

FILE NAME: Pytech.wpt (9/08/06)

**ATTENTION: All commodity terms must comply with the Food and Feed Commodity Vocabulary database (<http://www.epa.gov/pesticides/foodfeed/>).**

**COMPANY FEDERAL REGISTER DOCUMENT SUBMISSION TEMPLATE  
(9/1/2002)**

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**INSTRUCTIONS:** Please utilize this outline in preparing tolerance petition documents. In cases where the outline element does not apply please insert "NA-Remove" and maintain the outline. The comment notes that appear on the left margin represent hidden typesetting codes designed to expedite the processing of the **Federal Register** document. Please do not remove or alter these comment notes or change the margins, font, or format in your document. Simply replace the instructions that appear in italics and brackets, i.e., "[insert company name]," with the information specific to your action.

**Summary of Petitions**

EPA has received a request from **[Pytech Chemicals GmbH, 9330 Zionsville Road, Indianapolis, IN 46268]** proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.438, section 3 by adding gamma-cyhalothrin to lambda-cyhalothrin. The residue definition under section 3 should read as follows:

**(3) A food additive tolerance of 0.01 part per million is established for residue of the insecticide lambda-cyhalothrin ((S)-alpha-cyano-3-phenoxybenzyl-(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,1-dimethylcyclopropanecarboxylate and (R)-alpha-cyano-3-phenoxybenzyl-(Z)-(1S,3S)-3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylate), or the isolated active isomer gamma-cyhalothrin ((S)-alpha-cyano-3-phenoxybenzyl(Z)-(1R,3R)-3-(2-chloro-3,3,3-trifluoripropenyl)-2,2-dimethylcyclopropanecarboxylate).** EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

**A. Residue Chemistry**

1. *Plant metabolism.* **[Gamma-cyhalothrin relies on the metabolism data conducted on lambda-cyhalothrin, which has been thoroughly tested and is adequately**

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understood.]

2. *Analytical method*. [An adequate analytical method is available for enforcement purposes.]

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3. *Magnitude of residues*. [Gamma-cyhalothrin, the isolated active isomer, will be applied at half the application rates of lambda-cyhalothrin. Comparison studies of gamma-cyhalothrin versus lambda-cyhalothrin used on the representative crops of tomatoes, sweet corn, broccoli and cottonseed prove that the established tolerances for lambda-cyhalothrin will be sufficient to cover the potential residues of gamma-cyhalothrin.]

## B. Toxicological Profile

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1. *Acute toxicity*. [The acute oral LD50 was >50 mg/kg bw in male rats and 55 mg/kg bw in female rats, acute dermal LD50 was >1500 mg/kg bw in male rats and 1643 mg/kg bw in female rats and the 4 hr-LC50 for male rats was 40.2 mg/m3 and, for female rats, 28.2 mg/m3.]

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2. *Genotoxicity*. [The following genotoxicity tests were all negative: *Salmonella- E.coli* Reverse Mutation Assay, Mouse Bone Marrow Micronucleus Test, *in vitro* chromosomal aberration in rat lymphocytes and mouse lymphoma forward mutation assay.]

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3. *Reproductive and developmental toxicity*. [A developmental toxicity study in rats given gavage doses of 0, 0.1, 0.5, and 2 mg/kg/day with no developmental toxicity observed under the conditions of the study. The developmental NOAEL is greater than 2 mg/kg/day, the highest dose tested. The maternal NOAEL and LOAEL are established at 0.5 and 2 mg/kg/day, respectively, based on reduced body weight, body weight gain and feed consumption.]

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4. *Subchronic toxicity*. [A 90-day feeding study in rats fed doses of 0, 2.5, 10, 50 and 100 ppm with a NOAEL of 50 ppm and a LOAEL of 100 ppm based on mortality, decreased feed consumption, decreased body weights and increases relative liver and kidney weight at 100 ppm.]

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5. *Chronic toxicity*. [Gamma-cyhalothrin, and lambda-cyhalothrin are contained within the chemical cyhalothrin. Cyhalothrin consists of four isomers, lambda-cyhalothrin consists of two of these isomers and gamma-cyhalothrin is the single active isomer contained in both. The chronic studies were conducted on cyhalothrin.]

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6. *Animal metabolism*. [NA-Remove.]

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7. *Metabolite toxicology*. [The Agency has previously determined that the metabolites of lambda-cyhalothrin are not of toxicological concern and need not be included in the tolerance expression. Given this determination, it is concluded that there is no need to discuss metabolite toxicity.]

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8. *Endocrine disruption*. [No studies have been conducted to investigate the potential of gamma-cyhalothrin to induce estrogenic or other endocrine effects. However, no evidence of such effects has been noted in the battery of toxicity studies which have been conducted on cyhalothrin/lambda-cyhalothrin, and there is no reason to suspect that any such effects would be likely.]

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### C. Aggregate Exposure

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The Agency has conducted an extensive assessment of the aggregate exposure for lambda-cyhalothrin. Results are reported in the Federal Register: September 27, 2002 (Volume 67, Number 188, page 60902-60915). In the Federal Register: April 8, 2004 (Volume 69, No. 68, page 18480) the Agency has also concluded that lambda-cyhalothrin's risk assessment is sufficient to cover gamma-cyhalothrin.

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1. *Dietary exposure*. [NA-Remove]

i. *Food*. [NA-Remove]

ii. *Drinking water*. [NA-Remove]

2. *Non-dietary exposure*. [NA-Remove]

### D. Cumulative Effects

[For purposes of this request, it has been assumed that cyhalothrin (i.e. gamma-cyhalothrin and lambda-cyhalothrin) does not have a common mechanism of toxicity with other substances.]

### E. Safety Determination

[The Agency has conducted an extensive assessment of the aggregate exposure. Results are reported in the Federal Register: September 27, 2002 (Volume 67, Number 188, page 60902-60915).]

1. *U.S. population*. [NA-Remove]

2. *Infants and children*. [NA-Remove]

### F. International Tolerances

[There are Codex maximum residue levels (MRL) established or pending for residues of cyhalothrin, as the sum of all isomers, in or on the

following crops and commodities.

Crop	MRL (mg/kg)
Apricots.....	0.2
Cabbage, head.....	0.2
Cherries.....	0.2
Cotton seed.....	0.02
Cotton seed, oil.....	0.02
Oil seed (including rapeseed oil)....	0.02
Peaches.....	0.2
Plums.....	0.1
Pome fruit.....	0.1
Potatoes.....	0.02
Tree nuts (shelled and unshelled)..	0.05

Canadian MRLs of 0.1 ppm for pome fruit, stone fruit and canola are established in Canada for lambda-cyhalothrin based on the "negligible" residue clause of Canadian Food & Drug Act Regulations (B.15.002(1)).]