

Estimated daily exposures from tolerance level residues (at the 95<sup>th</sup> percentile) and a 100% crop treated assumption for all crops resulted in margins of exposure (MOEs) greater than 430 for all population groups examined. The results of both the chronic and acute dietary exposure analyses clearly demonstrate a reasonable certainty that no harm will result from the proposed agricultural uses of aviglycine HCl.

ii. *Drinking water.* Aviglycine HCl is highly unlikely to contaminate ground water resources due to its high soil sorption, and short soil and water/sediment half-lives. Study results show that aviglycine HCl is easily adsorbed to soils, principally onto clay particles. Half-lives in soils vary between 1.7 and 4.7 days. Water-sediment studies have shown that aviglycine HCl will be readily adsorbed to sediment where it is mineralized and incorporated into the organic fraction of the sediment. Biodegradation occurs in both systems. The half-life of aviglycine HCl in the aqueous phase and total water/sediment system was calculated to be 1.5 and 4.3 days respectively. An aviglycine HCl water concentration assessment was conducted using EPA first tier screening models. FQPA Index Reservoir Screening Tool (FIRST) was used for surface water concentration assessment and screening concentration in ground water (SCI-GROW) was used for ground water assessment. There were no estimated ground water concentrations according to SCI-GROW. Peak surface water concentrations estimated using FIRST were 1,283 and the estimated annual average was 0.021 part per billion (ppb), assuming 87% crop treated. The contribution of drinking water to aggregate risk is considered to be negligible.

2. *Non-dietary exposure.* Aviglycine HCl has no product registrations for residential non-food uses. Non-occupational, non-dietary exposure for aviglycine HCl has thus been estimated to be extremely small. Therefore, the potential for non-dietary exposure is insignificant. The exposure from the commercial use is expected to be dermal in nature. A 21-day repeat dose dermal toxicity study resulted in no significant treatment related effects at 1,000 mg a.i./kg bwt/day, the highest dose tested (HDT).

#### E. Cumulative Exposure

Consideration of a common mechanism of toxicity is not necessary at this time because there is no indication that toxic effects of aviglycine HCl would be cumulative with those of any other chemical

compounds. Aviglycine HCl has a novel mode of action compared to other currently registered active ingredients. Therefore, Valent BioSciences Corporation believes it is appropriate to consider only the potential risks of aviglycine HCl in an aggregate risk assessment.

#### F. Safety Determination

1. *U.S. population.* Aviglycine HCl is an amino acid which has been generated through a fermentation of a soil microorganism. Using the chronic exposure assumptions and the proposed RfD described above, the dietary exposure to aviglycine HCl for the U.S. population was calculated to be 2.2% of the RfD. Therefore, taking into account the proposed uses, it can be concluded with reasonable certainty that residues of aviglycine HCl in food and drinking water will not result in unacceptable levels of human health risk.

2. *Infants and children.* FFDC section 408 (b)(2)(C)(i) provides that EPA shall apply an additional safety factor for infants and children to account for prenatal and postnatal toxicity and the lack of completeness of the data base. Only when there is no indication of increased sensitivity of infants and children and when the data base is complete, may the extra safety factor be removed. In the case of aviglycine HCl, the toxicology data base is complete. There is no indication of increased sensitivity in the data base overall, and specifically, there is no indication of increased sensitivity in the developmental and multi-generation reproductive toxicity studies. Therefore, Valent BioSciences Corporation concludes that there is no need for an additional safety factor and a safety factor of 100 be used for the assessment. Using the chronic exposure assumptions and the proposed RfD described above, the dietary exposure to aviglycine HCl for non-nursing infants, the most highly exposed population subgroup, was calculated to be 0.001110 mg a.i./kg bwt/day or 15.9% of the RfD. Daily exposure for the overall U.S. population was estimated to be 0.000153 mg a.i./kg bwt/day. The proposed tolerances will utilize 2.2% of the RfD for the U.S. population.

#### G. Effects on the Immune and Endocrine Systems

Lifespan, and multigenerational studies on mammals, and acute and subchronic studies on aquatic organisms and wildlife did not reveal any definite immune or endocrine effects. An immunotoxicity study in rats at 0, 1.25, 5, and 15 mg a.i./kg bwt/day presented a NOAEL of 5 mg a.i./kg bwt/day based

on decreased primary antibody (IgM) response to sheep red blood cells; decreased absolute and relative thymus weights; and decreased body weight, food consumption, and food efficiency at the high dose level. The LOAEL is 15 mg a.i./kg bwt/day. Any endocrine related effects would have been detected in this definitive array of required tests. The probability of any such effect due to agricultural uses of aviglycine HCl is considered negligible.

#### H. Existing Tolerances

Time limited tolerances have been established for the residues of aminoethoxyvinylglycine hydrochloride (aviglycine HCl, formerly aminoethoxyvinylglycine (AVG)) in or on the following food commodities:

Commodity	Parts per million	Expiration date
Apple	0.08	December 21, 2003
Pear	0.08	December 21, 2003

Temporary tolerances have been established for the residues of aminoethoxyvinylglycine hydrochloride (aviglycine HCl, formerly aminoethoxyvinylglycine (AVG)) in or on the following food commodities:

Commodity	Parts per million	Expiration date
Fruit, stone, group 12	0.170	December 21, 2003

#### I. International Tolerances

There are no codex maximum residue limits for use of aminoethoxyvinylglycine hydrochloride on apples or pears, stone fruits, or on any other crop.

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## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0325; FRL-7329-5]

### Issuance of an Experimental Use Permit

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** EPA has granted an experimental use permit (EUP) to the following pesticide applicant. An EUP permits use of a pesticide for experimental or research purposes only