

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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

### MEMORANDUM

SUBJECT: PP#6E3385. Simazine in or on stone fruit. Accession

> No. 261898. RCB No. 828.

FROM: Linda S. Propst. Chemist

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THRU:

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TO:

Hoyt Jamerson, PM 43

Emergency Response and Minor Use Section

Registration Division (TS-767)

Interregional Research Project No. 4 on behalf of the IR-4 National Director, Dr. R. H. Kupelian and the Agricultural Experiment Stations of California, Oregon, Washington, and the U.S. Department of Agriculture requests the establishment of a tolerance for the residues of the herbicide simazine (2-chloro-4,6-bis(ethylamino)-striazine) in or on the raw agricultural commodity group stone fruit (which includes apricots, sweet and sour cherries, nectarines, peaches, plums, and prunes) at 0.25 ppm.

Tolerances have already been established for residues of simazine in or on peaches, plums, and cherries at 0.25 ppm (40 CFR 180. 213). More recent tolerances for bananas and fish have been established for simazine and its two chloro metabolites, the mono-desethyl metabolite, 2-amino-4-chloro-6-ethylamino-s-triazine (G-28279) and the di-desethyl metabolite, 2,4-diamino- $6-\overline{chloro}$ -s-triazine (G-28273) (See 40 CFR.213a).

As a result of a decision made in the September 27, 1984 Policy Group meeting of the Office of Pesticide Programs (OPP), all new tolerances for the herbicide simazine must include the parent compound, the two chloro metabolites, and one additional hydroxy metabolite which has recently been recognized as a toxicological concern, 2,4-ethylamino-6-hydroxy-s-triazine (G-30414).

Ciba-Geigy Corporation has submitted a letter (Carolyn F. Brinkley, Regulatory Specialist, Ciba-Geigy Corporation) to Hoyt Jamerson (Minor Uses Officer, EPA) authorizing the use of all simazine data, submitted by Ciba-Geigy Corporation to EPA,

which are necessary to support the IR-4 request to establish tolerances in or on the raw agricultural commodity group stone fruit.

The Product Chemistry and Residue Chemistry chapters for the Simazine Registration Standard were completed 10/13/83.

### CONCLUSIONS

- 1. The metabolism in plants and animals is adequately understood. As of the 9/27/84 OPP Policy Group meeting, the residues of concern are considered to be the parent simazine, the two chloro metabolites, the mono-desethyl metabolite, (G-28279), 2-amino-4-chloro-6-ethylamino-s-triazine and the di-desethyl metabolite (G-28273), 2,4-diamino-6-chloro-s-triazine and the additional, toxicologically significant hydroxy metabolite, (G-30414), 2,4-ethylamino-6-hydroxy-s-triazine. Future tolerances for residues of simazine should include simazine, the two chloro metabolites and the hydroxy metabolite as part of the tolerance expression.
- 2. We defer a conclusion that adequate methodology is available for enforcement purposes in determining residues of simazine plus metabolites in or on stone fruit pending receipt of validated methodology with accompanying chromatograms demonstrating sensitivity that would support such a conclusion.
- 3a. The Simazine Registration Standard 10/13/83 has concluded that adequate residue data are not available to assess the adequacy of the 0.25 ppm tolerance covering simazine residues which may occur in or on peaches (a representative crop) from the currently registered uses. The geographic representation is inadequate.
- 3b. In addition to 3a, no analyses were performed for the mono-desethyl and di-desethyl metabolites or the hydroxy metabolite. In the absence of such data we are unable to draw any conclusion as to an appropriate tolerance level on stone fruit.
- 4. There are no feed items associated with stone fruit. Therefore, there should be no problem with secondary residues in meat, milk, poultry, and eggs as a result of the proposed use, providing a grazing and feeding restriction of cover crops to animals is included on the label.
- 5. An International Residue Limits Status sheet is attached. No simazine tolerances are established with Codex for stone fruit. Hence, no compatability questions exist with respect to Codex.

# RECOMMENDATIONS

We recommend that the proposed group tolerance on stone fruit not be established for the reasons stated in Conclusions 2, 3a and 3b.

For further consideration, the petitioner should be advised to do the following:

- Impose a restriction on the label against the grazing or feeding of cover crops to livestock.
- 2. Submit validated methodology with accompanying chromatograms for measuring residues of simazine plus the mono-desethyl, the di-desethyl, and the hydroxy metabolites in or on stone fruit.
- 3. Submit residue data for peaches as requested in the Simazine Registration Standard 10/13/83 which should include residues of the mono-desethyl, the di-desethyl, and the hydroxy metabolites as well as the parent compound. This residue data should be reflective of the proposed use.

### DETAILED CONSIDERATIONS

## Manufacture and Formulation

See Confidential Appendix.

The formulations proposed for use on stone fruit are Princep® 80W (EPA Registration #100-437) and Princep® Caliper® 90 (EPA Registration #100-603).

Princep® 80W contains 80% technical simazine and 20% inerts in a water dispersible product. Princep® Caliper® 90 contains 90% active ingredients in a water dispersible granule form.

All inerts in the proposed formulations are cleared under Section 180.1001. The formulations and purities have been discussed previously in petitions PP#2E2735 dated 11/3/82 by M.J. Nelson and and PP#3F1378 dated 9/20/73 by D. Reed.

# Proposed Use

For stone fruit grown outside the state of California, apply 2.0 - 4.0 lbs. simazine a.i. per acre to the orchard floor. Apply in late fall to early spring prior to weed emergence. Avoid contact with foliage. Make only one application per year.

For stone fruit grown in the state of California, apply 1.0 - 2.0 lbs simazine a.i. per treated acre in a 2 - 4 ft. band on each side of tree row. Apply before weeds emerge in late fall or early winter. Avoid contact with foliage. Make only one application per year.

A grazing restriction should be placed on the label or the registrant may submit a petition along with data reflecting combined residues of simazine plus its two chloro and one hydroxy metabolites which may occur on cover crops as a result of the proposed use.

### Nature of the Residue

No new metabolism studies were submitted with this petition. Previous studies have shown that simazine is metabolized via dealkylation, hydrolysis and/or conjugate formation in plants and animals (See memos by E. Kovach, 6/15/67, PP#7F0534; D. Reed, 9/20/73, PP#3F1378; and R. Perfetti, 4/2/79, PP#8E2069).

As of the 9/27/84 OPP Policy Group meeting, the residues of concern are considered to be the parent simazine, the two chloro metabolites (the mono-desethyl metabolite, G-28279, and the di-desethyl metabolite, G-28273) as well as the hydroxy metabolite, 2,4-ethylamino-6-hydroxy-s-triazine (G-30414).

The parent simazine, the mono- and di-desethyl metabolites, and the hydroxy metabolite, which has recently been recognized as being of toxicological significance, should all be included in the tolerance expression for stone fruit and for future tolerance petitions.

### Analytical Methodology

No residue data were submitted with this petition. The analytical method used to generate the residue data submitted in conjunction with PP#7F0534 determined parent simazine only. This method consisted of an alumina column clean-up, hydrolysis for the conversion of simazine to hydroxysimazine, and UV spectrophotometric determination using a base-line correction.

RCB concluded in the Simazine Registration Standard 10/13/83 that the above method is adequate for generating residue data but not for enforcement purposes.

The residue of concern for regulatory purposes consists of the combined residues of the parent simazine, its two chloro (monoand di-desethyl) metabolites, 2-amino-4-chloro-6-ethylamino-s-triazine (G-28279) and 2,4-diamino-6-chloro-s-triazine-(G-28273), respectively, as well as the hydroxy metabolite, 2-ethylamino-4-ethylamino-6-hydroxy-s-triazine. An analytical procedure that determines parent simazine, its mono- and di- desethyl metabolites, plus the hydroxy metabolite is needed. Such a procedure will require validation data as well as a successful method trial on stone fruit before a tolerance may be granted on the stone fruit crop grouping.

We defer a conclusion that adequate methodology is available for purposes of measuring residues of simazine plus metabolites in or on stone fruit pending receipt of validated methodology with accompanying chromatograms demonstrating sensitivity that would support such a conclusion.

### Residue Data

Cherries - In conjunction with PP#7F0534, Ciba-Geigy Corp. submitted five tests from Wisconsin, two tests from Michigan, and a single trial from Oregon representing 15 samples. Residues of intact

simazine in or on cherries were <0.09 ppm 2.3 months after single directed applications of the 80% WP at 2.5-40 lb. ai/A except for one case: one of two samples from trees treated at 20 lb ai/A (5X the recommended rate) showed a simazine residue of 0.44 ppm.

Peaches - The simazine residue data on peaches available in our files consist of a total of 35 samples from five tests conducted in California, three tests each in Pennsylvania and New Jersey, two tests performed in Maryland, and a single trial in Florida. Residues of intact simazine were <0.04 ppm in or on peaches 1.5 - 8 months after treatment with single directed applications of the 80% WP at <16 lb a.i./A.

Plums - Residue data of simazine on plums submitted in conjunction with PP#7F0534 consists of a total of 20 samples from 10 tests conducted in California, three tests from Pennsylvania, and one trial each from Oregon and Michigan. Residues of intact simazine in fresh plums and prunes were non-detectable (<0.04 ppm) 4-8 months after single directed applications of the 80% WP at <16 lb ai/A.

RCB reiterates here the conclusion given in the Simazine Registration Standard, i.e., a stone fruits group tolerance is currently not appropriate since sufficient data are not available to assess the adequacy of the 0.25 ppm tolerance covering simazine residues which may occur in or on peaches (a representative crop) from the currently registered uses. The available tests for California are adequate to satisfy data requirements for that state; however, the single sample submitted from Florida does not constitute sufficient representation for South Carolina and Georgia. Thus, geographic representation is not adequate.

# Residues in Meat, Milk, Poultry and Eggs

There are no feed items associated with stone fruits. Therefore, there should be no problem with secondary residues in meat, milk, poultry or eggs as a result of the proposed use, providing an additional restriction is placed on the label prohibiting the grazing or feeding of cover crops to animals.

## Other Considerations

An International Residue Limits (IRL) Status sheet is attached. No simazine tolerances are established with Codex for stone fruit. There is, however, a general Canadian limit of 0.1 ppm on citrus and pear orchards and several small berries. The Canadian tolerance is for the parent simazine only, expressed as 2-chloro-4,6-di(ethylamino)-1,3,5-triazine. No compatibility questions exist with this petition with respect to Codex.

Attachment 1: Codex sheet (copies to all cc's and addressees)
Attachment 2: Confidential Appendix (copies to TOX, PM 43,
PP#6E3385, Reading File, L. Propst, and PMSD/ISB only)
cc: Reading File, Circulation, Propst, TOX, EEB, EAB, PP#6E3385,
FDA, Robert Thompson, Frank Boyd, PMSD/ISB
RDI: A. R. Rathman, 6/30/86; R. D. Schmitt, 6/30/86
TS-769:RCB:LSP:lsp:CM#2:Rm810:557-7324:6/30/86