

Evaluation Report for Category B, Subcategory 1.1, 1.3 Application

Application Number: 2009-3237
Application: B.1.1 – New Source (site) Same Registrant
B.1.3 – Change to Chemistry Specifications
Product: Thiencarbazone-methyl Technical Herbicide
Registration Number: 29068
Active ingredients (a.i.): Thiencarbazone-methyl
PMRA Document Number: 2280111

Purpose of Application

The purpose of this application was to register a new site of manufacture and change the chemical specifications for Thiencarbozaone-methyl Technical Herbicide.

Chemistry Assessment

Common Name: Thiencarbazone-methyl

Chemical Name: methyl 4-[[[(4,5-dihydro-3-methoxy-4-methyl-5-oxo-1H-1,2,4-triazol-1-yl)carbonyl]amino]sulfonyl]-5-methyl-3-thiophenecarboxylate

Thiencarbazone-methyl Technical Herbicide has the following properties:

Property	Result								
Colour and physical state	Light yellow solid								
Nominal concentration	97.8 %								
Odour	no characteristic odour								
Specific gravity	1.52								
Vapour pressure	8.8×10^{-14} Pa (20 °C)								
pH	3.8 (1 % solution)								
Solubility in water	pH 4 172 mg/L pH 7 436 mg/L pH 9 417 mg/L distilled water:72 mg/L								
n-Octanol/water partition coefficient	<table> <thead> <tr> <th>pH</th> <th>$\log K_{ow}$</th> </tr> </thead> <tbody> <tr> <td>4</td> <td>-0.13</td> </tr> <tr> <td>7</td> <td>-1.98</td> </tr> <tr> <td>9</td> <td>-2.14</td> </tr> </tbody> </table>	pH	$\log K_{ow}$	4	-0.13	7	-1.98	9	-2.14
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4	-0.13								
7	-1.98								
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The chemistry requirements for Thiencarbazone-methyl Technical Herbicide are complete.

Health Assessment

The new site of manufacture of Thiencarbazone-methyl Technical Herbicide is considered toxicologically equivalent. Therefore, no new toxicological data were required.

As the new site of manufacture will not alter the chemical properties of the registered Thiencarbazone-methyl Technical Herbicide, no change in the magnitude of the residues is anticipated. Therefore, the dietary exposure is not expected to increase and will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.

Environmental and Value Assessments

Environmental and value assessments were not required for this application.

Conclusion

The PMRA has reviewed the information provided and has determined the new site of manufacture of Thiencarbazone-methyl Technical Herbicide is acceptable.

References

PMRA No	Title
1795041	2009, Thien carbazone-methyl Technical Herbicide Manufactured at [CBI removed], DACO: 2.0, 2.1, 2.11, 2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.12, 2.12.1, 2.13, 2.13.1, 2.13.2, 2.13.3, 2.2, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 CBI
1795053	2009, Thien carbazone-methyl (BYH 18636) - Description of the manufacturing process of the technical grade active substance - [CBI removed] CBI
1795052	2009, Thien carbazone-methyl (BYH 18636) technical material manufactured by [CBI removed] - Discussion of the formation of impurities, DACO: 2.11.4 CBI
1409997	2006, Thien carbazone-methyl / BYH 18636 - Determination of active substance in technical material HPLC - internal standard, DACO: 2.13.1, IIA 4.2.1 CBI
1409996	2006, Validation of Thien carbazone-methyl Determination of active substance in technical material HPLC - internal standard, DACO: 2.13.1, IIA 4.2.1 CBI
1410001	2006, Thien carbazone-methyl / BYH 18636 - By-products in technical grade active substance HPLC - external standard, DACO: 2.13.4, IIA 4.2.3 CBI
1410000	2006, Validation of HPLC-method AM0036006MP1 - Thien carbazone-methyl by-products in technical grade active substance HPLC - external standard, DACO: 2.13.4, IIA 4.2.3 CBI
1795054	2009, Material accountability of thien carbazone-methyl manufactured at [CBI removed] - Five batches of technical thien carbazone-methyl, DACO: 2.12.1, 2.13.2, 2.13.3 CBI
1795055	2009, Material accountability of thien carbazone-methyl manufactured at [CBI removed] - Six batches of technical thien carbazone-methyl, DACO: 2.12.1, 2.13.2, 2.13.3 CBI

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