



## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2023-4241  
**Application:** Application Subject to the Protection of Proprietary Interests in Pesticide Data (PPIP) Policy-Equivalency/Data Compensation Assessment  
**Applicant:** Northern CropScience Inc.  
**Product:** NCS SIKA 480 Herbicide  
**Registration Number:** 35320  
**Active ingredient (a.i.):** Trifluralin  
**PMRA Document Number:** 3627546

### Purpose of Application

The purpose of this application was to register the end-use product NCS SIKA 480 Herbicide, based on a registered precedent product.

### Chemistry Assessment

NCS SIKA 480 Herbicide is formulated as an emulsifiable concentrate containing trifluralin at a concentration of 480 g/L. This end-use product has a density of 1.0643 g/mL and a pH of 6.89. The required chemistry data for NCS SIKA 480 Herbicide have been provided, reviewed, and found to be acceptable.

### Health Assessments

NCS SIKA 480 Herbicide is considered toxicologically equivalent to the registered precedent product; therefore, no toxicology data were submitted or required. NCS SIKA 480 Herbicide is considered to be moderately acutely toxic by the oral route of exposure, and of low acute toxicity by the dermal and inhalation routes of exposure. It is considered to be a moderate eye irritant, a mild skin irritant, and a potential skin sensitizer.

The use pattern of NCS SIKA 480 Herbicide is comparable to the use pattern of the registered precedent product.

Therefore, potential exposure for mixers, loaders, applicators, bystanders and postapplication workers is not expected to exceed the current exposure to the registered products of 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 for trifluralin were submitted or were required to support the registration of NCS SIKA 480 Herbicide. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the NCS SIKA 480 Herbicide label, including the target crops, methods (ground), rates and timing of application, geographic restrictions, preharvest intervals, feeding restrictions, crop rotation restrictions, and tank-mix partners are comparable to those on the labels of the registered precedent end-use product.

Based on this assessment, residues are not expected to be greater than those from the currently registered uses and will be covered by the established maximum residue limits (MRLs). Consequently, dietary exposure to residues of trifluralin is not expected to increase with the registration of NCS SIKA 480 Herbicide, and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The environmental risks associated with the use of NCS SIKA 480 Herbicide on crops listed on the label are acceptable when used according to the label directions, which include statements to mitigate risk to the environment.

### **Value Assessment**

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

The formulation of NCS SIKA 480 Herbicide was compared to the formulation of the registered precedent product. The differences between the formulations were considered minor, and are unlikely to result in any significant impacts on product performance, in terms of efficacy and/or crop tolerance. Therefore, all uses and claims found on the registered precedent product label are supported for inclusion on the NCS SIKA 480 Herbicide label.

### **Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the registration of NCS SIKA 480 Herbicide.

## References

### PMRA

#### Document Number

#### Reference

3493988	2023, Manufacturing Process and Quality Control of Triflurazin 480 g/L EC, DACO: 3.2.1,3.2.2,3.2.3,3.3.1 CBI
3493990	2019, Validation of Analytical Method for the Determination of Active Ingredient Content of Trifluralin 480 g/L EC by HPLC Method, DACO: 3.4.1
3493991	2019, Determination of Miscibility of Trifluralin 480 g/L EC, DACO: 3.5.13
3493992	2019, Determination of pH of Trifluralin 480 g/L EC, DACO: 3.5.7 CBI
3493993	2019, Determination of Physical State, Color and Odor of Trifluralin 480 g/L EC, DACO: 3.5.1,3.5.2,3.5.3
3493994	2019, Determination of Viscosity of Trifluralin 480 g/L EC, DACO: 3.5.9
3493995	2019, Determination of Density of Trifluralin 480 g/L EC, DACO: 3.5.6
3493996	2019, Determination of Corrosion Characteristics of Trifluralin 480 g/L EC, DACO: 3.5.14
3493997	2019, Accelerated Storage Stability and Corrosion Characteristics of Trifluralin 480 g/L EC, DACO: 3.4.2,3.5.10,3.5.14
3493998	2019, Determination of Explosive Properties of Trifluralin 480 g/L EC, DACO: 3.5.12
3493999	2019, Determination of Flash Point of Trifluralin 480 g/L EC, DACO: 3.5.11
3494000	2019, Determination of Oxidation / Reduction Properties (Chemical Incompatibility) of Trifluralin 480 g/L EC, DACO: 3.5.8

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