United States Environmental Protection Agency

Office of Prevention, Pesticides and Toxic Substances (7505 P)

Pesticide Fact Sheet

Name of Chemical: **Pyriofenone**
Reason for Issuance: **New Chemical; Import Tolerances Established**
Year Issued: **March 2012**

DESCRIPTION OF CHEMICAL

Generic Name: (5-chloro-2-methoxy-4-methyl-3-pyridinyl)2,3,4-trimethoxy-6-methylphenyl)methanone

Common Name: Pyriofenone

EPA Chemical Code: 028828

Chemical Abstracts Service (CAS) Number: 688046-61-9

Registration Status: Not Registered; Import Tolerances Established

Pesticide Type: Fungicide

Chemical Class: Aryl phenyl ketone

U.S. Producer: ISK BioSciences Corporation
7470 Auburn Road, Suite A,
Concord, Ohio 44077

Tolerances Established

Import tolerances were established (without U.S. registrations) for residues of pyriofenone, including its metabolites and degradates, in the 40 CFR §180.660 in or on grape at 0.30 ppm and grape, raisin at 0.50 ppm.

Use Pattern and Formulations

Pyriofenone is an aryl phenyl ketone fungicide that is under consideration for registration in Europe to control powdery mildew (*Erysiphe necator*) on grape vines. There are currently no MRLs established by CODEX in Canada and Mexico for pyriofenone.

ISK BioSciences Corporation is supporting import tolerances on grape and grape, raisin. Pyriofenone is not registered for use on any crops in the U.S. The proposed foreign use of pyriofenone on grapes specifies a maximum of three foliar spray applications using a suspension concentrate (SC) formulation at 0.08 lb ai/A per application (90 g ai/ha per application) with a retreatment interval of 14 days. The total application rate on the proposed European label is 0.24 lb ai/A (270 g ai/ha). The proposed preharvest interval (PHI) is 28 days. The SC formulation may be applied at any crop growth stage.

Science Findings

Available product chemistry data supporting the use of pyriofenone are summarized below in Tables 1 and 2.

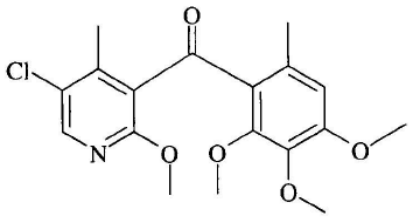
Table 1. Nomenclature of Pyriofenone	
Compound	Chemical Structure 
Common name	Pyriofenone
Company experimental name	IKF-309
IUPAC name	(5-chloro-2-methoxy-4-methyl-3-pyridyl)(2,3,4-trimethoxy-6-methylphenyl)ketone
CAS name	(5-chloro-2-methoxy-4-methyl-3-pyridinyl)2,3,4-trimethoxy-6-methylphenyl)methanone
CAS registry number	688046-61-9
End-use product (EP)	300 g/L suspension concentrate (SC; Property 300 SC®)

Table 2. Physicochemical Properties of Pyriofenone.	
Parameter	Value

Table 2. Physicochemical Properties of Pyriofenone.	
Parameter	Value
Melting point/range	93-95 °C
pH	3.1
Density	1.36
Water solubility (at 20°C)	1.56 mg/L
Solvent solubility (g/L)	n-heptane 10-20 xylene >250 1,2-dichloroethane >250 Acetone >250 Methanol 20-50 n-octanol 2-5 ethyl acetate >250
Vapor pressure at 25°C	1.9×10^{-6} Pa
Dissociation constant (pK_a)	No dissociation constant in environmental pH range of pH 4 to 10
Octanol/water partition coefficient $Log(K_{OW})$	3.2
UV/visible absorption spectrum	Not available

Toxicology Summary

Based on the proposed use pattern, exposure to pyriofenone for the general public can occur via dietary exposure (food) only. Chronic dietary exposure was assessed for all population subgroups. Acute dietary exposure was not assessed because no toxicological study indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. For the chronic assessment, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which the Environmental Protection Agency (the Agency) has concluded will results in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the point of departure (POD) (endpoint) divided by the required uncertainty and/or safety factors. For non-cancer chronic exposures, estimated dietary risk that are less than 100% of the PAD are not of concern. There are no drinking water, occupational or residential exposures associated with the establishment of the import tolerances.

Toxicity Endpoints

In risk assessments for import commodities, endpoints are typically selected for dietary exposure only. Endpoints for incidental oral, dermal and inhalation exposures are not selected for import tolerances due to lack of potential occupational or residential exposure. A summary of the toxicological endpoints for pyriofenone used for human risk assessment is shown in Table 3.

Acute Dietary: Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for pyriofenone; therefore, a quantitative acute dietary exposure assessment is unnecessary.

Chronic Dietary: The chronic population adjusted dose (cPAD) is derived from the 2-year carcinogenicity study in rats, which had a LOAEL of 46 mg/kg/day based on increased incidence of chronic nephropathy and a NOAEL of 9 mg/kg/day was selected from the same study. Since the

active ingredient is not registered or proposed for use in the United States, endpoints for occupational and residential exposures have not been determined. An uncertainty factor of 100X was applied to the chronic point of departure (POD) selected for oral exposure routes (10X for interspecies extrapolation, 10X for intraspecies variation).

Short- and Intermediate-Term Dermal and Inhalation: Dermal toxicity, inhalation toxicity, and ocular irritation studies are not available because these exposure routes are not applicable to non-domestic uses.

Carcinogenicity: EPA classified pyriofenone as "Not Likely to be Carcinogenic to Humans" based on lack of evidence for carcinogenicity in male and female mice and rats in chronic toxicity studies. This classification is supported by the lack of mutagenic potential both *in vivo* and *in vitro*. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is not necessary.

Neurotoxicity: There was no evidence of neurotoxicity in the pyriofenone hazard database, which included acute and subchronic neurotoxicity studies.

Developmental Toxicity: There was no evidence of increased quantitative or qualitative susceptibility to the fetus or to offspring. No developmental toxicity occurred in the rat developmental toxicity study. Abortions and premature delivery were attributed to maternal stress because they were associated with decreased maternal body weight gain and food consumption, occurred late in gestation, and were therefore attributed to maternal distress.

Reproductive Toxicity: No reproductive toxicity occurred in the 2-generation reproduction study. Parental effects at the high dose included liver and kidney pathology and decreased hematological parameters; the only offspring effect was decreased spleen weight at the high dose.
Dermal Toxicity: Dermal toxicity studies are not available because these exposure routes are not applicable to non-domestic uses.

Table 3. Summary of Toxicological Doses and Endpoints for Pyriofenone for Dietary Human Health Risk Assessments

Exposure/ Scenario	Point of Departure (POD)	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary	An acute dietary endpoint was not selected because toxicity from a single dose was not identified in the hazard database.			
Chronic Dietary (All Populations)	NOAEL= 9 mg/kg/day	UF_A= 10x UF_H= 10x FQPA SF= 1x	Chronic RfD = 0.09 mg/kg/day cPAD = 0.09 mg/kg/day	Chronic toxicity/ carcinogenicity study- rat NOAEL = 9 mg/kg/day based on increased nephropathy seen in female rats at LOAEL = 46 mg/kg/day.
Cancer (oral,	Classification: "Not likely to be Carcinogenic to Humans"			

Table 3. Summary of Toxicological Doses and Endpoints for Pyriofenone for Dietary Human Health Risk Assessments				
Exposure/ Scenario	Point of Departure (POD)	Uncertainty/FQPA Safety Factors	RfD, PAD, Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary	An acute dietary endpoint was not selected because toxicity from a single dose was not identified in the hazard database.			
dermal, inhalation)				

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (intraspecies). UF_H = potential variation in sensitivity among members of the human population (interspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose.

Food Quality Protection Act Considerations

FQPA Safety Factor: The proposed use pattern for pyriofenone may result in dietary exposure to infants and children. Thus, FQPA hazard considerations were addressed in the Agency's evaluation of the toxicology database. The Agency recommends that the 10x FQPA Safety Factor (for the protection of infants and children) be reduced to 1x. The toxicological database for pyriofenone is complete with regard to pre-and postnatal toxicity, neurotoxicity, and immunotoxicity; there are no residual uncertainties. Additionally, the dietary exposure assessment is based on conservative, health-protective assumptions that ensure that exposures to pyriofenone are not underestimated.

Exposure Assessment

Dietary Exposures Assessment: The Agency conducted screening-level chronic dietary risk assessments using the Dietary Exposure Evaluation Model with the Food Commodity Intake Database (DEEM-FCID™). Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For chronic dietary assessments, the risk is expressed as a percentage of a maximum acceptable dose (*i.e.*, the dose which EPA has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equal to the POD divided by all pertinent safety factors, including the FQPA SF. For acute and chronic exposures, the Agency is concerned when estimated dietary risk exceeds 100% of the PAD.

A conservative chronic dietary (food only) exposure analysis was performed for the general U.S. population and standard population subgroups. The assumptions of these unrefined assessments were tolerance level residues for grapes and raisins, 100% crop treated, and no processing factors for any other commodities as concentration was not observed in juice or wine. Chronic dietary risk estimates are not of concern for the general population or any other population subgroup. The most highly exposed population subgroup is children (1-2 years old), with exposures resulting in estimated risks of 1% of the cPAD. Exposures were 1% or less of the cPAD for all population subgroups

Table 4. Summary of Chronic Dietary (Food Only) Exposure and Risk for Pyriofenone		
Population Subgroup	Dietary Exposure (mg/kg/day)	% cPAD[1]
General U.S. Population	0.000158	<1
All Infants (< 1 year old)	0.000258	<1
Children 1-2 years old	**0.000885**	**1.0**
Children 3-5 years old	0.000540	<1
Children 6-12 years old	0.000206	<1
Youth 13-19 years old	0.000070	<1
Adults 20-49 years old	0.000098	<1
Adults 50+ years old	0.000114	<1
Females 13-49 years old	0.000105	<1

Water Exposure/Risk Pathway: As there are currently no registered or proposed domestic uses for pyriofenone, a drinking water assessment was not conducted.

Residential (Non-Occupational) Exposure/Risk Pathway: As there are currently no registered or proposed residential uses for pyriofenone, a residential (non-occupational) assessment was not conducted.

Occupational Exposure/Risk Pathway: As there are currently no registered or proposed domestic uses for pyriofenone, an occupational assessment was not conducted.

Aggregate Exposure: As stated previously, there are no existing or proposed US registrations of pyriofenone and the only route of exposure is via dietary ingestion from imported grape commodities. Therefore, aggregate exposure and risk estimates are equivalent to the dietary exposures and risk estimates.

Cumulative Risk

EPA does not have, at this time, available data to determine whether pyriofenone has a common mechanism of toxicity with other substances. Unlike other pesticides for which the Agency has followed a cumulative risk approach based on a common mechanism of toxicity, the Agency has not made a common mechanism of toxicity finding as to pyriofenone and any other substances and pyriofenone does not appear to produce a toxic metabolite produced by other substances which have tolerances in the U.S. For the purposes of this action, therefore, the Agency has not assumed that pyriofenone has a common mechanism of toxicity with other substances.

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DISCLAIMER: The information presented in this Pesticide Fact Sheet is for informational purposes only and may not be used to fulfill data requirements for pesticide registration or reregistration.

APPENDIX I

Citations Considered to be Part of the Data Base Supporting the Establishment of Pyriofenone Import Tolerances

MRID	Citation
48112800	ISK BioSciences Corporation (2010) Submission of Product Chemistry, Residue, Fate and Toxicity Data in Support of the Petition for Tolerance of Pyriofenone for Use in/on Grapes. Transmittal of 36 Studies.
48112802	Turner, B. (2010) Product Chemistry Studies for Technical Pyriofenone: Preliminary (Five Batch) Analysis. Project Number: IB/2010/MG/002/01, JSM0057. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 68 p.
48112803	Turner, B. (2009) Product Chemistry Studies for Technical Pyriofenone. Project Number: IB/2010/MG/001/01, ISK0392, ISK0399. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 180 p.
48112804	Crowe, A. (2009) IKF-309: Metabolism in Grapes. Project Number: ISK0299. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 82 p.
48112805	Haynes, L. (2010) IKF-309: Metabolism in Lactating Goats. Project Number: ISK0297. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 169 p.
48112806	Brewin, S. (2008) IKF-309: Validation of Methodology for the Determination of Residues in Wheat (Grain and Straw) and Grapes. Project Number: ISK/0341, ISK/0341/074208. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 45 p.
48112807	Gemrot, F. (2009) Independent Laboratory Validation of IKF-309: Analytical Method in Grapes, Wheat Grain and Straw. Project Number: S09/02866. Unpublished study prepared by Eurofins/ADME Bioanalyses. 79 p.
48112808	Schaufele, M. (2008) IKF-309: Residue Study (Decline) with IKF-309 300 SC (IBE 3985) Applied to Wine Grapes in Germany and Southern France in 2007. Project Number: ISK0301, LGV07/RE01. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 68 p.
48112809	Schaufele, M. (2009) IKF-309: Residue Study (at Harvest) with IKF-309 300 SC (IBE 3985) Applied to Wine Grapes in Southern France in 2008. Project Number: ISK0383, LGV08/RE03. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 44 p.
48112810	Schaufele, M. (2010) IKF-309 300 SC: Residue Study (Processing and Decline with IKF-309 300 SC (IBE 3985)) Applied to Wine Grapes in Germany, Spain and Italy in 2008. Project Number: ISK0381, LGV08/RE01, LGV08/RE02. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 169 p.
48112811	Schaufele, M. (2009) IKF-309 300 SC: Residue Study (at Harvest and

	Processing) with IKF-309 300 SC (IBE 3985) Applied to Wine Grapes in Northern and Southern France in 2008. Project Number: ISK0382, LGV08/RE04, LGV08/RE05. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 138 p.
48112812	Schaufele, M. (2010) IKF-309 300 SC: Residue Study (at Harvest) with IKF-309 300 SC (IBE 3985) Applied to Wine Grapes and Table Grapes in Northern France, Spain and Italy in 2009. Project Number: JSM0015, LGV09/RE03. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 77 p.
48112813	Rockwell, D. (2010) PAM 1 Multiresidue Protocol Testing for IKF-309 in Grapes. Project Number: 2125, IB/2010/JLW/009/01. Unpublished study prepared by Pyxant Labs, Inc. 82 p.
48112814	Moore, E. (2008) IKF-309 Technical: Acute Oral Toxicity to the Rat (Acute Toxic Class Method). Project Number: ISK0313. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 28 p.
48112815	Moore, E. (2009) IKF-309: Toxicity Study by Dietary Administration to CD-1 Mice for 13 Weeks. Project Number: ISK0291. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 268 p.
48112816	Ohtsuka, R. (2010) IKF-309 Technical: Repeated Dose 90-Day Oral Toxicity Study in Rats. Project Number: IET/06/0015. Unpublished study prepared by Institute of Environmental Toxicology. 423 p.
48112817	Nakashima, N. (2010) IKF-309 Technical: Repeated Dose 90-Day Oral Toxicity Study in Dogs. Project Number: IET/06/0109. Unpublished study prepared by Institute of Environmental Toxicology. 301 p.
48112818	Nakashima, N. (2010) IKF-309 Technical: Repeated Dose 1-Year Oral Toxicity Study in Dogs. Project Number: IET/06/0110. Unpublished study prepared by Institute of Environmental Toxicology. 369 p.
48112819	Ohtsuka, R. (2010) IKF-309 Technical: Carcinogenicity Study in Rats. Project Number: IET/06/0086. Unpublished study prepared by Institute of Environmental Toxicology. 696 p.
48112820	Moore, E. (2010) IKF-309 Carcinogenicity Study by Dietary Administration to CD-1 Mice for 78 Weeks. Project Number: ISK0305. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 1870 p.
48112821	Takahashi, K. (2010) IKF-309 Technical: Teratogenicity Study in Rabbits Preliminary Study: Final Report. Project Number: IET/06/0115. Unpublished study prepared by Institute of Environmental Toxicology. 104 p.
48112822	Takahashi, K. (2009) IKF-309 Technical: Teratogenicity Study in Rabbits. Project Number: IET/06/0116. Unpublished study prepared by Institute of Environmental Toxicology. 125 p.
48112823	Hojo, H. (2009) IKF-309 Technical: A Teratogenicity Study in Rats: A Dose

	Range-Finding Study. Project Number: IET/06/0113. Unpublished study prepared by Institute of Environmental Toxicology. 105 p.
48112824	Hojo, H. (2010) IKF-309 Technical: A Teratogenicity Study in Rats. Project Number: IET/06/0114. Unpublished study prepared by Institute of Environmental Toxicology. 137 p.
48112825	Hojo, H. (2009) IKF-309 Technical: A Reproduction Toxicity Study in Rats: A Dose Range-Finding Study. Project Number: IET/06/0111. Unpublished study prepared by Institute of Environmental Toxicology. 284 p.
48112826	Hojo, H. (2009) IKF-309 Technical: A Reproduction Toxicity Study in Rats. Project Number: IET/06/0112. Unpublished study prepared by Institute of Environmental Toxicology. 552 p.
48112827	May, K. (2007) IKF-309 Technical: Bacterial Reverse Mutation Test. Project Number: ISK/0311/073744. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 35 p.
48112828	Hynes, L. (2008) IKF-309 Technical: in vitro Mutation Test Using Mouse Lymphoma L5178Y Cells. Project Number: ISK/0310. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 41 p.
48112829	Pritchard, L. (2008) IKF-309 Technical in vitro Mammalian Chromosome Aberration Test in CHL Cells. Project Number: ISK/0322. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 50 p.
48112830	Hynes, G. (2028) IKF-309 Technical: Mouse Micronucleus Test. Project Number: ISK/0327. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 39 p.
48112831	Powell, L. (2009) IKF-309: Dose Range and Time to Peak Effect in Rats by Acute Oral Administration. Project Number: ISK0408. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 114 p.
48112832	Powell, L. (2010) IKF-309: Neurotoxicity Study by a Single Oral Gavage Administration to CD Rats followed by a 14 Day Observation Period. Project Number: ISK0407. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 323 p.
48112833	Arrowsmith, W. (2010) IKF-309: Neurotoxicity Study by Dietary Administration to CD Rats for 13 Weeks. Project Number: JSM0027. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 323 p.
48112834	Knight, L. (2010) IKF-309: Metabolism in Rats. Project Number: ISK0281. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 256 p.
48112835	Laurent, M. (2010) IKF-309: 4-Week Dietary Immunotoxicity Study in the Female Mouse. Project Number: JSM0036. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 118 p.

48112836	Chambers, P. (2010) IKF-309: 4-Week Dietary Immunotoxicity Study in the Female Rat. Project Number: JSM0037. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 122 p.
48125900	ISK BioSciences Corporation (2010) Submission of Toxicity and Residue Data in Support of the Petition for Tolerance of Pyriofenone for Use in or on Grapes. Transmittal of 2 Studies.
48125901	Ohtsuka, R. (2010) IKF-309 Technical: Repeated Dose 1-Year Oral Toxicity Study in Rats. Project Number: IET/06/0085. Unpublished study prepared by Institute of Environmental Toxicology. 608 p.
48125902	Brewin, S. (2010) IKF-309, 3HDPM and 4HDPM: Storage Stability in Wheat (Grain and Straw) and Grapes for a Period of 18 Months: Interim Report. Project Number: ISK0353. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 48 p.
48279100	ISK BioSciences Corporation (2010) Submission of Residue and Toxicity Data in Support of the Petition for Tolerance of Pyriofenone for Use on Grapes. Transmittal of 3 Studies.
48279101	Brewin, S. (2010) IKF-309, 3HDPM and 4HDPM: Storage Stability in Wheat (Grain and Straw) and Grapes for a Period of 18 Months: Final Report. Project Number: ISK0353. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 57 p.
48279102	Cooper, S. (2007) Validation of Neuropathology Procedures Neurotoxicity Study by Oral Gavage Administration of Acrylamide or Triethyltin Bromide to Male CD Rats. Project Number: HLS/367/053352. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 191 p.
48279103	Cooper, S. (2010) Further Validation of Neurotoxicity Procedures Following Oral Gavage Administration of D-Amphetamine or Di-isopropyl Fluorophosphate to CD Rats. Project Number: HLS0384/062633. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 281 p.
48295700	ISK Biosciences Corporation (2010) Submission of Product Chemistry Data in Support of the Petition for Tolerance of Pyriofenone for Use In or On Grapes. Transmittal of 7 Studies.
48295701	Turner, B. (2010) IKF-309: Method Validation for Determination of Related Impurities Detected by HPLC. Project Number: JSM0030. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 73 p.
48295702	Comb, A. (2009) Characterisation of Test Substance: Pyriofenone. Project Number: ISK0335. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 41 p.
48295703	Comb, A. (2009) Characterisation of Test Substance: Pyriofenone. Project Number: ISK0336. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 39 p.

48295704	Comb, A. (2009) Characterisation of Test Substance: Pyriofenone. Project Number: ISK0337. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 38 p.
48295705	Comb, A. (2009) Characterisation of Test Substance: Pyriofenone. Project Number: ISK0338. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 38 p.
48295706	Comb, A. (2009) Characterisation of Test Substance: Pyriofenone. Project Number: ISK0339. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 37 p.
48295707	Comb, A. (2009) Characterisation of Test Substance: Pyriofenone. Project Number: ISK0340. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 38 p.
48341300	ISK Biosciences Corporation (2010) Submission of Residue Data in Support of the Petition for Tolerance of Pyriofenone for Use on Grapes. Transmittal of 1 Study.
48341301	Brewin, S. (2010) IKF-309: Validation of Methodology for the Determination of Residues in Wheat (Grain and Straw) and Grapes: Amendment Report. Project Number: ISK/0341. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 9 p.
48459600	ISK Biosciences Corporation (2011) Submission of Residue and Product Chemistry Data in Support of the Petition for Tolerance of Pyriofenone for Use on Grapes. Transmittal of 4 Studies.
48459601	Gelin, M. (2011) Response to Request for Additional Information for IKF-309 Metabolism in Grapes (MRID #48112804). Project Number: IB/2011/MG/003/01. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 4 p.
48459602	Gelin, M. (2011) Response to Request for Additional Information for Independent Laboratory Validation of IKF-309 Analytical Method in Grapes, Wheat Grain and Straw (MRID #48112807). Project Number: IB/2011/MG/004/01. Unpublished study prepared by ADME Bioanalyses. 8 p.
48459603	Gelin, M. (2011) Response to Request for Additional Information for PAM I Multiresidue Protocol Testing for IKF-309 in Grapes (MRID #48112813). Project Number: IB/2011/MG/002/01. Unpublished study prepared by Pyxant Labs, Inc. 5 p.
48459604	Turner, B. (2009) IKF-309 (PAI) Spectra. Project Number: ISK0393. Unpublished study prepared by Huntingdon Life Sciences, Ltd. 29 p.
48476200	ISK Bioscience Corporation (2011) Submission of Toxicity Data in Support of the Petition for Tolerance of Pyriofenone for Use on Grapes. Transmittal of 5 Studies.

48476201	Gelin, M. (2011) Response to Request for Historical Control Data: IKF-309: Toxicity Study by Dietary Administration to CD-1 Mice for 13 Weeks. Project Number: ISK0291, IB/2011/MG/001/05. Unpublished study prepared by ISK Bioscience Corporation. 8 p.
48476202	Gelin, M. (2011) Response to Request for Historical Control Data: IKF-309 Technical: Repeated Dose 90-Day Oral Toxicity Study in Rats. Project Number: IB/2011/MG/001/06, IET/06/0015. Unpublished study prepared by ISK Bioscience Corporation. 13 p.
48476203	Gelin, M. (2011) Response to Request for Historical Control Data: IKF-309 Technical: Repeated Dose 90-Day Oral Toxicity Study in Dogs. Project Number: IB/2011/MG/001/07, IET/06/0109. Unpublished study prepared by ISK Bioscience Corporation. 30 p.
48476204	Gelin, M. (2011) Response to Request for Historical Control Data: IKF-309 Technical: Repeated Dose 1-Year Oral Toxicity Study in Rats. Project Number: IB/2011/MG/001/08, IET/06/0085. Unpublished study prepared by ISK Biosciences Corporation. 29 p.
48476205	Gelin, M. (2011) Response to Request for Historical Control Data: IKF-309 Carcinogenicity Study by Dietary Administration to CD-1 Mice for 78 Weeks. Project Number: IB/2011/MG/001/09, ISK0305. Unpublished study prepared by ISK Bioscience Corporation. 9 p.