

Evaluation Report for Category L, Subcategory 1.2 Application

| Application Number: | 2019-6440 |
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| Application: | Submission subject to the Protection of Proprietary Interests in |
| | Pesticide Data (PPIP) policy - Equivalency/Data Compensation |
| | Assessment |
| Product: | ClearUp GLUFOSINATE 150 SN |
| Registration Number: | 34578 |
| Active ingredient (a.i.): | Glufosinate-ammonium |
| PMRA Document Number : 3204381 | |

Purpose of Application

The purpose of this application was to register the new end-use product ClearUp GLUFOSINATE 150 SN, based on a registered precedent.

Chemistry Assessment

ClearUp GLUFOSINATE 150 SN is formulated as a solution containing glufosinate-ammonium at a concentration of 150 g/L. This end-use product has a density of 1075.4 g/L and pH of 4.17. The required chemistry data for ClearUp GLUFOSINATE 150 SN have been provided, reviewed and found to be acceptable.

Health Assessments

ClearUp GLUFOSINATE 150 SN was considered toxicologically equivalent to the precedent product; therefore, no toxicology data were required. ClearUp GLUFOSINATE 150 SN is considered to be of moderate acute inhalation toxicity and low acute oral and dermal toxicity. It is considered moderately irritating to the eyes and mildly irritating to the skin. It is not considered to be a dermal sensitizer in guinea pigs.

The use of ClearUp GLUFOSINATE 150 SN Herbicide as an herbicide treatment on various crops is not expected to result in potential occupational or bystander exposure over the registered uses of glufosinate-ammonium. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No new residue data for glufosinate-ammonium were submitted, or are required, to support the registration of ClearUp GLUFOSINATE 150 SN under the Protection of Proprietary Interest in Pesticide Data (PPIP) program. The use directions on the ClearUp GLUFOSINATE 150 SN label, including the target crops, methods, rates and timing of application, geographic restrictions, pre-harvest intervals, feeding restrictions, and crop rotation restrictions are identical to those on the precedent products. The formulation of ClearUp GLUFOSINATE 150 SN when compared to the precedent end-use products is not expected to significantly impact the magnitude of glufosinate-ammonium residues in/on the labeled crops. Based on this



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assessment, residues are not expected to increase and will be covered under the currently established maximum residue limits (MRLs) for glufosinate-ammonium (http://pr-rp.hc-sc.gc.ca/mrl-lrm/results-eng.php). Consequently, dietary exposure to residues of glufosinate-ammonium is not expected to increase with the registration of ClearUp GLUFOSINATE 150 SN and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

Environmental Assessment

The use pattern for ClearUp GLUFOSINATE 150 SN falls within the currently registered use pattern. No additional risk to the environment is expected from the registration of this end-use product provided that environmental label statements are followed.

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 field trials comparing ClearUp GLUFOSINATE 150 SN to that of the cited precedent products. Based on the weight of evidence, agronomic equivalence between ClearUp GLUFOSINATE 150 SN and the cited precedent products was established. Therefore, all labelled uses and claims found on the precedent product labels are supported for inclusion on the ClearUp GLUFOSINATE 150 SN label.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support the registration of ClearUp GLUFOSINATE 150 SN.

References

| PMRA Document | Reference |
|----------------------|--|
| Number | |
| 3057030 | 2019, Formulation process, DACO: 3.2.2 CBI |
| 3057034 | 2019, Chemical and physical properties, DACO: 3.5.1, 3.5.10, 3.5.11, |
| | 3.5.13, 3.5.14, 3.5.2, 3.5.3, 3.5.6, 3.5.7, 3.5.9 |
| 3198240 | 2020, Small scale trials of Clearup Glufosinate 150 SN, DACO: |
| | 10.2.3.3(B) |
| 3203850 | 2020, original records of field trial of Clearup Glufosinate 150 SN, |
| | DACO: 10.2.3.3 |

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