Health Canada Santé Canada

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2015-1782
Application: Changes to TGAI Prod Chemistry-New Source - same registrant
Product: Phostrol 53.6% Fungicide
Registration Number: 30448
Active ingredients (a.i.): Mono- and dibasic sodium, potassium and ammonium phosphites
PMRA Document Number : 2653510

Purpose of Application

The purpose of this application was to register a new a new source of the technical grade active ingredient (TGAI), Phostrol 53.6% Fungicide.

Chemistry Assessment

Common Name: Mono- and dibasic sodium, potassium and ammonium phosphites

IUPAC* Chemical Name:
1. Diammonium hydrogen phosphite
2. Dipotassium hydrogen phosphite
3. Disodium hydrogen phosphite
4. Ammonium dihydrogen phosphite
5. Potassium dihydrogen phosphite
6. Sodium dihydrogen phosphite

CAS† Chemical Name:
1. Phosphonic acid, diammonium salt
2. Phosphonic acid, dipotassium salt
3. Phosphonic acid, disodium salt
4. Phosphonic acid, monoammonium salt
5. Phosphonic acid, monopotassium salt
6. Phosphonic acid, monosodium salt

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

Phostrol 53.6% Fungicide has the following properties:

Property	Result
Colour and physical state	Colourless to faint yellow liquid
Nominal concentration	53.6%
Odour	Faint ammonia odour
Density	1.410-1.412 g/mL
Vapour pressure	Not applicable
pH	6.5-7.5
Solubility in water	Completely miscible

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Property	Result
n-Octanol/water partition coefficient	N/A

The required chemistry data for Phostrol 53.6% Fungicide have been provided, reviewed, and found to be acceptable.

Health Assessments

There were no significant signs of toxicity, dermal or eye irritation and no signs of dermal sensitization in the acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary eye irritation, primary dermal irritation and dermal sensitization studies conducted using the new source of TGAI. The new source of TGAI is toxicologically equivalent to the registered source of TGAI.

Environmental Assessment

An assessment was not required for this application.

Value Assessment

An assessment was not required for this application.

Conclusion

The PMRA has reviewed the information provided in support of this application and has determined that the addition of the new source of TGAI is acceptable.

References

PMRA No.	Reference Title
2530273	2015, Manufacturing Method, DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4,2.13.4 CBI
2530274	2015, Site of Manufacture for Mono- and dibasic sodium, potassium, and ammonium phosphites, DACO: 2.2 CBI
2530275	2015, Product Identification for DACO 2.1, 2.3 to 2.9 for Phostrol 53.6% Fungicide, DACO: 2.1,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9 CBI
2530276	2015, Sample Characterization, Stability, Corrosivity, and 5 batch analysis for Phostrol Fungicide, DACO: 2.13.3,2.14,2.14.1,2.14.10,2.14.11,2.14.12,2.14.13,2.14.14,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI
2530277	2015, Submission of Samples of Analytical Standards and Residues of Concern of Mono- and dibasic sodium, potassium, and ammonium phosphites, DACO: 2.15
2530278	2015, Analysis of Phostrol 53.6% Fungicide, DACO: 2.12,2.13.1,2.13.2
2644440	2016, Excel Spreadsheet - Method Validation [CBI Removed], DACO: 2.13.1 CBI
2644441	2016, Excel Spreadsheet - Method Validation Summary of Raw Data, DACO: 2.13.1 CBI
2644442	2016, Raw Data, DACO: 2.13.1 CBI

2645587 [Privacy removed], 2016, Determination of the [CBI Removed] content in Phostrol 53.6% Fungicide Production Batches, DACO: 2.13.3 CBI
2645588 2016, Rationale for Use of [CBI Removed] for Determination of the [CBI Removed] in Phostrol Fungicide, DACO: 2.13.3 CBI
2530279 2015, Acute Oral Toxicity - Up-and-Down Procedure in Rats, DACO: 4.2.1
2530280 2015, DER for Acute Oral Toxicity - Up-and-Down Procedure in Rats, DACO: 4.2.1
2530281 2014, Acute Dermal Toxicity in Rats, DACO: 4.2.2
2530282 2014, DER for Acute Dermal Toxicity in Rats, DACO: 4.2.2
2530283 2015, Acute Inhalation Toxicity in Rats, DACO: 4.2.3
2530284 2015, DER for Acute Inhalation Toxicity in Rats, DACO: 4.2.3
2530285 2014, Primary Eye Irritation in Rabbits, DACO: 4.2.4
2530286 2014, DER for Primary Eye Irritation in Rabbits, DACO: 4.2.4
2530287 2014, Primary Skin Irritation in Rabbits, DACO: 4.2.5
2530288 2014, DER for Primary Skin Irritation in Rabbits, DACO: 4.2.5
2530289 2014, Local Lymph Node Assay (LLNA) in Mice, DACO: 4.2.6
2530290 2014, DER for Local Lymph Node Assay (LLNA) in Mice, DACO: 4.2.6

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