# **SEPA** Pesticide Fact Sheet

Name of Chemical:

Fluxapyroxad

**Reason for Issuance:** 

**Registration of New Active Ingredient** 

May 2, 2012

# **I. DESCRIPTION OF CHEMICAL**

Common Name	Fluxapyroxad
Company Experimental Name	BAS 700 F
IUPAC Name	3-(difluoromethyl)-1-methyl- <i>N</i> -(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide
CAS Name	3-(difluoromethyl)-1-methyl- <i>N</i> -(3',4',5'-trifluoro[1,1'- biphenyl]-2-yl)-1 <i>H</i> -pyrazole-4-carboxamide
Year of Initial Registration	2012
Chemical Abstracts Service (CAS) Number	907204-31-3
EPA Chemical Code	138009
Pesticide Type	Fungicide
Chemical Class	Carboxamide
Company	BASF Corporation
Mode of Action:	Inhibition of succinate dehydrogenase in complex II of the mitochondrial respiratory chain

Chemical Structure:



## **II. USE PATTERN AND FORMULATIONS**

Fluxapyroxad is a new active ingredient (a.i.) developed by BASF Corporation to control a broad spectrum of fungal diseases. Fluxapyroxad belongs to the carboxamide class of chemicals and its mode of action is inhibition of succinate dehydrogenase in complex II of the mitochondrial respiratory chain, which results in inhibition of spore germination, germ tubes, and mycelial growth within the fungus target species. The review of fluxapyroxad was done jointly with Australia, Canada, and New Zealand (peer review only by New Zealand).

Fluxapyroxad is formulated as an emulsifiable concentrate (EC) or suspension concentrate (SC) and is registered for both foliar and seed treatment uses on a wide range of crops (cereal grains, legume vegetables, oil seed crops, peanuts, pome fruit, stone fruit, root and tuber vegetables, fruiting vegetables, and cotton). Crop applications may begin at emergence, but typical applications begin as plants touch across rows. Maximum single application rates range from 0.09 to 0.18 lb ai/acre. Maximum seasonal application rates range from 0.18 to 0.36 lb ai/acre. Pre-harvest intervals (PHIs) range from 0 to 21 days. A 365-day plant-back interval (PBI) is required for all crops that are not on the label. Applications may be made using groundboom, airblast, aerial, and standard slurry or mist-type seed treatment equipment. There are no fluxapyroxad products for homeowner use and there are no products for application to residential areas.

## III. HUMAN HEALTH RISK ASSESSMENT

## **Acute Toxicity**

Technical fluxapyroxad is of low acute toxicity by the oral, dermal and inhalation routes and is not irritating to the eyes and skin.

#### Subchronic, Chronic, Other Toxicity

The primary target organ for fluxapyroxad exposure via the oral route is the liver with secondary toxicity in the thyroid for rats only. Liver toxicity was observed in rats, mice, and dogs, with rats as the most sensitive species for all durations of exposure. In rats, adaptive effects of hepatocellular hypertrophy and increased liver weights and changes in liver enzyme activities

were first observed. As the dose or duration of exposure to fluxapyroxad increased, clinical chemistry changes related to liver function also occurred, followed by hepatocellular necrosis, neoplastic changes in the liver, and tumors. Thyroid effects were observed only in rats. These effects were secondary to changes in liver enzyme regulation, which increased metabolism of thyroid hormone, resulting changes in thyroid hormones, thyroid follicular hypertrophy and hyperplasia, and thyroid tumor formation. Tumors were not observed in species other than rats or in organs other than the liver and thyroid.

#### **Carcinogenicity**

In accordance with the EPA's Final Guidelines for Carcinogen Risk Assessment (March, 2005), fluxapyroxad is classified as **"Not likely to be Carcinogenic to Humans"** based on convincing evidence that carcinogenic effects are not likely below a defined dose range:

- No treatment-related tumors were seen in male or female mice when tested at doses that were adequate to assess carcinogenicity (including the Limit Dose);
- Treatment-related liver tumors were seen in male rats at doses ≥ 250 ppm (11 mg/kg/day) and in female rats at doses ≥ 1500 ppm (82 mg/kg/day);
- Treatment-related thyroid follicular cell tumors were seen in male rats only at doses > 1500 ppm (68 mg/kg/day);
- There is no mutagenicity concern from *in vivo* or *in vitro* assays;
- The hypothesized mode of action (i.e., a non-genotoxic) for each tumor type (i.e., the liver and thyroid) was supported by adequate studies that clearly identified the sequence of key events, dose-response concordance and temporal relationship to the tumor types. The mode of action met the criteria established by the Agency.

The Agency has determined that the chronic population adjusted dose (PAD) will adequately account for all chronic effects, including carcinogenicity that could result from exposure to fluxapyroxad.

## Food Quality Protection Act (FQPA) Safety Factor

EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. This reduction is based on the availability of a complete toxicity database with clear NOAELs for characterizing neurotoxicity and sensitivity during development, supplemental studies that characterize the effects of fluxapyroxad on thyroid hormones, and no residual uncertainties in the exposure database.

**Neurotoxicity:** Neither the acute nor the subchronic neurotoxicity studies indicated specific neurotoxicity responses to fluxapyroxad. Although treatment-related effects of decreased rearing and motor activity were observed in the acute neurotoxicity study on the day of dosing, these effects are equivocal as they may indicate transient and reversible neurotoxicity and/or general malaise. The Agency considered the potential for fluxapyroxad to cause developmental neurotoxicity as a result of thyroid hormone disruption, which is more sensitive than the endpoints used in a developmental neurotoxicity study. Based on its evaluation of thyroid hormone data submitted by the registrant and the ontogeny of thyroid hormone metabolism, the Agency has determined that adverse thyroid hormone disruptions in the young are unlikely to occur at dose levels similar to the points of departure chosen for risk assessment. The Agency has low concern for neurotoxic effects of fluxapyroxad at any life stage.

<u>Prenatal Developmental/Reproductive Toxicity</u>: No evidence of quantitative susceptibility was observed in a reproductive and developmental toxicity study in rats or in developmental toxicity studies in rats and rabbits. Developmental effects observed in both rats and rabbits occurred at the same doses as those that caused adverse effects in maternal animals, indicating no quantitative susceptibility. Since the maternal toxicities of thyroid hormone perturbation in rats and systemic toxicity in rabbits likely contributed to the observed developmental effects there is low concern for qualitative susceptibility. The observed effects were of low severity, were likely secondary to maternal toxicity, and demonstrated clear NOAELs. Based on the available data and the selection of risk assessment endpoints that are protective of developmental effects, there are no residual uncertainties with regard to pre- and/or postnatal toxicity.

#### Human Exposure and Risk

To assess the potential risks to human health from the proposed uses and associated tolerances, toxicological points of departure (POD) and levels of concern (LOC) were identified. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the "no-observed-adverse- effect- level," or NOAEL) and the lowest dose at which adverse effects of concern are identified (the "lowest-observed-adverse-effect-level," or LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) – and a safe margin of exposure (MOE). PODs were selected for dietary and occupational exposure scenarios. Acute and chronic RfDs and PADs [PAD = RfD/FQPA SF] were selected for assessment of food and drinking water exposures. An uncertainty factor of 100X was applied to PODs selected for all exposure routes (10X for interspecies extrapolation, 10X for intraspecies variation).

<u>Acute Dietary</u>: The acute PAD (aPAD) of 1.25 mg/kg/day was based on the observation of decreased motor activity and decreased rearing in the rat acute neurotoxicity study at a LOAEL of 500 mg/kg/day [NOAEL = 125 mg/kg/day].

<u>Chronic Dietary Exposure</u>: The chronic PAD (cPAD) of 0.021 mg/kg/day was based on the observation of non-neoplastic changes in the liver (foci and masses) in the chronic toxicity/carcinogenicity study in rats at a LOAEL of 11 mg/kg/day [NOAEL = 2.1 mg/kg/day].

<u>*Cancer:*</u> Fluxapyroxad is classified as "Not Likely to be Carcinogenic to Humans" based on convincing evidence that carcinogenic effects are not likely below a defined dose range. A full panel of in vitro and in vivo studies that showed no evidence of genotoxicity, together with mechanistic studies in the liver and thyroid of rats that satisfied stringent criteria for establishing tumorgenic modes of action were used for this determination. The Agency has determined that the cPAD will adequately account for all chronic effects, including carcinogenicity, likely to result from exposure to fluxapyroxad.

#### Aggregate Exposure and Risk

In accordance with the FQPA, the Agency must consider aggregate pesticide exposures and risk estimates from three major routes: oral, dermal, and inhalation. In an aggregate assessment, exposures from relevant sources (food, drinking water, and residential uses) are added together and compared to quantitative estimates of hazard (e.g., a NOAEL or PAD), or the risks themselves can be aggregated.

To evaluate dietary exposure to fluxapyroxad, the Agency considered exposure that individuals could receive through food consumption and drinking water. The acute and chronic dietary analysis assumed 100% crop treated for all commodities, tolerance-level residues adjusted to account for metabolites of concern and/or highest average field-trial residues. DEEM default and empirical processing factors were also used. The Agency used screening-level water exposure models in the dietary exposure analysis for fluxapyroxad in drinking water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

<u>Acute Dietary:</u> The acute risk estimate is 6 % of the aPAD for children 1-2 years old, the population subgroup with the highest exposure. The risk estimate for the general U.S. population is 2 % of the aPAD.

<u>Chronic Dietary</u>: The chronic risk estimate is 48 % of the cPAD for children 1-2 years old, the population subgroup with the highest exposure. The risk estimate for the general U.S. population is 14 % of the cPAD.

Fluxapyroxad uses are not expected to result in residential exposures. Therefore, the acute and chronic exposure estimates represent aggregate exposure. All risk estimates are below the Agency's level of concern.

#### **Occupational Exposure and Risk**

There is a potential for short- and intermediate-term occupational exposure to fluxapyroxad during mixing, loading, application, commercial seed treatments, planting activities and post-application activities. Chronic exposures are not expected from fluxapyroxad use patterns. Only short- and intermediate-term inhalation exposures were assessed for occupational handlers and post-application activities, with a target LOC or MOE of 100. Dermal exposures were not assessed because PODs for dermal exposure were not selected as no effects of concern were identified from the toxicity database. Worker exposures were assessed based on the product labels prescribed uses and expected exposure durations. For all exposure scenarios the MOEs are greater than 100. Therefore, occupational risks from fluxapyroxad uses are not of concern.

# IV. ECOLOGICAL RISK ASSESSMENT

## Environmental Fate

<u>*Persistence*</u>: The available fate data indicate that fluxapyroxad degrades slowly in soil and aquatic systems. Fluxapyroxad is stable to hydrolysis at pH values of 5, 7 and 9, and is stable to both soil and aqueous photolysis. Fluxapyroxad does not readily undergo aerobic or anaerobic

degradation in soil (half-lives ranging from 213 to 1,827 days) or in aquatic systems (half-lives ranging from 420 to 731 days), and therefore may persist in soil, water, and in benthic sediment once transported or partitioned to these environmental compartments.

<u>*Transport*</u>: Fluxapyroxad has a moderate potential to reach aquatic environments, including surface and ground water, for several months or more following terrestrial application. The available fate data indicate that fluxapyroxad is likely to dissipate to some extent through various mechanisms, including runoff, erosion, and leaching to ground water.

Fluxapyroxad is classified as moderately to slightly mobile (FAO soil mobility classification) with adsorption  $K_{oc}$  values ranging from 496 to 1,424 mL/g<sub>oc</sub>. Freundlich soil partitioning coefficients (K<sub>F</sub>) for adsorption ranged from 4.3 to 17.9 ml/g. Based on its mobility and environmental persistence, fluxapyroxad has the potential to leach to ground water, particularly where high water tables are present, high rainfall/irrigation occurs, and where sandy soils with low organic matter exist. Fluxapyroxad is not expected to volatilize (vapor pressure of 6.1 x 10<sup>-11</sup> Torr at 25° C).

<u>Bioaccumulation</u>: Fluxapyroxad is not likely to bioaccumulate. A bioconcentration in fish (BCF) laboratory study involving bluegill sunfish showed that after 28 days of exposure to fluxapyroxad, the whole fish BCF was less than or equal to 93  $\mu$ g/kg-ww per  $\mu$ g/L. The time to reach 90% depuration was approximately 2.5 days.

## Ecological Risk

The potential risks to nontarget organisms from the use of pesticides are evaluated by comparing the toxicity endpoints from ecological toxicity data to estimated environmental concentrations (EECs). The EEC values are based on environmental fate characteristics, soil and water chemistry, and pesticide use data. Risk Quotients (RQs), are calculated from the ratio of the EECs to the most sensitive toxicity endpoint values (such as the  $LC_{50}$  or the median lethal concentration). The calculated RQs represent a screening-level assessment. Since screening-level assessments are based on conservative assumptions, the highest EECs and the lowest toxicity values are always used. RQ values are then compared to levels of concern (LOCs), which indicate whether a pesticide, when used as labeled, has the potential to cause adverse effects on nontarget organisms. When the RQ exceeds the LOC for a particular category, the Agency presumes a potential risk of concern to that category. The following table describes the Agency's LOCs and its respective risk presumptions.

Risk Presumptions	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants (Terrestrial, Semi- aquatic, and Aquatic)
Acute Risk	≥0.5	≥0.5	$\geq 1$
Chronic Risk	≥1	≥1	N/A

#### Agency's LOCs and Risk Presumptions

N/A = not applicable

<u>*Risks to Aquatic Organisms:*</u> Exposure to the fluxapyroxad technical grade active ingredient (TGAI) is not expected to result in acute or chronic risk to aquatic organisms, including fish, amphibians, and plants in aquatic habitats. Despite the absence of chronic ecotoxicity data for estuarine/marine organisms, a comparison of the relatively low surface water EECs to the available chronic toxicity data for freshwater species suggests that risk is low. Estuarine/marine animals were similarly or less sensitive to the TGAI than freshwater animals in the acute studies; and when considered in the context of the relatively low EECs, new data would be unlikely to change the screening-level risk assessment conclusions. The likelihood of adverse effects to sediment-dwelling invertebrates and aquatic plants is considered low as RQ values do not approach or exceed the Agency's LOCs.

There is acute risk to aquatic animals based on endpoints for the fluxapyroxad formulations that contain the a.i. pyraclostrobin (which is evaluated in a separate risk assessment) and spray driftonly EECs. When the toxicity endpoints for freshwater fish and invertebrates are adjusted for the percentage of pyraclostrobin in each product, they are similar to toxicity endpoints for the pyraclostrobin TGAI, indicating that the enhanced toxicity of the dual active ingredient formulations appears to be driven by pyraclostrobin. Based on this screening-level assessment, there is acute risk to estuarine/marine species when dual a.i. formulations of fluxapyroxad are applied in areas that may result in spray drift to the estuarine/marine environment.

<u>*Risks to Terrestrial Organisms:*</u> Fluxapyroxad exhibits low acute toxicity to mammals by all exposure routes. Fluxapyroxad is practically non-toxic to birds on an acute oral exposure basis and ranges from slightly to practically nontoxic to birds on a subacute dietary exposure basis. Foliar and seed treatment uses of fluxapyroxad are not expected to result in acute risk of mortality to birds (and therefore reptiles and terrestrial-phase amphibians, for which birds serve as surrogates) or mammals based on a comparison of the available effects data to terrestrial EECs.

The screening-level risk assessment shows that uses of fluxapyroxad may result in chronic risk to mammals (dose-based RQ $\geq$ 1.0), including mammals that consume treated seed (estimated dose-based RQs range from 0.01 – 4.46). Despite the exceedances on some of the chronic RQs for mammals, EPA believes the potential for unreasonable chronic effects is low. The chronic RQs reflect risk at the site of application following applications at a maximum use rate. It is also assumed that mammals forage for food exclusively on the treated area and they consume a single food type (e.g., short grass or seed). For most mammals and birds, neither assumption is likely to be true. EPA also notes that the models used to estimate concentrations of fluxapyroxad in the environment are screening models, designed to provide high-end (i.e., protective) exposure estimates, further reducing the likelihood of actual risks.

Chronic risk to birds, reptiles, and amphibians in the terrestrial environment cannot be precluded because slight but statistically significant effects on growth were observed at all treatment levels in an avian reproduction study; therefore, EPA was unable to establish a lower threshold for this effect. This treatment-related effect was uniform across all test concentrations and is consistent with effects on body weight and body weight gain in rat pups (NOAEC=112 mg/kg diet) in a two-generation reproduction study. In the absence of a definitive NOAEC value for chronic effects on birds, and by proxy, for chronic effects on reptiles and terrestrial-phase amphibians, the Agency's presumes chronic risk to these taxa based on the slight, transient effect on hatchling body weight. Although a lower threshold for this effect was not established, additional data are not being

requested because such data would be unlikely to change the screening level risk conclusions. For example, in order to preclude chronic risk (*i.e.*, RQ<1), a chronic toxicity study (*i.e.*, avian reproduction) would need to establish that no adverse effects are observed at concentrations up to and including 80 mg/kg diet, based on EECs for fluxapyroxad uses. However, the existing study demonstrated that effects were observed at concentrations ranging from 100 to 1,000 mg/kg diet. Given the flat concentration response for the effect on hatchling body weight, an additional study would be unlikely to yield a NOAEC between 80 and 100 mg/kg diet and therefore would be unlikely to change the screening level risk conclusions. Therefore, additional avian reproduction data are not being requested at this time.

Fluxapyroxad is practically non-toxic on an acute exposure basis to terrestrial invertebrates. The available data show that fluxapyroxad and its formulated end-use products are practically non-toxic to the young adult honey bee (*Apis mellifera*) on both an acute contact and acute oral exposure basis.

Foliar uses and some seed treatment uses of fluxapyroxad may result in risk to federally-listed threatened and endangered species (listed) dicotyledonous (dicot) terrestrial and semi-aquatic plants. RQ values based on seed treatment uses exceed the Agency's LOC for the highest use rate evaluated for listed species of dicot plants in semi-aquatic areas, but are below the LOC for all other nontarget plants. The risk conclusion for seed treatment uses is dependent on parameters such as incorporation depth of the seeds and seeding rate; in cases where seeds are incorporated greater than or equal to one inch, exposure via runoff is expected to be reduced, and risk would not exceed the LOC. Risk to monocot plants and nonlisted dicot plants is not expected to exceed the LOC.

#### **Co- Formulated Products**

Formulated fluxapyroxad is in some cases more toxic than the TGAI to aquatic organisms. Exposure to dual active ingredient formulations of fluxapyroxad as a result of spray drift is expected to result in risk of acute mortality that exceeds the LOC for aquatic animals. The greater toxicity of the dual active ingredient formulations to fish and invertebrates, when compared to the fluxapyroxad TGAI and solo formulations, appears to be driven by pyraclostrobin.

Ecotoxicity data indicate that fluxapyroxad is practically non-toxic to young adult honey bees on an acute oral and contact exposure basis. However, the fluxapyroxad end-use products that are co-formulated with pyraclostrobin are similar in that respect to the BASF-registered product Pristine<sup>®</sup>, which contains the similarly structured (carboxamide) fungicide boscalid (25.2%) and pyraclostrobin (12.8%). Risk assessments for boscalid have described uncertainties regarding potential effects of Pristine<sup>®</sup> on development of honey bee brood, based on incident reports and communications with beekeepers. The available toxicity data indicate that neither fluxapyroxad, any of its end-use products, nor boscalid or Pristine<sup>®</sup> are acutely toxic to young adult honey bees. In addition, submitted semi-field studies with fluxapyroxad and with Pristine<sup>®</sup> demonstrated no overall effects on honey bee brood. However, in response to concerns raised by beekeepers regarding Pristine<sup>®</sup>, BASF is currently planning and conducting further tests to evaluate the potential for effects on larval honey bee development and queen cell production and survival. The structural similarities between boscalid and fluxapyroxad and the similarities in active ingredient content of Pristine<sup>®</sup>, Merivon® Xemium® brand fungicide, and Priaxor® Xemium® brand fungicide suggest that information from these forthcoming honey bee studies may be relevant to all three products.

# V. REGULATORY DECISION

EPA has determined that the available data provide adequate information to make the determinations required by FIFRA Sec. 3(c)(5) to grant unconditional registrations to fluxapyroxad formulated as a manufacturing-use product (Xemium Fungicide Technical) and the following end-use products :

Imbrex<sup>™</sup> Xemium® brand fungicide (5.96% a.i.) for a range of agricultural uses; Xemium® 2.78 fungicide ST (28.78% a.i.) for a range of seed treatment uses; Xemium® 2.72 fungicide ST (28.70% a.i.) for a range of seed treatment uses; Sercadis<sup>™</sup> Xemium® brand fungicide (26.55% a.i.) for a range of agricultural uses; Merivon® Xemium® brand fungicide (21.26% fluxapyroxad and 21.26% pyraclostrobin), for a range of agricultural uses; and Priaxor<sup>™</sup> Xemium® brand fungicide (14.33% fluxapyroxad and 28.58% pyraclostrobin), for a range of agricultural uses.

<u>Human Health</u>: The human health risk assessment concluded that the database for fluxapyroxad is adequate to support the registration of the subject fluxapyroxad products and that there is a reasonable certainty that no harm will result from dietary and occupational exposures to fluxapyroxad. There are no additional data needs associated with the subject uses for fluxapyroxad.

<u>Environmental Fate and Effects</u>: There are no data gaps related to environmental fate effects. There are no acceptable chronic toxicity data for estuarine/marine fish or aquatic invertebrates. The data submitted were classified as invalid and/or supplemental based on meaningful guideline deviations and/or uncertainty regarding the study results. However, based on the maximum use rates, the potential for exposure to fluxapyroxad at a level that is likely to cause direct acute or chronic effects on aquatic organisms is considered low. Therefore, the Agency is not requesting additional data at this time because such data would be unlikely to impact the screening-level risk conclusions of the risk assessment.

There is uncertainty regarding chronic effects on birds because a NOAEC was not established in the avian reproduction study with bobwhite quail. Effects on hatchling body weight, although transient, were observed at all treatment concentrations. However, given the flat concentrationresponse for this effect, an additional study would likely only provide confirmatory data and would be unlikely to change the screening level risk conclusions. Based on the conservative nature of the screening level risk assessment, and since it is unlikely that birds would forage exclusively on the treated area and for an extended period of time, the likelihood of actual chronic risk to birds is not expected to be above the levels of concern. Therefore, additional data are not being requested at this time. Potential risks to listed terrestrial plants are mitigated by the spray drift precautions on the products labels. These instructions are intended to keep the pesticide on the treatment area, thereby reducing the potential for non-target exposures.

Specific information on the studies received, the nature of the adverse effects caused by fluxapyroxad, and the Agency's human health and environmental risk assessments can be found in the following documents at http://www.regulations.gov in docket ID number EPA-HQ-OPP-2010-0421:

- "Fluxapyroxad. Human Health Risk Assessment for Use of New Active Ingredient on Cereal Grains, Legume Vegetables (Succulent and Dry), Oil Seed Crops (Canola and Sunflower), Peanuts, Pome Fruit, Stone Fruit, Root and Tuber Vegetables (Potatoes and Sugar Beets), Fruiting Vegetables, and Cotton," dated February 22, 2012. -"Environmental Fate and Ecological Risk Assessment for Foliar and Seed Treatment Uses of the New Fungicide Fluxapyroxad (BAS 700F)," dated March 5, 2012.

#### CONTACT PERSON AT USEPA

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**DISCLAIMER:** The information in this Pesticide Fact Sheet is for information only and is not to be used to satisfy data requirements for pesticide registration. The information is believed to be accurate as of the date on the document.

Parameter		Va	llue
Melting point/range	156.8 °C		
pH of 1% solution in water	5.8		
Density	1.47		
Water solubility ( 20°C)	3.88 mg/L at 3.78 mg/L at	t pH 5.8 () t pH 4	not buffered)
	3.44 mg/L at 3.84 mg/L at	рН 7 рН 9	
Solvent solubility (g/L at 20°C)	acetone		>250
	acetonitrile		$167.6\pm0.2$
	dichlorometh	nane	$146.1\pm0.3$
	ethylacetate		$123.3 \pm 0.2$
	methanol		$53.4 \pm 0.0$
	toluene		$20.0 \pm 0.0$
	n-octanol		$4.69 \pm 0.01$
	n-heptane		$0.106 \pm 0.001$
Vapor pressure at 25 °C	8.1 x 10 <sup>-9</sup> Pa	L	
Dissociation constant (pKa)	12. 58 (calculated)		
Octanol/water partition coefficient $Log(K_{OW})$	3.08 (deioniz 3.09 at pH 4 3.13 at pH 7 3.09 at pH 9	zed water	)
IW/wights abcomption apostum			
0 v/visible absorption spectrum	pH	λmax	3
	1.4	199	35913
		230	24137
		290	1145
	5.9	193	44100
		230	24010
		290	978
	12.2	215	23227
		229	23473
		290	2405
	$\epsilon$ : molar at mol <sup>-1</sup> cm <sup>-1</sup>	osorptio	n coefficient, [L

# **APPENDIX II - Toxicity Data**

# A. Acute Toxicity

A.1 Acute Toxicity Profile – Fluxapyroxad			
Guideline	Study Type	Results	Toxicity
No.			Category
870.1100	Acute oral – rat (females)	$LD_{50} = >2000 \text{ mg/kg}$	III
870.1200	Acute dermal – rat	LD <sub>50</sub> >2000 mg/kgM & F	III
870.1300	Acute inhalation – rat	LC <sub>50</sub> >5.1 mg/L M & F	IV
870.2400	Acute eye irritation – rabbit	Slightly irritating	IV
870.2500	Acute dermal irritation – rabbit	Slightly irritating	IV
870.2600	Dermal sensitization – guinea pig	No sensitization	-

A.2 Acute Toxicity Profile – Fluxapyroxad Metabolites			
Guideline	Study Type	Results	<b>Toxicity Category</b>
No.			
870.1100	Acute oral – rat (females) M-1	$LD_{50} = >2000 \text{ mg/kg}$	III
870.1100	Acute oral – rat (females) M-3	$LD_{50} = >2000 \text{ mg/kg}$	III
870.1100	Acute oral – rat (females) M-25	$LD_{50} = >2000 \text{ mg/kg}$	III
870.1100	Acute oral – rat (females) M-28	$LD_{50} = >2000 \text{ mg/kg}$	III
870.1100	Acute oral – rat (females) I-3	$LD_{50} = >2000 \text{ mg/kg}$	III
870.1100	Acute oral – rat (females) I-4	$LD_{50} = >2000 \text{ mg/kg}$	III
870.1100	Acute oral – rat (females) I-5	$LD_{50} = >2000 \text{ mg/kg}$	III

# **B.** Subchronic, Chronic, Other Toxicity

Table B.1 Subchronic, Chronic and Other Toxicity Profile Toxicity Profile for Fluxapyroxad (BAS 700F)		
Guideline No	MRID/Classification	Rosults
Study Type	Doses	Kesuits
870.3050	47923564 (2009)	Males
28 day dietary in rats	Acceptable, guideline	NOAEL=100 ppm ( 9.0 mkd)
	0, 100, 500, 2000, 6000	LOAEL 500 ppm (176 mkd) based on thyroid follicular
	ppm	hypertrophy/hyperplasia and clinical chemistry changes
	0/0, 9/9.4, 43.7/47.8,	Females
	176/183, 530/531, mkd	NOAEL=500 ppm (47.8 mkd)
	M/F	LOAEL=2000 ppm (531 mkd) based on decreased
		prothrombin time and clinical chemistry changes
Non-Guideline	47923594 (2009)	Increased TSH, decreased T4 in males only at 3000 ppm only
Thyroid hormone levels-	Acceptable, non-	days 14 through 28. Accompanied by increased absolute and
28 days-rat	guideline	relative liver and thyroid weights. Supports hypothesis that an
		increased conjugation and elimination of circulating thyroxine
	0, 50, 250, 1500, 3000	(T <sub>4</sub> ) leads to compensatory release of thyroid stimulating
	ppm	hormone (TSH) from the pituitary, secondary to BAS 700 F
	(0/0, 3.5/4.4, 19/20,	liver enzyme induction.
	105/117, 214/237 mkd)	
Non-Guideline	47923595 (2009)	The similarities in the behavior of BAS 700 F to phenobarbitol
Perchlorate discharge	Acceptable, non-	in this perchlorate discharge assay support the hypothesis that
study-28 days rat	guideline	BAS 700 F causes increases in thyroid hormones by an

Table B.1 Subchronic, Chronic and Other Toxicity Profile Toxicity Profile for Fluxapyroxad (BAS 700F)		
Guideline No	MRID/Classification	Regulte
Study Type	Doses	Kesuits
		indirect mechanism.
	0, 3000 ppm	
	0/0, 283/247 mkd	
Non-Guideline	47923599 (20210)	Mechanistic investigations of enzyme induction (thyroid and
Enzyme induction	Acceptable, non-	liver).
	guidenne	
	50 ppm	
Non-Guideline	47923593 (2010)	Mechanistic investigations of enzyme induction (thyroid and
Enzyme induction	Acceptable, non-	liver).
	guideline	
	0, 250, 1500, 3000 ppm	
	0/0, 16/19, 96/126,	
	192/234 mkd	
Non-Guideline	47923598 (2010)	Mechanistic investigations of hepatocellular proliferation.
S-phase induction	Acceptable, non-	
1-5-7-14 uays	guidenne	
	0, 50, 250, 1500, 3000	
	ppm	
Non-Guideline	47923597 (2010)	Mechanistic trestigations of hepatocellular proliferation.
S-phase induction	Acceptable, non-	
7-28-91 days	guideline	
	50 ppm only	
970 2050	47022565 (2000)	Malaa
070.5050 28 day dietary in mice	47925505 (2009)	NOAEL $-2500$ npm (552 mkd)
20 day dictary in milec	Acceptable, guidenne	LOAEL = 7000 ppm (1452 mkd) based on hematological
	0, 500, 2500, 7000 ppm	changes.
	, , , , , , , , , , , , , , , , , , , ,	
	0/0, 112/150, 552/746,	Females
	1452/2100 mkd M/F	NOAEL=7000 ppm (2100 mkd)
		LOAEL=Not observed
No EPA guideline,	47923566 (2009)	NOAEL=2500 ppm (74/85 mkd M/F)
OECD 407 - 28 day	Acceptable/non-EPA	LOAFL 7500
dietary in dogs	guideline	LOAEL-= $/500 \text{ ppm} (211/230 \text{ mkd M/F})$ based on vomiting $(M/F)$ and clinical chemistry changes
	0 2500 7500 20000	(WI/F) and entitieal chemistry changes
	ppm	
	PP···	
	0/0, 74/85, 211/230,	
	521/503 mkd M/F	
870.3100	47923568 (2009)	Males
90-day dietary in mice	Acceptable/guideline	NOAEL=2000 ppm (390 mkd)
	0 100 400 0000 0000	LOAEL 6000 ppm (1136 mkd) based on decreased body
	0, 100, 400, 2000, 6000	weight and body weight gain and multifocal necrosis in the
	ppm	liver
	0/0 21/32 77/128	Females
	390/610, and 1136/1657	NOAEL = $6000 \text{ ppm} (1657 \text{ mkd})$
	mkd (M/F)	LOAEL=Not observed.

Table B.1 Subchronic, Chronic and Other Toxicity Profile Toxicity Profile for Fluxapyroxad (BAS 700F)		
Guideline No	MRID/Classification	Dogulto
Study Type	Doses	Kesuits
870.3100	47923567 (2009)	NOAEL = 500 ppm (31.2 mkd) males; 100 ppm (7.3 mkd)
90-Day dietary in rats	Acceptable, guideline	females
	0, 100, 500, 2000, 6000	LOAEL = 2000  ppm (126  mkd)  males; 500  ppm (35.1  mkd)
	ppm	females) based on changes in thyroid hormone levels and
	0/0 6 1/7 3 31 2/35 1	myrord forneular nypertropiny/nyperprasta
	126/144 and $407/424$	
	mkd (M/F)	
870.3150	47923569 (2009)	NOAEL=1500 ppm (45/51 mkd M/F)
90-Day Oral Toxicity	Acceptable/guideline	
Feeding-dog	1 0	LOAEL=10000 ppm (295 mkd) males, 7500 ppm (238 mkd)
	0, 300, 1500,	females based on vomiting and clinical chemistry changes
	10000/7500 (M/F)	
	0/0, 9/10, 45/51,	
050 000	295/238 mkd M/F	
8/0.3200	47923571 (2009)	NOAEL=1000 mkd
28-Day Dermal	Acceptable, guideline	I O A EL - not observed
TOXICITY-Tat	0 100 300 1000 mkd	LOAEL-not observed
870 3465	0, 100, 500, 1000 liiku	Still required data gap
90-Day Inhalation		Still Tequiled, dutti gup
870.3700a	47923603 (2009)	Maternal
Prenatal Developmental-	Acceptable, guideline	NOAEL=200 mkd
rat	1 / 0	LOAEL =1000 mkd based on increased absolute and relative
	0, 25, 200 and 1000	thyroid weights and thyroid hypertrophy/hyperplasia
	mkd (gavage in CMC)	
		Offspring
		NOAEL=1000 mkd
070 07001	47022604 (2000)	LOAEL =Not observed
8/0.3/00b	47923604 (2009)	Maternal
robbit	Acceptable, guidenne	NOAEL=25 IIKu
Tabbit	0 10 25 and 60 mkd	LOAEL -00 linku based oli decreased body weight
	0, 10, 25 and 00 mild	Offspring
		NOAEL=25 mkd
		LOAEL =60 mkd based on decreased fetal body weights and
		increased incidence of paw hyperflexion
870.3800	47923602 (2009)	Parental
Reproduction and	Acceptable, guideline	NOAEL=10 mkd
Fertility Effects-rat		LOAEL = 50 mkd based on thyroid follicular
	0, 10, 50 and 300 mkd	hypertrophy/hyperplasia
		Fortility/Doman de stiers Douformeon os
		NOAFI = 300 mkd
		LOAFL = Not observed
		Offspring
		NOAEL=10 mkd
		LOAEL =50 mkd decreased pup body weight/body weight
		development
870.4100	47923570 (2009)	Females
Chronic Toxicity-dog	Acceptable/guideline	NOAEL=300 ppm (9 mkd)
		LOAEL =1500 ppm (43 mkd) based on hepatic fibrosis and

Table B.1 Subchronic, Chronic and Other Toxicity Profile Toxicity Profile for Fluxapyroxad (BAS 700F)		
Guideline No	MRID/Classification	Rosults
Study Type	Doses	
	0, 300, 1500,	clinical chemistry changes
	12000/9000 ppm (M/F)	Males
	0/0, 8/9, 39/43, 335/257	NOAEL=1500 ppm (39mkd)
	mka M/F	LOAEL=12000 ppm (335 mkd) based on vomiting, heptaic
		enzyme elevation)
870 4300	47923591 (2009)	Chronic toxicity
Chronic	Acceptable, guideline	Chrome toxicity
toxicity/carcinogenicity	, , , , , , , , , , , , , , , , , , ,	NOAEL=50 ppm (2.1/2.7 mkd in males/females)
in rats	0, 50, 250, 1500, 3000	LOAEL = $250$ ppm (11/1 mkd) based on neoplastic changes in
	ppm	the liver (foci, masses).
	0/0, 2.1/2.7, 11/14,	Carcinogenicity-see CARC report
	68/82, 145/182 mkd	Classified as" not likely to be carcinogenic to humans" at
070 1000	(M/F)	doses below those that cause liver enzyme induction in rats.
8/0.4300 Chronic	4/923592 (2009)	Chronic toxicity
Chronic toxicity/coroinogonicity	Acceptable, guidenne	NOAEL= $750$ ppm (158/107 mkd M/F)
in mice	0 150 750 3000 6000	body weight
III IIIee	ppm	body weight.
	PP	Carcinogenicity
	0/0, 21/33, 107/158,	NOAEL=6000 ppm (996/1307 mkd M/F)
	468/652, 996/1307 mkd	LOAEL =Not observed
	(M/F)	
Gene Mutation	47923572 (2008)	Not mutagenic in the reverse mutation assay in Salmonella
870.5100	Acceptable, guideline	<i>typhimurium</i> or <i>Escherichia coli</i> with or without metabolic
In vitro Bacterial Gene	0 20 100 500 2500	activation.
Mutation	0, 20, 100, 500, 2500,	
Cono Mutation	$5000 \ \mu g/plate \pm 59$	Does not induce forward mutations in CHO calls with or
870 5300	Accentable guideline	without metabolic activation
In vitro Mammalian	ricceptuble, guidenne	
Cells Gene Mutation	0-100 µg/ml ±S9	
(Chinese Hamster Ovary		
Cells)		
Cytogenetics	47923577 (2008)	Does not cause clastogenic effects in V79 cells with or without
870.5375	Acceptable, guideline	metabolic activation.
<i>In vitro</i> Mammalian		
Cytogenetics	0-400 μg/ml ±S9	
Chromosomal		
human peripheral blood		
lymphocytes		
Cytogenetics-other	47923584 (2006)	Did not lead to any increase in polychromatic erythrocytes
870.5395 <i>In Vivo</i>	Acceptable, guideline	
Mammalian	r	
Cytogenetics -	0, 500, 1000, 2000 mkd	
Erythrocyte		
Micronucleus-mouse		
870.6200a	47923605 (2009)	NOAEL (neurotoxicity) =125 mk
Acute Neurotoxicity-rat	Acceptable, guideline	
	0 125 500 2000 -1 1	LOAEL (neurotoxicity)=500 mk based on decreased motor
	0, 125, 500, 2000 mkd	activity (both sexes) and decreased rearing (males only).

Table B.1 Subchronic, Chronic and Other Toxicity Profile Toxicity Profile for Fluxapyroxad (BAS 700F)		
Guideline No	MRID/Classification	Results
Study Type	Doses	
870.6200b Subchronic Neurotoxicity-rat	47923606 (2009) Acceptable, guideline 0, 200, 100, and 5000 ppm	NOAEL (neurotoxicity)=5000 ppm (302/338 mkd M/F) LOAEL (neurotoxicity) =Not observed
	302.2/337.7 mkd M/F	
870.7485 Metabolism and Pharmacokinetics-rat	47923555 (2009) 47923556 (2009)	The times to maximum plasma levels $(T_{MAX})$ were 24 hours (500 mg/kg bw), 8 hours (50 mg/kg bw), and 1 hour (5 mg/kg bw) in both sexes. No sex differences in the rate or extent of absorption was observed. AUCs scaled with dose, indicating that absorption was not saturated. Radioactivity was widely distributed in both sexes with a similar pattern: the highest concentrations were found in the gut contents and stomach contents. However, lower concentrations were found in numerous other organs/tissues, including the liver, thyroid, adrenal glands, kidney, pancreas, testes/uterus, and brain. For males and females, radioactivity declined in all tissues over time. The time course of the amount of radioactivity found in urine and feces indicated the excretion occurred predominantly within three days after dosing. Bile duct cannulation experiments showed that the bile was a major route of excretion. The main biotransformation steps of BAS 700 F in rats are hydroxylation at the biphenyl ring system, N-demethylation at
		the pyrazole ring system, loss of a fluorine atom at the biphenyl ring system, and conjugation with glucuronic acid or with glutathione derivatives. A further, but negligible transformation route is cleavage at the amide bond between the pyrazole ring system and the biphenyl ring system.
870.7600	47923632 (2010)	The dermal absorption factor is 8.38%.
Dermal penetration	Acceptable, guideline 5.6, 33,4, 1670 µg/cm <sup>2</sup> for 8 h exposure and 24 and 120 h termination *In a formulation with pyraclostrobin (BAS 500 F)	
870.7800	47923633 (2009)	Not immunotoxic.
Immunotoxicity-mice (male)	Acceptable, guideline	
	0, 500, 2000 and 6000 ppm	
	0, 100, 450  and  1323 mg/kg/d	
Non-guideline	47923598 (2009)	Cell proliferation in both sexes was dose-dependent at

Table B.1 Subchronic, Chronic and Other Toxicity Profile Toxicity Profile for Fluxapyroxad (BAS 700F)		
Guideline No	MRID/Classification	Results
Study Type	Doses	Kesuits
S-phase Response Liver		maximal at Day 7 (males) and Days 7& 14 (females).
1, 3, 7, 14 days-rat	0, 50, 250, 1500 and	
	3000 ppm	
Non-guideline	47923596 (2009)	Cell proliferation in males was maximal at Day 7 and was
S-phase Response Liver	0, 50 ppm (nominal)-	nearly absent by Day 28. Cell proliferation in females was
7, 28, 91 days-rat	Acceptable, non-	maximal at Day 7 declined Days 28 and 91, but was still above
	guideline	controls in higher dose groups. All effects were dose-
		dependent.
	47923596 (2009)	
	Acceptable, non-	Reversibility investigated at 28 days treat/28 days recovery.
	guideline	
	0. 250, 1500, 3000 ppm	
	(nominal)	
Non-guideline	47923593 (2009)	Dose-dependent increase in Phase I and Phase II enzymes in
Enzyme induction	Acceptable, non-	both sexes and increased liver and thyroid weights with
(Phase I and Phase II)	guideline	correlating histopathology. Effects partially (thyroid
with Thyroid Hormone		histopathology) to totally (all other effects) reversible in 4
Levels-14 days	0, 250, 1500, 3000 ppm	week recovery group.
	1/1, 16/19, 96/126,	
	192/234 mkd	
Non-OPPTS guideline,	47923589 (2009)	Does not induce unscheduled DNA synthesis.
OECD 486	Acceptable, non-	
	guideline	
	0, 1000, 2000 mkd	

Table B.2	Subchronic, Chroni	c and Other Toxicity Profile Toxicity Profile for
Guideline No	Metal	Dolite M1/00F001
Study Type	Classification	Kesuits
Study Lype	Doses	
870.3100	47923608 (2009)	NOAEL=953.6/983.1 mkd in M/F
90-Day dietary in rats	Acceptable, -guideline	LOAEL=Not observed
	0/0, 94.6/98.8,	
	285.7/295.1,	
	953.6/983.1 mkd M/F	
870.3700b	47923613 (2009)	Maternal
Prenatal	Acceptable, guideline	NOAEL=250 mkd
Developmental-		LOAEL =Not observed.
rabbit	0, 40, 100, and 250	
	mkd	Offspring
		NOAEL=250 mkd
		LOAEL =Not observed
Gene Mutation	47923609 (2009)	Not mutagenic.
870.5100	Acceptable, guideline	
In vitro Bacterial Gene		
Mutation		
Gene Mutation	47923611 (2009)	Not mutagenic.
870.5300	Acceptable, guideline	
In vitro Mammalian		

Table B.2	Subchronic, Chronic	e and Other Toxicity Profile Toxicity Profile for
Metabolite M700F001		
Guideline No	MRID	Results
Study Type	Classification	
	Doses	
Cells Gene Mutation		
(Chinese Hamster		
Ovary Cells)		
Cytogenetics	47923610 (2009)	Not clastogenic.
870.5375	Acceptable, guideline	
In vitro Mammalian		
Cytogenetics		
Chromosomal		
Aberration Assay-		
human peripheral blood		
lymphocytes		
Cytogenetics-other	47923612 (2009)	Did not lead to any increase in polychromatic erythrocytes.
870.5395 In Vivo	Acceptable, guideline	
Mammalian		
Cytogenetics -	O, 500, 1000, 2000	
Erythrocyte	mkd	
Micronucleus-mouse		

Table B.3	Subchronic, Chroni	c and Other Toxicity Profile Toxicity Profile for
Metabolite M700F002		
Guideline No	MRID	Results
Study Type	Classification	
	Doses	
870.3050	47923615 (2009)	NOAEL= 1164.8/1253.3mkd in M/F
28 day dietary in rats	Acceptable, guideline	LOAEL=Not observed
	0/0 113/113 /	
	0/0, 115/115.4,	
	273.9/394.0, 1164.8/1252.2 mkd	
	1104.8/1255.5 mkd	
870.3100	47923616 (2009)	
90-Day dietary in rats	Acceptable, -guideline	NOAEL=958.4/928.7 mkg M/F
5 5	1 2	LOAEL=not observed
	0/0, 113/113.4,	
	275.9/394.8,	
	1164.8/1253.3 mkd	
	0/0, 95.1/98.0,	
	285.3/299.5,	
	958.4/928.7 mkd M/F	
870.3700b	47923622 (2000)	Maternal
Prenatal	Acceptable, -guideline	NOAEL=300 mkd
Developmental-		LOAEL =1000 mkd based on increased mortality and
rabbit	0, 100, 300, 1000 mkd	abortions.
		Offspring
		NOAEL=1000 mkd
		LOAEL =Not observed
Gene Mutation	47923617 (2007)	Not mutagenic.
870.5100	Acceptable, guideline	
In vitro Bacterial Gene		

Table B.3	Subchronic, Chroni	c and Other Toxicity Profile Toxicity Profile for
Metabolite MI/00F002		
Guideline No Study Type	MKID	Kesuits
Study Type	Dosos	
Mutation	Doses	
Gene Mutation	47923619 (2008)	Not mutagenic
870 5300	Acceptable -guideline	rot matageme.
<i>In vitro</i> Mammalian	Theophasic, galacinic	
Cells Gene Mutation		
(Chinese Hamster		
Ovary Cells)		
Cytogenetics	47923618 (2008)	Not clastogenic.
870.5375	Acceptable, -guideline	
In vitro Mammalian		
Cytogenetics		
Chromosomal		
Aberration Assay-		
human peripheral blood		
lymphocytes		
Cytogenetics-other	47923620 (2009)	Did not lead to any increase in polychromatic erythrocytes
870.5395 In Vivo	Acceptable, guideline	Did not read to any mercuse in poryemoniane or yunocytes.
Mammalian	, <b>0</b>	
Cytogenetics -	O, 375, 750, 1500 mkd	
Erythrocyte		
Micronucleus-mouse		
Non-OPPTS guideline,	47923621 (2009)	M700F002 is systemically bioavailable and its presence in
OECD 417	Acceptable, non-	the bone marrow and blood after an oral application is
	guideline	confirmed.
	1000 mkd, oral	
	(gavage)	

Table B.4 Subchronic, Chronic and Other Toxicity Profile Toxicity Profile for   Metabolite M700F048		
Guideline No	MRID	Results
Study Type	Classification	
	Doses	
870.3050	47923624 (2009)	NOAEL=47.1/51.4 mkd in males, 1477.8 mkd females.
28 day dietary in rats	Acceptable, guideline	LOAEL= 189.3 in mkd males based on decreased absolute
		and realtive monocyte counts. The LOAEL was not
	0, 50, 200, 1000 mkd	observed in females.
	(nominal)	
	0/0, 47.1/51.4,	
	189.3/208.2, not	
	calculable/1477.8 M/F	
870.3700b	47923631 (2009)	Maternal
Prenatal	Acceptable, guideline	NOAEL=30 mkd
Developmental-		LOAEL = 100 mkd based on mortality, abortions, and
rabbit	0, 10, 30 and 100	resorptions
	mg/kg bw/d	
		Offspring
		NOAEL=30  mkd
		LOAEL =100 mkd based on incresed aborptions and late

Table B.4Subchronic, Chronic and Other Toxicity Profile Toxicity Profile for Metabolite M700F048		
Guideline No Study Type	MRID Classification Doses	Results
		resorptions.
Gene Mutation 870.5100 <i>In vitro</i> Bacterial Gene Mutation	47923625 (2009) Acceptable, guideline	Not mutagenic.
Gene Mutation 870.5300 <i>In vitro</i> Mammalian Cells Gene Mutation (Chinese Hamster Ovary Cells)	47923627 (2009) Acceptable, guideline	Not mutagenic.
Cytogenetics 870.5375 <i>In vitro</i> Mammalian Cytogenetics Chromosomal Aberration Assay- human peripheral blood lymphocytes	47923626 (2009) Acceptable, guideline	Clastogenic with metabolic activation.
Cytogenetics-other 870.5395 <i>In Vivo</i> Mammalian Cytogenetics - Erythrocyte Micronucleus-mouse	47923628 (2009) Acceptable, guideline 0, 500, 1000, 2000 mkd	Did not lead to any increase in polychromatic erythrocytes.
870.7485 Metabolism and Pharmacokinetics-rat	47923557 (2009) Acceptable, guideline	In both sexes, the major route of excretion was the feces (85.47% in males and 86.4% in females) with maximum excretion within 12-24 hours after dosing. The minor route of excretion was in the urine (2.4% in males and 6.8% in females).
Non-OPPTS guideline, OECD 417	47923630 (2009) Acceptable, non- guideline 1000 mkd, oral (gavage)	M700F048 is 5077265 is systemically bioavailable and its presence in the bone marrow, blood and liver after an oral application is confirmed.
Non-OPPTS guideline, OECD 486	47923629 (2009) Acceptable, non- guideline 0, 1000, 2000 mkd	Does not induce unscheduled DNA synthesis.

Table B.5Subchronic, Chronic and Other Toxicity Profile Toxicity Profile for Artificial Batch		
Guideline No Study Type	MRID Classification Doses	Results
Gene Mutation 870.5100 <i>In vitro</i> Bacterial Gene Mutation	47923573 (2009) Acceptable, guideline	No evidence of mutagenicity.

Table B.5	Subchronic, Chroni Aı	c and Other Toxicity Profile Toxicity Profile for tificial Batch
Guideline No Study Type	MRID Classification Doses	Results
Gene Mutation 870.5300 <i>In vitro</i> Mammalian Cells Gene Mutation (Chinese Hamster Ovary Cells)	47923580 (2009) Acceptable, guideline	No evidence of forward mutations.
Cytogenetics 870.5375 <i>In vitro</i> Mammalian Cytogenetics Chromosomal Aberration Assay- human peripheral blood lymphocytes	47923578 (2009) Acceptable, guideline	Clastogenic in V79 cells in the presence or absence of metabolic activation.
Cytogenetics-other 870.5395 In Vivo Mammalian Cytogenetics - Erythrocyte Micronucleus-mouse	47023585 (2009) Acceptable, guideline 0, 500, 1000, 2000 mkd	Did not lead to any increase in polychromatic erythrocytes
Non-OPPTS guideline, OECD 486	47923590 (2009) Acceptable, non- guideline 0, 2.5, 5 mkd	Does not induce unscheduled DNA synthesis.

Table B.6	Subchronic, Chroni	c and Other Toxicity Profile Toxicity Profile for
Impurity B		
Guideline No	MRID	Results
Study Type	Classification	
	Doses	
Gene Mutation	47923574 (2009)	Not mutagenic.
870.5100	Acceptable, guideline	
In vitro Bacterial Gene		
Mutation		
Gene Mutation	47923581 (2009)	Not mutagenic.
870.5300	Acceptable, guideline	
In vitro Mammalian		
Cells Gene Mutation		
(Chinese Hamster		
Ovary Cells)		
Cytogenetics-other	47923586 (2009)	Did not lead to any increase in polychromatic erythrocytes.
870.5395 In Vivo	Acceptable, guideline	
Mammalian		
Cytogenetics -	0, 15, 30, 60 mkd	
Erythrocyte		
Micronucleus-mouse		

Table B.7	Subchronic, Chronic and Other Toxicity Profile Toxicity Profile for
	Impurity C

Guideline No	MRID	Results
Study Type	Classification	
	Doses	
Gene Mutation	47923576 (2008)	Not mutagenic.
870.5100	Acceptable, guideline	
In vitro Bacterial Gene		
Mutation		
Gene Mutation	47923583 (2008)	Not mutagenic.
870.5300	Acceptable, guideline	
In vitro Mammalian		
Cells Gene Mutation		
(Chinese Hamster		
Ovary Cells)		
Cytogenetics-other	47923588 (2008)	Did not lead to any increase in polychromatic erythrocytes.
870.5395 In Vivo	Acceptable, guideline	
Mammalian		
Cytogenetics -	0, 500, 1000, 2000	
Erythrocyte	mkd	
Micronucleus-mouse		

# **APPENDIX III – <u>Data Base Supporting Fluxapyroxad</u>**

MRID	Citation
47923500	BASF Corporation (2010) Submission of Product Chemistry, Efficacy, Toxicity and Residue Data in Support of the Application for Registration of Xemium Fungicide Technical. Transmittal of 99 of 280 Studies.
47923501	O'Byrne, D. (2010) BAS 700 F: Applicant Information. Project Number: 2010/7003734/OCR. Unpublished study prepared by BASF Corporation. 10 p.
47923502	Koradin, C.; Mayer, K. (2009) Product Identity and Composition of BAS 700 F. Project Number: 2009/1079882/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 105 p.
47923503	Doetzer, R.; Deppermann, N. (2009) Confirmation of Identity of Minor Components in Technical-Grade BAS 700 F. Project Number: 2009/1091108/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 47 p.
47923504	Bentz, A. (2009) Chemical Analysis of Five Batches BAS 700 F Technical Grade Active Ingredient. Project Number: 2009/1049717/OCR, 275605/1/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 133 p.
47923505	Kroehl, T. (2006) Physical Properties: Pure Active Ingredient. Project Number: 2006/1036276/OCR, 267469/1/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 20 p.
47923506	Kroehl, T. (2008) Physical and Chemical Properties of BAS 700 F TC: Accelerated Storage Stability up to 2 Weeks at 54 Degrees Celsius. Project Number: 2008/1014896/OCR, 275716/1/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 21 p.
47923507	Brem, G. (2008) Henry's Law Constant for BAS 700 F: Supplement. Project Number: 2008/1070047/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 4 p.
47923508	Kroehl, T. (2008) Spectra (UV-VIS, NMR, IR, MS) of BAS 700 F PAI. Project Number: 2008/1066533/OCR, 267490/1/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 22 p.
47923509	Wilfinger, W. (2008) Water Solubility of BAS 700 F at 20 Degrees Celsius. Project Number: 2007/1056999/OCR, 267487/1EXT/OCR, 20071489/01/PCSB. Unpublished study prepared by Eurofins-GAB GmbH. 53 p.
47923510	Wilfinger, W. (2008) Solubility of BAS 700 F in Organic Solvents. Project Number: 2007/1057003/OCR, 20071490/01/PSBO/OCR, 267472/1EXT. Unpublished study prepared by Eurofins-GAB GmbH. 55 p.
47923511	Wilfinger, W. (2008) Partition Coefficient of BAS 700 F (HPLC Method). Project Number: 2007/1057001/OCR, 20071489/01/PCPC/OCR, 267475/1EXT. Unpublished study prepared by Eurofins - GAB GmbH. 42 p.
47923512	Hassink, J. (2009) BAS 700 F: Aqueous Hydrolysis at Four Different pH Values. Project Number: 2009/1049061/OCR, 324301/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 17 p.
47923513	Hassink, J. (2009) Aqueous Photolysis of BAS 700 F. Project Number: 2009/1031228/OCR,

	314718/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 26 p.
47923514	Wilfinger, W. (2008) Dissociation Constant of BAS 700 F in Water. Project Number: 2007/1057000/OCR, 267478/1EXT/OCR, 20071489/01/PCDC. Unpublished study prepared by Eurofins - GAB GmbH. 30 p.
47923515	Hassink, J. (2009) Photochemical Oxidative Degradation of BAS 700 F (QSAR Estimates). Project Number: 2009/1070299/OCR, 314737/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 11 p.
47923516	Loehr, S. (2008) Evaluation of Physical and Chemical Properties According to Directive 94/37/EC (67/548/EC Annex V). Project Number: 2008/1070100/OCR, SIK/NR//08/2251/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 17 p.
47923517	Yacoub, R. (2010) BAS 700 F (TGAI): Determination of Oxidation/Reduction: Final Report. Project Number: 2010/7003376/OCR, 375474/20/OCR. Unpublished study prepared by BASF Agricultural Research Center. 13 p.
47923518	Kroehl, T. (2010) BAS 700 F (TC/TGAI): Storage Stability and Corrosion Characteristics in Commercial Type Containers when Stored for up to 2 Weeks at 54 Degrees Celsius: (Final Report). Project Number: 2010/1007161/OCR, 275719/2/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 15 p.
47923519	Bentz, A. (2009) BAS 700 F TGAI: Storage Stability. Project Number: 2009/1075862/OCR. Unpublished study prepared by BASF Aktiengesellschaft. 8 p.
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