



## Evaluation Report for Category L, Subcategory 1.2 Application

**Application Number:** 2021-2158  
**Application:** Submission subject to the Protection of Proprietary Interests in Pesticide Data (PIIP) policy - Equivalency/Data Compensation Assessment  
**Product:** ADAMA Fluazinam 500 SC AG  
**Registration Number:** 35050  
**Active ingredient (a.i.):** Fluazinam  
**PMRA Document Number:** 3406972

### Purpose of Application

The purpose of this application was to register a commercial end-use product, ADAMA Fluazinam 500 SC AG, for the control or suppression of labeled diseases on various outdoor food and feed crops, based on a precedent product.

### Chemistry Assessment

ADAMA Fluazinam 500 SC AG is formulated as a suspension containing fluazinam at a concentration of 500 g/L. This end-use product has a density of 1.22 – 1.28 g/mL and pH of 6.5 – 8.5. The required chemistry data for ADAMA Fluazinam 500 SC AG have been provided, reviewed and found to be acceptable.

### Health Assessments

ADAMA Fluazinam 500 SC AG is of low acute toxicity by the oral, dermal, and inhalation routes. It is mildly irritating to the eye and slightly irritating to the skin. It is not a skin sensitizer.

The use pattern of ADAMA Fluazinam 500 SC AG 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 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 fluazinam were submitted or are required to support the registration of ADAMA Fluazinam 500 SC AG under the Protection of Proprietary Interest in Pesticides (PIIP) program. Previously reviewed residue data were re-assessed in the framework of this application.

The use directions on the ADAMA Fluazinam 500 SC AG label, including the target crops which are a subset of the registered uses on the precedent label, method (ground), rates and timing of application, preharvest intervals, feeding restrictions, and crop rotation restrictions are comparable to those on the label of the 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 fluazinam is not expected to increase with the registration of ADAMA Fluazinam 500 SC AG and will not pose health risks of concern to any segment of the population, including infants, children, adults and seniors.

### **Environmental Assessment**

The use of ADAMA Fluazinam 500 SC AG will not pose any additional risks to the environment. The required environmental precautions statements and spray buffer zones to mitigate risks to the environment are included in the label. When used according to label directions, the environmental risks are acceptable for ADAMA Fluazinam 500 SC AG.

### **Value Assessment**

Based on a comparison of formulations, ADAMA Fluazinam 500 SC AG is considered biologically equivalent to a registered precedent product and is expected to perform similarly against labelled diseases when applied as per label directions. The registration of ADAMA Fluazinam 500 SC AG will provide growers with an alternative product to manage disease on labelled crops.

### **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 ADAMA Fluazinam 500 SC AG.

## References

### PMRA

#### Document

Number	Reference
3206059	2021, Chemistry-3.1.1-3.1.4, 3.5.3-3.5.5, 3.5.14-Fluazinam 500 SC-15feb2021, DACO: 3.1.1,3.1.2,3.1.3,3.1.4,3.5.14,3.5.3,3.5.4,3.5.5
3206060	2020, Product identity and composition, Description of materials used to produce the product, Description of Formulation Process, Discussion of formation of impurities, Certified Limits and Submittal of Samples for MCW 465 500 SC, DACO: 3.2.1,3.2.2,3.2.3
3206061	2006, Validation of analytical HPLC method for determination of active substance content in a suspension concentrate formulation containing fluazinam, DACO: 3.4.1
3206062	2008, Accelerated Storage Stability of MCW 465 500 SC, DACO: 3.4.1,3.5.10
3206063	2019, MCW 465 500 SC-3.5.1,2,6,7- FSD_070419, DACO: 3.5.1,3.5.2,3.5.6, 3.5.7 CBI
3206065	2006, Physicochemical Properties of MCW 465 50 SC, DACO: 3.5.11,3.5.12, 3.5.8,3.5.9
3206066	2020, Acute Oral Toxicity Study of MCW465 500 SC Formulation in Rats, DACO: 4.6.1
3206067	2020, Acute Dermal Toxicity Study of MCW465 500 SC Formulation in Rats, DACO: 4.6.2
3206068	2008, MCW465 500 SC (Fluazinam) Acute Inhalation Toxicity Study (nose only) in Rats, DACO: 4.6.3
3206069	2020, Acute Eye Irritation (corrosion) Test of MCW465 500 SC in Rabbits, DACO: 4.6.4
3206070	2020, Acute Dermal Irritation (corrosion) Test (parch test) of MCW465 500 SC in Rabbits, DACO: 4.6.5
3206071	2020, Examination of MCW465 500 SC Formulation in the Skin Sensitization Test in Guinea Pigs Acute Dermal Irritation (corrosion) Test (parch test) of in Rabbits, DACO: 4.6.6

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