

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

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March 26, 2004

MEMORANDUM

SUBJECT: Mesosulfuron Methyl Section 3 - Uses on Winter Wheat (OSPREY; 4.5% mesosulfuron-methyl) and Spring Wheat, Including Durum (SILVERADO, 2.0% mesosulfuron-methyl)

Company Code(s) for Active Ingredient: AE F130060; HOE 130060

CAS Registry Number 208465-21-8

CAS: Methyl 2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-4-[[methyl-sulfonyl]amino]methyl]benzoate

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This memorandum transmits the ecological and environmental risk conclusions for Mesosulfuron methyl, the Environmental Fate and Ecotoxicity Assessments, and the Data Evaluation Records (DERs) of the studies submitted by Bayer in support of registration of this new sulfonylurea herbicide for use on spring and winter wheat.



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## Risk Conclusions

A major shortcoming of this risk assessment is that the terrestrial plant toxicity studies were not performed with the formulations proposed for use. Rather, a mixture of active ingredient, safener, and adjuvant were combined in ratios which differ from those in the proposed formulations. It is believed, based on an analysis of the combined materials and their ratios, that the tested material will underestimate the risks to terrestrial plants, with the possible exception of wheat. Wheat toxicity may actually be underestimated because a much lower ratio of safener to active ingredient was used in the test material. In addition, the test may not have been conducted for a sufficient duration for adverse effects to be fully expressed. ALS inhibitors do not act quickly, and symptoms of phytotoxicity are slow to develop. Had the study been conducted for a longer time, it is possible that phytotoxic effects would have been seen at lower test concentrations in more of the tested species.

Despite these rather serious shortcomings, the resulting screening-level ecological risk assessment still indicates that mesosulfuron exceeds Levels of Concern (LOC) for acute risk to non-target, endangered terrestrial plants. For aerial applications, the exceedances include all types of tested plants (with the exception of the safener protected wheat) for all of the proposed maximum application rates. Mesosulfuron methyl is not acutely toxic to animals, but animals may indirectly be affected by any loss of plant habitat. Dicot species are generally more sensitive to mesosulfuron than monocots, and the LOC (1) is exceeded by spray drift for both non-endangered and endangered plants. RQs ranged up to 27 for endangered dicots affected by spray drift. The distance (as estimated by AgDRIFT) from a aerially-treated area at which the  $EC_{05}$  (the endpoint for endangered species) is no longer exceeded is more than 1000 feet.

The LOC for aquatic vascular plants (LOC=0.5) was not exceeded. Although the level for endangered aquatic vascular plants was exceeded (LOC=3.7), there are no endangered aquatic vascular plants. However, a considerable uncertainty in the aquatic plant assessment is introduced by failure to conduct the test for the required 14 days. Had it been conducted for the required period, it is possible the LOC for aquatic vascular plants may have been exceeded.

With respect to chronic toxicity testing for animals, effects were not seen in the range of potential EEC's with one exception. The mallard duck exhibited a reproductive effect (reduced number of live embryos to viable embryos). However, the NOAEC could not be determined. If further testing with avian species demonstrates reproductive effects may occur within the residue range expected for mesosulfuron uses, then a more accurate estimate of the significance of effects to avian populations and the likelihood of recovery can be attempted. At this time potential avian reproductive effects remain an uncertainty.

## Environmental Fate

Biotransformation is the major route of degradation of mesosulfuron in the environment, as evidenced by mineralization (i.e., formation of  $CO_2$ ) in aerobic soils and persistence varying with microbial population and temperature. In water-sediment systems, persistence is also variable, mineralization is negligible and, like in soils, non-extractable residues increase with time.

Mesosulfuron produces degradates that have been identified for other sulfonylurea herbicides as well as degradates that are unique to this chemical.

As implied by the long replanting intervals recommended on the labels (up to 12 months), mesosulfuron remains phytotoxic in soils long after application. There have been instances of plant injury caused by dust blowing from areas treated with sulfonylurea herbicides. However, at this time, a means of estimating risk due to wind-blown residues has not been developed.

#### Data needed

##### 1. *Ecotoxicity data*

All ecotoxicity basic data requirements for an herbicide to be used in a terrestrial environment are fulfilled, but the following, higher tier data are needed to further understand the ecotoxicity of mesosulfuron methyl.

#### Guideline 122-1: Terrestrial Plant Vegetative Vigor Tier II (OPPTS GLNs 850.4150 )

A Tier II Vegetative Vigor test should be repeated using the Osprey (4.5% ai) formulated product. The Tier II Seedling Emergence study need not be repeated, since the greater risk to plants is from drift to growing plants. Registrant submitted plant testing was not performed with the proposed formulations (either Osprey or Silverado) or the appropriate adjuvants/surfactants. In addition, the test may not have been conducted for a sufficient duration for adverse effects to be fully expressed. Plant testing conducted with the actual products proposed for the U.S. market is generally required to satisfy terrestrial plant testing guidelines for U.S. EPA registration.

Although the Level of Concern (LOC) for both endangered and non endangered terrestrial plants has been exceeded using the registrant-submitted studies in EFED's risk assessment, the value added by a new Vegetative Vigor study is high because the risk to these plants may be greater (or lower) than presently estimated.

#### Guideline 71-4: Avian Reproduction (Mallard) (OPPTS GLN 850.2300)

In avian species testing with mallard, reduced numbers of viable embryos were observed at the lowest test dose (38 ppm). Thus, an accurate NOAEC for reproductive effects to sensitive waterfowl is not established. Since the predicted maximum mesosulfuron residue concentration on food items is 3 ppm, and the NOAEC for reproductive effects has not been proven to be higher than residue levels expected in the field, the value of this information is high..

#### **Waiver Requests**

EFED concurs with granting a waiver request for the freshwater fish early life stage study (D296120; GLN 72-4(a); OPPTS GLN 850.1400). Although no chronic reproductive effects data on fish were provided by the registrant, the OECD 28 day subchronic study with rainbow trout submitted by the registrant (MRID 45386232), while not adhering to current U.S. test

guideline requirements for a fish early life stage test, does provide sufficient information to determine that no adverse effects were present at the lowest concentration tested (29.6 ppm). Since maximum EECs from the proposed use of mesosulfuron on wheat are less than 1 ppb (4 orders of magnitude lower than the NOAEC), it is very unlikely that chronic effects to fish reproduction will occur.

### 3. *Environmental Fate and Analytical Chemistry Methods for Residues in Water*

All of the submitted environmental fate studies were scientifically sound and were deemed to be acceptable to support the registration of mesosulfuron **in winter-wheat growing areas**. The registrant requested waivers for the Volatility from Soil and Bioaccumulation in Fish studies (D 297232); the waivers were granted. However, the following data gaps remain:

#### Terrestrial Field Dissipation (GLN 164-1; OPPTS GLN 835.6100).

The registrant has provided terrestrial field dissipation studies from Florida, Illinois, and California, which are sufficient to support the winter wheat registration. However, no terrestrial field dissipation study conducted in a spring wheat-growing with a cold weather climate (such as North Dakota, the state most extensively planted with spring wheat) has been submitted to support the spring wheat registration. Because biotransformation is the major route of degradation of mesosulfuron in the environment, and its persistence varies with microbial population and temperature, the studies conducted in the warmer areas will likely underestimate the persistence of mesosulfuron in colder climates. The value of the additional information is medium.

#### Analytical Chemistry methods

The registrant did not submit any analytical chemistry methods to identify and quantify residues of mesosulfuron methyl and its degradates in water, as required. Therefore, the registrant must submit independently validated analytical chemistry methods to identify and quantify residues in water. The methods must be sufficiently sensitive to adequately determine and characterize mesosulfuron residues in water resources down to levels of ecotoxicological importance (e.g. aquatic animal NOAEC, aquatic plant EC<sub>05</sub>). The value of this additional information is high as it needed to complete the above recommended aquatic tests and will provide a means to assess irrigation water impacts, should that become necessary.