

Evaluation Report for Category L, Subcategory 1.2 Application

Application Number: 2020-6060
Application: Submissions Subject to Protection of Proprietary Interests in Pesticide Data Policy - Equivalency/ Data Compensation
Product: Czar Herbicide
Registration Number: 34338
Active ingredient (a.i.): Clomazone
PMRA Document Number: 3206824

Purpose of Application

The purpose of this application was to register the end-use product Sharda Clomazone 360 CS, based on a precedent.

Chemistry Assessment

Sharda Clomazone 360 CS is formulated as a microcapsule suspension containing clomazone at a concentration of 360 g/L. This end-use product has a density of 1.1527 g/mL and pH of 8.7. The required chemistry data for Sharda Clomazone 360 CS have been provided, reviewed and found to be acceptable.

Health Assessments

Sharda Clomazone 360 CS was considered to be toxicologically equivalent to the precedent product; therefore, no toxicology data were required. Sharda Clomazone 360 CS is considered to be of low acute toxicity via the oral, dermal and inhalation routes of exposure. It is expected to be non-irritating to the eyes and skin, although it is considered to be a potential dermal sensitizer.

The use pattern of Sharda Clomazone 360 CS containing clomazone is identical to the use pattern of the precedent product. Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered product. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data for clomazone were submitted or are required to support the registration of Sharda Clomazone 360 CS. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the Sharda Clomazone 360 CS label, including the target crops, method (ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are identical to the precedent end-use product.

Residues are not expected to be greater than those for the currently registered uses and will be covered by the established MRLs. Consequently, dietary exposure to residues of clomazone is not expected to increase with the registration of the new end-use product Sharda Clomazone 360 CS and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The uses are within the currently registered use pattern of the active ingredient, clomazone, and therefore, no increase in exposure to the environment is expected when Sharda Clomazone 360 CS is used according to label directions. The label includes the required environmental precautions and hazards statements.

Value Assessment

Registration of a generic product may increase product competition in the marketplace, which may in turn reduce purchasing costs of similar products.

Value information consisted of a comparison of the formulation of Sharda Clomazone 360 CS to that of the cited precedent product. Based on the weight of evidence, agronomic equivalence between Sharda Clomazone 360 CS and the cited precedent product was established. Therefore, all labelled uses and claims found on the precedent product label are supported for inclusion on the Sharda Clomazone 360 CS label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided and has found it sufficient to support the registration of Sharda Clomazone 360 CS.

References

PMRA Document Number	References
3047764	2019, Composition of CZAR (Clomazone 36% CS)/ SHA 5800 C, DACO: 3.2,3.2.1,3.2.3,3.3.1 CBI
3047765	2017, Clomazone 36% CS: Validation of the Analytical Method for the Determination of the Active Ingredient Content, DACO: 3.3.1,3.4.1,3.4.2
3047767	2018, Clomazone 36% CS: Determination of the Accelerated Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14
3047771	2018, Clomazone 36% CS: Determination of the Oxidizing Properties and Explosive Properties, DACO: 3.5.12,3.5.8
3047768	2019, CLOMAZONE 36 CS. Miscibility and Corrosion Test, DACO: 3.5.13,3.5.14
3047766	2018, Clomazone 36% CS: Determination of the Physico-chemical Properties, DACO: 3.5.1,3.5.11,3.5.2,3.5.3,3.5.6,3.5.7,3.5.9,3.7

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