

US EPA ARCHIVE DOCUMENT

3F 4177



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

MAR - 9 1994

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for the Proposed Use of Dimethenamid (San 582H) on Soybeans (PP#3F04177)

FROM: Stephen A. Schaible *Stephen A. Schaible*  
Dietary Risk Evaluation Section  
Science Analysis Branch/ HED (7509C)

TO: Cynthia Giles-Parker/James Stone, PM 22  
Fungicide-Herbicide Branch  
Registration Division (7505C)

THROUGH: James P. Kariya, *James P. Kariya* Head  
DRES/SAB  
Health Effects Division (7509C)

Action Requested

Provide estimates of dietary exposure and risk for the proposed use of SAN 582H on soybeans. This permanent tolerance would replace a temporary tolerance on soybeans which expired 3/1/94.

Discussion

1. Toxicological Endpoint: This DRES chronic exposure analysis used a Reference Dose (RfD) of 0.05 mg/kg body weight/day, based on a No Observed Effect Level (NOEL) of 5.1 mg/kg bwt/day and an uncertainty factor of 100 (G. Ghali memorandum to J. Miller, 11/25/92). The NOEL was taken from a two year feeding study in rats which demonstrated as effects parathyroid hyperplasia in males and bile duct hyperplasia in females. There are no data gaps in the studies supporting the RfD.

The HED Carcinogenicity Peer Review Committee has classified SAN 582H as a Group C possible human carcinogen; the committee has also recommended that for the purpose of risk characterization, the Reference Dose approach should be used for quantification of human risk (D. McCall and E. Rinde memo to C. Giles-Parker, 7/15/92).

2. Residue Information: Food uses evaluated in this analysis were the published use on corn grain (at 0.01 ppm) listed in 40 CFR 180.464 and in TIS, and the proposed use on soybeans. While the petition being recommended in favor of by CRTS proposes a



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tolerance of 0.01 ppm; the recommendation is made in M. Bradley's 2/18/94 memo to use a residue of 0.2 ppm for the purpose of assessing dietary exposure and risk. This value represents the total radioactive residue observed in the soybean metabolism study, and is entered in the analysis as the anticipated residue (AR) for soybean commodities. The HED Metabolism Committee concluded no meat or milk tolerances were needed for corn grain (M. Flood memo, 1/4/93), and the feed use of soybean forage, hay and straw is restricted (M. Bradley, 2/18/94); therefore, no meat or milk tolerances are needed for the present uses of SAN 582H.

A summary of the residue information included in this analysis is attached as Table 1.

3. Exposure Analysis: The DRES chronic exposure analysis used tolerance level residues and 100 percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. The Anticipated Residue Contributions (ARCs) for these population groups reflect 100 percent crop treated for both uses, but the recommended residue of 0.2 ppm instead of the proposed tolerance of 0.01 ppm for soybeans. The ARC can therefore be considered to more accurately estimate exposure from the residue of concern. A summary of the TMRCs, the ARCs and their representations as percentages of the RfD is attached as Table 2.

The ARC for the U.S. population from the published use on corn is 0.000003 mg/kg bwt/day, which represents 0.007% of the RfD. The proposed use on soybeans would contribute an additional 0.000068 mg/kg bwt/day, raising the ARC to 0.000071 mg/kg bwt/day, or 0.14% of the RfD. The ARC from the published use for the subgroup most highly exposed, children aged one through six, is 0.000009 mg/kg bwt/day (0.017% of the RfD). If the proposed use on soybeans is added, the ARC is raised to 0.000136 mg/kg bwt/day, or 0.27% of the RfD. Given these risk estimates, it appears that chronic dietary exposure from these uses of SAN 582H is minimal.

#### Attachments

cc: DRES  
CBTS  
Tox 2  
Caswell # 195J

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Table 1

|  |   |  |  |                    |                                     |
|--|---|--|--|--------------------|-------------------------------------|
| SAN 582H<br>Caswell #195J<br>CAS No. 87674-68-8<br>A.I. CODE: 129051<br>CFR No. 180. | STUDY TYPE<br>2yr feeding- fat<br>NOEL= 5.1000 mg/kg<br>100.00 ppm<br>LEL= 36.0000 mg/kg<br>700.00 ppm<br>ONCO: C (HED) | EFFECTS<br>Parathyroid hyperplasia<br>in M; Bile duct hyper-<br>plasia in F (both are<br>threshold effects); Evid-<br>ence of onco in rats (M:<br>liver; F: Ovaries) | REFERENCE DOSES  | DATA GAPS/COMMENTS | STATUS<br>Rfd/PR reviewed 08/13/92. |
|  |   |  | ADI<br>UF -->100<br>OPP Rfd= 0.050000<br>EPA Rfd= 0.000000 | No data gaps.      |                                     |

| FOOD CODE | FOOD             | FOOD FORM                         | PET.#  | TOLERANCE (ppm) | ANTICIPATED RESIDUE (ppm) | AR STATISTIC TYPE | % CROP TREATED | RES. VALUE USED IN TAS RUN (ppm) |
|-----------|------------------|-----------------------------------|--------|-----------------|---------------------------|-------------------|----------------|----------------------------------|
| 15029AA   | SOYBEAN-SPROUTED | 00 NOT SPECIFIED (NO CONSUMPTION) | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 24002EA   | CORN, GRAIN-ENDO | 10 RAW-FRESH OR NFS               | 0F3918 | P 0.010000      | 0.010000                  |                   | 100.00         | 0.010000                         |
| 24002EA   | CORN, GRAIN-ENDO | 21 COOKED-NFS                     | 0F3918 | P 0.010000      | 0.010000                  |                   | 100.00         | 0.010000                         |
| 24002EA   | CORN, GRAIN-ENDO | 22 COOKED-FRESH-BAKED             | 0F3918 | P 0.010000      | 0.010000                  |                   | 100.00         | 0.010000                         |
| 24002EA   | CORN, GRAIN-ENDO | 23 COOKED-FRESH-BOILED            | 0F3918 | P 0.010000      | 0.010000                  |                   | 100.00         | 0.010000                         |
| 24002HA   | CORN, GRAIN-BRAN | 00 NOT SPECIFIED (NO CONSUMPTION) | 0F3918 | P 0.010000      | 0.010000                  |                   | 100.00         | 0.010000                         |
| 24002SA   | CORN SUGAR       | 10 RAW-FRESH OR NFS               | 0F3918 | P 0.010000      | 0.010000                  |                   | 100.00         | 0.010000                         |
| 24002SA   | CORN SUGAR       | 21 COOKED-NFS                     | 0F3918 | P 0.010000      | 0.010000                  |                   | 100.00         | 0.010000                         |
| 24002SA   | CORN SUGAR       | 22 COOKED-FRESH-BAKED             | 0F3918 | P 0.010000      | 0.010000                  |                   | 100.00         | 0.010000                         |
| 270020A   | CORN, GRAIN-OIL  | 18 PROCESSED OIL                  | 0F3918 | P 0.010000      | 0.010000                  |                   | 100.00         | 0.010000                         |
| 270100A   | SOYBEANS-OIL     | 18 PROCESSED OIL                  | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023AA   | SOYBEANS-UNSPEC  | 21 COOKED-NFS                     | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023AB   | SOYBEANS-DRY     | 10 RAW-FRESH OR NFS               | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023AB   | SOYBEANS-DRY     | 21 COOKED-NFS                     | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023AB   | SOYBEANS-DRY     | 23 COOKED-FRESH-BOILED            | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023AB   | SOYBEANS-DRY     | 25 COOKED-FRESH-FRIED             | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023AB   | SOYBEANS-DRY     | 31 COOKED-FRESH OR CANNED         | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023WA   | SOY-FL, FULL FAT | 21 COOKED-NFS                     | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023WA   | SOY-FL, FULL FAT | 22 COOKED-FRESH-BAKED             | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023WA   | SOY-FL, FULL FAT | 31 COOKED-FRESH OR CANNED         | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023WB   | SOY-FL, LOW FAT  | 21 COOKED-NFS                     | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023WC   | SOY-FL,DEFAT     | 10 RAW-FRESH OR NFS               | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023WC   | SOY-FL,DEFAT     | 21 COOKED-NFS                     | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023WC   | SOY-FL,DEFAT     | 22 COOKED-FRESH-BAKED             | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023WC   | SOY-FL,DEFAT     | 51 COOKED-CANNED                  | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |
| 28023WC   | SOY-FL,DEFAT     | 53 COOKED-CANNED-BOILED           | 3F4177 | N 0.010000      | 0.200000                  |                   | 100.00         | 0.200000                         |

0.2 represents total radio-active residue (M.Bradley memo to C.Giles-Parker, 2/18/94)

Table 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 03/07/94

PAGE: 1

| CHEMICAL INFORMATION   | STUDY TYPE  | EFFECTS   | REFERENCE DOSES   | DATA GAPS/COMMENTS | STATUS                    |
|--|---|---|---|--------------------|---------------------------|
| SAN 582H<br>Caswell #195J<br>CAS No. 87674-68-8<br>A.I. CODE: 129051<br>CFR No. 180. | 2yr feeding- rat<br>NOEL= 5,1000 mg/kg<br>100.00 ppm<br>LEL= 36,0000 mg/kg<br>700.00 ppm<br>ONCO: C (HED) | Parathyroid hyperplasia<br>in M; Bile duct hyper-<br>plasia in F (both are<br>threshold effects); Evid-<br>ence of onco in rats (M;<br>liver; F: Ovaries) | ADI UF -->100<br>OPP RFD= 0.050000<br>EPA RFD= 0.000000 | No data gaps.      | RFD/PR reviewed 08/13/92. |

| POPULATION SUBGROUP                             | TOTAL TMRC (MG/KG BODY WEIGHT/DAY) |            | DIFFERENCE AS PERCENT OF RFD | EFFECT OF ANTICIPATED RESIDUES |         |
|---|------------------------------------|------------|------------------------------|--------------------------------|---------|
|   | CURRENT TMRC*                      | NEW TMRC** |                              | ARC                            | %RFD    |
| U.S. POPULATION - 48 STATES                     | 0.000003                           | 0.000007   | 0.006800                     | 0.000071                       | 0.14264 |
| U.S. POPULATION - SPRING SEASON                 | 0.000003                           | 0.000007   | 0.006560                     | 0.000069                       | 0.13767 |
| U.S. POPULATION - SUMMER SEASON                 | 0.000003                           | 0.000007   | 0.006782                     | 0.000071                       | 0.14246 |
| U.S. POPULATION - FALL SEASON                   | 0.000003                           | 0.000007   | 0.007018                     | 0.000074                       | 0.14713 |
| U.S. POPULATION - WINTER SEASON                 | 0.000003                           | 0.000007   | 0.006838                     | 0.000072                       | 0.14333 |
| NORTHEAST REGION                                | 0.000002                           | 0.000005   | 0.006152                     | 0.000064                       | 0.12777 |
| NORTH CENTRAL REGION                            | 0.000003                           | 0.000006   | 0.006836                     | 0.000071                       | 0.14279 |
| SOUTHERN REGION                                 | 0.000004                           | 0.000007   | 0.006852                     | 0.000073                       | 0.14517 |
| WESTERN REGION                                  | 0.000004                           | 0.000008   | 0.007518                     | 0.000079                       | 0.15815 |
| HISPANICS                                       | 0.000006                           | 0.000010   | 0.007104                     | 0.000077                       | 0.15401 |
| NON-HISPANIC WHITES                             | 0.000003                           | 0.000006   | 0.006854                     | 0.000071                       | 0.14298 |
| NON-HISPANIC BLACKS                             | 0.000005                           | 0.000008   | 0.006328                     | 0.000068                       | 0.13582 |
| NON-HISPANIC OTHERS                             | 0.000003                           | 0.000006   | 0.006516                     | 0.000068                       | 0.13629 |
| NURSING INFANTS (< 1 YEAR OLD)                  | 0.000003                           | 0.000007   | 0.007782                     | 0.000081                       | 0.16199 |
| NON-NURSING INFANTS (< 1 YEAR OLD)              | 0.000010                           | 0.000026   | 0.032616                     | 0.000336                       | 0.67187 |
| FEMALES (13+ YEARS, PREGNANT)                   | 0.000002                           | 0.000005   | 0.004532                     | 0.000048                       | 0.09534 |
| FEMALES 13+ YEARS, NURSING                      | 0.000002                           | 0.000005   | 0.005956                     | 0.000062                       | 0.12334 |
| CHILDREN (1-6 YEARS OLD)                        | 0.000009                           | 0.000015   | 0.012724                     | 0.000136                       | 0.27179 |
| CHILDREN (7-12 YEARS OLD)                       | 0.000006                           | 0.000011   | 0.009784                     | 0.000104                       | 0.20819 |
| MALES (13-19 YEARS OLD)                         | 0.000004                           | 0.000007   | 0.007056                     | 0.000074                       | 0.14878 |
| FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING) | 0.000003                           | 0.000006   | 0.005886                     | 0.000062                       | 0.12394 |
| MALES (20 YEARS AND OLDER)                      | 0.000002                           | 0.000005   | 0.005396                     | 0.000056                       | 0.11215 |
| FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS) | 0.000002                           | 0.000004   | 0.004810                     | 0.000050                       | 0.09988 |

\*Current TMRC does not include new or pending tolerances.

\*\*New TMRC includes new, pending, and published tolerances.

TOLERANCE ASSESSMENT SUMMARY FOR SAN 582H  
USING ANTICIPATED RESIDUES  
CASWELL #195J

DATE: 03/07/94

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)  
RESULT IN AN ARC OF: 0.000003 MG/KG/DAY  
THE EXISTING ARC IS EQUIVALENT TO: 0.007 % OF THE ADI.

PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)  
RESULT IN AN ARC OF: 0.000068 MG/KG/DAY  
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY: 0.136 % OF THE ADI.

IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)  
ARE APPROVED THE RESULTANT ARC WILL BE: 0.000071 MG/KG/DAY  
THE NEW ARC WILL OCCUPY 0.143 % OF THE ADI.

NO OTHER PENDING ANTICIPATED RESIDUES ARE IN THE FILE

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)  
RESULT IN AN ARC OF: 0.000010 MG/KG/DAY  
THE EXISTING ARC IS EQUIVALENT TO: 0.020 % OF THE ADI.

PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)  
RESULT IN AN ARC OF: 0.000326 MG/KG/DAY  
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY: 0.652 % OF THE ADI.

IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)  
ARE APPROVED THE RESULTANT ARC WILL BE: 0.000336 MG/KG/DAY  
THE NEW ARC WILL OCCUPY 0.672 % OF THE ADI.

NO OTHER PENDING ANTICIPATED RESIDUES ARE IN THE FILE

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)  
RESULT IN AN ARC OF: 0.000009 MG/KG/DAY  
THE EXISTING ARC IS EQUIVALENT TO: 0.017 % OF THE ADI.

PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)  
RESULT IN AN ARC OF: 0.000127 MG/KG/DAY  
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY: 0.254 % OF THE ADI.

IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)  
ARE APPROVED THE RESULTANT ARC WILL BE: 0.000136 MG/KG/DAY  
THE NEW ARC WILL OCCUPY 0.272 % OF THE ADI.

NO OTHER PENDING ANTICIPATED RESIDUES ARE IN THE FILE

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