Health Canada Santé Canada

Evaluation Report for Category L, Subcategory 1.1 Application

Application Number: 2022-4973
Application: Application Subject to Protection of Proprietary Interests in Pesticide Data (PPIP) Policy – Equivalency/Data Compensation Assessment
Product: Flumioxazin Agrogill Technical Grade Active Ingredient
Registration Number: 35130
Active ingredient (a.i.): Flumioxazin
PMRA Document Number: 3529970

Purpose of Application

The purpose of this application was to register Flumioxazin Agrogill Technical Grade Active Ingredient, a new source of flumioxazin, based on a registered precedent product.

Chemistry Assessment

Common Name: Flumioxazin
IUPAC* Chemical Name: *N*-[7-fluoro-3,4-dihydro-3-oxo-4-(prop-2-ynyl)-2*H*-1,4-benzoxazin-6-yl]cyclohex-1-ene-1,2-dicarboximide
CAS† Chemical Name: 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propyn-1-yl)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione

* International Union of Pure and Applied Chemistry
† Chemical Abstracts Service

Flumioxazin Agrogill Technical Grade Active Ingredient has the following properties:

Property	Result
Colour and physical state	Light yellow powder
Nominal concentration	99.17 %
Odour	Odourless
Density	1.41 – 1.44 g/mL
Vapour pressure	3.02 mPa at 25 °C
pH	6.83

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Property	Result
Solubility in water	pH / Solubility (mg/L) 5 / 1.781 7 / 1.775
n-Octanol/water partition coefficient	log K_{ow} = 2.56

The required chemistry data for Flumioxazin Agrogill Technical Grade Active Ingredient have been provided, reviewed, and found to be acceptable.

Health, Environmental and Value Assessments

Health, environmental and value assessments were not required for this application.

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 Flumioxazin Agrogill Technical Grade Active Ingredient.

References

PMRA Document Number	Reference
3392014	2014, Validation of analytical method for determination of Flumioxazin active ingredient content and its associated impurities, DACO: 2.13.1,2.13.2 CBI
3392015	2014, Preliminary analyses of Five representative production batches of Flumioxazin Technical Grade Active Ingredient (TGAI) to determine % Flumioxazin and to Quantify its associated impurities, DACO: 2.13.3 CBI
3392016	2014, Appearance (Colour, Physical state and odour) of Flumioxazin, DACO: 2.14.1,2.14.2,2.14.3 CBI
3392017	2014, 20, 3392017, APPL, 2.14.4, 2022-09-15, DACO: 2.14.4 CBI
3392018	2014, Specific Gravity of Flumioxazin, DACO: 2.14.6 CBI
3392019	2014, Water Solubility of Flumioxazin, DACO: 2.14.7 CBI
3392020	2014, Solubility of Flumioxazin in Organic solvents, DACO: 2.14.8 CBI
3392021	2014, Vapour Pressure of Flumioxazin, DACO: 2.14.9 CBI
3392022	2014, Dissociation constant of Flumioxazin, DACO: 2.14.10 CBI
3392023	2014, Partition coefficient (n-Octanol/water) of Flumioxazin, DACO: 2.14.11 CBI
3392024	2014, Development and Validation of analytical method for active ingredient analysis of Flumioxazin, DACO: 2.14.12 CBI
3392025	2014, Accelerated storage stability and corrosion Characteristics of Flumioxazin, DACO: 2.14.13 CBI
3392026	2015, One year storage stability and corrosion characteristics study of Flumioxazin, DACO: 2.14.14 CBI
3392027	2014, pH of Flumioxazin, DACO: 2.14.15,830.7000 CBI
3442865	2023, DACO 2.11.2 Starting materials, DACO: 2.11.2 CBI
3442868	2023, Analysis of [CBI Removed] in 5 batch samples of Flumioxazin technical including full validation, DACO: 2.13.4 CBI
3501178	2023, DACO 2.11.2 Description of starting materials, DACO: 2.11.2 CBI
3501179	2023, DACO 2.11.3 Detailed Production Process Description -REV, DACO: 2.11.3 CBI
3505740	2023, DACO 2.13.1 Methodology Validation - in reference to JRF studies points 1,2 and 3 in the letter, DACO: 2.13.1 CBI
3505741	2023, Study report amendment, DACO: 2.13.1 CBI
3505742	2023, DACO 2.14.12 UV Visible absorption spectrum clarification, DACO: 2.14.12