

application of a.i., targeting a rate of 1.0 lb a.i./acre. The spinach was harvested 45 to 56 days after the application. No residues of CGA-49751 were detected above the LOQ, 0.05 ppm, in spinach samples from two of the three remaining sites. CGA-49751 was detected at 0.1 ppm in one treated sample from Arkansas. Residues of CGA-37913 were detected above the LOQ in samples from all three field sites. The CGA-37913 residues ranged from < 0.10 ppm to 0.33 ppm. The resulting maximum total combined residues of CGA-49751 + CGA-37913 in samples treated at the 1.0 lb a.i./acre rate is < 0.38 ppm.

In 1995, eight field trials were conducted in Maryland, Michigan, New Jersey, Texas, and California. Each of the eight trials consisted of at least an untreated control and one treated plot, where the treated plot received one post-seeding, pre-emergence, broadcast application of a.i., targeting a rate of 1.0 lb a.i./acre. The California and Texas trials also included a second treated plot, which received post-seeding, pre-emergence, broadcast application of a.i., targeting a rate of 2.0 lbs a.i./acre. The spinach was harvested 34 to 69 days after the application. The residues found in 1995 spinach samples, treated targeting the 1.0 lb a.i./acre rate, ranged from less than the LOQ, 0.05 ppm, to 0.85 ppm of CGA-49751, and ranged from less than the LOQ, 0.03 ppm, to 0.107 ppm for CGA-37913 for a maximum combined residue of 0.174 ppm. In the spinach samples treated targeting the 2.0 lbs a.i./acre rate, CGA-49751 residues ranged from < 0.05 ppm to 0.188 ppm and CGA-37913 residues ranged from 0.032 ppm to 0.075 ppm. The maximum combined residues for a.i. at the 2.0 lbs a.i./acre application rate is 0.263. The maximum residues found in or on spinach treated with the proposed labeled rate of 1.0 lbs a.i./acre, was < 0.38 ppm for the combined residues of CGA-37913 and CGA-49741. Residues in spinach treated at the 2.0 lbs a.i./acre application rate did not exceed this combined residues, with a maximum combined residue of 0.263 ppm. IR-4 is conducting additional research to support the 2.0 lbs a.i./acre application rate.

ii. *Sugarbeets*. Eleven sugar beet trials were conducted using six different treatment scenarios. The maximum 1X use rate was 4.0 lbs. a.i./acre applied preplant surface or preplant incorporated (1.33 lbs. a.i./acre) plus a post foliar spray (2.66 lbs. a.i./acre). 3X and 5X treatments were also conducted. Maximum residues at the 1X rate were 14 ppm in sugar beet tops and 0.32 ppm in sugar beet roots. In the processing study, it was determined that tolerances

would be required in dried pulp and molasses, but not in refined sugar.

iii. *Sunflower*. A total of 15 residue trials were conducted in major sunflower growing areas of the United States. Applications were made at 1X and 2X the maximum labeled rate of 3.0 lbs. a.i./acre. Processing was also conducted with seeds processed into meal, hulls, crude oil, refined oil and soapstock. Based on these studies, tolerances are proposed in sunflower seed at 0.5 ppm and in sunflower meal at 1.0 ppm.

iv. *Tomato*. Thirteen field trials were conducted in major tomato production areas across the United States. Both tomato and its processed fractions were analyzed for residues of parent, measured as CGA-37913 and CGA-49751. One application at 3.0 lbs. a.i./acre (1X) was made post-foliar to tomato transplants. Exaggerated rate applications (2X, 3X and 5X) were also made. Two of the 13 trials were used for processing into tomato commodity products. No residues LOQ of 0.08 ppm were found at the 1X rate in the RAC tomatoes. In processed commodities at the 1X rate of 3.0 lbs a.i./acre, residues of parent were found below the method LOQ in tomato puree (0.4 ppm) and above the method LOQ in dry pomace and tomato paste (0.16 and 0.13 ppm, respectively). Because residues in tomato puree and paste (commodities listed in Table 1 of OPPTS 860.1000 as processed commodities of tomatoes) are less than 2X the LOQ of 0.08 ppm, tolerances are not required according to OPPTS 860.1520 (f)(3).

B. Toxicological Profile

1. *Acute toxicity*. The database for acute toxicity for S-metolachlor is complete. S-metolachlor is moderately acutely toxic (Toxicity Category III) by the oral and dermal route and relatively non-toxic (Toxicity category IV) by the inhalation route. It causes slight eye irritation (Toxicity Category III) and is non-irritating dermally (Toxicity Category IV); the a.i. was found to be positive in a dermal sensitization test but this effect is mitigated in end-use product formulations.

2. *Genotoxicity*. The database for S-metolachlor has been deemed to be adequate by EPA. Gene mutation studies (Guideline 870.5100), micronucleus (Guideline 870.5395), and unscheduled DNA synthesis (Guideline 870.5550) studies have recently been reviewed and approved by EPA. There is no evidence of a mutagenic or cytogenetic effect *in vivo* or *in vitro* with S-metolachlor.

3. *Reproductive and developmental toxicity*. The database for developmental and reproductive toxicity for S-

metolachlor are considered complete according to EPA reviews. The prenatal developmental studies in the rat and rabbit with S-metolachlor revealed no evidence of a qualitative or quantitative susceptibility in fetal animals. No significant developmental toxicity was observed in most studies even at the highest doses tested (HDT). In a 2-generation reproduction study, there was no evidence of parental or reproductive toxicity at the HDT (80 milligrams/kilogram/day (mg/kg/day)). The results indicate that S-metolachlor is not embryotoxic or teratogenic in either species at maternally toxic doses.

4. *Subchronic toxicity*. In a 90-day dietary study in rats with S-metolachlor, no effects were observed in male or females at 208 and 236 mg/kg/day, respectively. In another 90-day dietary study in rats, decreased body weight, reduced food consumption and food efficiency in both sexes and increased kidney weight in males at 150 mg/kg/day; the no observe adverse effect level (NOAEL) was 15 mg/kg/day. A 90-day dog study with S-metolachlor in dogs has been accepted by EPA; no effects were observed in males and females at 62 mg/kg/day and 74 mg/kg/day, respectively, the HDT.

5. *Chronic toxicity*. The database that supports S-metolachlor is considered adequate by EPA. A combined chronic toxicity/ carcinogenic study in the rat satisfies the requirements for both the chronic toxicity and carcinogenicity studies. No significant chronic toxicity was found in either rats or dogs. In the rat, a decrease in body weight was observed at the HDT. In the chronic dog study that supports S-metolachlor, the only adverse effect was decreased body weight gain in females at 33 mg/kg/day; the NOAEL was 10 mg/kg/day.

6. *Animal metabolism*. The database for S-metolachlor is considered to be complete. In animals, S-metolachlor is extensively absorbed, rapidly metabolized and almost totally eliminated in the excreta of rats, goats, and poultry. Metabolism in animals proceeds through common Phase 1 intermediates and glutathione conjugation.

7. *Metabolite toxicology*. The metabolism of S-metolachlor has been well characterized in standard FIFRA metabolism studies. The metabolites found are considered to be toxicologically similar to parent. S-metolachlor does not readily undergo dealkylation to form an aniline or quinone imine as has been reported for other members of the chloroacetanilide class of chemicals. Therefore, as EPA has agreed, it is not appropriate to include S-metolachlor with the group of