

Evaluation Report for Category B, Subcategory 2.6 Application

Application Number:	2008-1023
Application:	B.2.6 : New Manufacturing Concentrate – New Combination of
	TGAIs
Product:	PP-23235 MUP
Registration Number:	29276
Active ingredients (a.i.):	Metsulfuron-methyl, Tribenuron-methyl and Thifensulfuron-
	methyl
PMRA Document Number:	: 1725701

Purpose of Application

The purpose of this application is to register the new manufacturing concentrate PP-23235 MUP.

Chemistry Assessment

PP-23235 MUP is a solid containing the active ingredients tribenuron-methyl, thifensulfuronmethyl and metsulfuron-methyl at nominal concentrations of 23.1%, 23.1% and 4.6% respectively. This manufacturing concentrate has a pour density of 0.57 - 0.67 g/cm3 and pH of 7.5. The chemistry requirements for PP-23235 MUP have been completed.

Health Assessments

Based on the availability of complete acute toxicity studies for the three registered manufacturing use products present in PP-23235 MUP, no additional toxicological data were required.

No new residue data were submitted to support the registration of the new manufacturing concentrate PP-23235 MUP, a formulation containing three registered active ingredients; thifensulfuron methyl, tribenuron methyl and metsulfuron methyl. The disposition, translocation and magnitude of the residues of each active ingredient are not expected to be affected when they are formulated together. This new manufacturing concentrate will be used to formulate registered end-use products and thus the dietary risk 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 Assessment

An environmental assessment of PP-23235 MUP for use in the manufacture and formulation of herbicides was not required since the active ingredients used are the same and in the same amounts as that currently registered. Thus, there will be no increase in environmental exposure. Environmental concerns have been mitigated through adequate statements on the product label.

Value Assessment

Value assessment is not required for this application.

Conclusion

PP-23235 MUP is acceptable for full registration.

References

PMRA 857087.	2004, Tribenuron Methyl 50SG Water Soluble Granular Herbicide Formulation: Laboratory Study of Physical and Chemical Properties, Dupont-11674, MRID: N/S, DACO: 3.5 CBI (sub# 2004-1883).
PMRA 832683.	Thifensulfuron Methyl/Tribenuron methyl 50SG (33.3/16.7% active ingredient ratio) Water-soluble Granular Blend of Herbicide Formulations: Laboratory Study of Physical and Chemical Properties. Date Study Completed: July 8, 2003. du Pont-12260, DACO: 3.5 CBI (sub # 2004-1563).
PMRA 1604081.	1999, Summary Report of Physical and Chemical Characteristics of End- Use Product Metsulfuron Methyl 60% Herbicide Formulation, DuPont- 2489, MRID: n/a, DACO: 3.5,3.5.1,3.5.2,3.5.3,3.5.6,3.5.7 (Data # 1).
PMRA 1044736.	Thifensulfuron Methyl 50SG Tribenuron Methyl 50SG 1:1 End Use Product Herbicide Blend Formulation: Laboratory Study of Storage Stability and Corrosion Characteristics, 13296, DACO: 3.5.10,3.5.14 CBI (sub # 2004-1563).
PMRA 1604083.	2000, Storage Stability and Corrosion Characteristics of End-Use Product Metsulfuron Methyl 60% Herbicide Formulation, DuPont-2490, MRID: n/a, DACO: 3.5.10,3.5.14 (sub # 2007-7518).
PMRA 1224126.	2006, Chemical and Physical Properties. (M6316 SG Herbicide, sub # 2006-3125).

PMRA 832430.	2004, Product Identity of End Use Product Thifensulfuron methyl 50SG/tribenuron methyl 50SG(DPX-R9674), a 2 to 1 Blend of Paste Extruded Granules(33.4% + 16.6% Active), Dupont-14050, MRID: N/S, DACO: 3.2,3.3.1 CBI (sub# 2004-1563).
PMRA 864672.	2003, Product Identity and Composition of End-Use Product Tribenuron Methyl 50SG, Dupont-12816, MRID: N/S, DACO: 3.2 CBI (sub# 2004-1563).
PMRA 864673.	2003, Product Identity and Composition of End-Use Product Thifensulfuron Methyl 50SG, Dupont-12821, MRID: N/S, DACO: 3.2 CBI (sub# 2004-1563).
PMRA 857083.	2003, Product Identity and Composition of End-Use Product Tribenuron Methyl 50SG, Dupont-12816, MRID: N/S, DACO: 3.2,3.3.1 CBI (sub# 2004-1883).
PMRA 1604076.	2001, Product Identity and Composition of End-Use Product Metsulfuron Methyl 60 WG (Paste Extruded Granule) CONFIDENTIAL ATTACHMENT, DuPont-4548 RV1, MRID: n/a, DACO: 3.2,3.2.1,3.2.2,3.2.3,3.3.1 CBI (sub # 2007-7518).
PMRA 1224120.	2006, Product Identity and Composition of End-Use Product Thifensulfuron Methyl 50 SG, MRID: n/a, DACO: 3.2 CBI (sub # 2006- 3125).
PMRA 832431.	2004, Validation of the HPLC/UV analytical method to verify the certified true limits of thifensulfuron methyl (DPX M6316), tribenuron methyl(DPX-L5300), and metsullfuron methyl(DPX T-6376) in WG and SG blended end-use products, DuPont-12950 RV 1, MRID: N/A, DACO: 3.4.1 (sub # 2004-1563 for PCP # 28144).

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