

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.5 Application

Application Number: 2010-4498
Application: New end use product / change in guarantee, identity of
formulants and formulation.
Product: GF-1966 SG Herbicide
Registration Number: 30620
Active ingredients (a.i.): Clopyralid
PMRA Document Number: **2198212**

Purpose of Application

The purpose of this application is to register a new end-use product, GF-1966 SG Herbicide, containing clopyralid for control of perennial and annual broadleaved weeds in field crops, Christmas tree plantations, pasture, rangeland, vegetable and fruit crops, and non-cropland. GF-166 SG Herbicide is based on the precedent product Lontrel 360 Herbicide (Registration Number 23545). Master product status was also requested for GF-1966 SG Herbicide.

Chemistry Assessment

GF-1966 SG Herbicide is formulated as a soluble granule containing clopyralid, present as monoethanolamine salt, at a nominal concentration of 72%. This end-use product has a density of 0.58-0.63 g/mL and pH of 4.3 for a 1% dilution. The chemistry requirements for GF-1966 SG Herbicide have been fulfilled.

Health Assessments

All data, with the exception of an acute eye irritation study, were bridged with formerly reviewed products with toxicological equivalency. GF-1966 SG Herbicide was minimally irritating to the eye in the rabbit.

Handler risk was calculated for the use of GF-1966 SG Herbicide to control various weeds and no risks of concern were identified. Postapplication exposure for the use of GF-1966 SG Herbicide is not expected to exceed that of the currently registered use pattern. No risks of concern are expected for handlers or postapplication workers when workers follow the precautions on the label.

No new residue data were submitted to support the new end-use product GF-1966 SG Herbicide. Since GF-1966 SG Herbicide is applied as soil-directed treatment either postplanting, at early crop emergence, or postharvest, and there is no change proposed to the application rates or timing with respect to the registered uses of clopyralid. The new formulation is not anticipated to have an impact on the magnitude of the residues in the registered crops. Therefore, the dietary exposure is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The proposed new formulation GF-1966 SG Herbicide and its use pattern will not result in an increase in the environmental exposure relative to its precedent product Lontrel 360 Herbicide. Therefore, acceptable risk is expected. Environmental concerns have been mitigated through adequate statement on the product label.

Value Assessment

Trial data and scientific rationales were provided to support the registration of the new end-use product GF-1966 SG Herbicide. European trial data were generated for GF-1966 SG Herbicide and compared to data generated for another product that contains the same salt of clopyralid (i.e. monoethanolamine salt), which was considered to be similar in performance (i.e., efficacy and crop tolerance) to the registered product Lontrel 360 Herbicide. The submitted data and rationales indicated that the performance of GF-1966 SG Herbicide can be expected to be similar to that of Lontrel 360 Herbicide in terms of both efficacy and crop safety when applied at equivalent rates of active ingredient. Overall, the weight of evidence supports the same use pattern for GF-1966 SG Herbicide as that registered for Lontrel 360 Herbicide from a value perspective.

Conclusion

Following the review of all available data, GF-1966 SG Herbicide for control of perennial and annual broadleaved weeds in field crops, Christmas tree plantations, pasture, rangeland, vegetable and fruit crops, and non-cropland has been approved and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

References

PMRA Number	Reference
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1958441	2010, Formulation Process, GF-1966 SC Herbicide, DACO: 3.2,3.2.1 CBI
1958444	2009, Analytical Method and Validation for the Determination of Clopyralid in formulation GF-1966, DACO: 3.2,3.2.1,3.4.1 CBI
1958448	2010, Summary of Chemical & Physical Properties, DACO: 3.5 CBI
1958450	2009, Two-Week Accelerated Storage Stability of GF-1966 in Glass, DACO: 3.5.10 CBI
1958451	2009, Storage Stability and Package Corrosion Characteristics of GF-1966 in HDPE and WSP in Overpack Bag: Eight-Week Accelerated Study, DACO: 3.5.10,3.5.14 CBI
1958452	2009, Storage Stability and Package Corrosion Characteristics of GF-1966 in PET: Eight-Week Accelerated Study, DACO: 3.5.10,3.5.14 CBI
1958453	2010, 2 Year Storage Stability Study and Corrosion Characteristics in commercial containers study, DACO: 3.5.10,3.5.14
1958454	2009, Determination of Flammability (solids), Explosive Properties, Relative Self-Ignition Temperature and bulk density for GF-1966, DACO: 3.5.11,3.5.12,3.5.6 CBI
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1958467	2010, Efficacy Trials, DACO: 10.2.3.3
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ISSN: 1911-8082

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