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

SEP 23 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM OF CONFERENCE

SUBJECT: PP#0F3918 -- SAN-582H in/on Corn.

Time/Location: 10:00 A.M., 9/17/92; Rm. 247, CM2.

Participants: Thomas Bade, Ada Breaux, Jim Fickle; Sandoz Agro
Inc. Mike Flood, Jim Stone; EPA.

Representatives of Sandoz met with EPA to discuss CBTS' 7/29/92 review. Deficiencies in the plant and ruminant metabolism studies are being resolved, and a submission is planned for this October. Residue data have already been obtained on one of the two metabolites for which we requested residue data. However the detection limit (LOD) for the sulfonate conjugate of SAN-582H is high (0.1-0.2 ppm). Sandoz explained that the reason for the high LOD is not the chromatography but the varying background levels. They argued that it should be possible to verify the absence of this metabolite at a lower level by examination of individual chromatograms. Without examining these chromatograms we could not comment. The method for the sulfoxide of thiolactic acid conjugate is being developed. Presently the LOD is only 0.2 ppm in forage, but they expect to eventually obtain better sensitivity.

In our 7/29/92 memo we stated that submitted TLC data could not substitute for controlled storage stability studies. In the meeting we explained that there was no problem with TLC data, per se, but any method used to obtain storage stability data must be suitably validated. In particular we must have some idea of the reproducibility of the analyses. [Sandoz's TLC data consisted of radioscan of extracts from the metabolism study. The AMBIS detector used at the conclusion of the study was more accurate than the detector used at the start, and recoveries were generally higher than one hundred per cent.] We suggested that if suitable validation data were developed for the metabolites in soybeans using the TLC method, we would be inclined to accept the data already submitted for corn in support of storage stability.

Product chemistry data required by CBTS/Dynamac's latest review will be submitted.

cc: SF, RF, Circu., Mike Flood, E. Haeberer, Jim Stone (H7505C),
PP#0F3918.



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