Registration Decision RD2010-07

Mesosulfuron-methyl

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Table of Contents

Registration Decision for Mesosulfuron-methyl

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Mesosulfuron-methyl Technical Herbicide and Silverado WDG Herbicide containing the technical grade active ingredient Mesosulfuron-methyl to control wild oats in spring and durum wheat.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2010-01, *Mesosulfuron-methyl.* This Registration Decision[2] describes this stage of the PMRA's regulatory process for Mesosulfuron-methyl and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2010-01.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-01, *Mesosulfuron-methyl* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Mesosulfuron-methyl?

Silverado WDG Herbicide (containing the active ingredient mesosulfuron-methyl) is a postemergent herbicide, i.e., a herbicide applied after the crop has emerged from the ground. It is applied to spring and durum wheat using ground application equipment to control wild oats.

Silverado WDG herbicide contains the active ingredient mesosulfuron-methyl which belongs to the sulfonylurea family of herbicides and is classified as a Group 2 Herbicide. The primary mode of action of mesosulfuron-methyl is to block the enzyme acetohydroxyacid synthase (AHAS). Without this enzyme weeds typically die within 4 to 6 weeks after application.

Health Considerations

Can Approved Uses of Mesosulfuron-methyl Affect Human Health?

Mesosulfuron-methyl is unlikely to affect your health when used according to label directions.

Potential exposure to mesosulfuron-methyl may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when mesosulfuron-methyl products are used according to label directions.

The technical grade active ingredient mesosulfuron-methyl was of low acute oral and dermal toxicity and of slight toxicity by the inhalation route in rats. It was not irritating when applied to the skin of the rabbit but was minimally irritating to the rabbit eye. Mesosulfuron methyl was not a skin sensitizer in the guinea pig.

The formulation Silverado WDG Herbicide containing 2.26% of the technical active ingredient, mesosulfuron-methyl was of low acute toxicity via the oral, dermal and inhalation routes. It was minimally irritating to the skin but moderately irritating to the eye of the rabbit. Similar to the active ingredient, it was not a skin sensitizer.

Mesosulfuron-methyl did not cause cancer in animals and did not damage genetic material (DNA). There was also no indication that mesosulfuron-methyl caused damage to the nervous system and there were no adverse effects on the reproduction system. The first signs of toxicity in animals given daily doses of mesosulfuron-methyl over longer periods of time were effects in the stomach. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

When mesosulfuron-methyl was given to pregnant animals, no treatment related effects on the developing foetus or the mother were observed up to the limit dose, indicating that the foetus is not more sensitive to mesosulfuron-methyl than the adult animal. Because of this observation, extra protective factors were not warranted for risk assessment.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation which would ingest the most mesosulfuron-methyl relative to body weight, are expected to be exposed to less than 1% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from mesosulfuron-methyl is not of concern for all population sub-groups. Mesosulfuron-methyl is not carcinogenic; therefore, a cancer dietary exposure assessment is not required.

A single dose of mesosulfuron-methyl is not likely to cause acute health effects in the general population (including infants and children). An acute reference dose was not established, therefore an acute dietary intake estimate is not required.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States using mesosulfuron-methyl on wheat were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of the Proposed Registration Decision for mesosulfuron-methyl (PRD 2010-01).

Occupational Risks From Handling Mesosulfuron-methyl

Occupational risks are not of concern when Silverado WDG Herbicide is used according to the label directions, which include protective measures.

Farmers and pesticide applicators mixing, loading or applying Silverado WDG Herbicide as well as field workers re-entering freshly treated wheat fields can come in direct contact with Silverado WDG Herbicide on the skin or through inhalation of spray mists.

Therefore, the label will specify that anybody who is handling Silverado WDG Herbicide must wear a long-sleeved shirt, long pants, chemical resistant gloves and shoes plus socks during mixing, loading, clean-up and repair. In addition, the label will also specify to wear goggles or face shield during mixing/loading and for applicators to wear long-sleeved shirt, long pants and shoes plus socks.

Taking into consideration these label requirements and that occupational exposure is expected to be short to intermediate term, because this herbicide can only be applied once per season to any given field, risk to farmers, applicators or workers is not a concern.

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

For post-application, exposure is expected to be minimal since Silverado WDG Herbicide is applied directly to the ground using a groundboom sprayer shortly after it has been planted. Therefore, health risks to workers entering treated fields are not of concern.

Environmental Considerations

What Happens When Mesosulfuron-methyl is Introduced Into the Environment?

Mesosulfuron-methyl and its transformation products are non-persistent to moderately persistent in the environment (terrestrial and aquatic). The potential of these chemicals to reach groundwater is minimal. Mesosulfuron-methyl is expected to impact terrestrial plants, therefore, buffer zones are needed for the protection of non-target plants.

Mesosulfuron-methyl is transformed by micro-organisms in soil and aquatic systems. In soil, mesosulfuron-methyl is non-persistent to moderately persistent and its transformation products are not expected to be persistent. Adsorption studies indicate mesosulfon-methyl has relatively high soil mobility. However, a field dissipation study did not detect the herbicide below 30 cm. Leaching of mesosulfuron-methyl into ground water is, therefore, not expected to be a major route of contamination under Canadian wheat growing conditions. This is supported by the results of groundwater modelling scenarios. In aquatic systems, mesosulfuron-methyl is non-persistent to moderately persistent. Mesosulfuron-methyl and its transformation products are unlikely to accumulate in sediments as they transform rapidly under anaerobic conditions.

Mesosulfuron-methyl does not present a risk to earthworms, bees, birds, small mammals, fish, aquatic vascular plants, aquatic invertebrates and algae. As a herbicide, mesosulfuron-methyl poses a risk to non-target terrestrial plants. Precautionary statements are thus included on the end-use product (Silverado WDG Herbicide) label and buffer zones of 1 metre (terrestrial habitats) are required to mitigate risk to non-target plants from spray drift.

Value Considerations

What Is the Value of Silverado WDG Herbicide?

Silverado WDG Herbicide, a postemergence herbicide, controls wild oats in wheat (spring and durum).

A single application of Silverado WDG Herbicide provides effective control of wild oats in spring and durum wheat. Silverado WDG Herbicide is compatible with integrated weed management practices, conservation tillage, and conventional crop production systems. Silverado WDG Herbicide is applied after weed emergence, allowing growers to better assess whether the herbicide is suitable for the particular weed species present.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Silverado WDG Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a concern with users coming into direct contact with Silverado WDG Herbicide on the skin or through inhalation of spray mists, anyone mixing, loading and applying Silverado WDG Herbicide must wear appropriate personal protective equipment.

Wear a long-sleeved shirt, long pants, chemical resistant gloves and shoes plus socks during mixing, loading, clean-up and repair. In addition, wear goggles or face shield during mixing/loading. Applicators must wear long-sleeved shirt, long pants and shoes plus socks.

In addition, standard label statements to protect against drift during application were added to the labels.

Environment

A hazard statement was added to the product label because of the end-use product’s toxicity to non-target terrestrial plants. Buffer zones of 1 metre (terrestrial habitats) are required for their protection.

Other Information

1. The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

2. Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act.*

Appendix I Comments and Responses

1) **Comments on the toxicity profile of Technical Mesosulfuron-methyl and addition of supporting documentation to the Reference List.**
   Two comments were received regarding the incorrect citation of the PMRA reference numbers and the omission of PMRA document numbers in the Reference list.

   Response:
   The Reference List has been revised and corrected in the document. All original data that was reviewed in support of this decision has now been included in the Reference List in this document.

2) **Comment on the Nature of the Residue in Laying Hen.**
   A comment was received in regards to the calculation of total radioactive residue (TRR) values for egg white and yolk in Table: The Nature of the Residue in Laying Hen, Rows 9 and 10 on p. 36.

   Response:
   The PMRA concurs and the TRR values have been corrected to 0.011ppm for Egg Whites (Day 8) and 0.012 ppm for Egg Yolks (Day 10).

3) **Comment on the Toxicity to Non-target Species, Mallard Duck**
   A comment was received in regards to the incorrect LD50 value for a 5 day acute dietary study.

   Response:
   The PMRA concurs and the LD_{50} value has been corrected to >1210 mg ai/kg bw/day.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA No.	Title
1436929	2001, Description of the manufacturing process of the technical AI Mesosulfuron-methyl Coe: AE F130060, DACO: 2.11.1,2.11.2,2.11.3 CBI
1436930	2000, Discussion of the formation of impurities Mesosulfuron (proposed ISO) technical grade active ingredient Code: AE F130060, DACO: 2.11.4 CBI
1436931	2000, Analytical profile of five preliminary production batches Mesosulfuron (proposed ISO) technical grade active ingredient Code: AE F130060, DACO: 2.12.1,2.13.3 CBI
1436932	2000, Validation of the analytical method to determine AE F130060 in technical and pure mesosulfuron Mesosulfuron (proposed ISO) technical grade active ingredient Code: AE F130060, DACO: 2.13.1 CBI
1436933	2000, Validation of the analytical method AL065/96-3 to determine the organic impurities of AE F130060 in technical and pure mesosulfuron Mesosulfuron (proposed ISO) technical grade active ingredient Code: AE F130060, DACO: 2.13.1 CBI
1436934	2000, Validation of the analytical methods AL103/99-0 for the determination of [CBI REMOVED] and AL082/99-0 for the determination of [CBI REMOVED], DACO: 2.13 CBI
1436935	2000, Validation of the analytical method AL102/99-0 for the determination of AE F130060 (mesosulfuron), [CBI REMOVED] in AE F130060 02 WG15 A4, AE F130060 00 WG75 A1, AE F130060 02 WG13, DACO: 2.13.1 CBI
1436936	2000, Determination of the organic impurities in technical grade and pure active ingredient by HPLC (Analytical method) Mesosulfuron (proposed ISO) technical grade active ingredient Code: AE F130060, DACO: 2.13.1,2.13.2 CBI
1436937	2000, Analytical method Determination of [CBI REMOVED] in AE F130060 active ingredient technical by gas chromatography (GC) Code, DACO: 2.13.1, 2.13.2 CBI
1436938	2000, Determination of AE F130060 in technical grade and pure active ingredient by HPLC (Analytical method) Mesosulfuron (proposed ISO) technical grade active ingredient Code: AE F130060, DACO: 2.13.1,2.13.2 CBI

1436939 2000, Analytical method Determination of [CBI REMOVED] in AE F130060 active ingredient technical by gas chromatography (GC) Code: AE F130060, DACO: 2.13.1,2.13.2 CBI

1436940 2000, Determination of the colour AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 2.14.1

1436941 1997, The acid dissociation constant of Hoe 130060, DACO: 2.14.10

1436942 1997, The n-Octanol/Water Partition Coefficient of Hoe 130060, DACO: 2.14.11

1436943 2000, Spectral data (UV / VIS, IR, 1H-NMR, 13C-NMR, MS) and molar extinction coefficient Mesosulfuron (proposed ISO) technical grade active ingredient Code: AE F130060, DACO: 2.14.12

1436944 2000, Stability AE F130060, DACO: 2.14.13

1436945 2005, Stability of mesosulfuron technical, DACO: 2.14.14

1436947 2000, Determination of the physical state AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 2.14.2

1436948 2000, Determination of the odour AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 2.14.3

1436949 2000, Melting point / melting range. Boiling point / boiling range. Thermal stability. Explosive properties AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 2.14.4,2.14.5

1436950 2000, Relative density AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 2.14.6

1436951 1996, Report on the solubility of methyl-2-(3-(4,6-dimethoxypyrimidin-2- yl) ureidosulfonyl)-4-methansulfonamidomethyl-benzoate, Hoe 130060, in water and aqueous buffer solutions of pH 4, 5, 7, 9 and 10, DACO: 2.14.7

1436952 1996, Report on the solubility of methyl-2-(3-(4,6-dimethoxypyrimidin-2-yl) ureidosulfonyl)-4- methansulfonamidomethyl-benzoate, Hoe 130060, in organic solvents, DACO: 2.14.8

1436953 1996, The temperature dependence of the vapour pressure of Hoe 130060, DACO: 2.14.9

1436955 1997, AE F130060 substance, technical; AE F130060 00 1C95 0001 - Flammability (solids), DACO: 2.16

1436956 2000, Determination of the pH-value Ae F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 2.16

1436957 2007, Mesosulfuron-Methyl Technical Herbicide - Manufacturers Name and Office Address and Manufacturing Plants Name and Address, DACO: 2.2

1633680 2006, Material Accountability of AEF130060 (Mesosulfuron-methyl) Analytical Profile of Five Production Batches from [CBI REMOVED], DACO: 2.11.3,2.13.1,2.13.2,2.13.3 CBI

1633681 2005, Statement on the assignment of the structures of the impurities [CBI REMOVED] in technical AE F130060 (mesosulfuron-methyl), DACO: 2.13.2 CBI

1633682 safety data sheet, DACO: 2.15

1758276 2009, Mesosulfuron-methyl Technical Material ¿¿¿ Formation of the Impurities [CBI REMOVED], DACO: 2.11.4 CBI

1758277 2005, Analytical Method Determination of the Organic Impurities in Technical Grade and Pure Active Ingredient / HPLC External Standard, DACO: 2.13.1 CBI

1758278 2005, Validation of HPLC-Method AM009305FP1 Determination of By-Products in Technical Grade and Pure Mesosulfuron-Methyl by High Performance Liquid Chromatographie (HPLC), DACO: 2.13.1 CBI

1758279 2006, 1. Amendment to Report PA99/036 Mesosulfuron-methyl (Technical Grade Active Ingredient) Validation of the Analytical Method AL065/96-3 to Determine the Organic Impurities of AE F130060 in Technical and Pure Mesosulfuron, DACO: 2.13.1 CBI

1758280 2006, 1. Amendment to Report PA02/052 Mesosulfuron-methyl (technical grade Active Ingredient) Validation of the Analytical Method AL065/96-3 for the Determination of the Organic Impurities in Technical Grade and Pure AE F130060 by HPLC for the Additional Impurities AE F156657 an AE 0516803, DACO 2.13.1 CBI

1758281 2009, Statement on the identity of technical grade Mesosulfuron-methyl (AE F130060) and of organic impurities with regard to DACO 2.13.2 from PMRA (received April 2009), DACO: 2.13.2 CBI

1758282 2009, Statement on the identification, assignment and quantification of the organic impurities [CBI REMOVED] in technical grade mesosulfuron-methyl (AE F130060), DACO: 2.13.2,2.13.3 CBI

1758284 2009, Statement regarding DACO 2.13.4 from PMRA (received April 2009) concerning Mesosulfuron-methyl technical grade active ingredient, DACO: 2.13.4 CBI

1453427 2001, Dissipation of AE F115008 and AE F130060 in soil following application of AE F115008 WDG and AE F122006 WDG or AE F130060 WDG and AE F107982 WDG to a bare plot at the maximum proposed rates, USA, 1998, DACO: 8.2.2.1,8.2.2.2

1453429 2007, Analytical Method for Mesosulfuron-methyl In Sediment, DACO: 8.2.2.2

1453430 2000, Validation of the enforcement method EM F15/99-0 for surface and drinking water by HPLC-UV Code: AE F130060, DACO: 8.2.2.3

1453431 2000, Enforcement method for surface and drinking water by HPLC-UV Code: AE F130060, DACO: 8.2.2.3

1633683 2008, Mesosulfuron-methyl Technical Herbicide (Sub. No, 2007-4507) - A Scientific Rationale to address the Analytical Methodology For Soil and Sediment (DACO: 8,2.2.1 and 8.2.2.2), DACO: 8.2.2.1,8.2.2.2

1633684 2000, An Analytical Method for the Determination of Residues of AE F130360 in Soil by Liquid Chromatography Using UV Detection and for the Determination of its Metabolite AE F092944 in Soil by Gas Chromatography Using Mass Spectrometric Detection, DACO: 8.2.2.1, 8.2.2.2

1633685 2003, Method and Validation: Mesosulfuron-methyl (AE F130060) and its Metabolites AE F154851 and AE F099095 in Soil by LC/MS/MS, DACO: 8.2.2.1,8.2.2.2

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1758287 2003, Method and Validation: Mesosulfuron-methyl (AE F130060) and its Metabolites AE F160459 and AE F147447 in Water by LC-MS/MS, DACO: 8.2.2.3

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1437132 2007, Silverado WDG Herbicide - Formulating Plant's Name and Address, DACO: 3.1.2

1437133 2003, Product chemistry of Silverado herbicide, DACO: 3.1.4,3.2.1,3.2.2,3.3.1,3.4.1,3.4.2,3.5.1,3.5.11,3.5.12,3.5.13,3.5.14,3.5.15, 3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9 CBI

1437134 2000, Determination of AE F130060 (mesosulfuron), [CBI REMOVED] in formulated products by liquid chromatography (HPLC) (analytical method) Code: AE F130060 02 WG15 A4, DACO: 3.4.1 CBI

1437135 2000, Validation of the analytical method AL102/99-0 for the determination of AE F130060 (mesosulfuron), [CBI REMOVED] in AE F130060 02 WG15 A4, AE F130060 00 WG75 A1, AE F130060 02 WG13, DACO: 3

1437136 2000, Determination of the colour AE F130060 water dispersible granule 750 g/kg Code: AE F130060 00 WG75 A103, DACO: 3.5.1

1437137 2004, Stability of SILVERADO 2% WG, DACO: 3.5.10

1437138 2000, Flammability (Solids) AE F130060 water dispersible granule, 75% Code: AE F130060 00 WG75 A103, DACO: 3.5.11

1437139 2000, Auto - Flammability (Solids - Determination of relative self-ignition temperature) AE F130060 water dispersible granule 75% Code: AE F130060 00 WG75 A103, DACO: 3.5.11

1437140 2000, Explosive properties AE F130060 water dispersible granule 75% Code: AE F130060 00 WG75 A103, DACO: 3.5.12

1437141 2000, Determination of the corrosion characteristics AE F130060 water dispersible granule 750 g/kg Code: AE F130060 00 WG75 A103, DACO: 3.5.14

1437142 2000, Determination of the physical form AE F130060 water dispersible granule 750 g/kg Code: AE F130060 00 WG75 A103, DACO: 3.5.2

1437143 2000, Determination of the odour AE F130060 water dispersible granule 750 g/kg Code: AE F130060 00 WG75 A103, DACO: 3.5.3

1437144 2000, Determination of apparent density and tap density AE F130060 water dispersible granule 750 g/kg Code: AE F130060 00 WG75 A103, DACO: 3.5.6

1437145 2000, Determination of the pH-value AE F130060 water dispersible granule 750 g/kg Code: AE F130060 00 WG75 A103, DACO: 3.5.7

1437146 2000, Determination of the oxidizing and reducing properties AE F130060 water dispersible granule 750 g/kg Code: AE F130060 00 WG75 A103, DACO: 3.5.8

2.0 Human and Animal Health

PMRA No.	Title
1453419	2001, Summary of Residues and Plant & Farm Animal Metabolism of Mesosulfuron-Methyl, DACO: 6.1
1453420	2001, Summary of Toxicology and Animal Metabolism of Mesosulfuron-Methyl, DACO: 6.1
1453421	1999, Poultry - Metabolism, distribution and nature of the residues in eggs and edible tissues Code: AE F130060, DACO: 6.2
1453422	1999, Ruminant - Metabolism, distribution and nature of the residues in milk and edible tissues Code: AE F130060, DACO: 6.2
1453423	2000, Metabolism in wheat (Triticum aestivum) following single and double treatment at a nominal application rate of 30 g a.s./ha Each Code: (U-14C-phenyl)-AE F130060, DACO: 6.3
1453424	2001, Metabolism in wheat (Triticum aestivum) following single and double treatment at a nomial application rate of 10 g a.s./ha each Code: (2-14C-pyrimidil)-AE F130060, DACO: 6.3
1453444	2001, Summary of Residue Analytical Methods for Mesosulfuron-methyl (AE F130060), DACO: 12.7,8.2.2.4
1519725	1999, Poultry - Metabolism, distribution and nature of the residues in eggs and edible tissues, DACO: 6.2
1519726	2000, Metabolism in wheat (Triticum aestivum) following single and double treatment at a nominal application rate of 30 g a.s./ha each, DACO: 6.3
1530194	2007, “Metabolism in Wheat (Triticum aestivum) Following Single and Double Treatment at the Nominal Application Rate of 10 g as/ha Each, [2-14C-pyrimidyl]-AE 130060” (Mesosulfuronmethyl), DACO: 6.3
1437155	1999, Data generation method and validation for cereal by LC-MS/MS Code: AE F130060, DACO: 7.2.1
1437156	2001, Aged residue in wheat straw and shoot Radio validation of the residue analytical method EM F 08/99-0 Mesosulfuron-methyl Code: AE F130060, DACO: 7.2.1
1437157	2001, An Analytical Method for the Determination of Residues of AE F130060 in Cereal Crops by Liquid Chromatography Using Mass Spectrometric Detection (MS/MS), DACO: 7.2.1

1437158 2000, Enforcement Method for Cereal Grain, Straw and Shoot by LC-MS/MS Amidosulfuron (AE F075032) Metsulfuron-methyl (AE F075735) Iodosulfuron-methyl-sodium (AE F115008) AE F130060 AE F130360, DACO: 7.2.2

1437159 2000, Validation of the enforcement method EM F08/99-0 in cereal grain, straw and shoot by LC-MS/MS Code: AE F130060, DACO: 7.2.2

1437160 2000, Independent laboratory validation of the method of analysis EM F08/99-0 for the determination of AE F130060 in cereal (grain), DACO: 7.2.3

1437161 2001, Independent laboratory validation of the method of analysis EM F08/99-0 for the determination of AE F130060 in cereal (plant and straw), DACO: 7.2.3

1437162 2001, Multiresidue Method Testing for AE F130060 According to PAM, Appendix II, as Updated January, 1994, DACO: 7.2.4

1437163 2001, At Harvest AE F130060 and AE F115008 Derived Residues in Wheat (Grain, Straw, Hay and Forage) Following a Single Application of AE F130060 WDG or AE F115008 WDG at the Maximum Proposed Application Rates and Shortest PHI, USA, 1998, DACO: 7.2.5,7.4.

1437164 2003, Stability of AE F130060 in wheat shoot during deep freeze storage Mesosulfuron-methyl Code: AE F130060, DACO: 7.3

1437165 2001, Stability of AE F130060 in wheat grain during deep freeze storage Code: AE F130060 Interim report, DACO: 7.3

1437167 2003, Stability of AE F130060 in wheat straw during deep freeze storage Mesosulfuron-methyl Code: AE F130060, DACO: 7.3

1437168 2007, Rationale for Waiver of Requirement for Additional Supervised Residue And Residue Decline Studies, DACO: 7.4.1,7.4.2

1437169 2001, At Harvest AE F130060 and AE F115008 Derived Residues in Wheat (Grain, Straw, Hay and Forage) Following a Single Application of AE F130060 WDG and AE F115008 WDG at the Maximum Proposed Application Rates and Shortest PHI, USA, 1997, DACO: 7.4.1,7.4.

1437170 2000, Residues in rotated crops sown 31 days after application to bare soil at a rate of 15 g a.s./ha (2-14C-pyrimidyl)-AE F130060, DACO: 7.4.3

1437171 2000, Residues in rotated crops sown 1 year after application to bare soil at a rate of 15 g a.s./ha Code: (2-14C-pyrimidyl)-AE F130060, DACO: 7.4.3

1437172 2000, Residues in rotated crops sown 32 days after application to bare soil at a rate of 15 g a.s./ha (U-14C-phenyl)-AE F130060, DACO: 7.4.3

1437173 2000, Residues in rotated crops sown 1 year after application to bare soil at a rate of 15 g a.s./ha Code: (u-14C-phenyl)-AE F130060, DACO: 7.4.3

1437174 2000, Residues in rotated crops sown 4 months after application to bare soil at a rate of 15 g a.s./ha Code: (2-14C-pyrimidyl)-AE F130060, DACO: 7.4.3

1437175 2000, Residues in rotated crops sown 4 months after application to bare soil at a rate of 15 g a.s./ha Code: (U-14C-phenyl)-AE F130060, DACO: 7.4.3

1437176 2001, AE F130060 and AE F107892 Derived Residues in Wheat Grain and Processed Wheat Commodities Following Applications AE F130060 WDG and AE F107892 EC at Exaggerated Rates and the Shortest Proposed PHI, USA, 1999, DACO: 7.4.5

1437177 2001, Demonstrations that the Feeding Study Requirements for Mesosulfuron-methyl (AE F130060) Are Not Triggered, DACO: 7.5

1634539 2000, Validation of the Enforcement Method EM F08/99-0 of Cereal Grain, Straw and Shoot by LC-MS/MS Amidosulfuron (AE F075032) Metsulfuron-methyl (AE F075736) Iodosulfuron-methyl-sodium (AE F115008) AEF130060 AEF130360, DACO: 7.2.2

1634540 2000, Validation of the Enforcement Method EM F08/99-0 in Cereal Grain, Straw and Shoot by LC-MS/MS AEF130060, DACO: 7.2.2

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1634542 2001, Enforcement Method for Animal tissue, Milk and Egg by LC-MS/MS Amidosulfuron (AE F075032) Metsulfuron-methyl (AE F075736) Iodosulfuron-methyl-sodium (AE F115008) Mesosulfuron-methyl (AE F130060) Foramsulfuron (AE F130360), DACO: 7.2.2,7.2.3

1634543 2001, Validation of the Enforcement Method EM F07/00-0 for Animal tissue, Milk and Egg by LC-MS/MS Amidosulfuron (AE F075032) Metsulfuron-methyl (AE F075736) Iodosulfuron-methyl-sodium (AE F115008) Mesosulfuron-methyl (AE F130060) Foramsulfuron (AE F13036), DACO: 7.2.2, 7.2.3

1634545 2008, Rationale for Use of Mesosulfuron-methyl Residue Data Generated in the Presence of Synperonic A7 Adjuvant to Support Expected Residues in the Presence of Hasten Spray Adjuvant, DACO: 7.4.1

1634547 2003, Mesosulfuron-methyl: Magnitude of Residues in/on Wheat RAC treated with One Application of AE F130060 03 WG60 A1, with Various Tank Adjuvants and with Two PHIs (2001), DACO: 7.4.1

1436958 1996, Hoe 130060; Substance, technical; (Code: Hoe 130060 00 ZC96 0001) - Testing for acute oral toxicity in the male and female Wistar rat, DACO: 4.2.1

1436959 1996, Hoe 130060; Substance, technical; (Code: Hoe 130060 00 ZC96 0001) - Testing for acute dermal toxicity in the male and female Wistar rat, DACO: 4.2.2

1436960 2001, Testing for acute dust inhalation toxicity in male and female Sprague Dawley rats 4-hour LC50 AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 4.2.3

1436961 1996, Hoe 130060; Substance, technical; (Code: Hoe 130060 00 ZC96 0001) - Testing for primary eye irritation in the rabbit, DACO: 4.2.4

1436962 1996, Hoe 130060; Substance, technical; (Code: Hoe 130060 00 ZC96 0001) - Testing for primary dermal irritation in the rabbit, DACO: 4.2.5

1436963 1998, Sensitizing properties in the Pirbright-White guinea pig in a maximization test AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 4.2.6

1436964 1999, Subchronic (90 days feeding) oral toxicity study in mice Hoe 130060 substance technical Code: Hoe 130060 00 ZC96 0002, DACO: 4.3.1

1436967 1999, Subchronic (90 days feeding) oral toxicity study in rats Hoe 130060 substance technical Code: Hoe 130060 00 ZC96 0002, DACO: 4.3.1

1436969 2000, Dog 12 month dietary toxicity study Code: AE F130060 00 1C95 0001, DACO: 4.3.2

1436970 2000, In vivo dermal absorption in the rat using an oil suspension formulation (14C)-AE F130060 Code: AE F130060 01 1K12 A7, DACO: 4.3.4

1453395 2007, Waiver Request for 21-Day Dermal Study on Mesosulfuron-methyl, DACO: 4.3.5

1453397 2001, Dog oral 90 day repeated dose toxicity study (dietary administration) AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 4.3.8

1453398 2000, Mouse dietary oncogenicity (18 months) study AE F130060 technical substance Code: AE F130060 00 1C95 0001, DACO: 4.4.3

1453400 2000, Rat combined dietary chronic (12 and 24 months) and oncogenicity study AE F130060 technical substance Code: AE F130060 00 1C95 0001, DACO: 4.4.4

1453402 2000, Rat two-generation feeding-reproduction toxicity study with AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 4.5.1

1453403 1999, Rat oral developmental toxicity (teratogenicity) study AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 4.5.2

1453404 2001, Rabbit oral developmental toxicity (teratogenicity) study AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 4.5.3

1453405 1996, Hoe 130060; Substance, technical; (Code: Hoe 130060 00 ZC96 0001) - Bacterial reverse mutation test, DACO: 4.5.4

1453406 1998, AE F130060; substance, technical; Code: AE F130060 00 1C95 0001 - In vitro chinese hamster lung V79 cell HPRT mutation test, DACO: 4.5.5

1453407 1998, In vitro mammalian chromosome aberration test in V79 Chinese hamster lung cells AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 4.5.5

1453408 1998, Detection of DNA strand breaks in primary hepatocytes of male rats in vitro. UDS-test in primary rat hepatocytes AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 4.5.6

1453409 1998, AE F130060; substance, technical; Code: AE F130060 00 1C95 0001 - Mouse micronucleus test, DACO: 4.5.7

1453410 1997, Rat preliminary toxicokinetics: Absorption, distribution and elimination - oral low dose (10 mg/kg body weight) and oral high dose (1000 mg/kg body weight) Code: (2-pyrimidyl-14C) AE F130060, DACO: 4.5.9

1453411 1997, Rat - Absorption, distribution and elimination - single oral low dose (10 mg/kg body weight) Code: (phenyl-U-14C) AE F130060, DACO: 4.5.9

1453412 1999, Rat - Excretion via the bile - single oral low dose (10 mg/kg body weight) Code: (phenyl-U-14C) AE F130060, DACO: 4.5.9

1453413 1999, Rat - Absorption, distribution and elimination - repeated oral dose (7 x 250 mg/kg body weight) Code: (phenyl-U-14C) AE F130060, DACO: 4.5.9

1453414 2000, Rat preliminary toxicokinetics: Metabolism - oral low dose (10 mg/kg body weight) and oral high dose (1000 mg/kg body weight) Code:(2-14C-pyrimidyl)-AE F130060, DACO: 4.5.9

1453415 2000, Rat metabolism - single oral high dose (1000 mg/kg body weight) Code: (U-14C-phenyl)-AE F130060, DACO: 4.5.9

1453416 2000, Rat metabolism - single oral low dose (10 mg/kg body weight) (U-14C-phenyl)-AE F130060, DACO: 4.5.9

1453417 2000, Rat metabolism - repeated oral dose (7 x 250 mg/kg body weight) (U-14C-phenyl)-AE F130060, DACO: 4.5.9

1453418 1998, (Phenyl-U-14C) AE F130060 - Rat absorption, distribution and elimination - oral high dose (1000 mg/kg body weight), DACO: 4.5.9

1501631 2001, Testing for acute dust inhalation toxicity in male and female Sprague Dawley rats 4-hour LC50 AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 4.2.3 CBI

1501632 1998, Sensitizing properties in the Pirbright-White guinea pig in a maximization test AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 4.2.6 CBI

1501633 1999, Subchronic (90 days feeding) oral toxicity study in mice Hoe 130060 substance technical Code: Hoe 130060 00 ZC96 0002, DACO: 4.3.1 CBI

1501634 1999, Subchronic (90 days feeding) oral toxicity study in rats Hoe 130060 substance technical Code: Hoe 130060 00 ZC96 0002, DACO: 4.3.1 CBI

1501635 2001, Dog oral 90 day repeated dose toxicity study (dietary administration) AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 4.3.8 CBI

1501636 2000, Mouse dietary oncogenicity (18 months) study AE F130060 technical substance Code: AE F130060 00 1C95 0001, DACO: 4.4.3 CBI

1501637 2000, Rat combined dietary chronic (12 and 24 months) and oncogenicity study AE F130060 technical substance Code: AE F130060 00 1C95 0001, DACO: 4.4.4 CBI

1453521 2003, An Acute Oral LD50 Study in the Rat with AE F130060 01 WG14 B001, DACO: 4.6.1

1453522 2003, An Acute Dermal LD50 Study in the Rat with AE F130060 01 WG14 B001, DACO: 4.6.2

1453523 2003, An Acute Nose-Only Inhalation Study in Rats with AE F130060 01 WG14 B001, DACO: 4.6.3

1453524 2003, An Primary Eye Irritation Study in Rabbits with AE F130060 01 WG14 B001, DACO: 4.6.4

1453525 2003, An Primary Skin Irritation Study in Rabbits with AE F130060 01 WG14 B001, DACO: 4.6.5

1453526 2003, An Dermal Sensitization Study in guinea Pigs with AE F130060 01 WG14 B001 - Modified Buehler Design, DACO: 4.6.6

3.0 Environment

PMRA No.	Title
1436922	2004, EUROPEAN COMMISSION, HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL, Review report for the active substance mesosulfuron, DACO: 12.5
1453445	2000, Hydrolysis of 14C-AE F130060 at different pH values, DACO: 8.2.3.2
1453446	2000, Photolysis of 14C-AE F130060 on soil surface under laboratory conditions, DACO: 8.2.3.3.1
1453447	2000, Aqueous photolysis under laboratory conditions Code: (U-14C)-phenyl-AE F130060, DACO: 8.2.3.3.2
1453450	2000, Kinetics and metabolism in soil LS 2.2 at 10 degrees C and 20 degrees C under aerobic conditions Code: (2-14C-pyrimidyl)AE F130060, DACO: 8.2.3.4.2
1453452	2000, Degradation in three soils at 20 degrees C under aerobic conditions Code: (2-14C-pyrimidyl)AE F130060, DACO: 8.2.3.4.2
1453450	2000, Kinetics and metabolism in soil LS 2.2 at 10 degrees C and 20 degrees C under aerobic conditions Code: (2-14C-pyrimidyl)AE F130060, DACO: 8.2.3.4.2
1453449	2000, Degradation in four soils at 20 degrees C under aerobic conditions Code: (2-14C-pyrimidy)AE F130060, DACO: 8.2.3.4.2
1453458	2000, Aerobic degradation in two water/sediment - systems at 20 degrees C 14C-AE F130060 Code: AE F130060, DACO: 8.2.3.5.2,8.2.3.5.4
1453460	2001, Degradation in a water/sediment-system at different temperatures under anaerobic conditions in the laboratory (2-14C-pyrimidyl)- and (U-14C-phenyl)-AE F130060, DACO: 8.2.3.5.6
1453462	2000, Adsorption in three soils Code: AE F154851, DACO: 8.2.4.2
1453463	2000, Adsorption in three soils Code: AE F099095, DACO: 8.2.4.2
1453461	2000, The adsorption/desorption of (14C)-AE F130060 on nine soils Code: AE F130060, DACO: 8.2.4.2
1453465	1998, Acute toxicity to earthworms (Eisenia fetida) AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 9.2.3.1

1453466 1997, Code: Hoe 130060 00 ZC96 0002; identical to new AgrEvo code: AE F130060 00 1C96 0002 - Contact toxicity (LD50) to honey bees (Apis mellifera L.), DACO: 9.2.4.1

1453467 1996, Code: Hoe 130060 00 ZC96 0002 - Oral toxicity (LD 50) to honey bees (Apis mellifera L.), DACO: 9.2.4.2

1453468 1999, Acute toxicity to waterflea (Daphnia magna) AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 9.3.2

1453469 2000, Effects on growth and reproduction of Daphnia magna (waterflea) AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 9.3.3

1453469 2000, Effects on growth and reproduction of Daphnia magna (waterflea) AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 9.3.3

1453470 2001, 96 Hour Acute Toxicity to the Mysid Shrimp, Mysidopsis bahia, in a Static System AE F130060 Technical 95.7% w/w, DACO: 9.4.2

1453471 2000, AE F130060 00 1C96 0004 - Acute Toxicity to Eastern Oysters (Crassostrea virginica) Under Flow-Through Conditions, DACO: 9.4.4

1453472 1999, Acute toxicity to rainbow trout (Oncorhynchus mykiss) AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 9.5.2.1

1453473 1999, Acute toxicity to bluegill sunfish (Lepomis macrochirus) AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 9.5.2.2

1453474 2001, 96 Hour acute toxicity to the sheepshead minnow, Cyprinodon variegatus, in a static system AE F130060 technical 95.7 percent w/w, DACO: 9.5.2.4

1453475 2000, Effects on juvenile growth of rainbow trout (Oncorhynchus mykiss) in a 28 days static renewal system AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 9.5.3.1

1453476 1998, Bobwhite quail acute oral toxicity test AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 9.6.2.1

1453477 1998, Mallard duck acute oral toxicity study AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 9.6.2.2

1453478 1999, Bobwhite quail dietary LC50 study AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 9.6.2.4

1453479 1998, Mallard duck dietary LC50 study AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 9.6.2.5

1453480 2000, Bobwhite quail dietary reproduction study AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 9.6.3.1

1453481 1999, Mallard duck dietary reproduction toxicity study AE F130060 substance technical Code: AE F130060 00 1C95 0001, DACO: 9.6.3.2

1453482 2000, Algal growth inhibition - Pseudokirchneriella subcapitata AE F147447 (metabolite of AE F130060) substance, technical Code: AE F147447 00 1C93 0001, DACO: 9.8.2

1453485 2000, Algal growth inhibition - Navicula pelliculosa AE F130060 substance, technical Code: AE F130060 00 1C95 0001, DACO: 9.8.2

1453486 2001, Effect to Anabaena flos-aquae (Blue-Green Alga) in a Growth Inhibition Test, AE F130060 Technical, 95.7% w/w, DACO: 9.8.2

1453484 1998, Algal growth inhibition (Pseudokirchneriella subcapitata) AE F130060 substance, technical 94.6% Code: AE F130060 00 1C95 0001, DACO: 9.8.2

1453482 2000, Algal growth inhibition - Pseudokirchneriella subcapitata AE F147447 (metabolite of AE F130060) substance, technical Code: AE F147447 00 1C93 0001, DACO: 9.8.2

1453487 2001, Effect to Skeletonema costatum (Marine Diatom) in a Growth Inhibition Test AE F130060 Technical 95.7% w/w, DACO: 9.8.3

1453490 2002, Effect on Seedling Emergence of Non-Target Terrestrial Plants (Tier II), AE F130060+AE F107892, Water Dispersible Granule (75.3% w/w), Including a Representative Adjuvant, DACO: 9.8.4

1453489 2002, Effect on Vegetative Vigor of Non-Target Terrestrial Plants (Tier II), AE F130060+AE F107892, Water Dispersible Granule (75.3% w/w), Including a Representative Adjuvant, DACO: 9.8.4

1453491 2000, Duckweed (Lemna gibba G3) growth inhibition test AE F130060 substance, technical, 95.3 % Code: AE F130060 00 1C95 0001, DACO: 9.8.5

1453493 2000, Duckweed (Lemna gibba G3) growth inhibition test AE F160460 (metabolite of AE F130060) substance, pure Code: AE F160460 00 1B96 0001, DACO: 9.8.5

1453492 2000, Duckweed (Lemna gibba G3) growth inhibition test AE F160459 (metabolite of AE F130060) substance, pure Code: AE F160459 00 1B97 0001, DACO: 9.8.5

1453494 2000, Duckweed (Lemna gibba G3) growth inhibition test AE F147447, substance, technical (Metabolite of AE F130060) Code: AE F147447 00 1C93 0001, DACO: 9.8.5

1633687 2005, Request (DP 309996; decision# 350586) for the acceptance of a mallard duck reproductive toxicity study (MRID 45386229) for mesosulfuron-methyl (PC# 122009), DACO: 12.5.9

4.0 Value

1437128 2007, Mesosufuron herbicide for control of wild oat in spring and durum wheat..5.2, 10.5.3, 10.5.4. pp. 396, DACO: 10.1, 10.2.1, 10.2.2, 10.2.3.3, 10.3.2, 10.3.3, 10.4, 10.5.1, 10