

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

**Application Number:** 2016-7637  
**Application:** New End-Use Product - Product Chemistry – Identity of Formulants and Proportion of Formulants  
**Product:** Komodo Herbicide  
**Registration Number:** 33599  
**Active ingredient (a.i.):** S-metolachlor and R-enantiomer  
**PMRA Document Number:** 2853853

### Purpose of Application

The purpose of this application was to register the end-use product, Komodo Herbicide, based on a precedent under the data protection program.

### Chemistry Assessment

Komodo Herbicide is formulated as an emulsifiable concentrate containing S-metolachlor and R-enantiomer at a concentration of 915 g/L. This end-use product has a density of 1.115 g/mL and pH of 5.23. The required chemistry data for Komodo Herbicide have been provided, reviewed and found to be acceptable.

### Health Assessments

Komodo Herbicide is toxicologically equivalent to the precedent product. Consequently, no toxicological data were submitted or are required.

The use of the end-use product Komodo Herbicide for application to forests and woodlots, terrestrial food and feed crops, as well as outdoor ornamentals, is not expected to result in potential occupational or bystander exposure over the registered uses of S-metolachlor and R-enantiomer. No health risks of concern are expected when workers follow label directions and wear personal protective equipment as stated on the label.

No residue data for the active ingredient, S-metolachlor, or for the safener, benoxacor, were submitted to support the registration of the end-use product, Komodo Herbicide based on a precedent. The established maximum residue limits (MRLs) for the active ingredient, S-metolachlor, and for the safener, benoxacor, are adequate to cover the expected residues resulting from the use of Komodo Herbicide. In those cases where no MRLs have been established, maximum residues for S-metolachlor and benoxacor continue to be covered under subsection B.15.002(1) of Division 15 of the Food and Drugs Regulations (0.1 ppm).

The dietary exposure assessments on file are also considered acceptable to estimate the dietary exposure to residues of the active ingredient and the safener, and no health risks of concern have been identified for any segment of the population including infants, children, adults and seniors.

### **Environmental Assessment**

An environmental assessment was conducted and the changes for this product do not pose an increased risk to the environment. Environmental concerns are mitigated on the existing label. No additional environmental data were required.

### **Value Assessment**

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

The formulation of Komodo Herbicide was compared to the formulation of the cited precedent product. It was concluded that differences in the formulations would be unlikely to result in any significant impact on product performance, in terms of both efficacy and crop tolerance.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the available information and has found it sufficient to support the registration of Komodo Herbicide.

## References

PMRA Document Number	References
2705744	2016, Appearance (Colour, Physical State and Odour) of S-metolachlor 915 g/L EC, DACO: 3.5.1,3.5.2,3.5.3
2705745	2016, Explodability of S-metolachlor 915 g/L EC, DACO: 3.5.12
2705746	2016, Viscosity of S-Metolachlor 915 g/L EC, DACO: 3.5.9
2705747	2016, Accelerated Storage Stability and Corrosion Characteristics of S-metolachlor 915 g/L EC AT 54C, DACO: 3.5.9
2705748	2016, flash point of S-metolachlor 915 g/L EC, DACO: 3.5.11
2705749	2016, Validation of Analytical Method for Determination of Active Ingredient Content of S-metolachlor 915 g/L EC, DACO: 3.4.1
2705750	2016, Miscibility of S-metolachlor 915 g/L EC, DACO: 3.5.13
2705751	2016, Oxidation/Reduction Properties of S-metolachlor 915 g/L EC, DACO: 3.5.8
2705752	2016, pH OF S-metolachlor 915 g/L EC, DACO: 3.5.7
2705753	2016, Specific Gravity of S-metolachlor 915 g/L EC, DACO: 3.5.6
2705754	2016, Moccasin II Herbicide Product Identity, Composition and Analysis, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
2817769	2017, Validation of Analytical Method for Determination of [CBI Removed] Active Ingredient Content in S-metolachlor 915 g/L EC, DACO: 3.4.1 CBI
2817770	2017, Accelerated Storage Stability and Corrosion Characteristics of S-metolachlor 915 g/L EC, DACO: 3.5.10 CBI

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