

Evaluation Report for Category B, Subcategory 1.2 Application

Application Number: 2011-5716
Application: New Source of Technical Grade Active Ingredient by a New Registrant
Product: S-Metolachlor Agrogill Technical Grade Active Ingedient
Registration Number: 32076
Active ingredients (a.i.): S-metolachlor
PMRA Document Number : 2577787

Purpose of Application

The purpose of this application is to register a new source of the active ingredient, S-metolachlor, by a different Registrant.

Chemistry Assessment

Common Name: S-metolachlor
IUPAC Chemical Name: mixture of 80–100% 2-chloro-*N*-(6-ethyl-*o*-tolyl)-*N*-[(1*S*)-2-methoxy-1-methylethyl]acetamide and 20–0% 2-chloro-*N*-(6-ethyl-*o*-tolyl)-*N*-[(1*R*)-2-methoxy-1-methylethyl]acetamide
CAS Chemical Name: 2-chloro-*N*-(2-ethyl-6-methylphenyl)-*N*-[(1*S*)-2-methoxy-1-methylethyl]acetamide

S-Metolachlor Agrogill Technical Grade Active Ingredient has the following properties:

Property	Result
Colour and physical state	Yellow liquid
Nominal concentration	98.89%
Odour	No charateristic odour
Specific gravity	1.1169
Vapour pressure	3.58 mPa at 25°C
pH	6.73 (1% aqueous solution)

Property	Result
Solubility in water at 20°C	pH
	5.03
	7.02
	9.05
n-Octanol/water partition coefficient (K_{ow})	$\log K_{ow} = 3.03 \pm 0.02$

The chemistry requirements for S-Metolachlor Agrogill Technical Grade Active Ingredient have been completed.

Health and Environmental Assessments

As the new source of S-metolachlor is chemically equivalent to the registered source, the health and environmental risk profiles are expected to be similar to that of the product used to determine chemical equivalence. No additional assessments were required.

Value Assessment

A value assessment is not required for technical grade active ingredient products.

Conclusion

The PMRA has completed an evaluation of the subject application and has determined that it can support the registration of S-Metolachlor Agrogill Technical Grade Active Ingredient.

References

PMRA Document Number	Reference
2132948	DACO 2.1 Applicant's Name and Office address, DACO: 2.1
2132951	Name and address of manufacturer, DACO: 2.2
2132952	DACO 2.3 Product Trade Name, DACO: 2.3
2132955	DACO 2.4 Common name, DACO: 2.4
2132958	DACO 2.5 Chemical Name, DACO: 2.5
2132960	Chemical Abstracts Registry Number, DACO: 2.6
2132961	DACO 2.7 Structural Formula, DACO: 2.7
2132962	DACO 2.8 Molecular formula, DACO: 2.8
2132964	DACO 2.9 Molecular weight, DACO: 2.9

2132965	DACO 2.11.1 Manufacturing summary, DACO: 2.11.1 CBI
2132966	DACO 2.11.2 Description of starting materials, DACO: 2.11.2 CBI
2132969	2.11.2 MSDS, DACO: 2.11.2
2132971	2.11.2 MSDS, DACO: 2.11.2
2132973	2.11.2 MSDS, DACO: 2.11.2
2132974	2.11.2 MSDS, DACO: 2.11.2
2132975	2.11.2 MSDS, DACO: 2.11.2
2132976	2.11.2 MSDS, DACO: 2.11.2
2132977	MSDS, DACO: 2.11.2
2132978	MSDS, DACO: 2.11.2
2132982	2.11.3 Detailed Production Process, DACO: 2.11.3 CBI
2132983	2.11.4 Discussion on Formation of Impurities, DACO: 2.11.4 CBI
2132984	DACO 2.12.1 Establishing certified limits, DACO: 2.12.1 CBI
2132985	2011, Validation of analytical methods for determination of S-Metolachlor and its associated impurities in S-Metolachlor technical samples, DACO: 2.13.1,2.13.2,2.13.3,2.14.12 CBI
2132986	2011, Preliminary analysis of Five representative production batches of S-Metolachlor Technical Grade Active Ingredieint (TGAI) To Determine% S-Metolachlor and to quantify associated impurities, DACO: 2.13.3 CBI
2132988	2011, Appearance (Colour, Physical state and Odour) of S-Metolachlor, DACO: 2.14.1,2.14.2,2.14.3
2132989	2011, Boiling Point or Boiling Range of S-Metolachlor, DACO: 2.14.5
2132991	2011, Specific Gravity of S-Metolachlor, DACO: 2.14.6
2132992	2011, water solubility of S-Metolachlor, DACO: 2.14.7
2132995	2011, Solubility of S-Metolachlor in organic solvents, DACO: 2.14.8
2133000	2011, Vapour Pressure of S-Metolachlor, DACO: 2.14.9
2133002	2011, Dissociation constant of S-Metolachlor, DACO: 2.14.10
2133003	2011, Partition coefficient (n-Octanol/water) of S-Metolachlor, DACO: 2.14.11
2133005	2011, Accelerated storage stability of S-Metolachlor, DACO: 2.14.13
2133006	No document: The samples are being sent directly from the Factory to PMRA., DACO: 2.15
2133007	2011, Validation of analytical method for the active ingredient analysis of S-Metolachlor, DACO: 2.16

2133008	2011, pH of S-Metolachlor, DACO: 2.16
2214691	DACO: 2.13.1 CBI
2214692	DACO: 2.13.4 CBI

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