

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number:	2014-2081	
Application:	New/Changes TGAI – new source same registrant and	
	specifications	
Product:	Cyprosulfamide Manufacturing Use Concentrate	
Registration Number:	29072	
Active ingredients (a.i.):	Cyprosulfamide	
PMRA Document Number : 2543725		

Purpose of Application

The purpose of this application was twofold: to add an alternate manufacturing method to the registered F.1 source of cyprosulfamide safener (to be called F.2) and to register a new source (F.3) under the same registration number, PCPA Reg. #29072.

Chemistry Assessment

Common Name: IUPAC* Chemical Name:	Cyprosulfamide <i>N</i> -[4-(cyclopropylcarbamoyl)benzene-1-sulfonyl]-2- methoxybenzamide (PIN)	
	or N-[4-(cyclopropylcarbamoyl)phenylsulfonyl]- <i>o</i> -anisamide or	
CAS [†] Chemical Name:	<i>N</i> -[4-(cyclopropylcarbamoyl)phenylsulfonyl]-2-methoxybenzamide <i>N</i> -[[4-[(cyclopropylamino)carbonyl]phenyl]sulfonyl]-2- methoxybenzamide	

* International Union of Pure and Applied Chemistry

† Chemical Abstracts Service

Cyprosulfamide N		α (1)	4 6 11 1	· ·
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Cyprosuntaining iv	ianulaciuming Os		has the rono wh	ig properties.

Property	Result
Colour and physical state	White powder
Nominal concentration	98.7%
Odour	No characteristic odour
Relative density	1.64
Vapour pressure	$1.10 \times 10^{-8} \mathrm{Pa} \ (\mathrm{at} \ 25^{\circ} \mathrm{C})$



Property	Result	
рН	4.8	
Solubility in water	pH buffer 4 (target pH 4) buffer 6.9 (target pH 7) buffer 8.1 (target pH 9) bidistilled water (pH 5.1)	<u>Solubility (g/L)</u> 0.0034 1.09 26.1 0.0125
n-Octanol/water partition coefficient		<u>z K_{ow}</u> 77 80

The chemistry requirements for Cyprosulfamide Manufacturing Use Concentrate have been fulfilled.

Health Assessments

The alternate manufacturing method for cyprosulfamide and cyprosulfamide manufacturing in the new site were considered toxicologically equivalent to the currently registered source. No additional toxicological data are required at this time.

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 in support of the product, Cyprosulfamide Manufacturing Use Concentrate, and has found the information sufficient to add an alternate manufacturing method to the registered F.1 source of cyprosulfamide safener and to register a new source under the same registration number, PCPA Reg. #29072.

References

2433297	2014, Cyprosulfamide Manufacturing Use Concentrate - Information to Address PMRA
	DACO Elements 2.1 and 2.2, DACO: 2.1,2.2 CBI
2433298	2014, Cyprosulfamide (AE 0001789) Description of the Manufacturing Process of the
	Technical Grade Active Substance (Specification No. 102000006398), DACO:
	2.11.1,2.11.2,2.11.3 CBI
2433299	2014, Cyprosulfamide (AE 0001789) Description of the Manufacturing Process of the
	Technical Grade Active Substance (Specification No. 102000028697), DACO:
	2.11.1,2.11.2,2.11.3 CBI

- 2433300 2014, Cyprosulfamide (AE 0001789) Discussion of the Formation of Impurities in Cyprosulfamide (Specification No. 102000028697), (Specification No. 10200006398), DACO: 2.11.4 CBI
- 2433302 2013, Material accountability of technical Cyprosulfamide (AE 0001789), DACO: 2.12.1,2.13.1,2.13.2,2.13.3 CBI
- 2433303 2013, Material accountability of technical Cyprosulfamide (AE 0001789), DACO: 2.12.1,2.13.1,2.13.2,2.13.3 CBI
- 2484510 2009, Identification of Substances by NMR (1H, 13C, 19F, 31P), DACO: 2.13.1 CBI
- 2484511 2010, Cyprosulfamide Determination of active substance in technical material, DACO: 2.13.1 CBI
- 2484512 2010, Validation of [CBI REMOVED] AM008509MP1, DACO: 2.13.1 CBI
- 2484513 2010, Cyprosulfamide Determination of impurities in technical material, DACO: 2.13.1 CBI
- 2484514 2010, Validation of HPLC-method AM008609MP1 Cyprosulfamide Byproducts in technical grade active substance, DACO: 2.13.1 CBI
- 2484515 2013, Determination of [CBI REMOVED] in Cyprosulfamide technical grade active substance, DACO: 2.13.1 CBI
- 2484517 2013, Validation of [CBI REMOVED] Determination of [CBI REMOVED] in Cyprosulfamide technical grade active substance, DACO: 2.13.1 CBI
- 2484518 2013, Cyprosulfamide Determination of [CBI REMOVED] in Cyprosulfamide technical grade active substance, DACO: 2.13.1 CBI
- 2484519 2013, Validation of [CBI REMOVED] Determination of [CBI REMOVED] in Cyprosulfamide technical grade active substance, DACO: 2.13.1 CBI
- 2539193 2015, Spectral Data (NMR and MS) of Organic Impurities specified in Cyprosulfamide (AE0001789) Technical Material, DACO: 2.13.2 CBI

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