

**CALIFORNIA DEPARTMENT OF PESTICIDE REGULATION
PUBLIC REPORT 2004-06**

Clothianidin

Tracking ID 200970 N

DESCRIPTION OF ACTION

Gustafson LLC submitted an application seeking a California registration of Poncho 600, EPA Reg. No. 264-789-7501, to control insects on corn, canola and rapeseed. This product contains the new active ingredient, clothianidin. Gustafson's Poncho 600 is a distributor registration of the Bayer Corporation's product, Poncho 600, EPA Reg. No. 264-789. Bayer's product was registered by the U.S. EPA on May 30, 2003.

The Department of Pesticide Regulation (DPR) evaluated the product label and scientific data supporting registration of this product and found them to be acceptable. The acute health risks from exposure to clothianidin are minimal due in part to its low mammalian toxicity. The precautionary and first aid statements on the product label, as well as label directions requiring work clothing and other protective measures adequately mitigate potential health risks to persons who may come in contact with the pesticide. DPR does not expect significant adverse environmental impacts to result from registration of this product.

BACKGROUND

Registrant:	Gustafson LLC
Common name:	Clothianidin
Chemical name:	(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine
Brand name:	Poncho 600
Uses:	To control various insects on corn, canola and rapeseed
Pests controlled:	Corn rootworm, southern corn billbug, chinch flea beetle, corn leaf aphid, black cutworm, grape colaspis, seedcorn maggot, southern corn leaf beetle, southern green stinkbug, white grub, thrips, wireworm and flea beetle
Type of registration:	Unconditional

Poncho 600 is formulated as a liquid seed treatment containing 48% clothianidin. Poncho 600 is a systemic insecticide belonging to the nitroguanidine subgroup of nicotinoid insecticides. This product is intended to aid in the protection of seeds and seedlings against injury by certain early season insects.

Poncho 600 is labeled for use indoors in a processing plant using commercial liquid or slurry treaters designed for seed treatment only. This product is not for use in hopper-box, slurry-box or similar "on farm" seed treatment applicators used at planting. Poncho 600 is intended to control corn rootworm, southern corn billbug, chinch bug, corn flea beetle, corn leaf aphid, black cutworm, grape colaspis, seedcorn maggot, southern corn leaf beetle, southern green stinkbug, white grub, thrips and wireworm on corn and flea beetle and wireworm on canola and rapeseed.

As specified on the product label, application rates vary based on the crop, pest and the amount of insect pressure.

SCIENTIFIC REVIEW

A. Chemistry

1. Product Chemistry: DPR evaluated the submitted chemistry studies for the formulated product Poncho 600 and summarized the results in the following table.

Table 1. Certified Limits for the Active Ingredient (%)

Product	Nominal Amount	Lower Limit	Upper Limit
End-Use	48.0	45.6	48.5

Table 2. Physical and Chemical Properties of Poncho 600

Data Item	Value
Color	Off-White
Physical State	Liquid
Odor	Latex Paint-like
Specific Gravity at 20°C	1.263
PH (10% Solution)	5.5
Viscosity at 25°C	600 cps
Corrosion Characteristics	Slightly corrosive to Steel and Copper

2. Residues in Food and Animal Feed: The submitted residue studies support the uses listed on the label. No residue of clothianidin greater than the limit of quantitation of 0.01 ppm was observed in any canola seed sample. Residues were below tolerance in forage and stover (0.03 – 0.09 ppm). No residue was detected in grain.

Table 3. U.S. EPA Established Tolerances for Clothianidin

Commodity	Fraction	Tolerance (ppm)
Canola	Seed	0.01
Field Corn	Forage	0.10
	Grain	0.01
	Stover	0.10
Popcorn	Grain	0.01
	Stover	0.10
Sweet Corn	Forage	0.10
	Kernels + Corn With Husks Removed	0.01
	Stover	0.10

3. Environmental Fate: The clothianidin product is a seed treatment. Therefore, environmental fate data are not required.

B. Toxicology

Gustafson LLC Corporation submitted adequate toxicology studies to conduct a complete toxicological evaluation of Poncho 600. DPR evaluated the submitted data to ascertain the potential for adverse health effects from exposure. The acute toxicity parameters for Poncho 600 are summarized in Table 4.

Table 4. Acute Toxicity of Poncho 600

Type of Study	Acute Toxicity Values	Acute Toxicity Category
Acute oral	LD ₅₀ >2000 mg/kg	III
Acute dermal	LD ₅₀ >4000 mg/kg	III
Acute inhalation	LC ₅₀ >2628 mg/m ³	IV
Primary eye irritation	N/A	IV
Primary dermal irritation	N/A	IV
Dermal sensitization	N/A	Not a dermal sensitizer
Signal word	N/A	CAUTION

DPR's evaluation of the acute toxicity studies indicates that Poncho 600 is low in mammalian toxicity. The precautionary language on the product label adequately identifies the acute toxicity hazards noted in the studies.

DPR found the submitted toxicology studies sufficient to satisfy the data requirements of the Birth Defects Prevention Act (Food and Agricultural Code section 13121 *et. al.*). Possible adverse health effects were observed in two of the gene mutation studies. A possible adverse effect was observed in the mouse lymphoma assay for chromosome effects. DPR prioritizes pesticide active ingredients for risk assessment based on the nature of the potential adverse health effects, number of potential adverse health effects, number of species affected, no observed effects levels (NOELs), potential for human exposure, use patterns, and similar factors. Based on these criteria, pesticides with the greatest potential for health problems are placed in high priority, with other chemicals being placed in moderate or low priority. The purpose of the risk assessment would be to appraise the potential for clothianidin to cause adverse health effects in humans if exposed to the pesticide as the result of a legal use. Further toxicity information is available in DPR's Summary of Toxicology Data for clothianidin, available on DPR public website at <http://www.cdpr.ca.gov/docs/toxsums/pdfs/5792.pdf>.

C. Health & Safety

An evaluation of the medical management information on the Poncho 600 label and the acute toxicity study results indicate the product label bears all of the required statements and warnings

regarding safety to handlers and other persons who may be exposed to the pesticide. The product label bears an adequate first aid statement. In addition, the product label requires persons handling and applying Poncho 600 to wear a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride and/or viton and shoes plus socks.

D. Fish & Wildlife

As a seed treatment product, Poncho 600 will be applied in an enclosed processing plant using commercial seed treatment equipment. There is little or no exposure to fish and wildlife, or the environment from this type of application. Therefore, DPR does not require fish and wildlife data.

E. Efficacy & Phytotoxicity

Submitted efficacy data indicate that Poncho 600 provides control from insect damage. The application of clothianidin at the labeled rate did not cause a reduction in percent germination and frequently resulted in higher grain yields. Phytotoxicity was absent even when the subject product was applied as a seed treatment with various fungicides.

ALTERNATIVES

Clothianidin is a systemic insecticide belonging to the nitroguanidine subgroup of nicotinoid insecticides. It is also referred to as a chloronicotinyl or neonicotinoid. Poncho 600 is intended for use as a seed treatment for corn, canola and rapeseed to protect against damage from a broad spectrum of early season insects. Clothianidin is a major metabolite of the insecticide, thiamethoxam, which is a broad-spectrum insecticide possessing activity against sucking and chewing insects. The use of a seed treatment product to protect seeds and seedlings from insect damage versus broadcast spraying with an insecticide after planting reduces exposure of humans and the environment to pesticide chemicals. In addition, Poncho 600 provides improved control of certain insects over other currently registered seed treatments products.

CONCLUSION

DPR evaluated the product label and scientific data submitted to support the registration of Poncho 600 and found them acceptable to support registration. The acute health risks to humans from exposure to clothianidin are minimal due to its low mammalian toxicity. The precautionary and first aid statements on the product label, as well as the required PPE and other protective measures mitigate potential health risks to persons who may be exposed to the pesticide. If, after the risk assessment, DPR determines that exposure to clothianidin may result in unacceptable margins of exposure, further restrictions will be placed on the use of clothianidin at that time. Submitted data also indicate that no significant adverse environmental impacts are expected to occur from the use of Poncho 600. When used in accordance with label directions, the product will be effective for its intended use.