



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

JUN 18 1990

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for the Proposed Use of  
Nicosulfuron (Accent) on Corn, PP#9F3763.

FROM: James P. Kariya *Kariya*  
Dietary Risk Evaluation System (DRES) Staff  
HED/SACB (H7509C)

TO: Robert Taylor, PM-25  
Fungicide-Herbicide Branch  
Registration Division (H7505C) *Robert Taylor*

Action Requested

Estimate the risk of adverse health effects from dietary exposure to Accent through the proposed use on corn.

Discussion

1. Toxicology Endpoint: The routine chronic DRES analysis used a reference dose (RfD) of 1.25 mg/kg body weight/day, based upon a NOEL of 125 mg/kg body weight/day and an uncertainty factor of 100 from a 1-year feeding study in dogs. Effects of concern include decreased gain in body weight, and increased relative liver and kidney weights. The RfD was approved by the HED reference dose committee on 6-14-90, but has not been reviewed by the EPA RfD Committee.

2. Residue Information: There are no published tolerances for Accent. The current analysis includes only the proposed tolerance on corn grain (0.1 ppm). Since there is no human consumption of corn forage, corn fodder, or corn silage, the proposed tolerances on these commodities have not been used.

The Dietary Exposure Branch concluded that tolerances for milk, meat, fat, or meat by-products are not needed (memo, J.B. Stokes to R. Taylor, 6-13-90, page 2), so these commodities are not included in the DRES run.

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

3. Exposure Analysis: The DRES chronic exposure analysis uses tolerance level residues and 100 per cent crop treated to estimate

the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. Results of the DRES analysis are given in Table 2.

4. Comments: Given the assumptions listed in section 2 above, the proposed tolerance on corn grain is likely to lead to exposures that are well below 1/100th of 1 percent of the RfD (the level below which no effects are likely to occur if exposure occurs continuously for a lifetime). Risk is likely to be even less if, as noted in the DEB memo (J.B. Stokes to R. Taylor, 6-13-90, page 10) the levels in corn are below 0.05 ppm rather than the 0.1 ppm level assumed for this DRES run. Finally, please note that this DRES analysis assumed a concentration factor of 1.5 for corn sugar, which may also lead to an overestimate of the risk.

Although the risk of effects from chronic exposure appears to be negligible, and although there is no reason to believe that Accent causes effects through acute exposures, it should be noted that this substance has not been rated for its carcinogenic potential. Therefore, no conclusion can be made at this time concerning the presence, absence, or degree of risk of carcinogenicity.

Attachments

cc: DRES (Kariya), DEB (Loranger), Caswell #359J, G. Ghali

Table 1.

## TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 06/14/90

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| CHEMICAL INFORMATION |  | STUDY TYPE           |  | EFFECTS                                                                   |  | REFERENCE DOSES                                         |  | DATA GAPS/COMMENTS                          |  | STATUS                    |  |
|----------------------|--|----------------------|--|---------------------------------------------------------------------------|--|---------------------------------------------------------|--|---------------------------------------------|--|---------------------------|--|
| Accent (IN V9360-7)  |  | 1yr feeding- dog     |  | Decreased body wt gain; increased relative liver & kidney weights.        |  | ADI UF -->100<br>OPP RfD= 1.250000<br>EPA RfD= 0.000000 |  | No data gaps.                               |  | RfD/PR complete 06/14/90. |  |
| Caswell #359J        |  | NOEL= 125.0000 mg/kg |  |                                                                           |  |                                                         |  |                                             |  |                           |  |
| CAS No. 111991-09-4  |  | 5000.00 ppm          |  |                                                                           |  |                                                         |  |                                             |  |                           |  |
| A.I. CODE: 129008    |  | LEL= 500.0000 mg/kg  |  | Onco classification pending submission of historical control information. |  |                                                         |  | Does not require Developmental Peer Review. |  |                           |  |
| CFR No. 180.         |  | 20000.00 ppm         |  |                                                                           |  |                                                         |  |                                             |  |                           |  |
|                      |  | ONCO: Pending.       |  |                                                                           |  |                                                         |  |                                             |  |                           |  |

## LISTING OF EXPOSURE BY RAC FOR: U.S. POPULATION - 48 STATES

| FOOD CODE                            | FOOD NAME             | -----TOLERANCE (PPM)----- |         | --EXISTING TOLERANCES-- |                     | --NEW & PENDING TOLERANCES-- |                     |
|--------------------------------------|-----------------------|---------------------------|---------|-------------------------|---------------------|------------------------------|---------------------|
|                                      |                       | NEW                       | PENDING | PUBLISHED               | TMRC<br>(UG/KG/DAY) | %RfD                         | TMRC<br>(UG/KG/DAY) |
| 24002EA                              | CORN, GRAIN-ENDOSPERM | 0.10000                   |         |                         | 0.016540            | 0.0013                       |                     |
| 24002HA                              | CORN, GRAIN-BRAN      | 0.10000                   |         |                         | 0.000000            | 0.0000                       |                     |
| 24002SA                              | CORN SUGAR            | 0.10000                   |         |                         | 0.014575            | 0.0011                       |                     |
| 270020A                              | CORN, GRAIN-OIL       | 0.10000                   |         |                         | 0.002280            | 0.0001                       |                     |
| CROP GROUP TOTALS FOR CEREAL GRAINS: |                       |                           |         |                         |                     |                              |                     |
| GRAND TOTAL TMRC:                    | 0.033395              |                           |         | 0.0027                  | 0.033395            | 0.0027                       |                     |

|                            |          |                               |        |  |        |          |        |
|----------------------------|----------|-------------------------------|--------|--|--------|----------|--------|
| POPULATION SUBGROUP TOTALS |          |                               |        |  |        |          |        |
| POPULATION TOTAL TMRC      | 0.033395 | POPULATION TOTAL % OF THE RfD | 0.0026 |  | 0.0000 | 0.033395 | 0.0026 |

Table 2.

## TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 06/14/90

PAGE: 1

| CHEMICAL INFORMATION |                     | STUDY TYPE                          | EFFECTS                                                                      | REFERENCE DOSES                                         | DATA GAPS/COMMENTS                          | STATUS                    |
|----------------------|---------------------|-------------------------------------|------------------------------------------------------------------------------|---------------------------------------------------------|---------------------------------------------|---------------------------|
| Accent (IN V9360-7)  |                     | 1yr feeding- dog                    | Decreased body wt gain;<br>increased relative liver<br>& kidney weights.     | ADI UF -->100<br>OPP RfD= 1.250000<br>EPA RfD= 0.000000 | No data gaps.                               | RfD/PR complete 06/14/90. |
| Caswell #359J        | CAS No. 111991-09-4 | NOEL= 125.0000 mg/kg<br>5000.00 ppm | Onco classification pending<br>submission of historical control information. |                                                         | Does not require Developmental Peer Review. |                           |
| A.I. CODE: 129008    |                     | LEL= 500.0000 mg/kg<br>20000.00 ppm |                                                                              |                                                         |                                             |                           |
| CFR No. 180.         |                     | ONCO: Pending.                      |                                                                              |                                                         |                                             |                           |

| POPULATION SUBGROUP                             | TOTAL TMRC (MG/KG BODY WEIGHT/DAY) |            | NEW TMRC             |                      | DIFFERENCE           |     | EFFECT OF ANTICIPATED RESIDUES |  |
|-------------------------------------------------|------------------------------------|------------|----------------------|----------------------|----------------------|-----|--------------------------------|--|
|                                                 | CURRENT TMRC*                      | NEW TMRC** | AS PERCENT<br>OF RFD | AS PERCENT<br>OF RFD | AS PERCENT<br>OF RFD | ARC | %RFD                           |  |
| U.S. POPULATION - 48 STATES                     | 0.000000                           | 0.000033   | 0.002672             | 0.002672             | 0.002672             |     |                                |  |
| U.S. POPULATION - SPRING SEASON                 | 0.000000                           | 0.000032   | 0.002598             | 0.002598             | 0.002598             |     |                                |  |
| U.S. POPULATION - SUMMER SEASON                 | 0.000000                           | 0.000034   | 0.002729             | 0.002729             | 0.002729             |     |                                |  |
| U.S. POPULATION - FALL SEASON                   | 0.000000                           | 0.000034   | 0.002727             | 0.002727             | 0.002727             |     |                                |  |
| U.S. POPULATION - WINTER SEASON                 | 0.000000                           | 0.000033   | 0.002632             | 0.002632             | 0.002632             |     |                                |  |
| NORTHEAST REGION                                | 0.000000                           | 0.000024   | 0.001898             | 0.001898             | 0.001898             |     |                                |  |
| NORTH CENTRAL REGION                            | 0.000000                           | 0.000030   | 0.002415             | 0.002415             | 0.002415             |     |                                |  |
| SOUTHERN REGION                                 | 0.000000                           | 0.000041   | 0.003242             | 0.003242             | 0.003242             |     |                                |  |
| WESTERN REGION                                  | 0.000000                           | 0.000039   | 0.003103             | 0.003103             | 0.003103             |     |                                |  |
| HISPANICS                                       | 0.000000                           | 0.000060   | 0.004760             | 0.004760             | 0.004760             |     |                                |  |
| NON-HISPANIC WHITES                             | 0.000000                           | 0.000030   | 0.002363             | 0.002363             | 0.002363             |     |                                |  |
| NON-HISPANIC BLACKS                             | 0.000000                           | 0.000046   | 0.003710             | 0.003710             | 0.003710             |     |                                |  |
| NON-HISPANIC OTHERS                             | 0.000000                           | 0.000030   | 0.002391             | 0.002391             | 0.002391             |     |                                |  |
| NURSING INFANTS (< 1 YEAR OLD)                  | 0.000000                           | 0.000032   | 0.002538             | 0.002538             | 0.002538             |     |                                |  |
| NON-NURSING INFANTS (< 1 YEAR OLD)              | 0.000000                           | 0.000098   | 0.007817             | 0.007817             | 0.007817             |     |                                |  |
| FEMALES (13+ YEARS, PREGNANT)                   | 0.000000                           | 0.000023   | 0.001871             | 0.001871             | 0.001871             |     |                                |  |
| FEMALES 13+ YEARS, NURSING                      | 0.000000                           | 0.000021   | 0.001678             | 0.001678             | 0.001678             |     |                                |  |
| CHILDREN (1-6 YEARS OLD)                        | 0.000000                           | 0.000087   | 0.006927             | 0.006927             | 0.006927             |     |                                |  |
| CHILDREN (7-12 YEARS OLD)                       | 0.000000                           | 0.000063   | 0.005008             | 0.005008             | 0.005008             |     |                                |  |
| MALES (13-19 YEARS OLD)                         | 0.000000                           | 0.000038   | 0.003063             | 0.003063             | 0.003063             |     |                                |  |
| FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING) | 0.000000                           | 0.000031   | 0.002494             | 0.002494             | 0.002494             |     |                                |  |
| MALES (20 YEARS AND OLDER)                      | 0.000000                           | 0.000021   | 0.001674             | 0.001674             | 0.001674             |     |                                |  |
| FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS) | 0.000000                           | 0.000018   | 0.001460             | 0.001460             | 0.001460             |     |                                |  |

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

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