

Evaluation Report for Category B, Subcategory 3.13 Application

Application Number: 2008-3576
Application: Changes to product label - Precautions
Product: Fluazifop-p-butyl Technical
Registration Number: 21208
Active ingredients (a.i.): Fluazifop-p-butyl and s-isomer
PMRA Document Number : 1736815

Purpose of Application

The purpose of this application is to amend the Fluazifop-P-butyl Technical (Reg No. 21208) label by updating the human health precautions section as the technical has been found to be a potential skin sensitizer.

Chemistry Assessment

As there were no changes in the chemistry of this product, a chemistry assessment was not required.

Health Assessments

Fluazifop-P-butyl Technical is of low toxicity to rats via the oral route and slightly toxic to rabbits via the dermal route. It is mildly irritating to the eye and slightly irritating to the skin of rabbits. The original study regarding sensitization in guinea pigs was inconclusive. The recently submitted Local Lymph Node Assay provides evidence that indicates that Fluazifop-P-butyl Technical does have sensitizing potential (EC₃: 72% w/v) and in light of this evidence, Fluazifop-P-butyl Technical is considered to be a skin sensitizer in mice.

With the addition of the skin sensitization statement on the Fluazifop-P-butyl Technical label, the personal protective equipment statement and other precautions on the label are adequate to protect workers from potential dermal sensitization.

No new residue data were required to support the change of the precautionary statement. The amendment of the precautionary statement is not expected to impact the magnitude of the residues in/on commodities treated with end-use products containing the active ingredient fluazifop-P-butyl. Therefore, no increase in dietary exposure is anticipated.

Environmental Assessment

No additional increase in environmental exposure is expected from the added statement in the precautions section of the technical label. Therefore, additional environmental data were not required to support this amendment to the label. Environmental concerns are mitigated on the existing label.

Value Assessment

As the proposed label change does not alter the value of this product, a value assessment was not required.

Conclusion

The PMRA has completed an assessment of available information for Fluazifop-P-butyl Technical and has found the information sufficient to support the amendment of the label to include a precautionary skin sensitization statement.

References

PMRA Document Number	Reference
1636736	2008. Fluazifop-P-butyl Technical – Local Lymph Node Assay (LLNA) in Mice: Amended final report. Laboratory report number 080632. DACO 4.2.6

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