

Evaluation Report for Category B, Subcategory 2.1, 2.3, 2.4, 2.5 Application

Application Number: 2009-0600
Application: Product chemistry – guarantee, identity and proportion of
formulants and formulation type
Product: Mesotrione WP Manufacturing Concentrate
Registration Number: 29656
Active ingredients (a.i.): Mesotrione (MER)
PMRA Document Number : 1876285

Purpose of Application

The purpose of this application was to register a new formulation for the new manufacturing concentrate, Mesotrione WP Manufacturing Concentrate.

Chemistry Assessment

Mesotrione WP Manufacturing Concentrate is formulated as a wettable powder containing mesotrione at a nominal concentration of 45.0%. This product has a density of 0.231 g/mL and a pH of 4-6. The chemistry requirements for Mesotrione WP Manufacturing Concentrate are complete.

Health Assessments

Mesotrione WG Manufacturing Concentrate is toxicologically equivalent to Mesotrione 50 WG Herbicide. Mesotrione 50 WG Herbicide is of low toxicity to rats via the oral ($LD_{50} > 5000$ mg/kg), dermal ($LD_{50} > 5000$ mg/kg), and inhalation routes ($LC_{50} > 2.58$ mg/L). It is minimally irritating to the eye but is not an irritant to the skin of rabbits. It is not a dermal sensitizer in guinea pigs.

Environmental Assessment

Use of the proposed Mesotrione WP Manufacturing Concentrate is not expected to pose a risk to the environment.

Value Assessment

A value assessment was not required for this application.

Conclusion

The PMRA has conducted a review of the available information for this application and can support full registration for Mesotrione WP Manufacturing Concentrate.

References

List of Studies/Information Submitted by Registrant

Chemistry Assessment

PMRA No.	Title
1721923	2009, Identification, DACO: 3.1.1,3.1.3,3.1.4 CBI
1721924	2009, Identification- Mesotrione WG Manufacturing Concentrate, DACO: 3.1.2 CBI
1721925	2009, Starting Materials- Mesotrione WG Manufacturing Concentrate, DACO: 3.2.1 CBI
1721926	2009, Identification- Mesotrione WG Manufacturing Concentrate, DACO: 3.2.2 CBI
1721927	2009, Note to Reviewer- Mesotrione WG Manufacturing Concentrate, DACO: 3.2.2 CBI
1721928	2009, Discussion of Formation of Impurities- Mesotrione WG Manufacturing Concentrate, DACO: 3.2.3 CBI
1721929	2009, Certification of Limits- Mesotrione WG Manufacturing Concentrate, DACO: 3.3.1 CBI
1721930	2004, Enforcement Analytical Method- Mesotrione WG Manufacturing Concentrate, DACO: 3.4.1 CBI
1721931	2009, Chemical and Physical Properties- Mesotrione WG Manufacturing Concentrate, DACO:3.5.1,3.5.10,3.5.11,3.5.12,3.5.13,3.5.14, 3.5.15,3.5.2,3.5.3,3.5.4,3.5.5,3.5.6,3.5.7,3.5.8,3.5.9 CBI
1828098	2009, Mesotrione WP Manufacturing Concentrate- Response to clarifax for 2009-0600- Correction of DACO 3.1.1, 3.1.3 - 3.1.4, DACO: 3.1.1,3.1.3,3.1.4 CBI
1828099	2009, Mesotrione WP Manufacturing Concentrate- Response to clarifax for 2009-0600- DACO 3.5 CBI

Health Assessment

PMRA No.	Title
1721843	2004, Acute Oral Toxicity Up and Down Procedure in Rats with Mesotrione WG (50), DACO: 4.6.1
1721844	2004, Acute Dermal Toxicity Study in Rats- Limit Test with Mesotrione WG (50), DACO: 4.6.2
1721845	2004, Acute Inhalation Toxicity Study in Rats with Mesotrione 50 WG, DACO: 4.6.3
1721846	2004, Primary Eye Irritation Study in Rabbits with Mesotrione WG (50), DACO: 4.6.4
1721847	2004, Primary Skin Irritation Study in Rabbits with Mesotrione WG (50), DACO: 4.6.5
1721848	2004, Dermal Sensitization Study in Guinea Pigs (Buehler Method) with Mesotrione WG (50), DACO: 4.6.6
1721849	2005, Dermal Sensitization Study in Guinea Pigs (Buehler Method) with Mesotrione 50 WG, DACO: 4.6.6

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