



Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED)

Diquat Dibromide



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 25, 2002

CERTIFIED MAIL

Mr. Jerry Wells
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300

Dear Mr. Wells:

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of FQPA Tolerance Reassessment Eligibility Decision (TRED) for **diquat dibromide**. A Notice of Availability, soliciting public comment for a thirty day period will be published in the *Federal Register* (FR) shortly.

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the date of the enactment of the Food Quality Protection Act (FQPA) in August of 1996 against the new safety standard adopted in the FQPA. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made. A reregistration eligibility decision (RED) for diquat dibromide was completed in July 1995, prior to FQPA enactment. Therefore, it needed to be updated to reassess the tolerances under the FQPA standard.

The Agency has evaluated the dietary risk associated with diquat dibromide and has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to diquat dibromide when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, no mitigation measures are needed, and the forty-four tolerances established for residues of diquat dibromide in/on raw agricultural commodities are now considered reassessed as safe under section 408(q) of the FFDCA.

FQPA requires that EPA consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect, as would a higher level of exposure to any of the other substances individually. EPA did not perform a cumulative risk assessment as part of this reregistration review of diquat dibromide, because the Agency has not determined that there are any other chemical substances that have a mechanism of toxicity common with that of diquat dibromide. If EPA identifies other substances that share a common mechanism of toxicity with diquat dibromide, then a cumulative risk assessment will be conducted that includes diquat dibromide once the final framework EPA will use for conducting cumulative risk assessments is available. Further, EPA is in the process of developing criteria for characterizing and testing endocrine disrupting chemicals and plans to implement an Endocrine Disruptor Screening Program. Diquat dibromide will be reevaluated at that time and additional studies may be required.

The Agency’s human health findings for the pesticide diquat dibromide were discussed in a closure conference call and are summarized in the enclosed chemical overview of the risk assessments. The risk assessments and other documents pertaining to the diquat dibromide tolerance reassessment decision are listed at the end of this document and are available on the Internet at http://www.epa.gov/pesticides/reregistration/diquat_dibromide.htm and the public docket for viewing.

The Codex Commission has established several maximum residue limits (MRLs) for residues of diquat dibromide in/on various raw agricultural and processed commodities. The Codex MRLs are expressed in terms of diquat dibromide *per se*. The Codex MRLs and the U.S. tolerances will be incompatible when the U.S. tolerance expression for plant commodities is revised to include both residues of diquat dibromide.

Tolerances are established for residues of diquat dibromide in/on raw agricultural commodities as defined in 40 CFR 180.226. The tolerance reassessment for diquat dibromide recommends raising tolerances for fat, meat byproducts, and meat for the following: cattle, goats, hogs, horses, poultry, and sheep. The tolerance reassessment also recommends raising tolerances for avocados, cottonseed, eggs, citrus fruits, small fruits, hops, fruiting vegetables, leafy vegetables, seed/pod vegetables, fish, forage grasses, forage legumes and shellfish.

New tolerance recommendations have been established for alfalfa seed, clover seed, sorghum grain, soybean hulls and soybean seed. Table I summarizes EPA’s tolerance reassessment decision.

Table I: Diquat Dibromide Tolerance Reassessment Summary.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/[Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.226(a)			
Cattle, fat	0.02	0.05	The established tolerance for ruminant, swine and egg commodities may be raised to achieve compatibility with the Codex MRL. [Cattle, meat byproducts] [Goat, meat byproducts] [Hog, meat byproducts] [Horse, meat byproducts]
Cattle, mby	0.02	0.05	
Cattle, meat	0.02	0.05	
Eggs	0.02	0.05	
Goats, fat	0.02	0.05	
Goats, mby	0.02	0.05	
Goats, meat	0.02	0.05	
Hogs, fat	0.02	0.05	
Hogs, mby	0.02	0.05	
Hogs, meat	0.02	0.05	
Horses, fat	0.02	0.05	
Horses, mby	0.02	0.05	
Horses, meat	0.02	0.05	
Milk	0.02	0.02	
Potatoes	0.1	0.1	[Potato]
Poultry, fat	0.02	0.05	The established tolerance for poultry fat, meat and meat byproducts may be raised to achieve compatibility with Codex. [Poultry, meat byproducts]
Poultry, mby	0.02	0.05	
Poultry, meat	0.02	0.05	
Sheep, fat	0.02	0.05	The established tolerance for ruminant commodities may be raised to achieve compatibility with Codex. [Sheep, meat byproducts]
Sheep, mby	0.02	0.05	
Sheep, meat	0.02	0.05	
Additional Tolerances That Need To Be Proposed Under 40 CFR §180.226(a)			
Alfalfa seed	None	3.0	[Alfalfa, seed]
Clover seed	None	2.0	[Clover, seed]
Sorghum, grain	None	2.0	[Sorghum, grain, grain]
Sorghum, grain, aspirated grain fractions	None	TBD	[Aspirated grain fractions]
Soybean, seed	None	0.2	[Soybean, seed]
Soybean, aspirated grain fractions	None	TBD	[Aspirated grain fractions]

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/[Correct Commodity Definition]
Tolerances Listed Under 40 CFR §180.226(a)(2)(I) (Irrigation Uses)			
Avocados	0.02	0.2	Higher tolerances are needed based on available data.
Cottonseed	0.02	0.2	[Avocado] [Cotton, undelinted seed]
Cucurbits	0.02	0.02	[Vegetable, cucurbit, group]
Fish	0.1	2.0	Higher tolerances are needed based on available data.
Fruits, citrus	0.02	0.05	[Fruit, citrus, group]
Fruits, pome	0.02	0.02	[Fruit, pome, group]
Fruits, small	0.02	0.05	[Fruit, small and berry group]
Fruits, stone	0.02	0.02	[Fruit, stone, group]
Grain, crops	0.02	0.02	[Grain, cereal, group] and [Grain, cereal, forage, fodder, and straw, group]
Grasses, forage	0.1	0.2	[Grass, forage, fodder and hay, group]
Hops	0.02	0.2	Higher tolerances are needed based on available data. [Hop, dried cones]
Legumes, forage	0.1	0.2	[Vegetable, foliage of legume, group]
Nuts	0.02	0.02	[Nut, tree, group]
Shellfish	0.1	20	Higher tolerances are required based on available data.
Sugarcane	0.02	0.2	Higher tolerances are required based on available data.
Vegetables, fruiting	0.02	0.05	Higher tolerances are required based on available data. [Vegetable, fruiting, group]
Vegetables, leafy	0.02	0.05	Higher tolerances are required based on available data. [Vegetable, leafy, except Brassica, group] and [Vegetable, brassica, leafy, group]
Vegetables, root crop	0.02	0.02	[Vegetable, root and tuber, group]

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/[Correct Commodity Definition]
Vegetables, seed and pod	0.02	0.05	<i>[Vegetable, seed and pod, group]</i>
Processed potatoes (including potato chips)	0.5	0.5	Based on the 5.3x concentration factor observed in dried potato.[Expressed in terms of potatoes, granules/flakes at 0.50 ppm and potato chips at 0.50 ppm.] <i>[Potato, chips]</i> <i>[Potato, granules/flakes]</i>
Processed potato waste	1.0	1.0	<i>[Potato, processed potato waste]</i>
Tolerances Listed Under 40 CFR §180.226(a)(3)			
Banana	0.05	0.05	Tolerance with no US Registration / <i>Banana</i>
Coffee	0.05	0.05	Tolerance with no US Registration / <i>Coffee</i>
Additional Tolerances That Need To Be Proposed			
Soybean, hulls	None	0.6	A tolerance is needed based on a concentration factor of ~3x in soybean hulls. <i>[Soybean, hulls]</i>

Table II lists generic and/or product specific data requirements for this chemical. Note that you will be sent a Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 3(c)(2)(B) data call-in (DCI) letter in a separate mailing.

Table II: Data Requirements.

Guideline Number	Guideline Name	Products Required	Comment
860.1200	Directions for Use	All	
860.1500	Magnitude of residue in plant studies for sorghum and soybean aspirated grain fractions.		<p>The soybean processing data indicate that residues of diquat dibromide concentrated 2.6x in soybean hulls processed from soybean bearing detectable residues. No concentration was observed in other soybean processed fractions.</p> <p>The sorghum processing data indicate that residues of diquat dibromide concentrated 4x in sorghum dry milling bran fraction processed from sorghum bearing detectable residues. Residue data are not needed for flour at this time, since sorghum flour is used exclusively in the U.S. as a component for drywall, and not as either a human or animal feed item. The Agency reserves the right to require data if needed at a later date.</p>
830.1700	Batch Analysis	100-1062	Due to presence of ethylene dibromide (EDB).
830.7050	UV/Visible Absorption	100-1062	Data will be used to satisfy requirement for 100-1062 and 100-1063.

If you have questions on this document, please contact the Chemical Review Manager, Tyler Lane, at (703) 305-2737.

Sincerely,

/SIGNED 4-25-02/

Lois A. Rossi, Director
Special Review and
Reregistration Division

2 Enclosures:

Diquat Dibromide Overview (4/2/02).

Diquat Dibromide Summary (4/2/02).

Relevant Documents:

- 1) Use Closure Memo. Tyler Lane (10/31/01).
- 2) HED Risk Assessment for Tolerance Reassessment Eligibility Document (TRED).
B. Daiss (4/25/02, D281890).
- 3) Tier I Drinking Water and Aquatic Ecological Exposure Assessments for Diquat Dibromide. J
Breithaupt (3/5/02, D281199).