

Evaluation Report for Category B, Subcategory 3.13 Application

Application Number: 2009-0410
Application: B.3.13 – Changes to Product Labels - Precautions
Product: Fomesafen Technical Grade Herbicide
Registration Number: 28828
Active ingredients (a.i.): Fomesafen (FOF)
PMRA Document Number English PDF: 2020531

Purpose of Application

The purpose of this application was to amend precaution label statements based on new toxicity data.

Health Assessments

No new residue data were required to support the amendment of precaution statements on the label for Fomesafen Technical Grade Herbicide. The amendment of the precaution statements is not expected to impact the magnitude of the residues in/on commodities treated with the end-use product containing the active ingredient, fomesafen. Therefore, no increase in dietary exposure is anticipated.

As there are no changes proposed to the use pattern of Fomesafen Technical Grade Herbicide, the proposed label revisions should not result in an increase in potential occupational exposure when compared to the registered use pattern.

The product was of low acute toxicity by the oral ($LD_{50} = 5000$ mg/kg bw), dermal ($LD_{50} \geq 5050$ mg/kg bw), and inhalation ($LC_{50} \geq 2.63$ mg/L) routes in rats. It was non-irritating to the eyes and skin of rabbits. It was not a dermal sensitizer in guinea pigs.

Environmental Assessment

No environmental data were submitted nor were there any requests to revise existing environmental label statements. No additional risk reduction measures were required.

Chemistry and Value Assessments

The chemistry and value assessments were not required for this application.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the subject application and found the information sufficient to amend the precautions on the Fomesafen Technical Grade Herbicide label.

References

PMRA# Reference

- 1715496 2004, 4.6.6-1 Fomesafen Technical (FL-031976): Skin sensitization Study in Guinea Pigs - Update precautions, DACO: 4.6.1,4.6.6
- 1715497 2004, 4.6.5-1 - Acute Dermal Irritation Study in Rabbits with Fomesafen Technical (FL-031976) - Update precautions, DACO: 4.6.1,4.6.5
- 1715499 2004, 4.6.4-1 - Acute Eye Irritation Study in Rabbits with Fomesafen Technical (FL-031976) - Update precautions, DACO: 4.6.1,4.6.4
- 1715500 2004, 4.6.3-1 - Acute Inhalation Toxicity Study in Rats with Fomesafen Technical (FL-040154) - Update precautions, DACO: 4.6.1,4.6.3
- 1715501 2004, 4.6.2-1 - Acute Dermal Toxicity Study in Rats with Fomesafen Technical (FL-031976) - Update precautions, DACO: 4.6.1,4.6.2
- 1715502 2004, 4.6.1-1 - Acute Oral Toxicity Study in Rats with Fomesafen Technica (FL-031976) - Update precautions, DACO: 4.6.1

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