

Evaluation Report for Category B, Subcategory 1.1 Application

Application Number: 2013-3201
Application: Changes to TGAI Product Chemistry - New Source (site) Same Registrant
Product: Gibberellic Acid Technical Grade Active Ingredient
Registration Number: 28509
Active ingredients (a.i.): Gibberellic Acid [GIA]
PMRA Document Number : 2427428

Purpose of Application

The purpose of this application was to amend the registration of Gibberellic Acid Technical Grade Active Ingredient, PCPA Reg. No. 28509 by discontinuing one of the currently registered sites and adding three new manufacturing sites.

Chemistry Assessment

Common Name: Gibberellic acid
IUPAC Chemical Name: (3*S*,3*aS*,4*S*,4*aS*,7*S*,9*aR*,9*bR*,12*S*)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4*a*,7-methano-9*b*,3-propenoazuleno[1,2-*b*]furan-4-carboxylic acid
 or
 (3*S*,3*aR*,4*S*,4*aS*,6*S*,8*aR*,8*bR*,11*S*)-6,11-dihydroxy-3-methyl-12-methylene-2-oxo-4*a*,6-ethano-3,8*b*-prop-1-enoperhydroindeno[1,2-*b*]furan-4-carboxylic acid
CAS Chemical Name: (1*S*,2*S*,4*aR*,4*bR*,7*S*,9*aS*,10*S*,10*aR*)-1,2,4*b*,5,6,7,8,9,10,10*a*-decahydro-2,7-dihydroxy-1-methyl-8-methylene-13-oxo-4*a*,1-(epoxymethano)-7,9*a*-methanobenz[*a*]azulene-10-carboxylic acid

Gibberellic Acid Technical Grade Active Ingredient has the following properties:

Property	Result
Colour and physical state	White to pale yellow
Nominal guarantee	Gibberellic acid at 95.0%. Available chlorine present as 1-bromo-3-chloro-5,5-dimethylhydantoin and related hydantoins at 28.6% (limits 27.7-29.5%)
Odour	Practically odourless
Density	0.59-0.63 g/cm ³ at 24°C
Vapour pressure at 65°C	Not determined, <7 × 10 ⁻⁷ Torr (0.13 kPa)
pH	2.7 (1% slurry)
Solubility in water	0.46 g/100 mL

Property	Result
n-Octanol/water partition coefficient	$K_{ow} = 0.096$ at pH 5

The chemistry requirements for Gibberellic Acid Technical Grade Active Ingredient have been fulfilled.

Health Assessment, Environmental Assessment, and Value Assessment

These assessments were not required for this application.

Conclusion

PMRA has reviewed the information provided by the applicant for the three new manufacturing sites. It has been determined, based on this review, that these three new manufacturing sites are acceptable for registration.

References

7.1.1 Studies/Information Provided by Applicant/Registrant

PMRA Document Number	Reference
2315733	Product Identity Manufacturing Process Formation of Unintentional Ingredients Gibberellic Acid (GA3), DACO: 2.1, 2.11, 2.2, 2.3, 2.6 CBI
2315734	Gibberellic Acid (GA3) Technical Grade Active Ingredient Product Chemistry: Certification Of Limits, DACO: 2.12.1 CBI
2315735	GA3 Five-Batch Analysis CBI REMOVED, DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4 CBI
2315749	ID MFG Report GA3; 213-RE., DACO: 2.1, 2.11, 2.2, 2.3, 2.6 CBI
2315752	GA3_5-lot analysis CBI REMOVED., DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4 CBI
2315767	ID MFG Report GA3; 413-Q, DACO: 2.1, 2.11, 2.2, 2.3, 2.6 CBI
2315770	GA3_5-lot analysis_ CBI REMOVED DACO: 2.13.1, 2.13.2, 2.13.3, 2.13.4 CBI
2411325	CBI REMOVED Raw Material Consumption, DACO: 2.11.3
2411327	Reference to CBI REMOVED Co, DACO: 2.11.3
2411328	2013, GA3 Method Validation, DACO: 2.13.1 CBI
2411329	2010, Characterization of Gibberellic Acid (GA3) Reference Substance (Lot No. 138-361-VB-00), DACO: 2.13.2

PMRA Document Number	Reference
2411330	2012, Characterization of Gibberellic Acid Impurities for use as Reference Substances, DACO: 2.13.2 CBI
2411331	Dates of Manufacturing: CBI REMOVED, DACO: 2.13.3
2411332	CBI REMOVED - Certificates of Analysis (Manufacturing Dates), DACO: 2.13.3
2419796	2012, Spectroscopic Data for Gibberellin Reference Substances, DACO: 2.13.2 CBI
2419797	2014, Characterization of Gibberellins; Various Gibberellin TGAI's and Impurities (Identities presented in confidential appendix), DACO: 2.13.2 CBI
2419799	2014, Characterization of Gibberellins; Various Gibberellin TGAI's and Impurities (Identities presented in confidential appendix), DACO: 2.13.2 CBI

ISSN: 1911-8082

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