fig. 25).

DISCUSSION:

1. The citing of a protocol in the appendix section in lieu of the material and methods section is not acceptable for reviewing studies and will not be accepted in the future. What actually was done, i.e.-the sampling interval, was not specifically mentioned and it has to be assumed that this interval was as specified in Table III of the results.

2. It was reported that SAN 582 H degraded by light in at least five different pathways (Fig 25). Pathway one is replacement of the chlorine atom by a hydroxyl to form M11. Path two consists of o-demethylation at the methoxy moiety. Path three consists of ring cyclization of the photoproduct from path two. Path four is direct cyclization to the ring methyl of the thiophene ring. Path five is hydroxylation of one of the thiophene ring methyl groups or the thiophene ring proton. SAN 582 H was also reported to degrade and be incorporated into the fulvic acid and humic acid

in the soil and a portion was also mineralized to CO_2.

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