Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4 Application

Application Number: 2019-3435
Application: New End-Use Product Chemistry – Guarantee, Identity of Formulants, Proportion of Formulants
Product: MON 301108 Liquid Herbicide
Registration Number: 33940
Active ingredient (a.i.): Glyphosate present as potassium salt
PMRA Document Number: 3166895

Purpose of Application

The purpose of this application was to register a commercial herbicide, MON 301108 Liquid Herbicide, for use in terrestrial food and feed crops, outdoor ornamentals, turf, forests and woodlots, industrial oil seed and fibre crops and for industrial and domestic vegetation control.

Chemistry Assessment

MON 301108 Liquid Herbicide is formulated as a solution containing glyphosate present as potassium salt at a concentration of 577 g/L. This end-use product has a density of 1.384 g/mL and pH of 4.70. The required chemistry data for MON 301108 Liquid Herbicide have been provided, reviewed and found to be acceptable.

Health Assessments

MON 301108 Liquid Herbicide is of low acute toxicity via the oral, dermal, and inhalation routes in rats. It is moderately irritating to the eyes and slightly irritating to the skin of rabbits. MON 301108 Liquid Herbicide is not a potential dermal sensitizer in guinea pigs.

The use pattern of the MON 301108 Liquid Herbicide, for applications to various cropland and non-cropland areas, fits within the registered use pattern of glyphosate. The potential exposure for mixers, loaders, applicators, and postapplication workers, is not expected to exceed the current exposure to the previously registered products of glyphosate. There are no health risks of concern for workers and bystanders when label directions, precautions and restrictions are followed.

No residue data for glyphosate were submitted to support the registration of the end-use product, MON 301108 Liquid Herbicide. The end-use product has a higher concentration of the active ingredient in the guarantee, but a lower application volume, leading to an identical application to target crops/sites on a g a.e./ha basis compared to the precedent product. The target crops, timing and number of applications, application methods and rates, spray volumes, preharvest intervals, restricted-entry intervals, rotational crop intervals, as well as all other use

directions, restrictions or limitations remained unchanged from the precedent product. Therefore, the dietary exposure to residues of glyphosate is not expected to increase over the currently registered uses. In addition, the established MRLs for residues of this active ingredient in/on food commodities are expected to adequately cover the level of residues resulting from the use of MON 301108 Liquid Herbicide.

Environmental Assessment

The use pattern of MON 301108 Liquid Herbicide is the same as the precedent product. The label is similar except for the application rates, which have been modified in order to deliver the same amount of the active ingredient when applied thus, no additional environmental risk is expected from the use of this commercial class end-use product. Environmental concerns are addressed in the environmental label statements.

Value Assessment

Registration of MON 301108 Liquid Herbicide will provide a new formulation of glyphosate to control weeds and unwanted vegetation in cropland and non-cropland situations.

Value information submitted for review consisted of data from replicated field trials and extrapolations from registered uses. Based on the weight of evidence, the registration of MON 301108 Liquid Herbicide is supported from a value standpoint.

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 MON 301108 Liquid Herbicide.

References

PMRA Document Number	Reference
3014070	2018, Product Chemistry Data, DACO: 3.1,3.2,3.2.2,3.3.1,3.4.1,3.5,3.5.1,3.5.10, 3.5.11, 3.5.12, 3.5.13,3.5.14,3.5.15,3.5.2,3.5.3,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
3014082	2018, Validation of Analytical Methods for the Determination of Glyphosate, [CBI Removed] in MON 301108, DACO: 3.4.1 CBI
3014071	2018, MON 301108: Acute Oral Toxicity - Up and down procedure in rats, DACO: 4.6.1
3014072	2018, MON 301108: Acute dermal toxicity in Rats, DACO: 4.6.2
3014073	2018, MON 301108: Acute Inhalation Toxicity in Rats, DACO: 4.6.3
3014074	2018, MON 301108: Primary Eye Irritation in Rabbits, DACO: 4.6.4
3014075	2018, MON 301108; Primary skin irritation in rabbits, DACO: 4.6.5
3014076	2018, MON 301108: Dermal Sensitization Test In Guinea Pigs, DACO: 4.6.6
3014077	2018, Value Summary, DACO: 10.1

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