



Evaluation Report for Category B, Subcategory 2.5, 3.12 Application

Application Number: 2008-1331
Application: B.2.5: Product Chemistry - Formulation Type
B.3.12: Product Label – New Site or Host
Product: Pinnacle SG Herbicide
Registration Number: 29349
Active ingredients (a.i.): Thifensulfuron-methyl [MMM]
PMRA Document Number: 1764492

Purpose of Application

E.I. Dupont Canada company has submitted an application to register a new end-use product containing the active ingredient thifensulfuron-methyl as a 50% soluble granular formulation for use on soybeans and tomatoes. The proposed end-use product is a repack of the manufacturing concentrate, Reg. No 28809, and is the same as the commercial product, M6316 SG Herbicide. The precedent product for the label uses and rates is Pinnacle 75 Toss-N-Go Herbicide (Reg. No. 22002), a 75% dry flowable formulation.

Chemistry Assessment

The product chemistry is complete as it is based on a precedent product owned by the same company.

Health Assessments

Pinnacle SG Herbicide is of low acute toxicity by the oral route ($LD_{50} > 5000$ mg/kg bw/d) and by the dermal route ($LD_{50} > 5000$ mg/kg bw/d) in rats. Pinnacle SG Herbicide is non-irritating to the eyes ($MAS = 0/110$) and non-irritating to the skin ($MAS = 0/8$) of rabbits. It is not a dermal sensitizer to the guinea pigs. An adequate waiver for acute inhalation toxicity was provided. Pinnacle SG Herbicide contains large, non-inhalable particles which are resistant to attrition and therefore the potential for acute inhalation toxicity is negligible.

The use of Pinnacle SG Herbicide should not result in an increase in potential occupational or bystander exposure over the registered uses of the active ingredient thifensulfuron methyl. No unacceptable risk is expected when workers follow label directions and wear personal protective equipment required on the label.

The use directions on the Pinnacle SG Herbicide label are identical to those on the precedent product Pinnacle 75 Toss-N-Go Herbicide label. The residue profile in/on treated tomatoes and soybeans for the soluble granular formulation is not expected to be different from the dry

flowable formulation of Pinnacle 75 Toss-N-Go Herbicide. Residues of thifensulfuron-methyl in/on soybean and tomatoes treated according to the use directions on the Pinnacle SG herbicide label should therefore not increase. Accordingly, exposure to residues of thifensulfuron-methyl in/on treated soybean and tomato commodities should also not increase for each population subgroup.

Environmental Assessment

The use pattern (application rates, number of applications and use areas) and the method of application of Pinnacle SG Herbicide are identical to those of Pinnacle 75 Toss-N-Go Herbicide. The soluble granules formulation of Pinnacle SG Herbicide is not of environmental concern. Therefore no increase in environmental risk is expected. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

No change in efficacy or crop tolerance is anticipated with the soluble granular formulation of thifensulfuron-methyl when compared to Pinnacle 75 Toss-N-Go.

Conclusion

Following the assessment of all available data, the PMRA is able to support the full registration of Pinnacle SG Herbicide.

References

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| PMRA 1224114 | Thifensulfuron Methyl (DPX-M6316) 50SG: Acute Oral Toxicity in Rats - Fixed Dose Method. Work request number 14321. Laboratory project ID: DuPont-12039. Study completion date: March 21, 2003. DACO: 4.6.1. |
| PMRA 1224115 | Thifensulfuron Methyl (DPX-M6316) 50SG: Acute Dermal Toxicity Study in Rats. Work request number 14321. Laboratory project ID: DuPont-12257. Study completion date: March 24, 2003. DACO: 4.6.2. |
| PMRA 1224132 | Rationale for Waiver of Requirement for Acute Inhalation Toxicity Study for M6316 Soluble Granule Formulation. Laboratory project ID: DuPont-11987. DACO: 4.6.3. |
| PMRA 1224116 | Thifensulfuron Methyl (DPX-M6316) 50SG: Acute Eye Irritation Study in Rabbits. Work request number 14321. Laboratory project ID: DuPont-12316. Study completion date: March 24, 2003. DACO: 4.6.4. |
| PMRA 1224117 | Thifensulfuron Methyl (DPX-M6316) 50SG: Acute Dermal Irritation Study in Rabbits. Work request number 14321. Laboratory project ID: DuPont-12179. Study completion date: March 20, 2003. DACO: 4.6.5. |

- PMRA 1224118 Thifensulfuron Methyl (DPX-M6316) 50SG: Dermal Sensitization – Magnusson-Kligman Maximization Method. Work request number 14321. Laboratory project ID: DuPont-11573. Study completion date: January 07, 2003. DACO: 4.6.6.
- PMRA # 1596701: Rationale for waiver of efficacy data requirements for bridging the uses of Pinnacle 75 Toss-N-Go Herbicide, PCP 22002 to Pinnacle SG (Soluble Granule) Herbicide. E.I. du Pont Canada Company. May 15, 2008. DACO 10.2.3.3 and 10.3.2. pp. 1.
- PMRA # 1272920: Efficacy and non-safety adverse effect reviews. Submission 2006-3125. DACO. 10.2.3.3 and 10.3.2. pp. 7.

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