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REGISTRATION DECISION

Thiacloprid

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Registration Decision for Thiacloprid

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the [Pest Control Products Act](#), is granting full registration for the sale and use of the active ingredient thiacloprid and the end-use product Calypso 480 SC Insecticide to control a variety of insect pests on pome fruit.

Current scientific data from the registrant were evaluated to determine if, under the proposed 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 Document¹ Proposed Registration Decision [PRD2007-02](#), *Thiacloprid*. This Registration Decision² describes this stage of the PMRA's regulatory process for thiacloprid 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 Proposed Registration Decision [PRD2007-02](#), *Thiacloprid*.

For more details on the information presented in this Registration Decision, please refer Proposed Registration Decision [PRD2007-02](#), *Thiacloprid*, which 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 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 registration³. The Act also requires that products have value⁴ when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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 the *Pest Control Products Act*.

⁴ "Value" as defined by subsection 2(1) of the *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 connexion with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g., children) and organisms in the environment (e.g., those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present 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 PMRA's website at www.pmra-arla.gc.ca.

What is Thiacloprid?

Thiacloprid is a neonicotinoid insecticide with locally systemic and translaminar characteristics, i.e., it penetrates the leaf tissues and forms a reservoir of active ingredient within the leaf. It is applied to pome fruit using ground application equipment to control a variety of insect pests. Thiacloprid acts as an agonist of the nicotinic acetylcholine receptor in the central nervous system, thus disturbing synaptic signal transmissions.

❖ Health Considerations

◆ Can Approved Uses of Thiacloprid Affect Human Health?

Thiacloprid is unlikely to affect your health when used according to the label directions.

Exposure to thiacloprid may occur through diet (food and water), when handling or applying the product or when picking apples. 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 (e.g., children and nursing mothers).

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 using thiacloprid products according to the label directions.

Both the technical grade active ingredient thiacloprid and the end-use product Calypso 480 SC Insecticide had health effects in animals when ingested and are considered to be potential skin sensitizers. Therefore, the label statements "Danger Poison" and "Potential Skin Sensitizer" are required as well as the skull and crossbones symbol. Health effects in animals given daily doses of thiacloprid over long periods of time included effects on the liver, thyroid gland, adrenal gland, testes and prostate gland. When thiacloprid was given to pregnant animals, effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus is not more sensitive to thiacloprid than the adult animal. Effects on reproduction were seen at doses that were highly toxic to adult animals. Thiacloprid was not genotoxic, but did cause cancer in animals. The risk assessment is conducted to ensure that the level of human exposure is well below the

lowest dose at which these effects occurred in animal tests. Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

There were also no indications that thiacloprid caused damage to the nervous system of adult animals, but signs of a structural change in the brain were observed in developing animals exposed before and after birth. Because of this observation in brain tissue, extra protective measures were applied to the risk assessment to further reduce the allowable level of human exposure to thiacloprid.

◆ **Residues in Water and Food**

Dietary risks from food and water are not of concern.

Aggregate dietary intake estimates (food and water) revealed that the general population and infants, the subpopulation that would ingest the most thiacloprid relative to body weight, are expected to be exposed to less than 6.2% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from thiacloprid is not of concern for all population subgroups. The lifetime cancer risk from the use of thiacloprid on pome fruit is considered acceptable.

A single dose of thiacloprid is not likely to cause acute health effects in the general population (including infants and children). An aggregate (food and water) dietary intake estimate for the highest exposed population (infants) was about 50% of the acute reference dose, which is not a health concern.

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using end-use products containing thiacloprid on apples and pears were sufficient to propose MRLs for pome fruit or processed food derived from pome fruit. These MRLs can be found in the Science Evaluation section of Proposed Registration Decision PRD2007-02, *Thiacloprid*.

◆ Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern provided that directions specified on the label are observed.

The risk to people who are exposed to thiacloprid both through diet or while picking apples at pick-your-own commercial operations has been assessed and is not of 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.

◆ Occupational Risks From Handling Calypso 480 SC Insecticide

Occupational risks are not of concern when Calypso 480 SC Insecticide is used according to the label directions, which include protective measures.

Pesticide applicators mixing, loading or applying Calypso 480 SC Insecticide and field workers entering freshly treated fields can come in direct contact with thiacloprid on the skin or through inhalation of spray mists. For this reason, the label will specify that anyone mixing or loading Calypso 480 SC Insecticide must wear a long-sleeved shirt, long pants, chemical-resistant gloves and boots, and that anyone applying Calypso 480 SC Insecticide must wear a long-sleeved shirt, long pants and boots. Taking into consideration these label requirements and that occupational exposure is expected to be limited as this insecticide is applied up to three times per season, risk to pesticide applicators and workers is not a concern.

❖ Environmental Considerations

◆ What Happens When Thiacloprid Is Introduced Into the Environment?

Thiacloprid is toxic to beneficial arthropods such as predatory and parasitoid insects; therefore, label instructions are required to protect these organisms during pesticide application. Thiacloprid is also toxic to freshwater and marine invertebrates; therefore, buffer zones are required during application.

Thiacloprid enters the environment when used as an insecticide on pome fruit trees. Thiacloprid is not persistent in soil and is slightly persistent to persistent in water. The major transformation products formed in the soil are moderately persistent to persistent in this medium. The major transformation product formed in water is moderately persistent. Neither thiacloprid nor its major transformation products are expected to leach through the soil profile beyond 30 cm; therefore, they are not expected to enter groundwater. Based on its low volatility (vapour pressure and Henry's law constant), thiacloprid residues are not expected in the air.

Thiacloprid and its major transformation products present a low risk to wild mammals, birds, earthworms, bees, terrestrial plants, fish, amphibians, algae and aquatic plants. However, given that thiacloprid is an insecticide, it is expected to adversely affect terrestrial insects other than bees as well as insects living in freshwater habitats in adjacent areas. It is also expected to adversely affect other freshwater and marine invertebrates. Therefore, specific instructions to reduce spray drift to terrestrial insects are provided on the product label. Also, buffer zones of 5 to 30 metres (depending on timing of application) are required to protect nearby freshwater and estuarine/marine habitats from the effects of spray drift.

❖ **Value Considerations**

◆ **What Is the Value of Thiacloprid?**

Thiacloprid, a neonicotinoid insecticide, controls a variety of insects in pome fruit.

A single application of Calypso 480 SC Insecticide provides effective control of a range of insect pests on pome fruit (apple, pear, crabapple, Oriental pear, quince, loquat and mayhaw). It is also compatible with current management practices and conventional crop production systems. Growers are familiar with monitoring techniques to determine if and when applications are needed.

Other insecticides from the same class as thiacloprid are currently registered for use on some crops in the pome fruit group; however, thiacloprid controls a broader range of pests and can be used on the entire crop group. Prudent use of insecticides in this class should be observed to prevent the development of resistance. When applied according to the label directions, thiacloprid is effective at controlling spotted tentiform leafminer, plum curculio, mullein bug, leafhoppers, codling moth, oriental fruit moth and apple maggot on pome fruit.

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 are required by law to be followed.

The key risk-reduction measures on the label of Calypso 480 SC Insecticide 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 having direct skin contact with Calypso 480 SC Insecticide, individuals must wear a long-sleeved shirt, long pants, chemical-resistant gloves and boots during mixing, loading, clean-up and repair activities. Applicators must wear a long-sleeved shirt, long pants and boots.

- **Environment**

Because Calypso 480 SC Insecticide is toxic to beneficial arthropods, exposure of these organisms to spray drift should be minimized. Specific instructions to reduce spray drift are provided on the product label.

Calypso 480 SC Insecticide cannot be sprayed within 5 to 30 metres of sensitive aquatic habitats. The distance allowed depends on the timing of application (early vs. late in the season).

Other Information

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.

Any person may file a notice of objection⁵ regarding this registration decision within 60 days from the date of publication of this Registration Decision Document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the information on [Requesting a Reconsideration of Decision](#) on the PMRA's website 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 maximum application rate per year**

In the document Proposed Registration Decision PRD2007-02, *Thiacloprid*, a discrepancy was noted in the maximum application rate per year of Calypso 480 SC Insecticide and its active ingredient thiacloprid.

Response

The noted discrepancy is due to a typographical error in the document. The correction is as follows:

“Section 1.3 Directions for Use

Calypso 480 SC Insecticide is to be applied no more than three times per season and a maximum application rate of ~~845~~ 875 mL product/ha/year cannot be exceeded.”

2. **Comments on the wording of “Section 7.4 Unsupported Uses”**

In the document Proposed Registration Decision PRD2007-02, *Thiacloprid*, it was noted that the wording “maximum application rate/ha/year” in “Section 7.4 Unsupported Uses” could be misinterpreted to mean a maximum single application of thiacloprid.

Response

The PMRA appreciates concern expressed regarding the wording of the “maximum application rate/ha/year” in Section 7.4 of Proposed Registration Decision PRD2007-02, *Thiacloprid*. Use instructions on the Calypso 480 SC Insecticide product label clearly addressed the concerns noted above.

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- PMRA 1043846 YRC 2894: Oncogenicity study in B6C3F1 mice (administration in the food over 2 years). Bayer AG. Study number: T9059195. Study report date: February 26, 1998. Part 6 of 8. DACO 4.4.2.
- PMRA 1043847 YRC 2894: Oncogenicity study in B6C3F1 mice (administration in the food over 2 years). Bayer AG. Study number: T9059195. Study report date: February 26, 1998. Part 7 of 8. DACO 4.4.2.
- PMRA 1043848 YRC 2894: Oncogenicity study in B6C3F1 mice (administration in the food over 2 years). Bayer AG. Study number: T9059195. Study report date: February 26, 1998. Part 8 of 8. DACO 4.4.2.
- PMRA 1043849 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 1 of 11. DACO 4.4.4
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- PMRA 1043850 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 2 of 11. DACO 4.4.4
- PMRA 1043851 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 3 of 11. DACO 4.4.4
- PMRA 1043852 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 4 of 11. DACO 4.4.4
- PMRA 1043866 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 5 of 11. DACO 4.4.4
- PMRA 1043867 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 6 of 11. DACO 4.4.4
- PMRA 1043853 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 7 of 11. DACO 4.4.4
- PMRA 1043854 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 8 of 11. DACO 4.4.4
- PMRA 1043855 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 9 of 11. DACO 4.4.4
- PMRA 1043856 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 10 of 11. DACO 4.4.4
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- PMRA 1043857 YRC 2894: Combined chronic toxicity carcinogenicity study in Wistar rats (dietary administration over 2 years). Bayer AG Institute of Toxicology. Study number: T7059067. Study report date: May 13, 1998. Part 11 of 11. DACO 4.4.4
- PMRA 1043858 YRC 2894 - Rationale for dose selection for a combined chronic toxicity/oncogenicity study in rats. Bayer AG, Fachbereich Toxikologie. Study report date: November 22, 1994. DACO 4.4.4.
- PMRA 1043859 A two-generation reproduction range-finding study with YRC-2894 technical in rats. Study number: MTD9425RH24084. Study report date: May 25, 1995. DACO 4.5.1.
- PMRA 1043860 A two-generation dietary reproduction study in rats using technical YRC 2894. Bayer Corporation. Study number: 95-672-FV. Study report date: December 8, 1997. Part 1 of 4. DACO 4.5.1.
- PMRA 1043861 A two-generation dietary reproduction study in rats using technical YRC 2894. Bayer Corporation. Study number: 95-672-FV. Study report date: December 8, 1997. Part 2 of 4. DACO 4.5.1.
- PMRA 1043862 A two-generation dietary reproduction study in rats using technical YRC 2894. Bayer Corporation. Study number: 95-672-FV. Study report date: December 8, 1997. Part 3 of 4. DACO 4.5.1.
- PMRA 1043863 A two-generation dietary reproduction study in rats using technical YRC 2894. Bayer Corporation. Study number: 95-672-FV. Study report date: December 8, 1997. Part 4 of 4. DACO 4.5.1.
- PMRA 1043864 A reproduction study in rats to determine if administration of technical YRC 2894 from gestation days 18 to 21 will cause Dystocia (Study number II). Bayer Corporation Agriculture Division Toxicology. Study number: 96-912-JK. Study report date: May 4, 1998. DACO 4.5.1.
- PMRA 1043865 A reproduction study in rats to determine if administration of technical YRC 2894 from gestation days 18 to 21 will cause Dystocia. Bayer Corporation Agriculture Division Toxicology. Study number: 96-972-ID. Study report date: July 24, 1998. DCO 4.5.1.
- PMRA 1043868 An experimental study to investigate the cause of dystocia and stillbirths in rats treated with technical grade YRC 2894. Bayer Corporation Agricultural Division Toxicology. Study number: 96-972-JE. Study report date: September 2, 1998. DACO 4.5.1.
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- PMRA 1043875 A one-generation dietary reproduction study in rats using technical grade YRC 2894 to evaluate the reproducibility of dystocia and an increase in stillbirths in the P generation of a two-generation dietary reproduction study in rats. Bayer Corporation Agriculture Division Toxicology. Study number: 96-972-12. Study report date: May 12, 1998. DACO 4.5.1.
- PMRA 1043876 Further examination of the increased occurrence of dystocia and stillbirths observed in a reproductive bioassay with an experimental cyanamide (YRC 2894). Bayer Corporation. Study number: 96-972-KF. Study report date: August 31, 1998. Part 1 of 2. DACO 4.5.1.
- PMRA 1043877 Further examination of the increased occurrence of dystocia and stillbirths observed in a reproductive bioassay with an experimental cyanamide (YRC 2894). Bayer Corporation. Study number: 96-972-KF. Study report date: August 31, 1998. Part 2 of 2. DACO 4.5.1.
- PMRA 1043890 An acute oral neurotoxicity screening study with technical grade YRC 2894 in Fischer 344 rats. Bayer Corporation, Agriculture Division, Toxicology. Study number: 95-412-GI, 97-912-MD. Study report date: May 12, 1997. DACO 4.5.12. Part 1 of 2.
- PMRA 1043891 An acute oral neurotoxicity screening study with technical grade YRC 2894 in Fischer 344 rats. Bayer Corporation, Agriculture Division, Toxicology. Study number: 95-412-GI, 97-912-MD. Study report date: May 12, 1997. DACO 4.5.12. Part 2 of 2.
- PMRA 1043892 A subchronic neurotoxicity screening study with technical grade YRC 2894 in Fischer 344 rats. Bayer Corporation, Agriculture Division, Toxicology. Study number: 95-472-DJ. Study report date: June 3, 1997. Part 1 of 2. DACO 4.5.13.
- PMRA 1043893 A subchronic neurotoxicity screening study with technical grade YRC 2894 in Fischer 344 rats. Bayer Corporation, Agriculture Division, Toxicology. Study number: 95-472-DJ. Study report date: June 3, 1997. Part 2 of 2. DACO 4.5.13.
- PMRA 1043894 Oral (diet) developmental neurotoxicity study of YRC 2894 in CRL:CD(SD)IGS BR VAF/PLUS. Study number: 99C-D72-ER. Study report date: September 24, 2001. Part 1 of 4. DACO 4.5.14.
- PMRA 1043895 Oral (diet) developmental neurotoxicity study of YRC 2894 in CRL:CD(SD)IGS BR VAF/PLUS. Study number: 99C-D72-ER. Study report date: September 24, 2001. Part 2 of 4. DACO 4.5.14.
- PMRA 1043896 Oral (diet) developmental neurotoxicity study of YRC 2894 in CRL:CD(SD)IGS BR VAF/PLUS. Study number: 99C-D72-ER. Study report date: September 24, 2001. Part 3 of 4. DACO 4.5.14.
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- PMRA 1043897 Oral (diet) developmental neurotoxicity study of YRC 2894 in CRL:CD(SD)IGS BR VAF/PLUS. Study number: 99C-D72-ER. Study report date: September 24, 2001. Part 4 of 4. DACO 4.5.14.
- PMRA 1043869 YRC 2894: Developmental toxicity study in rats after oral administration. Bayer AG. Study number: T2055246. Study report date: February 13, 1997. Part 1 of 3. DACO 4.5.2.
- PMRA 1043870 YRC 2894: Developmental toxicity study in rats after oral administration. Bayer AG. Study number: T2055246. Study report date: February 13, 1997. Part 2 of 3. DACO 4.5.2.
- PMRA 1043871 YRC 2894: Developmental toxicity study in rats after oral administration. Bayer AG. Study number: T2055246. Study report date: February 13, 1997. Part 3 of 3. DACO 4.5.2.
- PMRA 1043872 YRC 2894: Developmental toxicity study in rabbits after oral administration. Bayer AG Department of Toxicology. Study number: T5059074. Study report date: January 9, 1996. Part 1 of 2. DACO 4.5.3.
- PMRA 1043873 YRC 2894: Developmental toxicity study in rabbits after oral administration. Bayer AG Department of Toxicology. Study number: T5059074. Study report date: January 9, 1996. Part 2 of 2. DACO 4.5.3.
- PMRA 1043874 YRC 2894: Reverse mutation assay (Salmonella typhimurium and Escherichia coli). Nihon Bayer Agrochem K.K. Study number: 95A011. Study report date: August 21, 1995. DACO 4.5.4.
- PMRA 1043878 YRC 2894: Salmonella/Microsome Test. Bayer AG Department of Toxicology. Study number: T4049371. Study report date: February 13, 1995. DACO 4.5.4.
- PMRA 1043879 YRC 2894: Salmonella/Microsome Test: Plate incorporation and preincubation method. Bayer AG Department of Toxicology. Study number T5054097. December 9, 1994. DACO 4.5.4.
- PMRA 1043880 KKO 2254: Salmonella/Microsome Test: Plate incorporation and preincubation method. Bayer AG Department of Toxicology. Study number: T1053977. Study report date: October 31, 1995. DACO 4.5.4.
- PMRA 1043881 WAK 6999: Salmonella/Microsome Test: Plate incorporation and preincubation method. Bayer AG Department of Toxicology. Study number: T8053974. Study report date: October 26, 1995. DACO 4.5.4.
- PMRA 1043882 YRC 2894: DNA repair test in bacterial system. Nihon Bayer Agrochem K.K. Study number: 97220. Study report date: January 8, 1998. DACO 4.5.4.
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- PMRA 1043883 YRC 2894: Mutagenicity study for the detection of induced forward mutations in the V79-HPRT assay in vitro. Bayer AG Department of Toxicology. Study number: T7054080. Study report date: June 11, 1996. DACO 4.5.6.
- PMRA 1043884 YRC 2894: In vitro mammalian chromosome aberration test with Chinese hamster V79 cells. Bayer AG Department of Toxicology. Study number: T5054079. Study report date: November 23, 1995. DACO 4.5.6.
- PMRA 1043885 YRC 2894: Micronucleus test on the mouse. Bayer AG Department of Toxicology. Study number: T0059051. Study report date: November 23, 1995. DACO 4.5.7.
- PMRA 1043886 YRC 2894: Test of unscheduled DNA synthesis in rat liver primary cell cultures in vitro. Bayer AG Department of Toxicology. Study number: T8054081. Study report date: September 10, 1996. DACO 4.5.8.
- PMRA 1043887 [Methylene-¹⁴C]YRC 2894: General rat metabolism Part A: Distribution of the total radioactivity in the rat determined by conventional wholebody autoradiography and radioluminography. Bayer AG. Study number: M01819029. Study report date: June 26, 1996. DACO 4.5.9.
- PMRA 1043888 [Thiazolidine-4,5-¹⁴C] YRC 2894: Absorption, distribution, excretion and metabolism in the rat. Bayer AG. Study number: M81819036. Study report date: December 8, 1997. DACO 4.5.9.
- PMRA 1043889 [Methylene-¹⁴C] YRC 2894: General rat metabolism study. Part B: Toxicokinetics and metabolism in the rat. Bayer AG. Study number: M01819029. Study report date: February 5, 1998. DACO 4.5.9.
- PMRA 1043790 YRC 2894: Determination of aromatase activity in ovary and liver tissue of a modified 1-generation reproductive study in Sprague-Dawley rats. Bayer AG. Study number: PH-277 18E6062080. Study report date: July 27, 1998. DACO 4.8.
- PMRA 1043791 YRC 2894: Investigation of the inhibition of cytochrome P450 dependent monooxygenases in liver microsomes (in vitro). Bayer AG Department of Toxicology. Study number: T6053684. Study report date: July 21, 1998. DACO 4.8.
- PMRA 1043792 YRC 2894: Mechanistic studies on aromatase induction and toxicokinetics in rats (4-week feeding studies). Bayer AG Department of Toxicology. Study number: T 3062311. Study report date: July 27, 1998. DACO 4.8
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- PMRA 1043793 YRC 2894: Mechanistic studies on aromatase induction in mice (feeding study for 13 weeks). Bayer AG, Department of Toxicology. Study number: T7061541. Study report date: July 27, 1998. Part 1 of 2. DACO 4.8.
- PMRA 1043794 YRC 2894: Mechanistic studies on aromatase induction in mice (feeding study for 13 weeks). Bayer AG, Department of Toxicology. Study number: T7061541. Study report date: July 27, 1998. Part 2 of 2. DACO 4.8.
- PMRA 1043795 YRC 2894: Studies on the inhibition of thyroid peroxidase-catalyzed reactions by YRC 2894 and its metabolites in vitro. Bayer AG, Research Toxicology. Study report number: 23495A. Study report date: January 28, 1999. DACO 4.8.
- PMRA 1043796 Cancer hazard assessment and characterization of YRC 2894. Bayer Corporation. Study report number: 108890. Study report date: September 22, 1998. DACO 4.8.
- PMRA 1043797 YRC 2894 Position paper - toxicological overview and discussion of mechanistic investigation. Bayer Corporation. Study report number: 108961. Study report date: march 25, 1999. DACO 4.8.
- PMRA 1043898 A revised liquid chromatographic method for the determination of YRC 2894 in animal ration. Bayer Corporation. Study number: 95-899-DU. Study report date: January 11, 1996; revised April 22, 1997. DACO 4.8.
- PMRA 1043899 The homogeneity and stability of YRC 2894 in rodent ration. Bayer Corporation. Study number: 95-872-EF, 96-872-KI. Study report date: January 13, 1998. DACO 4.8.
- PMRA 1044148 YRC 480 SC 05776/0071: Study for acute oral toxicity in rats. Bayer AG, Department of Toxicology. Study number: T8061849. Study report date: March 19, 1998. DACO 4.6.1.
- PMRA 1044149 YRC 2894 480 SC 05776/0071: Study for acute dermal toxicity in rats. Bayer AG, Department of Toxicology. Study number: T0061850. Study report date: March 19, 1998. DACO 4.6.2.
- PMRA 1044150 YRC 2894 480 SC 05776/0096 (c.n.: Thiacloprid): Study for acute inhalation toxicity in rats according to OECD No. 403. Bayer AG Department of Toxicology. Study number: T6067418. Study report date: April 24, 1999. DACO 4.6.3.
- PMRA 1044151 Acute eye irritation study of YRC 2894 480 SC 05776/0071 by instillation into the conjunctival sac of rabbits. Study number: T3061196. Study report date: October 21, 1998. DACO 4.6.4.
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- PMRA 1044152 Acute skin irritation (patch test) of YRC 2894 4480 SC 05776/0070 in rabbits. Study number: T3061196. Study report date: September 29, 1998. DACO 4.6.5.
- PMRA 1044153 YRC 2894 480 SC 05776/0071: Study for skin sensitization effect in Guinea pigs (Buehler patch test). Bayer AG Department of Toxicology. Study number: T4061890. Study report date: May 12, 1998. DACO 4.6.6.
- PMRA 1044154 YRC 2894 480 SC 05776/0096: Study for skin sensitization effect in Guinea pigs (Buehler patch test). Bayer AG Department of Toxicology. Study number: T4068749. Study report date: January 25, 2000. DACO 4.6.6.
- PMRA 1044155 YRC 2894 480 SC: Skin sensitization effect in Guinea pigs (Guinea pig maximization test according to Magnusson and Kligman). Bayer AG Department of Toxicology. Study number: T2070186. Study report date: April 24, 2001. DACO 4.6.6.
- PMRA 1044156 Validation of the Magnusson- Kligman Maximization Test Method Used by the Fachbereich Toxikologie, Bayer AG, Performed in Guinea Pigs Off the Strain Hsd Poc:DH With 2- Mercaptobenzothiazole. Bayer AG. Study number: T1062427 Study report date: May 19, 1998. DACO 4.6.6.
- PMRA 1044157 Validation of the Buehler Patch Test Method Used by the Fachbereich Toxikologie, Bayer AG, Performed In Guinea Pigs of the Strain Hsd Poc:DH With Alpha Hexyl Cinnamic Aldehyde (Buehler Patch Test). Bayer AG. Study number: T6068200. Study report date: June 23, 1999. DACO 4.6.6.

3.0 Occupational Exposure Assessment Section

- PMRA 1247105 A Study to Determine the Dermal Absorption of Carbon 14 YR 28794 in SC 480 Formulation when Administered Dorsally to Male Rhesus Monkeys. 30-December-02. Bayer Report Number 200436. DACO 5.8
- PMRA 1251222 CALYPSO 4F - Dissipation of Dislodgeable Foliar Residues in Apple Tree Foliage. 13-January-04. Bayer Study Number Y4251601. Bayer Report Number 200479. DACO 5.9

4.0 Food Residue Exposure Assessment Section

- PMRA 1043776 [Methylene-¹⁴C]YRC 2894: Absorption, Distribution, Excretion and Metabolism in the Lactating Goat. Bayer Report No. 108707 (PF4372). Study report date:24-Jun-98. 275 pages. DACO 6.2

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- PMRA 1043772 [Methylene-¹⁴C]YRC 2894 Absorption, Distribution, Excretion and Metabolism in Laying Hens. Bayer Study No. M 01819038. Bayer Report No. 108483. Study report date: 15-Mar-99. 152 pages. DACO 6.2
- PMRA 1043780 Metabolism of [Pyridinyl-¹⁴C-Methyl]YRC 2894 in Apples. Bayer Report No. 107944 (PF 4306). Study report date:02-Oct-97. 55 pages. DACO 6.3
- PMRA 1043781 Metabolism of YRC 2894 in Tomatoes. Bayer Study No. M 1730631-1. Bayer Report No. 107908. Study report date:15-Aug-97. 83 pages. DACO 6.3
- PMRA 1043782 Translocation of [Pyridinyl-¹⁴C-Methyl]YRC 2894 in Tomato Plants. Supplemental Study in Support of Metabolism of YRC 2894 in Tomatoes. Bayer Study No. M1720696-1. Bayer Report No. 107908-1. Study report date: 19-Aug-97. 27 pages. DACO 6.3
- PMRA 1043783 Metabolism of YRC 2894 in Cotton. Bayer Report No. 108289 (PF4256). Study report date: 16-Mar-98. 234 pages. DACO 6.3
- PMRA 1043779 Metabolism of [Pyridinyl-¹⁴C-Methyl]YRC 2894 in Rice. Bayer Report No. 108333 (PF 4343). Study report date: 25-Feb-98. 91 pages. DACO 6.3
- PMRA 1043784 Degradation of YRC 2894 by plant cell suspension cultures (supplemental study in support of metabolism in plants). Bayer Report No. 108287 (PF 4346). Study report date: 10-Mar-98. 44 pages. DACO 6.3
- PMRA 1044174 An Analytical Method for the Determination of YRC 2894 Residues in Plant Matrices. Bayer Report Number 108450. Study Number: Y4121601. Study report date: 17-Mar-99. 74 pages. DACO 7.2.1
- PMRA 1044182 Independent Laboratory Validation of Analytical Method 108450 for the Determination of Total Residues of YRC 2894 in Cotton and Cotton Processed Products. Bayer Report Number 108831. Study Number: Y4111601. Study report date: 15-Jan-99. 66 pages. DACO 7.2.3
- PMRA 1044184 Radiovalidation of the YRC 2894 Total Residue Method for Cotton Seed and the Gin Trash. Bayer Report Number 108288 (PF 4297). Study report date: 11-Dec-97. 43 pages. DACO 7.2.3
- PMRA 1044177 Residue Analytical Method for the Determination of YRC 2894 Residues in Plant Materials by HPLC. Bayer Report No. 00419. Study report date: 16-Jun-98. 55 pages. DACO 7.2.1
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- PMRA 1044179 Residue Analytical Method for the Determination of Residues of Imidacloprid, Hydro- Imidacloprid, Olefin-Imidacloprid, YRC 2894, YRC 2894-Amide and 4-Hydroxy-YRC 2894-Amide in Plant Material by HPLC with Electrospray MS/MS-Detection. Bayer Report No. 00573. Bayer Report No. 108908. Study report date:09-Mar-99. 117 pages. DACO 7.2.1
- PMRA 1044180 An Analytical Method for the Determination of YRC 2894, Amide-YRC 2894, 4-Hydroxy YRC 2894 Amide Residues in Various Plant Matrices by LC-MS/MS. Bayer Report No. 110856. Study report date: 13-Jun-2003. 223 pages. DACO 7.2.1
- PMRA1044185 Independent Laboratory Validation of “An Analytical for the Determination of YRC 2894, Amide-YRC 2894, 4-Hydroxy YRC 2894 Amide Residues in Various Plant Matrices by LC-MS/MS” According to PR Notice 96-1 and OPPTS 860.1340 Guidelines. Bayer Report No. 110329. Study report date: 15-Oct-2001. 110 pages. DACO 7.2.3
- PMRA 1044176 Residue Analytical Method for the Determination of YRC 2894 Total Residues in Animal Material by GC-MSD. Bayer Report No. 00491. Study report date: 18-Jun-98. 182 pages. DACO 7.2.1
- PMRA 1044183 Radiovalidation of the Animal Residue Method for YRC 2894. Bayer Study No. P61374502 (MR-411/98). Study report date: 18-Sep-98. 39 pages. DACO 7.2.3
- PMRA 1044175 Residue Analytical Method for the Determination of YRC-2894 Residues in Animal Material by LC-MS/MS; Bayer Report No. 00490. Study report date: 13-May-98. 192 pages. DACO 7.2.1
- PMRA 1044178 Independent Laboratory Validation of “Residue Analytical Method for the Determination of YRC-2894 Residues in Animal Material by LC-MS/MS”, Study No. 44685. Bayer Report: 108913. Study report date: 11-Sep-98. 259 pages. DACO 7.2.1
- PMRA 1044186 Evaluation of YRC 2894 Through the FDA Multiresidue Methods. Bayer Report No. 108832. Study report date: 12-Jan-99. 66 pages. DACO 7.2.4
- PMRA 1044187 Storage Stability of YRC 2894 Residues in Crops during Freezer Storage. Bayer Report No. 108520 (MR-1026/97). Study report date: 09-Dec-97.39 pages. DACO 7.3
- PMRA 1044188 YRC 2894 480SC and 70WG - Magnitude of the Residue on Pome Fruit (Apple/Pear). Bayer Report No. 108812. Study report date: 11-Mar-99. 817 pages. DACO 7.4.1. Part 1 of 4
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- PMRA 1044189 YRC 2894 480SC and 70WG - Magnitude of the Residue on Pome Fruit (Apple/Pear). Bayer Report No. 108812. Study report date: 11-Mar-99. 817 pages. DACO 7.4.1. Part 2 of 4
- PMRA 1044190 YRC 2894 480SC and 70WG - Magnitude of the Residue on Pome Fruit (Apple/Pear). Bayer Report No. 108812. Study report date: 11-Mar-99. 817 pages. DACO 7.4.1. Part 3 of 4
- PMRA 1044191 YRC 2894 480SC and 70WG - Magnitude of the Residue on Pome Fruit (Apple/Pear). Bayer Report No. 108812. Study report date: 11-Mar-99. 817 pages. DACO 7.4.1. Part 4 of 4
- PMRA 1178241 Calypso 480SC - Magnitude of the Residue in/on Pome Fruit. Report Number: 06BCS-03/04. Study report date: 29-Mar-2006. 1734 pages. DACO 7.4.1
- PMRA 1044096 YRC 2984 480SC - Magnitude of the Residue in Apple Processed Commodities. Bayer Report No. 108813. Study report date: 11-Mar-99. 336 pages. DACO 7.4.5. Part 1 of 2
- PMRA 1044097 YRC 2984 480SC - Magnitude of the Residue in Apple Processed Commodities. Bayer Report No. 108813. Study report date: 11-Mar-99. 336 pages. DACO 7.4.5. Part 2 of 2
- PMRA 1241232 Determination of Residues of YRC 2498 SC Following Spray Application on Apple (Fruit, Pomace, Sauce, Fruit, washed, Fruit, dried) in the Federal Republic of Germany; Bayer Study Number 502758, Bayer Report Number RA-3062/95. Study report date: 06-Nov-97. 49 pages. DACO 7.4.5
- PMRA 1241185 Determination of residues of YRC 2894 480 SC Following Spray Application on Apple (Fruit, Juice, Pomace, Sauce, Fruit washed, Fruit dried) in Italy; Bayer Study No 502707; Bayer Report No. RA-3063/95; Study report date: 12-Nov-97. 50 pages. DACO 7.4.5
- PMRA 1043777 YRC 2894 - A 28-Day Dairy Cattle Feeding Study. Bayer Report No 108484 (Report MR-369/98); Study report date: 26-Jun-98. 1090 pages. DACO 7.5. Part 1 of 5
- PMRA 1043778 YRC 2894 - A 28-Day Dairy Cattle Feeding Study. Bayer Report No 108484 (Report MR-369/98); Study report date: 26-Jun-98. 1090 pages. DACO 7.5. Part 2 of 5
- PMRA 1043773 YRC 2894 - A 28-Day Dairy Cattle Feeding Study. Bayer Report No 108484 (Report MR-369/98); Study report date: 26-Jun-98. 1090 pages. DACO 7.5. Part 3 of 5
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- PMRA 1043774 YRC 2894 - A 28-Day Dairy Cattle Feeding Study. Bayer Report No 108484 (Report MR-369/98); Study report date: 26-Jun-98. 1090 pages. DACO 7.5. Part 4 of 5
- PMRA 1043775 YRC 2894 - A 28-Day Dairy Cattle Feeding Study. Bayer Report No 108484 (Report MR-369/98); Study report date: 26-Jun-98. 1090 pages. DACO 7.5. Part 5 of 5

5.0 Environmental Assessment Division

- PMRA 1043813 KKO 2254 Study for acute oral toxicity in rats. Bayer AG, Department of Toxicology. Laboratory Study Number T2060033. Study report date: 01-December-1995. Bayer Report Number 24553. 33 pages. DACO 9.7.
- PMRA 1043814 YRC 2894 Study for acute oral toxicity in rats. Bayer AG, Department of Toxicology. Laboratory Study Number T3059270. Study report date: 26-August-1996. Bayer Report Number 108854. 41 pages. DACO 9.7.
- PMRA 1043815 WAK 6999 Study for acute oral toxicity in rats. Bayer AG, Department of Toxicology. Laboratory Study Number T8060110. Study report date: 02-February-1996. Bayer Report Number 108860. 29 pages. DACO 9.7.
- PMRA 1043817 YRC 2894 Acute oral toxicity study in mice. Nihon Bayer Agrochem K.K., Research & Development Division, Yuki Research Center. Laboratory Study Number 97219. Study report date: 6-March-1998. Bayer Report Number 109285. 27 pages. DACO 9.7.
- PMRA 1043919 Hydrolysis of YRC 2894 in sterile aqueous buffer solutions. Bayer AG Crop Protection Development. Laboratory Study Number M 111 0678-4. Study report date: 16-February-1998. Bayer Report Number 108257. 40 pages. DACO 8.2.3.2.
- PMRA 1043920 Photolysis of YRC 2894 on soil surface. Bayer AG Crop Protection Development. Laboratory Study Number M 113 0672-0. Study report date: 26-February-1998. Bayer Report Number 108308. 61 pages. DACO 8.2.3.3.1.
- PMRA 1043921 Photolysis of YRC 2894 in aqueous buffer solution. Bayer AG Crop Protection Development. Laboratory Study Number M 112 0677-4. Study report date: 18-February-1998. Bayer Report Number 108262. 57 pages. DACO 8.2.3.3.2.
- PMRA 1043923 Calculation of DT50 values of YRC 2894 metabolite KKO 2254 in soil under aerobic conditions. Bayer AG Crop Protection Development. Study report date: 2-March-1998. Bayer Report Number 108300. 17 pages. DACO 8.2.3.4.2.

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- PMRA 1044076 Influence of YRC 2894 on the growth of the green alga, *Scenedesmus subspicatus*. Bayer AG Crop Protection Development. Laboratory Study Number E 3230973-7. Study report date: 30-August-1995. Bayer Report Number 108481. 19 pages. DACO 9.8.2.
- PMRA 1044119 Terrestrial field dissipation of YRC 2894 in Wisconsin soil, 1995. Study Number Y4022102. Study report date: 14-January-1999. Bayer Report Number 107900. 190 pages. DACO 8.3.2.
- PMRA 1044120 Terrestrial field dissipation of YRC 2894 in Georgia soil, 1996. Study Number Y4022101. Study report date: 8-February-1999. Bayer Report Number 108146. 203 pages. DACO 8.3.2.
- PMRA 1044121 Dissipation of YRC 2894 (480 SC) in soil under field conditions (France and Spain). Bayer AG Crop Protection Development. Study Numbers R502898 and R502928. Study report date: 22-January-1998. Bayer Report Number 108301. 83 pages. DACO 8.3.2.
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- PMRA 1044148 YRC 2894 480 SC 05776/0071 Study for acute oral toxicity in rats. Bayer AG, Department of Toxicology. Laboratory Study Number T8061849. Study report date: 19-March-1998. Bayer Report Number 108668. 32 pages. DACO 9.7.
- PMRA 1241509 Testing toxicity to beneficial arthropods Green lacewing - *Chrysopa carnea* STEPH. (extended laboratory test) following the proposal of semifield method (Bock 1992) and the IOBC Guideline (Bigler & Waldburger 1988) - YRC 2894 SC 480. Study Number 97 10 48 007. Study report date: 18-December-1997. Bayer Report Number not available. 15 pages. DACO 9.2.5.

PMRA 1278935 Foliar half-life for use in the terrestrial vertebrate exposure assessment for thiacloprid. Bayer CropScience. Laboratory Study Number: not applicable. Study report date: 29-June-2006. Bayer Report Number 201542. 16 pages. DACO 8.6.

6.0 Efficacy and Sustainability Assessment Division

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PMRA 1272178 Assessment of insecticides against first generation internal lepidoptera and plum curculio. 2005. Bayer Trial Number ID05NARAD1. 2 pages. DACO 10.2.3.3.