July 2016

Product Review for Opensight Herbicide

Opensight Herbicide (EPA Reg. No. 62719-597) is one of the formulated products containing the active ingredient aminopyralid that is being reviewed for the Sensitive Area Materials List. The OpenSight Herbicide contains the active ingredients aminopyralid in the form of a potassium salt (62.13% wt/wt; corresponding to an acid equivalent (a.e.) aminopyralid concentration of 52.5% (wt/wt) and metsulfuron-methyl (9.45% wt/wt). Aminopyralid is the subject of the current review for addition to the Sensitive Area Materials List, while metsulfuron-methyl is an active ingredient that is already included on the list.

Following the methods for evaluation of herbicides for the Sensitive Area Materials List ¹, a review of available toxicological data for the formulated product was done. The purpose of this review was to evaluate if product-specific characteristics significantly alter the exposure potential or toxicity of the active ingredients.

The registrant provided summaries of ecotoxicity studies on the effects of the formulated product identified as GF-2050 containing 52.8% wt/wt aminopyralid (a.e.) and 9.3% wt/wt metsulfuronmethyl. Table 1 includes a summary of ecotoxicity endpoint values from studies that measured the effect of OpenSight Herbicide on various test organisms. Study summaries are also briefly included below.

Table 1. Sur	mmary of ecoto	oxicity data	for Opensigh	t Herbicide

Species	Endpoint Values			
Bobwhite Quail	14-d LD ₅₀	> 2250 mg/kg bw	No-Mortality	1350 mg/kg bw
Rainbow Trout	96-hr LC ₅₀	> 120 mg/L	NOEC	120 mg/L
Water flea	48-h LC ₅₀	> 120 mg/L	NOEC	120 mg/L
Green Algae	72-h Growth	17.58 mg/L	NOEC	0.4 mg/L
	Inhibition			
Earthworms	14-d LC ₅₀	> 2000 mg/kg soil		

Birds: An Acute Oral Toxicity Study with the Northern Bobwhite

In a 14-day acute toxicity study, northern bobwhite *Colinus virginianus* were administered a single oral dose of Opensight Herbicide at dosage levels of 0, 292, 486, 810, 1350 and 2250 mg/kg body weight. The acute oral LD₅₀ value for northern bobwhite exposed to Opensight Herbicide as a single oral dose was calculated to be greater than 2250 mg/kg, the highest dosage tested. The no mortality level was 1350 mg/kg. This study is classified as acceptable and satisfies the guideline requirements for an acute oral toxicity study with northern bobwhite.

There were no mortalities in the control group and all control birds were normal in appearance and behavior throughout the test. In addition, there were no mortalities in the 292, 486, 810 and 1350 mg/kg treatment groups. However, there was 10% (1 of 10) mortality at the 2250 mg/kg

¹ MassDEP/MDAR. 2010. Herbicide Evaluation Technical Update No. 1 - Methods for the Evaluation of Herbicides for use in Sensitive Areas of Rights-of-Way

1

dosage level. Clinical signs of toxicity were noted at the 810 mg/kg and all higher dosage levels. When compared to the control group, from Day 0 to Day 3 there was a statistically significant (p < 0.01), treatment-related, loss of mean body weight among males and females at the 2250 mg/kg dosage level.

Fish: Acute toxicity to Rainbow Trout

In a 96-hour acute toxicity test, rainbow trout *Oncorhynchus mykiss* were exposed to Opensight Herbicide at nominal concentrations of 0 (control) and 120 mg/L under static-renewal conditions and in accordance with OECD Guideline 203.

After 96 hours of exposure, there was no mortality and no sublethal effects were observed in either the 0 (control) or 120 mg Opensight Herbicide/L treatments. The 96-hour LC $_{50}$ was >120 mg Opensight Herbicide/L, the highest treatment tested. The 96-hour no-observed-effect concentration (NOEC) was 120 mg OpenSight Herbicide/L based on the absence of any mortality.

Aquatic Invertebrates: Acute toxity to Daphnia magna:

In a 48-hour static-renewal toxicity test, the freshwater invertebrate *Daphnia magna* was exposed to Opensight Herbicide. The criterion for effect was immobilization. Immobilization was defined for this test as an inability of organisms to swim within 15 seconds after gentle agitation of the test vessel even if they are able to move their appendages. The primary objective of this test was to estimate the 48-hour median effect concentration (EC₅₀) for Opensight Herbicide. A secondary objective was to determine the 48-hour no-observed-effect concentration (NOEC), if possible. The NOEC is defined as the highest concentration tested at which there is an absence of any abnormal effects or immobility.

After 48 hours of exposure, there was no immobility in the control or test substance treatments and all daphnids were considered normal. Since there was no immobility in any test substance treatment, the 48-hour EC_{50} was estimated to be >120 mg Opensight Herbicide/L, the highest concentration tested. The 48-hour NOEC was 120 mg Opensight Herbicide/L based on the absence of any abnormal effects or immobility at this and lower test substance concentrations.

Growth Inhibition of Unicellular Green Algae:

The influence of Opensight Herbicide on the growth of the freshwater green algae $Pseudokirchneriella\ subcapitata$ was assessed in a 72-hour static dose-response test at nominal concentrations of 10.0, 2.0, 0.4, 0.08 and 0.016 mg test item/L and a control. The number of algal cells in the control at test termination was 175-times the number initially inoculated. The 72-hour EC₅₀ value was calculated to be 17.58 mg/L for the parameter growth rate and 3.16 mg/L for the parameter yield. The 72-hour NOEC was determined to be 0.4 mg herbicide/L for both parameters.

Acute toxity to Earthworms:

In a 14-day acute toxicity test, earthworms *Eisenia fetida* were exposed to at a single Opensight Herbicide concentration of 2000 mg/kg soil and a control. After 14 days of exposure, no mortality was observed in the control or at the single (dose limit) test item (Opensight Herbicide) concentration of 2000 mg/kg soil dry weight. The 14-day LC₅₀ was estimated to be greater than 2000 mg/kg soil dry weight.

Although statistically significant, the body weight loss of 10.3% compared to the 4.5% weight loss observed in the control was not considered to be biologically relevant and it was not considered to be an adverse effect. No behavioral effects were observed in any treatment group.

Exposure Assessment

In order to evaluate the risk to non-target organisms, potential exposure levels of the herbicide product in soils and water were estimated. A conservative high-end exposure scenario was considered by assuming that there was no interception of spray by foliage and that soil or water area was over-sprayed and received all applied product. These are conservative assumptions considering that the application is done by foliar application to target plants such that only a fraction potentially reaches the soil surface. With respect to exposure to water bodies, the assumed scenario represents an accidental over-spray or 100% drift situation.

The concentrations of herbicide product in soil and water were calculated based on the maximum application rate of 0.090 kg product per acre. For soil exposure it was also assumed that applied product was mixed into a top soil layer with thickness of 1 inch or 4 inches. For water exposure, uniform mixing into shallow water bodies with a depth of 1 inch or 4 inches was considered. The calculated concentrations are listed in Table 2.

Table 2 Calculated concentrations of Herbicide Product in soil and water

Scenario	Concentration of Herbicide Product			
	(mg/kg for soil; mg/L for water)			
	1-inch Soil/Water Layer	4-inch Soil/Water Layer		
Soil	0.58	0.15		
Water	0.88	0.22		

Risk Evaluation

Based on the ecotoxicity data presented above and summarized in Table 1, and the exposure levels calculated for worst-case scenarios as listed in Table 2, it can be concluded that adverse effects to non-target organisms are not expected, except for green algae. As can be expected with an herbicide, green algae are more sensitive to this product. The NOEC for green algae is only exceeded in the scenario with direct over-spray of a 1-inch deep water layer. The exposure

levels are expected to be much lower under more realistic circumstances (e.g., product is applied to target vegetation foliage and mostly intercepted and absorbed by vegetation, thus not reaching the ground; exposure to water bodies is minimized by drift reduction measures and regulatory setbacks from such areas).

Comparison with the toxicity of the active ingredients (see active ingredient reviews of aminopyralid and metsulfuron-methyl) indicates that the product formulation does not significantly alter the toxicity to non-target organisms.

Surfactants in Opensight Herbicide:

The general policy for surfactant review is that compounds will be designated for additional review when available information indicates a potential for increased risk to non-target species. Information on surfactants in the Opensight Herbicide formulation was provided by the registrant, but cannot be disclosed here for proprietary reasons. The toxicity information for the surfactants is summarized in a separate document (MDAR, 2016) ²

The evaluation of the formulated product described above indicates that the presence of surfactants in the product formulation does not substantially increase ecological toxicity and risks to non-target organisms. This is consistent with the review of the information on surfactants. The surfactant compounds are of a nature and present at levels in the formulated product such that the use of the product as directed on the product label would not result in exposure levels that would produce adverse effects in non-target organisms.

References

Study reports provided by Dow AgroSciences, LLC, Indianapolis, IN 46268 (unpublished reports):

- Hubbard, P.M., Beavers, J.B., 2007. GF-2050: An Acute Oral Toxicity Study with the Northern Bobwhite.
- Warbritton, R., 2007. GF-2050: Acute Toxicity Test to the Rainbow Trout, *Oncorhynchus mykiss*, Determined Under Static-Renewal Test Conditions.
- Hicks, S.L., 2008. GF-2050: Acute Toxicity to the Water Flea, *Daphnia magna*,
 Determined Under Static-Renewal Test Conditions.
- Pupp, A., 2009. Toxicity of GF-2050 to Pseudokirchneriella subcapitata in an Algal Growth Inhibition Test.
- Luhrs, U. 2008. GF-2050: Acute toxicity (14 days) of GF-2050 to the Earthworm *Eisenia fetida* in artificial soil.

MDAR, 2016. Surfactants in Opensight Herbicide Formulation. Document for internal use.

² Surfactants in Opensight Herbicide