

Evaluation Report for Category B, Subcategory B.3.13 Application

Application Number: 2006-0314 **Application:** B.3.13

Product: Reflex Liquid Herbicide

Registration Number: 24779

Active ingredients (a.i.): Fomesafen (FOF)

PMRA Document Number: 1380487

Background

Reflex Liquid Herbicide has been registered since March 20, 1997. It is registered for use on soybeans, dry edible beans and snap common beans. For specific details of uses, application rates and methods, precautions, restrictions, and personal protective equipment requirements, refer to the product label.

Purpose of Application

The purpose of this submission was to change the precautionary statements for Reflex Liquid Herbicide containing the active ingredient fomesafen. New first aid statements and new toxicological information statements were added, the spill cleanup statements were removed and the potential skin sensitizer statements were removed.

Chemistry Assessment

A chemistry assessment was not required since there was no change to product chemistry.

Health Assessments

Reflex Liquid Herbicide is of low toxicity to rats via the oral ($LD_{50} > 2000 \text{ mg/kg}$) and dermal ($LD_{50} > 2000 \text{ mg/kg}$) routes in rats, and of slight toxicity by the inhalation route ($LC_{50} > 1.24 \text{ mg/L}$ in males and $LC_{50} > 1.40 \text{ mg/L}$ in females). It is slightly irritating to the skin of rabbits, and extremely corrosive or irritating (irreversible within 21 days) to rabbit eyes. It is not a dermal sensitizer in guinea pigs.

The personal protective equipment recommended on the label is considered to be adequately protective for workers handling Reflex Liquid Herbicide.



Environmental Assessment

Reflex is currently registered in Canada for weed control in soybeans. The label amendment to change the health precautionary and spill cleanup statements does not pose additional risk to the environment.

Value Assessment

A value assessment is not required for changes to precautionary statements.

Conclusion

Following the review of all available data, the changes to the precautionary statements for Reflex Liquid Herbicide can be supported.

References

PMRA 1124132.	Fomesafen: Acute Oral Toxicity to the Rat of a 240g/l SL Formulation.
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	Macclesfield, Cheshire, UK. CTL study number AR6152. Study report
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PMRA 1124133.	Fomesafen: Acute Dermal Toxicity to the Rat of a 240g/l SL Formulation.
	Zeneca Central Toxicology Laboratory (CTL), Alderley Park,
	Macclesfield, Cheshire, UK. CTL study number CR3292. Study report
	date: 9-February-1996. pp. 1-37. DACO 4.6.2. Unpublished. PMRA
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PMRA 1124134.	Fomesafen 240g/L SL Formulation: 4-hour Acute Inhalation Toxicity
	Study in Rats. Central Toxicology Laboratory (CTL), Alderley Park,
	Macclesfield, Cheshire UK. CTL study number HR2286. Study report
	date: 12-February-1996. Pp. 1-1-116. DACO 4.6.3. Unpublished. PMRA
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PMRA 1124135.	Fomesafen: Eye Irritation to the Rabbit of a 240 g/l SL Formulation.
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	date: 8-December-1995. pp. 1-21. DACO 4.6.4. Unpublished. PMRA
	received date: 23-January-2006.

PMRA 1124136. Fomesafen: Skin Irritation to the Rabbit of a 240g/l SL Formulation. Zeneca Central Toxicology Laboratory (CTL), Alderley Park, Macclesfield, Cheshire UK. CTL study number EB4438. Study report date: 8-February-1996. pp. 1-21. DACO 4.6.4. Unpublished. PMRA received date: 23-January-2006.

PMRA 1241343. Fomesafen: Skin Irritation to the Rabbit of a 240g/l SL Formulation.

Zeneca Central Toxicology Laboratory (CTL), Alderley Park,

Macclesfield, Cheshire UK. CTL study number EB4438. Study report date: 8-February-1996. pp. 1-21. DACO 4.6.5. Unpublished. PMRA

received date: 5-May-2006.

PMRA 1124137. Fomesafen: Skin Sensitisation to the Guinea Pig of a 240g/l SL

Formulation. Zeneca Central Toxicology Laboratory (CTL), Alderley Park, Macclesfield, Cheshire UK. CTL study number GG6618. Study report date: 9-February-1996. pp. 1-36. DACO 4.6.6. Unpublished.

PMRA received date: 23-January-2006.

PMRA 1254526. Fomesafen - Science Review. PMRA-HED. Study report date: 01-March-

1996. DACO 12.2.

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