Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number: 2011-5143
Application: B.2.6 (New combination of TGAIs)
Product: Optill Bulk
Registration Number: 30755
Active ingredients (a.i.): Imazethapyr (IMP) and Saflufenacil (SFF)
PMRA Document Number : 2135804

Purpose of Application

The purpose of this application was to register a new repackaged manufacturing concentrate containing the active ingredients imazethapyr and saflufenacil. Optill Bulk will only be used for manufacturing, formulating and repackaging purposes.

Chemistry Assessment

Optill Bulk is formulated as water dispersible granules containing saflufenacil at 17.8% and imazethapyr at 50.2%. The manufacturing concentrate has a density between 0.46-0.56 g/mL and a pH between 3.0-4.5. The chemistry requirements for Optill Bulk are complete.

Health Assessments

Optill Bulk is of low acute toxicity to rats via the oral (LD_{50} > 2000 mg/kg bw), dermal (LD_{50} > 2000 mg/kg), and inhalation routes (LC_{50} > 5.1 mg/L). It is mildly irritating to the eye and slightly irritating to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

No new residue data for imazethapyr and saflufenacil were submitted, or were required, to support the registration of the new manufacturing concentrate Optill Bulk.

Environmental Assessment

Optill Bulk is not expected to adversely affect the environment if used according to the label instructions.

Value Assessment

Given that Optill Bulk will only be used for manufacturing, formulating and repackaging purposes a value assessment was not required for this application

Conclusion

Canada

The Pest Management Regulatory Agency has completed an assessment of the available information and is able to support the registration of Optill Bulk, a new manufacturing concentrate containing the active ingredients imazethapyr and saflufenacil.

References

PMRA No.	Title
2119642	2011, DACO 3 Chemistry Requirements for the Registration of Manufacturing Concentrates and End-Use Products Formulated from Registered Sources of Active Ingredients, DACO Requirements 3.1.1- 3.1.4, DACO: 3.1.1,3.1.2,3.1.3,3.1.4
2119643	2008, BAS 804 00 H Group A - Product Identity, Composition, and Analysis, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.4.2 CBI
2119644	2011, Description of Formulations of Optill, DACO: 3.2.1,3.7 CBI
2119645	2007, GLP Validation of Analytical Method AFR0067/01 and Certification of BAS 804 00 H Formulation Lot Number 1641-22, DACO: 3.4.1
2119647	2007, BAS 804 00 H: Determination of Physical state, pH, Explodability, and Density., DACO: 3.5.1,3.5.12,3.5.2,3.5.6,3.5.7
2119648	2010, BAS 804 00 H: Storage Stability and Corrosion Characteristics in Commercial Type Containers, DACO: 3.5.10,3.5.14
2119649	2009, Odor Determination of BAS 800 H Products, DACO: 3.5.3
2119650	2011, 3.5.4 Formulation Type, DACO: 3.5.4
2119651	2011, 3.5.5- Container Material and Description, DACO: 3.5.5
2119652	2007, BAS 804 00 H: Determination of Oxidation/Reduction, DACO: 3.5.8
2119653	2011, 3.5.9- Viscosity, 3.5.11- Flammability, 3.5.13- Miscibility, 3.5.15- Dielectric Breakdown Voltage, DACO: 3.5.11,3.5.13,3.5.15,3.5.9
2119654	2007, BAS 804 00 H - Acute Oral Toxicity Study with Rats (Acute Toxic Class Method), DACO: 4.6.1
2119655	2007, BAS 804 00 H - Acute Dermal Toxicity Study with Rats, DACO: 4.6.2
2119656	BAS 804 00 H: 4-hour Acute Inhalation Toxicity Study in Rats, DACO: 4.6.3
2119659	2007, BAS 804 00 H: Acute Eye Irritation in Rabbits, DACO: 4.6.4
2119660	2007, BAS 804 00 H: Acute Dermal Irritation/Corrosion in Rabbits, DACO: 4.6.5
2119661	2007, BAS 804 00 H: Modified BUEHLER Test (9 Inductions) in Guinea Pigs, DACO: 4.6.6

ISSN: 1911-8082