



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

MAY 23 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID# 039039-00004. Registration of Python Insecticide Cattle Ear Tag (Cypermethrin, Piperonyl butoxide). MRID#s 425511-08 & -09. Barcode D185396. Case 015542. CBTS# 11035.

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TO: George Larocca, Product Manager
Sheila Moats, Team 13 Reviewer
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Y-Tex Co. is seeking to register a new product, Python Insecticide Cattle Ear Tag, which contains cypermethrin and piperonyl butoxide as the active ingredients. Python is intended to replace an existing product, Max-Con, which contains cypermethrin, piperonyl butoxide and chlorpyrifos. Python differs from Max-Con in the use of the enriched (S)-isomer technical of cypermethrin, an increased percentage of piperonyl butoxide and in the omission of chlorpyrifos. Tolerances are established for cypermethrin under 40 CFR § 180.418 for milk and cattle fat, meat and mbp at a level of 0.05 ppm. Tolerances are established for piperonyl butoxide under 40 CFR § 180.127 for milk fat at 0.25 ppm and cattle fat, meat and mbp at a level of 0.1 ppm.

RECOMMENDATIONS

CBTS recommends in favor of the proposed registration of Python Insecticide Cattle Ear Tag.



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CONCLUSIONS

1. Release studies show that the maximum rate of application of piperonyl butoxide is 38.27 mg/day. Dermal residue studies have been performed for piperonyl butoxide at a level of 2.95 g/day. No piperonyl butoxide residues in milk and tissues in excess of the established tolerances were observed. CBTS thus concludes that the use of Python tags is not likely to result in piperonyl butoxide residues in excess of the established tolerances.

2. In the original registration of Max-Con, the registrant submitted a study in which dairy cattle were treated with ear tags which contained 806 mg cypermethrin or 85% of the 950 mg in the Python tags. The maximum residue in milkfat was 0.0096 ppm, less than 20% of the tolerance for whole milk. This milkfat residue would represent a level of 0.38 ppb in whole milk (0.8% of the tolerance level). Studies were also submitted in which beef cattle were treated with Max-Con tags. Cypermethrin residues were non-detectable (<0.04 ppm) in all tissues. Based on the low potential for transfer of cypermethrin residues to tissues in these studies, CBTS concludes that the use of Python tags is not likely to result in cypermethrin residues in excess of the established tolerances.

DETAILED CONSIDERATIONS

Each ear tag weighs 9.5 g and has a nominal concentration of 10% cypermethrin-(S) and 20% piperonyl butoxide. A CSF was included in this submission. The registrant has also included a depletion study in which the release rate of piperonyl butoxide and cypermethrin from tags applied to cattle was determined (MRID# 425511-09). Two tags were applied per animal (1X) and the depletion of the active ingredients was determined over 12 weeks. A total of 29.5% of the cypermethrin and 37.3% of the piperonyl butoxide was released with the greatest release rate observed in the first 4 weeks (Table 1).

Table 1- Percent of active ingredients of Python ear tags released to cattle during use.

Interval (Days)	% Released per Interval		% Released Daily	
	Cypermeth.	Pip. Butox.	Cypermeth.	Pip. Butox.
1-28	19.6	28.2	0.699	1.007
29-56	3.4	9.0	0.122	0.321
57-84	6.5	1.0	0.230	0.002
Total	29.5	37.3		

Piperonyl butoxide

Y-Texs' current product, Max-Con Ear Tag, contains 3.5% piperonyl butoxide. The Python formulation (20% piperonyl butoxide) represents a substantial increase in piperonyl butoxide and thus an increased potential for transfer of residues to meat and milk. In the original registration of Max-Con, the registrant submitted a study in which dairy cattle were sprayed with piperonyl butoxide daily for 21 days (Memo, W. Anthony 2/12/88). The daily dose was 2.95 g. Milk residues plateaued at 0.25 ppm (in milkfat) and tissue residues remained below the tolerance level (0.1 ppm). Based on the release study, the maximum daily exposure for piperonyl butoxide from Python tags can be calculated. The greatest exposure would be in the first 28 days, in which an average of 1.007% was released daily. The exposure is thus:

$$1900 \text{ mg/tag} \times 1.007 \%/\text{day} \times 2 \text{ tags} = 38.27 \text{ mg/day}$$

This level is only 13% of the level used in the dermal absorption study. CBTS thus concludes that the use of Python tags is not likely to result in piperonyl butoxide residues in excess of the established tolerances.

Cypermethrin

Y-Texs' current product, Max-Con Ear Tag, contains 7% cypermethrin. The Python formulation (10% cypermethrin-(S)) represents an increase in cypermethrin and thus an increased potential for transfer of residues to meat and milk. In the original registration of Max-Con, the registrant submitted a study in which dairy cattle were treated with ear tags which contained 806 mg cypermethrin or 85% of the 950 mg in the Python tags (Memo, W. Anthony 2/12/88). The maximum residue in milkfat was 0.0096 ppm, less than 20% of the tolerance for whole milk. This milkfat residue would represent a level of 0.38 ppb in whole milk (0.8% of

the tolerance level). Studies were also submitted in which beef cattle were treated with Max-Con tags. Cypermethrin residues were non-detectable (<0.04 ppm) in all tissues. Based on the low potential for transfer of cypermethrin residues to tissues in these studies, CBTS concludes that the use of Python tags is not likely to result in cypermethrin residues in excess of the established tolerances.

cc: piperonyl butoxide S.F., cypermethrin S.F., Kramer, circ.,
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