

Evaluation Report for Category B, Subcategory B.1.1, B.1.3 Application

Application Number: 2017-2397
Application: Changes TGAI Product Chemistry-New Source(site) same registrant, Changes TGAI Product Chemistry-Specifications
Product: Gibberellins A4 + A7 Technical Plant Growth Regulator
Registration Number: 28769
Active ingredients (a.i.): Gibberellins A4 and A7
PMRA Document Number : 2890464

Purpose of Application

The purpose of this application was to register a new source of active by the same registrant.

Chemistry Assessment

Common Name: Gibberellins A4 and A7
IUPAC* Chemical Name:

A ₄ :	(3S,3aR,4S,4aR,7R,9aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-3,9b-propanoazuleno[1,2-b]furan-4-carboxylic acid
A ₇ :	(3S,3aR,4S,4aR,7R,9aR,9bR,12S)-12-hydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]furan-4-carboxylic acid

CAS† Chemical Name:

A ₄ :	(1 α ,2 β ,4 α ,4b β ,10 β)-2,4a-dihydroxy-1-methyl-8-methylenegibbane-1,10-dicarboxylic acid 1,4a-lactone
A ₇ :	(1 α ,2 β ,4 α ,4b β ,10 β)-2,4a-dihydroxy-1-methyl-8-methylenegibb-3-ene-1,10-dicarboxylic acid 1,4a-lactone

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Gibberellins A4 + A7 Technical Plant Growth Regulator has the following properties:

Property	Result
Colour and physical state	White solid
Nominal concentration	96.74%
Odour	No detectable odour
Specific gravity	1.27
Vapour pressure	1.0×10^{-5} Pa (at 25°C)
pH	3.83

Property	Result
Solubility in water	127.0 mg/L (20°C, pH 4.4)
n-Octanol/water partition coefficient	Log K _{ow} = 2.47 (20°C, pH 4)

The required chemistry data for Gibberellins A4 + A7 Technical Plant Growth Regulator have been provided, reviewed, and found to be acceptable.

Health Assessments

The new source of the TGAI, Gibberellins A4 + A7 Technical Plant Growth Regulator, was found to be toxicologically equivalent to the registered source. Impurities or contaminants of concern to human health were not identified.

Gibberellins A4 + A7 Technical Plant Growth Regulator is of low acute oral, dermal, and inhalation toxicity, minimally irritating to the eyes, non-irritating to the skin, and is not a dermal sensitizer.

Occupational and dietary exposure assessments were not required for this application.

Environmental and Value Assessments

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 is able to support the new source for Gibberellins A4 + A7 Technical Plant Growth Regulator.

References

PMRA

Document

Number	Reference
2762055	2017, Applicant's Name and Office Address, DACO: 2.1
2762056	2017, Manufacturer's Name and Office Address and manufacturing Plant's Name and Address, DACO: 2.2 CBI
2762057	2017, Manufacturing Summary, DACO: 2.11.1 CBI
2762058	2017, Description of Starting Materials, DACO: 2.11.2 CBI
2762059	2017, Detailed Production Process Description, DACO: 2.11.3 CBI
2762060	2017, Discussion of Formation of Impurities, DACO: 2.11.4 CBI
2762061	2017, Establishing Certified Limits, DACO: 2.12.1 CBI
2762062	2017, Methodology/Validation, DACO: 2.13.1 CBI

	2016, 5 Batch Analysis of GA4/7 Technical Material, DACO:
2762063	2.13.1,2.13.2,2.13.3,2.13.4 CBI
2762064	2017, Confirmation of Identity, DACO: 2.13.2 CBI
2762065	2017, Batch Data, DACO: 2.13.3 CBI
2762066	2017, Impurities of Toxicological Concern, DACO: 2.13.4 CBI
	2009, Validation of GC Laboratories Ltd Method M652 [CBI removed]
	Determination of Impurities in Technical Gibberellins AG4/GA7 and
2859885	Determination of GA7 in Technical Gibberellin GA4/GA7, DACO: 2.13.1 CBI
	2009, Validation of GC Laboratories Ltd Analytical Method M564 [CBI
	removed] Determination of Gibberellins GA4 and GA7 in Technical Materials
	and Formulations Validation for GA47 in GA4/GA7 Technical Gibberellin,
2859886	DACO: 2.13.1 CBI

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