

## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2020-1555  
**Application:** Submission subject to the *Protection of Proprietary Interests in Pesticide Data* (PPIP) policy – Equivalency / Data Compensation Assessment  
**Product:** Tide Mesotrione 480 SC Herbicide  
**Registration Number:** 34428  
**Active ingredient (a.i.):** Mesotrione  
**PMRA Document Number :** 3196482

### Purpose of Application

The purpose of this application was to register Tide Mesotrione 480 SC Herbicide, a new end-use product for the control of annual broadleaf weeds in corn (field, seed and sweet), based on a registered precedent.

### Chemistry Assessment

Tide Mesotrione 480 SC Herbicide is formulated as a suspension containing mesotrione at a concentration of 480 g/L. This end-use product has a density of 1.1735 g/cm<sup>3</sup> and pH of 3.47. The required chemistry data for Tide Mesotrione 480 SC Herbicide have been provided, reviewed and found to be acceptable.

### Health Assessments

Tide Mesotrione 480 SC Herbicide is of low acute toxicity via the oral and dermal routes of exposure. It is of slight acute toxicity in rat via inhalation route. It is non-irritating to the eyes and the skin. It is not a skin sensitizer.

The use pattern of Tide Mesotrione 480 SC Herbicide is comparable to the registered 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 with this active ingredient. No health risks of concern are expected for workers and bystanders when label directions, precautions and restrictions are followed.

No new residue data were submitted or are required to support the registration of Tide Mesotrione 480 SC Herbicide. Previously reviewed residue data were re-assessed in the framework of this application. The use directions for corn on the Tide Mesotrione 480 SC Herbicide label, including the method (ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to the precedent product. Based on this assessment, residues are not expected to be greater than that for the currently registered corn uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues

of mesotrione is not expected to increase with the registration of Tide Mesotrione 480 SC Herbicide and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

As the use patterns, application method, and application rates are the same as those for the precedent product, the registration of Tide Mesotrione 480 SC Herbicide will not pose any additional risks to the environment. The required environmental precautions and hazard statements to mitigate risks to the environment are included in the label. When used according to label directions, the environmental risks are acceptable for Tide Mesotrione 480 SC Herbicide.

### **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 assessment consisted of a comparison of the formulation of Tide Mesotrione 480 SC Herbicide to that of the precedent product. Based on the weight of evidence, agronomic equivalence between Tide Mesotrione 480 SC Herbicide and the precedent product was established. Therefore, all labelled uses and claims found on the precedent product label are supported for inclusion on the Tide Mesotrione 480 SC Herbicide 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 Tide Mesotrione 480 SC Herbicide.

### **References**

<b>PMRA Document Number</b>	<b>Reference</b>
3115650	2020, Summary of DACO Part 3 Product Chemistry Data Supporting Tide Mesotrione 480 SC Herbicide, DACO: 12.7.3, Document J, Document M
3115652	2020, The Formulation Process of Tide Mesotrione 480 SC Herbicide, DACO: 3.2.1, 3.2.2, 3.2.3 CBI
3115654	2017, Purity of Mesotrione Tide and Analytical Method Validation for active ingredient content Mesotrione, DACO: 3.4.1
3115655	2017, Physical State, Appearance, Color, and Odor of Mesotrione Tide, DACO: 3.5.1, 3.5.2, 3.5.3 CBI
3115656	2017, Determination of the Thermal and Air Stability of Mesotrione Tide and corrosion characteristic, DACO: 3.5.10 CBI
3115657	2017, Flash point of Mesotrione Tide, DACO: 3.5.11 CBI
3115658	2017, Miscibility in water and organic solvents of Mesotrione Tide, DACO: 3.5.13 CBI

<b>PMRA Document Number</b>	<b>Reference</b>
3115660	2017, Determination of the density of Mesotrione Tide, DACO: 3.5.6 CBI
3115661	2017, Determination of the pH value of an aqueous solution of Mesotrione Tide, DACO: 3.5.7 CBI
3115662	2017, Oxidation/reduction: Chemical Incompatibility of Mesotrione Tide, DACO: 3.5.8 CBI
3115664	2017, Viscosity of Mesotrione Tide, DACO: 3.5.9 CBI
3115667	2017, Study of Acute Oral Toxicity in Rats ( <i>Rattus norvegicus</i> ) with the test substance Mesotrione Tide, DACO: 4.6.1
3115668	2017, Acute Dermal Toxicity in Rats ( <i>Rattus norvegicus</i> ) with the test substance Mesotrione Tide, DACO: 4.6.2
3115669	2017, Acute Inhalation Toxicity Test with Mesotrione Tide in Rats ( <i>Rattus norvegicus</i> ), DACO: 4.6.3
3115670	2017, Acute Eye Irritation/Corrosion in Rabbits ( <i>Oryctolagus cuniculus</i> ) with the Test Substance Mesotrione Tide., DACO: 4.6.4
3115671	2017, Acute Dermal Irritation/Corrosion study in Rabbits ( <i>Oryctolagus cuniculus</i> ) with the Test Substance Mesotrione Tide, DACO: 4.6.5
3115672	2017, Study of Skin Sensitization test In Guinea Pigs ( <i>Cavia porcellus</i> ) with the test substance Mesotrione Tide (Buehler Test Method), DACO: 4.6.6

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