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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: EFED Registration Review Problem Formulation for Metaflumizone

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The Environmental Fate and Effects Division (EFED) has completed its problem formulation document (attached) for the ecological risk, environmental fate, endangered species, and drinking water assessments to be conducted as part of the registration review of metaflumizone.

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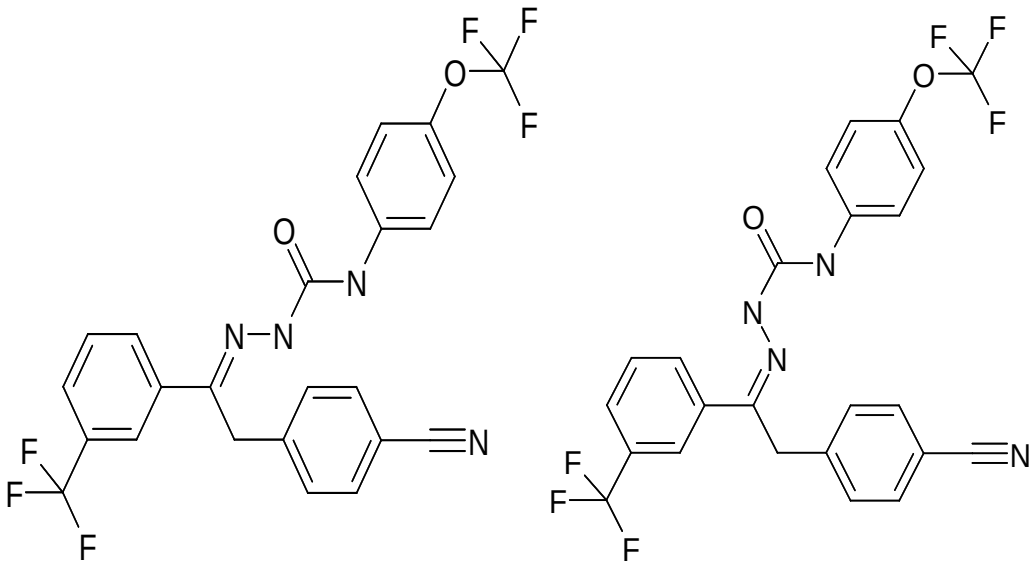
EFED Registration Review Problem Formulation for Metaflumizone



Metaflumizone: E-Isomer **Metaflumizone: Z-Isomer**

A Mixture of E and Z Isomers with an E: Z ratio of 12:1

Metaflumizone: (E+Z)-2-[2-(4-Cyanophenyl)-1-[3-(trifluoromethyl) phenyl] ethylidene]-N-[4-(trifluoromethoxy) phenyl]-hydrazinecarboxamide
CAS No.: 139968-49-3 and PC codes: 281250 & 281251

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1. Executive Summary

This problem formulation document describes the methods planned to be used during the completion of the upcoming metaflumizone registration review ecological and drinking water assessments. The document provides an overview of the environmental fate, ecological effects, and uncertainties. Additionally, it identifies required studies that would be beneficial to the conduct of the referenced assessments.

The fate database for metaflumizone is mostly complete and only the following study is requested:

An independent laboratory validation study (ILV) (OCSPP Guideline No. 850.6100) for the environmental chemistry method submitted under MRID 462642-27.

Additionally, the registrant is requested to follow the un-extracted residues guidance[1] and provide the necessary lines of evidence to prove that appropriate procedures were employed to extract residues that were much higher than 10% of the applied radioactivity (Only in the aerobic soil studies: MRIDs 462644-05/07 in which the maximum un-extracted residues ranged from 21 to 38%).

The ecological database for metaflumizone is largely complete with some outstanding data gaps for terrestrial and aquatic receptors. Among the terrestrial organisms, birds are the taxonomic group that are most at risk from registered uses based on previous assessments. Currently, toxicity data for passerine birds are not available and therefore, an acute dietary study for passerines is requested. A protocol for passerine bioassay must be submitted to the EPA for review prior to initiating the study. Justifications for these data needs as well as assumptions that will be made in the absence of these data are provided in Table 8.

2. Introduction

Metaflumizone belongs to the semicarbazone class of pesticides, and is a stereo-isomeric insecticide that is a mixture of E and Z isomers at a ratio of nearly 12:1. Metaflumizone is a voltage-dependent sodium channel blocker that inhibits nerve impulses and leads to paralysis in susceptible insects. Currently, metaflumizone is registered as a fly and fire ant granular baits.

EFED evaluated the most recent ecological risk assessments for metaflumizone in association with updated toxicity, exposure, and usage information to determine if sufficient data are available and if further updates are needed to support of the upcoming Registration Review. In addition, EFED considered the latest Agency science policies and risk assessment methodologies. Recent EFED ecological risk assessments for metaflumizone include:

[1] Un-extracted Residues Guidance, URL: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-addressing-unextracted-pesticide-residues

(1) The 2007 risk assessment entitled: *Environmental Fate and Effects Division's (EFED) Risk Assessment for the Section 3 Registration of the New Active Ingredient Metaflumizone* (D381254 & 381255 dated May 15, 2007);
(2) The 2010 risk assessment entitled: Environmental Fate and Effects Division's (EFED) Risk Assessment for the Section 3 New Use Registration of Metaflumizone for Control of Fire Ants in Citrus/Nut Orchards, Grape Vineyards, Nurseries, and Agricultural/Residential Areas (D345127 dated March 23, 2010); and
(3) The 2011 risk assessment entitled: Environmental Fate and Effects Division's (EFED) Risk Assessment for the Section 3 New Use Registration of Metaflumizone Fly Bait for Use on Numerous Sites (D361157 dated December 21, 2011).

3. Use Characterization

Labelled Use

Metaflumizone was first registered by EPA in May 2007 for limited agricultural and non-agricultural use patterns. Currently, there are five section 3, one technical, and two experimental use permits (EUP). Registered products are all formulated as granular baits and may be categorized into two categories. The ***first category*** is Fly Bait which is co-formulated with the biochemical pesticide (Z)-9-tricosene (a sex attractant pheromone for the house fly female). This end use product is scattered at a maximum rate of 1.0 lb of product/2000 ft^2 (equivalent to 0.0137 lb a.i/A) or in bait stations/trays at a maximum rate of 1.25 lb of product/2000 ft^2 (equivalent to 0.01713 lb a.i/A). Applications are allowed both indoors and outdoors in many sites including sites described below. The label provides no maximum number of applications or minimum retreatment interval. The ***second category*** is a fire ant bait which is applied broadcast or scattered around fire ant mounds in many sites described below. Labels for this product provide required application parameters for all uses. Table 1 lists the labeled use patterns and important application parameters including: use sites, maximum single/yearly application rates, and minimum intervals between applications.

Table 1. Labeled use patterns for Metaflumizone

Use Pattern	*Formulations; When/Where/How to Use; and Application Rates*
Fire Ant Bait	**Formulations:** ***(1) Metaflumizone INSECTICIDE Fire Ant Bait*** (Reg. No.: **7969-231**; active ingredient= **a.i.: 0.063%** metaflumizone); and ***(2) Can Do™ Granular Fire Ant Bait*** (Reg. No.: **7969-346**; **a.i.: 0.063%** metaflumizone) **Where/When/How to Use (Both Products): Where:** Outdoors in lawns, recreational areas, landscape and garden areas, and around the home perimeter. The bait can be used around out-buildings and animal holding areas/structures (e.g. poultry houses and livestock corrals). **When:** Apply at the first sign of fire ant activity and when the ants are most active (early morning or late afternoon when temperatures are above 60° F. The bait is not to be applied when the ground is saturated with water, heavy dew, or when heavy rains are expected within 48 hours. **How:** Bait may be applied in two ways depending on the mound density as follows: **(a)** Mound density <1 mound/2,000 sq. ft. (<22 mounds/A): use **mound treatment** in which the bait is uniformly distributed 3-4 ft.

Use Pattern	*Formulations; When/Where/How to Use; and Application Rates*
	around the mound perimeter **(b)** Mound density >1 mound/2,000 sq. ft. (>22 mounds/A): use **broadcast treatment** by a hand held or walk behind spreader **Application Rate (Both Products/Mound or Broadcast):** Max. Single application Rate x Max. No. of applications= Max. Yearly rate (Min. Application intervals) **0.001 lb. a.i/A x 4= 0.004 lb. a.i/A/year (28 days)**
	Formulation: ***Siesta™ INSECTICIDE Fire Ant Bait*** (Reg. No.: **7969-232**; active ingredient= **a.i.: 0.063%** metaflumizone) **Where/When/How to Use:** **Where:** On areas planted with non-bearing fruit, citrus and tree nut orchards; in nurseries in and around non-bearing container or field-grown fruit and nut tree stock; on lawns, turf, landscaped areas, golf courses, sod farms, industrial/municipal sites, other outdoor non-crop/non-grazed areas, such as airports, roadsides, cemeteries, commercial grounds, parks, school grounds, picnic grounds, athletic fields and other recreational areas; on grounds surrounding poultry houses (excluding runs and ranges) or corrals and other animal holding areas; and outdoor areas around residences and residential areas, commercial and other structures, warehouses, hotels, motels, supermarkets, hospitals, and nursing homes. **When:** To be applied at the first sign of fire ant activity and when the ants are most active (early morning or late afternoon when temperatures are above 60° F. The bait is not to be applied when the ground is saturated with water, heavy dew, or when heavy rains are expected within 12 hours. **How:** Bait may be applied in two ways: **(a) Broadcast treatment:** in areas with high mound density at a distance of 10 ft. from water bodies using broadcast equipment capable of applying 1.5 lbs. of product/A **(b) Mound treatment** in which the bait is uniformly distributed 3-4 ft. around the mound perimeter: A maximum of 12 m mounds/A can be treated, therefore, this treatment is used when mound density is low and to treat individual mounds in the 10 ft. buffer zone **Application Rate (Mound or Broadcast):** Max. Single application Rate x Max. No. of applications= Max. Yearly rate (Min. Application intervals) **0.001 lb. a.i/A x 4= 0.004 lb. a.i/A/year (28 days)**
	Formulation: ***Altrevin™ Fire Ant Bait INSECTICIDE*** (Reg. No.: **7969-270**; active ingredient= **a.i.: 0.063%** metaflumizone); **Where/When/How to Use:** **Where:** On areas planted with citrus fruit, grapes, pome fruit, stone fruit, and tree nuts. **When:** To be applied at the first sign of fire ant activity and when the ants are most active (early morning or late afternoon when temperatures are above 60° F. The bait is not to be applied when the ground is saturated with water, heavy dew, or when heavy rains are expected within 48 hours. **How**: Bait may be applied in two ways depending on the mound density as follows: **(a)** Mound density <1 mound/2,000 sq. ft. (<22 mounds/A): use **mound treatment** in which the bait is uniformly distributed around the mound perimeter **(b)** Mound density >1 mound/2,000 sq. ft. (>22 mounds/A): use **broadcast treatment** using broadcast equipment capable of applying 1.5 lbs. of product/A **Application Rate (Both Products/mound or broadcast):** Max. Single application Rate x Max. No. of applications= Max. Yearly rate (Min. Application intervals) **0.001 lb. a.i/A x 4= 0.004 lb. a.i/A/year (28 days)**
Fly Bait	**Formulation:** ***Metaflumizone Fly Bait*** (Reg. No.: **7969-293**; active ingredient= **a.i.: 0.063%** metaflumizone + 0.050% (Z)-9-Tricosene); **Where/When/How to Use:** **Where:** Can be used at the following sites: **(1)** ***Outdoors:*** around Food and beverage processing plants, meat and poultry processing plants, food handling establishments, restaurants, cafes, fast-food establishments, supermarkets, farm markets, bakeries, commissaries, warehouses, livestock handling and feeding facilities including broiler and layer houses, swine production facilities, livestock barns, horse stables, milking parlors, dairy barns, feed lots, feed storage buildings, feed silos, and other animal handling and feeding facilities; **(2)** ***Outdoors:*** Around recreational facilities and in areas of parks, picnic grounds, camp grounds, and outdoor latrines. **(3)** ***Indoors:*** in livestock handling and feeding facilities (Only in areas where livestock cannot come in contact with

Use Pattern	*Formulations; When/Where/How to Use; and Application Rates*
	or ingest bait granules): Walkways or manure pits in caged layer houses, dairy barns, and swine facilities. **When:** at the beginning of the season to prevent large infestations and to keep populations at manageable levels. **How:** Bait may be applied ***Scattered*** or in ***Bait/Tray Stations*** (for Areas listed in 1 & 2, above) **Application Rate (Both Products/mound or broadcast):** Max. Single application Rate x Max. No. of applications= Max. Yearly rate (Min. Application intervals) **Maximum Scattered Rate: 0.00137214 lb. a.i/A x 26= 0.264 lb. a.i/A/year** (Label states: Re-apply as bait is consumed; Assume 26 applications @ 14 day intervals) **Maximum Bait/Tray Station Rate: 10 Stations/2,000 sq. ft. = 0.0172 lb a.i/A** (Label states: Re-apply as bait is consumed)

It is noted, that **Table 1** contains values marked as "assumed" because they are not stated in the labels. These values are conservative and will be used in future modeling unless labels are modified, by the registrant, to include the required missing/assumed information.

Usage

As per the Biological and Economic Analysis Division (BEAD), the only reported use of metaflumizone was (<I lb a.i.). This negligible quantity was reportedly used in California in 2013 on landscapes and rights-of-ways areas (BEAD Memo entitled "BEAD Chemical Profile for Registration Review: Metaflumizone (281250)" and dated February, 25, 2016).

4. Conclusions from Previous Risk Assessments

4.1 Ecological Risk Assessment

EFED has conducted ecological risk assessments on metaflumizone that serve as the basis for this problem formulation. Risk conclusions are listed below and summarized in **Table 2**:

- Acute and chronic exposure from direct ingestion of granular fire-ant bait and granular fly bait containing metaflumizone may pose risks to avian species. Most sensitive endpoint was avian reproduction.
- Acute and chronic risks to mammals from direct ingestion are not expected, in part because metaflumizone is practically non-toxic to mammals on an acute basis.
- Acute and chronic risk to birds and mammals consuming contaminated invertebrates, fish, or earthworms are not indicated.
- Acute and chronic risks to fish, aquatic invertebrates (benthic and water column-dwelling), and aquatic plants resulting from runoff with the previous fire ant use are not expected due to very low levels of metaflumizone predicted concentrations in water. This determination is based upon the 2010 (USEPA, 2010; D345127). With the previous fly bait use, no acute or chronic risks were indicated for non-listed fish, aquatic

invertebrates or aquatic plants (USEPA 2011; D361157). However, acute RQ values ranged from 0.02 to 0.33 which exceeded the risk to listed species LOC of 0.05 for fish and aquatic invertebrates. As noted in the 2011 fly bait assessment, these risk findings are likely sensitive to several conservative assumptions made for exposure modeling (*e.g.*, 26 applications per year) due to lack of use restrictions specified on the label.

Table 2. Summary of conclusions from previous risk assessment

Birds	Mammals	Terr Plants	Terr Inverts	Fish	BC/BAF	Aquatic Inverts	Aquatic Plants	Groundwater Contamination	Persistence	Degradates of Concern
Yes[1]	No	No	No	No	Yes	No	No	No	Yes	None

[1] Potential for chronic and acute risks to birds
.

4.2 Drinking Water Exposure Assessments

The latest drinking water exposure assessment for metaflumizone was conducted in March, 30, 2015 and was based on modeling all current uses employing tier II surface water concentration calculator model (SWCC) for surface water and tier I PRZM-GW model for groundwater[2]. In the referenced assessment, the stressor of concern for drinking water was considered to be parent metaflumizone alone (MARC meeting 10/25/2005).

4.3 Clean Water Act Programs

Metaflumizone is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act at:

http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885

Furthermore, OPP aquatic life benchmarks and Office of Water aquatic life criteria have not been established for metaflumizone as per the following URLs:
(a) The aquatic life benchmark list:
https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/aquatic-life-benchmarks-pesticide-registrationn
(b) The National recommended aquatic life criteria: Aquatic life criteria Table:
https://www.epa.gov/wqc/national-recommended-water-quality-criteria-aquatic-life-criteria-table

[2] Water Memo entitled: Revision 2: Estimated Drinking Water Concentrations of metaflumizone for All Current Uses as Fire Ant and Fly bait for Use in Human Health Risk Assessment (DP Barcode: 421741 dated March, 30, 2015.

5. Environmental Fate and Transport

Metaflumizone active ingredient is poorly soluble in water and volatilization into the air from dry/wet soils and water is expected to be limited due to its relatively low vapor pressure (9.3 x 10^{-11} torr at 20 ^{o}C) and Henry's law constant (3.5 x 10^{-7} atm m^3 $mole^{-1}$ at 20 ^{o}C). Possible bio-accumulation in fish and aquatic organisms is suggested by the relatively high K_{ow} (E isomer= 125, 893 (Log K_{ow} = 5.1) and for the Z isomer = 25,119 (Log K_{ow} = 4.4). Results of the bioaccumulation test in bluegill sunfish confirmed the expected high bioconcentration factors (Max. BCFs= 3,500 (edible) and 12,000 (non-edible).

Based on submitted fate studies, metaflumizone is expected to be mainly affected by abiotic degradation: photolysis in water (t ½ = 4.6 days). Therefore, significant degradation of the chemical is expected only in shallow clear water bodies. In contrast, the chemical appears to be highly persistent in most other important environmental compartments/conditions. It is hydrolytically stable in neutral and alkaline condition, practically stable in anaerobic soil, anaerobic aquatic systems (t ½ >378 days), and degrades slowly by photolysis on soil (t ½ = 54 days) and by biodegradation in soils (90th percentile t ½ = 134 days). Finally, metaflumizone appears to have very high affinity to soil and sediment particles rendering it to be immobile in systems with varied textures and organic matter content (an average K_{oc} value of 30,753 L Kg^{-1} in a range of 16,534-51,031 L Kg^{-1}). A Summary of the physical/ chemical and fate and transport properties of metaflumizone is included in **Appendix A**.

6. Receptors

A summary of the terrestrial and aquatic taxonomic groups and most sensitive surrogate species tested to characterize the acute and chronic ecological effects of metaflumizone is included in **Table 3** and **Table 4.**

The active ingredient of metaflumizone consists of E- and Z-isomers with a ratio of 12:1. Because the respective proportions of the E-Z isomers varied among the studies summarized in **Table 3** and **Table 4**, additional footnotes enumerating these variations have been included.

6.1 Effects to Terrestrial Organisms

Metaflumizone may be categorized as highly toxic to birds on an acute dietary basis. Although acute oral gavage tests did not yield toxic effects, the 5-day dietary study yielded a bimodal pattern of mortality with increasing concentration. Because a monotonic dose-response curve could not be fitted to the data, the acute LC_{50} value was assumed to be > 156 mg/kg-diet based on the lowest concentration that yielded a significant mortality (70% mortality at 309 mg/kg-diet). The avian reproduction test conducted on Bobwhite quail showed treatment-related sublethal effects of metaflumizone in hatched chicks. Effects such as spasms and death were observed at concentrations 15 ppm, thus designating the NOEC at 7.6 ppm. Currently, no data

are available on the acute oral toxicity of metaflumizone to passerine birds, which is a data requirement that was required subsequent to the initial registration of metaflumizone.

Table 3. Summary of most sensitive endpoints for terrestrial organisms to metaflumizone

Taxonomic Group	Study Type	Species	Toxicity Value	Acute Toxicity Classification	Source
Mammals	Acute	Laboratory Rat (*Rattus norvegicus*) and Laboratory Mice (*Mus musculus*)	LD_{50}>2000 mg a.i./kg bw in all tests (no mortality)	Practically nontoxic	46264528[1] 46264231[2] 46264232[4] 46264233[3] 46264234[4]
	Chronic (2-generation repro gavage study)	Laboratory Rat (*Rattus norvegicus*)	NOAEL = 20 mg a.i./kg bw/day NOAEC = 400 ppm LOAEL = 50 mg a.i./kg bw/day LOAEC = 1000 ppm		46264315[5]
Birds	Acute[5]	Northern Bobwhite *Colinus virginianus* Mallard *Anus platyrhynchos*	LD_{50}>2025 mg/kg (no mortality) LD_{50}>2025 mg/kg (no mortality)	Practically nontoxic Practically nontoxic	46264425 Acceptable 46264426 Acceptable
	Sub-acute Dietary[6]	Mallard *Anus platyrhynchos*	LC_{50} >156 ppm	Highly toxic	46264428[8] Supplemental
	Chronic[7]	Northern Bobwhite *Colinus virginianus*	NOAEC= 7.6 ppm	Very highly toxic	41993202 Acceptable
Insects	Acute[9]	Honey bee *Apis mellifera*	Contact LD_{50}=1.65 µg/bee Oral LD_{50}=2.44 µg/bee	Very highly toxic	46264516 Contact: Acceptable Oral: Supplemental
Plants-Tier I Seedling Emergence	Monocot[10] (Single application)	N/A	EC_{25} = N/A[11] NOAEC = N/A	Practically nontoxic	46264541 Acceptable
	Dicot[10] (Single application)	Lettuce (*Latuca sativa*)	EC_{25} = N/A[12] NOAEC = 0.225 lb a.i./A	Practically nontoxic	46264541 Acceptable

[1]Conducted using TEP (11.9:1 E:Z ratio; 21.97% a.i.)
[2]Conducted using TGAI (Z-isomer; 96.9% a.i.)
[3]Conducted using TGAI (E:Z isomer ratio NA; 98.7% a.i.)
[4]Conducted using TGAI (12:1 E:Z ratio; 96.3% a.i.)
[5]Conducted using TGAI (92:8 E:Z ratio; 96.3% a.i.)

[6]Conducted using TGAI (93.9:6.1 E:Z ratio; 96.9% a.i.)
[7]Conducted using TGAI (15.4:1 E:Z ratio; 96.9% a.i.)
[8]Study classified as supplemental due to a lack of a dose-response patter of mortality. No reliable LC_{50} was generated.
[9]Conducted using TGAI (92:8 E:Z ratio; 96.3% a.i.). The acute contact study where doses were applied to the ventral thorax yielded more sensitive results than the acute contact study where doses were applied to the dorsal thorax
[10]Conducted using TEP (21.82% a.i.)
[11]There were no detrimental effects ≥25% for any test species and no species or endpoint exhibited a significant reduction from the controls.
[12]There were no detrimental effects ≥25% for any test species.

Table 4 Summary of most sensitive endpoints for aquatic organisms to metaflumizone

Taxonomic Group	Study Type	Species	Toxicity Value	Acute Toxicity Classification	Source
Fish	Acute[1]	Rainbow Trout *Oncorhynchus mykiss*	Effects occurred at 1.79 ppb	Very highly toxic	46264435 Supplemental[2]
Benthic Fish	Acute[1]	Common Carp *Cyprinus carpio*	Effects occurred at 1.79 ppb	Very highly toxic	46264437 Supplemental[2]
Invertebrates	Acute[1]	Water Flea *Daphnia magna*	Effects occurred at 1.79 ppb	Very highly toxic	46264505 Supplemental[2]
	Chronic[1]	Water Flea *Daphnia magna*	Effects occurred at lowest concentration of 0.0908 ppb[3]	None	46264507 Supplemental[2]
Plants	Acute[1]	Algae *Pseudokirchneriella subcapitata*	Effects occurred at 1.79 ppb	Very highly toxic	46264511 Supplemental[2]
	Acute[4]	Duckweed *Lemna gibba*	Effects occurred at 1.79 ppb	Very highly toxic	46264515 Supplemental[2]

[1]Conducted using TGAI (92:8 E:Z ratio; 96.3% a.i.).
[2]Samples were not centrifuged prior to analysis. Study classified as supplemental because the concentration bioavailable to the organisms was unknown. Due to this uncertainty, EFED assumed that observed effects occurred at the limit of solubility (1.79 ppb).
[3]No definitive endpoint established. Mortality occurred at all concentration levels.
[4]Conducted using TGAI (93.6:6.1 E:Z ratio; 96.9% a.i.).

6.2 Ecological Incidents

The Ecological Incident Information System (EIIS) is an OPP database that houses ecological incidents that have been reported to the Agency. When available, EIIS includes date and location of an incident, type and magnitude of effects observed in various species, uses of pesticides known or suspected of contributing to the incident and results of any chemical residue analysis or other analyses conducted during incident investigation. EIIS incidents are categorized according to the certainty that the incident results from pesticide exposure. The

Avian Monitoring System (AIMS) is a database maintained by the American Bird Conservancy that contains publicly available data on reported avian incidents involving pesticides. Many of the incidents listed in AIMS are also listed in EIIS. A preliminary review of EIIS returned no incidents attributed to metaflumizone use.

7. Exposure Pathways of Concern

The environmental fate and transport properties and use patterns of metaflumizone indicate that runoff with eroded soil and spray drift represent the important transport mechanisms of the chemical to aquatic and terrestrial organisms. Drinking water and inhalation exposure pathways were investigated using the Screening Imbibition Program (SIP) and Screening Tool for Inhalation Risk (STIR) screening methods and were found to be exposure pathways of low concern. SIP and STIR are described in detail at: http://www.epa.gov/pesticides/science/models_pg.htm#terrestrial.

SIP is used to provide an upper bound estimate of exposure of birds and mammals to pesticides through drinking water alone. It is used to determine whether or not drinking water exposure alone is a potential pathway of concern; it does not aggregate drinking water exposure with other exposure routes. The results of SIP conclude that drinking water exposure alone to metaflumizone is not a potential concern for mammals or birds on an acute or chronic basis. . STIR indicated that exposure via the inhalation pathway was not likely significant for mammals or avian species. Output from models can be found in **Appendix B** and **Appendix C.**

8. Analysis Plan

8.1 Stressors of Concern

The stressor of concern for drinking water and aquatic and terrestrial organisms is parent metaflumizone. Currently available data indicate that the chemical is highly persistent. Degradates forming in most important environmental compartments, are therefore expected to be at low concentrations.

8.2 Measures of Exposure

EFED will use standard available models (identified in **Table 5**) to evaluate potential exposures to aquatic and terrestrial organisms as described at http://www.epa.gov/pesticides/science/models_db.htm

Aquatic exposure estimates will be based on estimated environmental concentrations (EECs) generated using the Pesticide Water Calculator (PWC) model to simulate a waterbody that is

considered representative of vulnerable aquatic environmental (*e.g.*, ponds and streams in headwater watersheds).

The terrestrial models TREX (version 1.5.2; dated 6/6/2013) and TerrPlant will be used to assess metaflumizone exposure to terrestrial vertebrates and plants respectively using conservative values. Because metaflumizone is currently formulated into granular baits, the granular characterization module of TREX will be used. Further analysis on avian risks will be conducted with MCnest. Since currently registered products of metaflumizone involve granular bait applications only, risks to bees will not be assessed as previous studies have found that metaflumizone is not transported systemically in plants (MRIDs: 462644-01/02/03). Finally KBAM will be used to estimate potential bioaccumulation of metaflumizone in freshwater aquatic food webs. For more information on the various models that will be used in the risk assessment see the links as outlined in **Table 5.**

Table 5 List of various models and the related taxa for which the models will be used

Environment	Taxa of Concern	Model(s)
Aquatic	Fish/Invertebrates/Birds	PWC, KBAM
Terrestrial	Birds/Mammals	TREX
		MCnest
	Plants	TerrPlant

8.3 Measures of Effect

Toxicity data presented in **Table 3** of this problem formulation will be used to calculate risk quotients in future risk assessments. Any additional information submitted by the registrant or found in the open literature prior to conduct of the risk assessment will also be considered. The open literature studies are identified using EPA's ECOTOXicology database (ECOTOX), which employs a literature search engine for locating chemical toxicity data for aquatic life, terrestrial plants, and wildlife. The evaluation of both sources of data can also provide insight into the direct and indirect effects of pesticides on biotic communities from loss of species that are sensitive to the chemicals and from changes in structure and functional characteristics of the affected communities.

9. Endangered Species Assessments

Consistent with EPA's responsibility under the Endangered Species Act (ESA), the Agency will evaluate risks to federally listed threatened and endangered (listed) species from registered uses of pesticides in accordance with the Joint Interim Approaches developed to implement the

recommendations of the April 2013 National Academy of Sciences (NAS) report, *Assessing Risks to Endangered and Threatened Species from Pesticides*. The NAS report outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the ESA and FIFRA. EPA will address concerns specific to metaflumizone in connection with the development of its final registration review decision for metaflumizone.

In November 2013, EPA, the U.S. Fish and Wildlife Service, National Marine Fisheries (the Services), and USDA released a white paper containing a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the NAS recommendations, and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. Details of the joint Interim Approaches are contained in the November 1, 2013 white paper, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report.*

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, this ecological problem formulation supporting the Preliminary Work Plan for metaflumizone does not describe the specific ESA analysis, including effects determinations for specific listed species or designated critical habitat, to be conducted during registration review. While the agencies continue to develop a common method for ESA analysis, the planned risk assessment for the registration review of metaflumizone will describe the level of ESA analysis completed for this particular registration review case. This assessment will allow EPA to focus its future evaluations on the types of species where the potential for effects exists, once the scientific methods being developed by the agencies have been fully vetted. Once the agencies have fully developed and implemented the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats, these methods will be applied to subsequent analyses of metaflumizone as part of completing this registration review.

10. Endocrine Disruptor Screening Program

Metaflumizone was not included in the first group of chemicals issued an order to conduct Tier 1 EDSP. For additional information the EDSP program, visit http://www.epa.gov/endo/

11. Preliminary Identification of Data Gaps

11.1 Environmental Fate

Table 6 identifies environmental fate studies by MRID that offer data for each guideline requirement, as well as study classifications. With the exception of ILV for water study, No data is requested at this time with the limited use pattern of metaflumizone.

Table 6. Submitted environmental fate and transport data for Metaflumizone (Mixed isomers)

OCSPP Guideline	*Data Requirement*	*Submitted Studies (MRID)*	*Study Classifications*
835.2120	Hydrolysis	462644-19	Acceptable
835.2240	Aqueous photolysis	462644-20	Acceptable
835.2410	Soil photolysis	462644-06	Acceptable
835.4100	Aerobic soil metabolism	468077-04	Supplemental
		462644-07 & 462644-05	Acceptable**
835.4200	Anaerobic soil metabolism	466233-41	Acceptable
835.4300	Aerobic aquatic metabolism	466233-43	Acceptable
835.4400	Anaerobic aquatic metabolism	462644-22	Acceptable
835.1230/40	Adsorption/ desorption & leaching	462644-11 & 462644-12	Acceptable
835.6100	Terrestrial field dissipation	462644-08/09/10 & 465404-14	Acceptable
		468077-05 & 466233-44	Supplemental
850-1730	Bio-concentration in Fish	462645-04	Acceptable
850.6100	ECM/ILV* for soil/sediment	462642-25/26	Acceptable
850.6100	ECM for tap/surface water	462642-27	Acceptable
850.6100	ILV for tap/surface water	**None submitted and is required**	

*__ECMs=__ Environmental Chemistry Methods & Associated __ILVs=__ Independent Laboratory Validations (ILVs)
** It is noted that clarifying information on the un-extractable residues is being requested, herein.

11.2 Ecological Effects

Table 7 and **Table 8** identify ecological effects studies by MRID that offer data for each guideline requirement, as well as study classifications and whether or not further data are needed in order to support risk assessment. Rationale for the additional data requested is presented below the tables.

Table 7. Submitted aquatic ecological effects data for Metaflumizone (Mixed isomers)

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed to conduct risk assessment?	Justification and Assumptions EPA will Make in Absence of Data
850.1010	Freshwater invertebrate acute toxicity	46264505	Acceptable	No	--
		46264538	Acceptable		
850.1025 850.1055	Saltwater oyster acute toxicity	46264519	Supplemental	No	--
850.1075	Freshwater fish acute toxicity	46264437	Supplemental	No	--
850.1075	Saltwater fish acute toxicity	46264521	Supplemental	No	--
		46264438	Supplemental		

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed to conduct risk assessment?	Justification and Assumptions EPA will Make in Absence of Data
850.1300	Freshwater invertebrates life cycle	46264507	Supplemental	No	--
850.1400	Freshwater fish early-life stage	None	NA	No	--
850.1400	Saltwater fish early-life stage	46264502	Supplemental	No	--
850.1400	Saltwater benthic fish early-life stage	None	NA	No	--
850.1710	Saltwater oyster BCF	None	NA	No	--
850.1735	Freshwater Benthic Invertebrates Subchronic toxicity (10-day)	46264513	Supplemental	No*	--
850.1740	Saltwater Benthic Invertebrates Subchronic toxicity (10-day)	46264512	Supplemental	No	--
850.1790	Freshwater Benthic Invertebrates Chronic toxicity	None	NA	No*	--
850.----	Saltwater Benthic Invertebrates Chronic toxicity	None	NA	No*	--
850.4400	Aquatic plant Toxicity Test using Lemna	46264515	Supplemental	No	--
850.4500	Algal toxicity	46264511 46264539	Supplemental	No	--

* Although the Agency requires two freshwater benthic invertebrate species (the amphipod, *Hyalella azteca*, and the midge, *Chironomus dilutus*) for outdoor uses of pesticides, EFED has conclude that requesting additional data for *C. dilutus* would not likely alter the risk assessment conclusions for the current use pattern of metaflumizone, which result in EECs that are several orders of magnitude below the toxicity endpoints. Furthermore, the need for chronic (life cycle) studies with benthic invertebrates is also considered of low value at this time. Should the registrant propose changes to the use pattern in the future, then additional data may be required for benthic invertebrates.

Table 8. Submitted terrestrial ecological effects data for Metaflumizone

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment ?	Justification and Assumptions EPA will Make in Absence of Data
870.1100	Laboratory rat (*Rattus rattus*) Laboratory mice (*Mus musculus*)	46264528 46264231 46264232 46264233 46264234	Acceptable	No	--
870.3800	Laboratory rat (*Rattus rattus*)	46264315	Acceptable	No	--
850.2100	Avian oral toxicity	46264425 (quail)	Acceptable	No	--
		46264426 (mallard)	Acceptable		
		None for Passerines	NA		
850.2200	Avian dietary toxicity	46254428 (mallard)	Supplemental	No	--
		Quail	Non Guideline	No	

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment ?	Justification and Assumptions EPA will Make in Absence of Data
		None for Passerines	NA	**YES**	Acute oral toxicity tests conducted on mallards and quail produced results that suggested metaflumizone was only slightly toxic to birds (LD_{50} > 2025 mg a.i. / kg bw). However, one acute dietary toxicity test (MRID: 46254428) produced a NOEC of 156 ppm in mallards. Because mortality was bimodal across the dose range, a probit curve could not be fit to the data. Although a definitive LC_{50} could not be estimated, the study demonstrated that toxicity of metaflumizone increased as it was ingested over time. A subsequent avian reproduction study demonstrated that continued ingestion of metaflumizone produced toxic effects in hatching chicks and further reduced the NOEC to 7.6 ppm. These chronic data contradicted results from the acute oral gavage studies and suggest that gavage studies alone did not fully elucidate the toxic effects of metaflumizone. There are no submitted data for passerine birds, yet granular formulation of metaflumizone may be an attractive food source for foraging passerines because the formulation consists of impregnated soybean oil on a corn-grit carrier. An acute dietary toxicity study for passerines is requested in place of an acute oral toxicity study. A protocol for a passerine study must be submitted to the EPA for review *a priori*.
850.2300	Avian reproduction	46264430 (quail)	Acceptable	No	--
		None for Passerines	NA	No	--
850.3020	Honey bee acute contact and oral toxicity	46264516	Contact: Acceptable Oral: Supplemental	No*	--
850.Supplemental (48 hr. acute contact toxicity)	Parasitic wasps	46499502	Supplemental	No	--

OCSPP Guideline	Data Requirement	Submitted Studies (MRID)	Study Classifications	Are data needed for risk assessment ?	Justification and Assumptions EPA will Make in Absence of Data
850.Supplemental (40 day chronic toxicity)	Parasitic wasps	46623338	Not rated. Data submitted to United Kingdom; study not submitted in initial package to EPA	No	--
850.4100	Seedling Emergence and Seedling Growth	46264541	Acceptable	No	--
850.4150	Vegetative Vigor	46264540 (monocots and dicots)	Acceptable	No	--

* No additional data are being required for bees given the current granular bait use pattern for metaflumizone. . Should changes in this use pattern be proposed in the future *(e.g.,* foliar sprays) or if the assumption that metaflumizone is not systemically transported is not substantiated, then additional bee toxicity data would be required (*e.g.*, chronic data for larvae and adults).

12. References

PC Code 281251 Metaflumizone Fate Bibliography Revised 21 January 2016

161-1 Hydrolysis

MRID		Citation Reference
46264419	2025680 2025695	Fang, C. (2004) Hydrolysis of 14C-BAS 320 I in Aqueous Media. Project Number: 83451, 2003/5000476. Unpublished study prepared by BASF Corporation. 96 p.
46807701	amended	Fang, C. (2004) Hydrolysis of (Carbon 14)-BAS 320 I in Aqueous Media (25 degrees Celcius): Amended Final Report. Project Number: 2004/7007518, 83451. Unpublished study prepared by BASF Corporation. 96 p.

161-2 Photodegradation-water

MRID		Citation Reference
46264420	2025680 2025696	Ta, C. (2004) Aqueous Photolysis of (Carbon 14)-BAS 320 I. Project Number: 83453, 2003/5000571. Unpublished study prepared by BASF Corporation. 120 p.
46807702		Chanh, T. (2004) Aqueous Photolysis of 14C-BAS 320 I (Including Amendment 1). Project Number: 2004/7010666, 83453, 2003/5000571. Unpublished study prepared by BASF Corporation. 130 p.

161-3 Photodegradation-soil

MRID		Citation Reference
46264404		Paulick, R.; Jackson, S. (2004) Environmental Fate Summary for BAS 320 I. Project Number: 2004/5000150. Unpublished study prepared by BASF Corporation. 14 p.
46264406	2025685	Ta, C. (2002) BAS 320 I: Soil Photolysis: Final Report. Project Number: 83521, 2002/5004748. Unpublished study prepared by BASF Corp. 132 p.
46807703	2053618	Trollinger, J.; Ta, C. (2005) Photolysis of 14C-BAS 320 I on Soil: Final Report. Project Number: 2004/5000731, 134033. Unpublished study prepared by BASF Agro Research and Agvise Inc. 64 p.

162-1 Aerobic soil metabolism

MRID		Citation Reference
46264405	2025680 2025684	Ta, C. (2004) BAS 320I: Aerobic Soil Metabolism. Project Number: E/00/032, 2004/5000067. Unpublished study prepared by BASF Corp. 130 p.

46264407	2025680 2025686 -83?	Ta, C. (2004) Rate of Degradation of (Carbon 14)-BAS 320 I in US Soils. Project Number: 97559, 2004/5000036. Unpublished study prepared by BASF Corporation and Agvise Inc. 147 p.
46540415	2053610	Ta, C. (2004) Rate of Degradation of (Carbon 14)-M320I06 in Soils: Final Report. Project Number: 83419, 2004/5000716. Unpublished study prepared by BASF Agro Research and Agvise Inc. 61 p.
46540416	2053611	Oddy, A. (2004) (Carbon 14)-M320I23: Rate of Degradation in Soils: Final Report. Project Number: 2004/1022514, 134030, MX/04/014. Unpublished study prepared by Battelle Agrifood, Ltd. 87 p.
46540417	2053612	Staudenmaier, H. (2005) Rate of Degradation in Soil of Reg. No. 4108253 (M320I29, Metabolite of BAS 320I): Final Report. Project Number: 135782, 2004/1022508. Unpublished study prepared by: BASF Aktiengesellschaft. 49 p.
46807704	2053619	Bayer, H.; Janz, U. (2005) Aerobic Rate of Degradation of BAS 320 I)CF3-(Carbon 14)-phenyl) in Soil (DT50/DT90). Project Number: 83523, 2004/1022504. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng). 110 p.

162-2 Anaerobic soil metabolism

MRID		Citation Reference
46623341	2053614	Panek, M. (2005) BAS 32- I Anaerobic Soil Metabolism. Project Number: 83801, 2004/5000728. Unpublished study prepared by BASF Corporation and Agvise Inc. 99 p.

162-3 Anaerobic aquatic metabolism

MRID		Citation Reference
46264406	2025685	Ta, C. (2002) BAS 320 I: Soil Photolysis: Final Report. Project Number: 83521, 2002/5004748. Unpublished study prepared by BASF Corp. 132 p.
4626422	2025680 2025697	Singh, M.; Trollinger, J. (2003) Anaerobic Aquatic Metabolism of (Carbon 14)-BAS 320 I. Project Number: 83517, 2003/5000394. Unpublished study prepared by BASF Corporation and Agvise Inc. 144 p.
46623341	2053614 2053615 2053616	Panek, M. (2005) BAS 32- I Anaerobic Soil Metabolism. Project Number: 83801, 2004/5000728. Unpublished study prepared by BASF Corporation and Agvise Inc. 99 p.

162-4 Aerobic aquatic metabolism

MRID		Citation Reference
46264421	2025680 2025699	Ta, C. (2004) BAS 320 I: Aerobic Aquatic Metabolism. Project Number: 131708, 2004/5000037. Unpublished study prepared by BASF Corporation and Agvise Inc. 124 p.

46623342	2053615	Rosenwald, J. (2003) Degradation of BAS 320 I in Water/Sediment Systems under Aerobic Conditions: (Final Report). Project Number: 0729/227, 1859/0729/227, 2003/1018146. Unpublished study prepared by Covance Laboratories, Gmbh. 151 p.
46623343	2053616	Ta, C. (2004) Aerobic Aquatic Degradation of (Carbon 14)-BAS 320 I Under Dark and Light Conditions: Amended Final Report. Project Number: 132131, 2004/5000715. Unpublished study prepared by BASF Corporation and Agvise Inc. 313 p.

163-1 Leaching and adsorption/desorption

MRID		Citation Reference
46264411	2025680	Zirnstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I (Reg. No. 4080134) on Five European Soils: Final Report. Project Number: 83449, 2003/1009293, 102859/1. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 36 p.
46264412	2025680 2025692	Zirnstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I (Reg. No. 4080134) on Two North American Soils: Final Report. Project Number: 102607/5, 2004/1003832, 102859/5. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 34 p.
46264413	2025680 2025691	Zirnstein, M. (2003) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I06 (Reg. No. 121464) on Five European Soils: Final Report. Project Number: 102607/1, PI020016, 03/10/35/085. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 46 p.
46264414	2025680 2025690	Zirnstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I06 (Reg. No. 121464) on Two North American Soils: Final Report. Project Number: 102607/6, 2004/1003833, PI020016. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 39 p.
46324415	2025701	Zirnstein, M. (2004) Adsorption/Desorption - Study on BAS I Metabolite M320I23 (Reg. No. 4984051) on Five European Soils: Final Report. Project Number: 102607/3, 2004/1003829, 102859/403/10/35/085. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 51 p.
46264416	2025680 2025693	Zirnstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I23 (Reg. No. 4984051) on Two North American Soils: Final Report. Project Number: 102607/8, 2004/1003835, 102859/4. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 42 p.
46264417	2025680 2025694	Zirnstein, M. (2003) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I04 (Reg. No. 4096485) on Five European Soils: Final Report. Project Number: 102607/2, 2003/1009292, 102859/2. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 52 p.

46264418	2025680 2025700	Zirnstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I04 (Reg. No. 4096485) on Two North American Soils. Project Number: 102607/7, 2004/1003834, 102859/2. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 39 p.
46264419	2025695 2025696	Fang, C. (2004) Hydrolysis of 14C-BAS 320 I in Aqueous Media. Project Number: 83451, 2003/5000476. Unpublished study prepared by BASF Corporation. 96 p.
46623340	2053613	Zirstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I29 (Reg.No. 410 8253) on Five European and Two North American Soils: (Final Report). Project Number: 01/1297, 03/736/03, 99/1403. Unpublished study prepared by BASF Aktiengesellschaft and Agvise Inc. 67 p.

164-1 Terrestrial field dissipation

MRID		Citation Reference
46264407	2025686 2025684 2025697 2025699 2025685 2025680	Ta, C. (2004) Rate of Degradation of (Carbon 14)-BAS 320 I in US Soils. Project Number: 97559, 2004/5000036. Unpublished study prepared by BASF Corporation and Agvise Inc. 147 p.
46264408	2025680 2025688	Jackson, S.; Saha, M. (2002) 2002 Field Dissipation of BAS 320 ..I in Terrestrial Use Patterns. Project Number: 67702, 2003/5000493, A67702. Unpublished study prepared by BASF Agro Research, Research Options, Inc., South Texas Ag. Research, Smith Biological Services, Research for Hire and Agvise Laboratories. 850 p.
46264225	2061761 2061282	Saha, M.; Gooding, R. (2003) Validation of BASF Method No. D0301: The Determination of Residues of BAS 320 I and its Metabolites M320I04 (Reg. no. 4096485), M320I06 (Reg. no. 121464), and M320I23 (Reg. no. 4984051) in Soil Using LC-MS/MS. Project Number: 83435, 2003/5000302, D0301. Unpublished study prepared by BASF Corporation. 100 p.
46264226	2061761 2061282	Perez, R. (2004) Independent Laboratory Validation of BASF Analytical Method D0301: "The Determination of Residues of BAS 320 I and its Metabolites, M320I04 (Reg No. 4096485), M320I06 (Reg. No. 121464), and M320I23 (Reg. No. 4984051) in Soil Using LC-MS/MS". Project Number: 83437, 2003/5000437, ADPEN/903/2K30818. Unpublished study prepared by Adpen Labs. 76 p.
46264227	2061761	Zangmeister, W. (2003) Validation of Analytical Method 534/0: Method for the Determination of BAS 320 I, E-isomer (Reg. no. 4102472), BAS 320 I, Z-isomer (Reg.no.4102572) M320I04 (Reg.no.4096485) and M320I23 (Reg.no.4984051) in Tap- and Surface Water: Final Report. Project Number:

		93005, 2003/1009280, 534/0. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 65 p.
46264408	2025688 2025680 2025687	Jackson, S.; Saha, M. (2002) 2002 Field Dissipation of BAS 320 I in Terrestrial Use Patterns. Project Number: 67702, 2003/5000493, A67702. Unpublished study prepared by BASF Agro Research, Research Options, Inc., South Texas Ag. Research, Smith Biological Services, Research for Hire and Agvise Laboratories. 850 p.
46264409	2025687 2025688	Malinsky, S. (2004) Freezer Storage Stability Study of BAS 320 I (E and Z Isomers) and Its Metabolites (M320I04, M320I06 and M320I23) in Soil. Project Number: 121739, 2003/5000554. Unpublished study prepared by BASF Corporation. 88 p.
46264410	2025686	Ta, C. (2004) Freezer Storage Stability Study of BAS 320 I and Its Metabolites, M320I04, M320I06 and M320I23 in Soil. Project Number: 131228, 2004/5000038. Unpublished study prepared by BASF Corporation. 42 p.
46540414		Malinsky, D. (2005) Freezer Storage Stability Study of BAS 320 I (E and Z Isomers) and its Metabolites (M320I04, M320I06 and M320I23) in Soil: Final Report. Project Number: 2004/5000781, 121739, 2003001. Unpublished study prepared by BASF Agro Research. 104 p.
46623344	2053617	Kellner, O.; Zangmeister, W.; Platz, K. (2004) Field Soil Dissipation of BAS 320 I in Formulation BAS 320 00 I on Bare Soil in Spain and France, 2002-2003: Final Report. Project Number: 130445, 2003/1009248, 204. Unpublished study prepared by BASF Aktiengesellschaft. 50 p.
46807705	2053620	Kellner, O.; Eberhardt, R.; Platz, K. (2004) Study on the Residue Behavior of BAS 320 I in Soil After Application of BAS 320 FA I Under Field Conditions in Great Britain, Germany, Spain, Italy 2001. Project Number: 83871, 2004/1009152. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng). 94 p.

165-1 Confined rotational crop

MRID		Citation Reference
46264401	Check with HED	Hofs, R. (2004) BAS 320 I (AC 836519): Confined Accumulation Study of (Carbon 14) BAS 320 I in Rotational Crops: Final Report. Project Number: M01P519DE1, 2004/1000741, 24/2003JR00029/M01P5. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. and BASF Agro Research. 180 p.
46264402	Check with HED	Hofs, R. (2004) Additional Trials to the Confined Rotational Crop Study with (Carbon 14)-BAS 320 I: Final Report. Project Number: 130967, 2004/1000742, PI020035. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. and BASF Aktiengesellschaft. 127 p.

165-4 Bioaccumulation in fish

MRID		Citation Reference
46226404	2025698	Paulick, R.; Jackson, S. (2004) Environmental Fate Summary for BAS 320 I. Project Number: 2004/5000150. Unpublished study prepared by BASF Corporation. 14 p.
46264522	2061761 citation only	Funk, M. (2004) Bioaccumulation of BAS 320 00I in an Aquatic Ecosystem: Final Report. Project Number: 131198, 2004/1003965. Unpublished study prepared by BASF Aktiengesellschaft. 222 p.

835.0001 Background for Environmental Fate, Transport, and Drift

MRID	Citation Reference
46623345	Rice, P. (2005) Predicted Environmental Concentrations of BAS 320 I (Metaflumizone) and Metabolites M320I06, M320I23 and M320I29 in Groundwater Following Applications of BAS 320 00 I Formulation to Tomatoes and Potatoes, According to Focus gw Scenarios. Project Number: 2005/7000116, 2004/5000036, 2004/5000067. Unpublished study prepared by BASF Corporation. 56 p.
46623346	Rice, P. (2005) Predicted Environmental Concentrations of BAS 320 I (Metaflumizone) and Metabolites M320I04, M320I06, M320I23 and M320I29 in Surface Water and Sediment Following Applications of BAS 320 00 I Formulation to Tomatoes and Potatoes, According to FOCUS sw Scenarios. Project Number: 2005/7000157, 2004/5000716, 2004/1022514. Unpublished study prepared by BASF Corporation. 106 p.
46623347	Rice, P.; Beigel, C. (2005) Predicted Environmental Concentrations of BAS 320 I (Metaflumizone) and Metabolites in Soil Followin Applications of BAS 320 00 I Formulation to Tomatoes and Potatoes. Project Number: 2005/7000158, OAT/18/01, OAT/19/01. Unpublished study prepared by BASF Corporation. 36 p.

835.1230 Sediment and soil absorption/desorption for parent and degradates

MRID		Citation Reference
46623340	2053613	Zirstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I29 (Reg.No. 410 8253) on Five European and Two North American Soils: (Final Report). Project Number: 01/1297, 03/736/03, 99/1403. Unpublished study prepared by BASF Aktiengesellschaft and Agvise Inc. 67 p.

46264411		Zirnstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I (Reg. No. 4080134) on Five European Soils: Final Report. Project Number: 83449, 2003/1009293, 102859/1. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 36 p.
46264412	2025692 2025690 2025700	Zirnstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I (Reg. No. 4080134) on Two North American Soils: Final Report. Project Number: 102607/5, 2004/1003832, 102859/5. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 34 p.
46264413	2025694 2025701 2025689 2025691	Zirnstein, M. (2003) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I06 (Reg. No. 121464) on Five European Soils: Final Report. Project Number: 102607/1, PI020016, 03/10/35/085. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 46 p.
46264414	2025690 2025692 2025700	Zirnstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I06 (Reg. No. 121464) on Two North American Soils: Final Report. Project Number: 102607/6, 2004/1003833, PI020016. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 39 p.
46264415	2025689 2025691 2025694 2025693	Zirnstein, M. (2004) Adsorption/Desorption - Study on BAS I Metabolite M320I23 (Reg. No. 4984051) on Five European Soils: Final Report. Project Number: 102607/3, 2004/1003829, 102859/403/10/35/085. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 51 p.
46264416	2025692 2025690	Zirnstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I23 (Reg. No. 4984051) on Two North American Soils: Final Report. Project Number: 102607/8, 2004/1003835, 102859/4. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 42 p.
46264417	2025691 2025701 2025689 2025694	Zirnstein, M. (2003) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I04 (Reg. No. 4096485) on Five European Soils: Final Report. Project Number: 102607/2, 2003/1009292, 102859/2. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 52 p.
46264418	2025693	Zirnstein, M. (2004) Adsorption/Desorption - Study of BAS 320 I Metabolite M320I04 (Reg. No. 4096485) on Two North American Soils. Project Number: 102607/7, 2004/1003834, 102859/2. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 39 p.
46264419	2025695 2025696	Fang, C. (2004) Hydrolysis of 14C-BAS 320 I in Aqueous Media. Project Number: 83451, 2003/5000476. Unpublished study prepared by BASF Corporation. 96 p.

835.2410 Photodegradation of parent and degradates in soil

MRID		Citation Reference
46264406	See GL 161-3	Ta, C. (2002) BAS 320 I: Soil Photolysis: Final Report. Project Number: 83521, 2002/5004748. Unpublished study prepared by BASF Corp. 132 p.

46807703	See GL 161-3	Trollinger, J.; Ta, C. (2005) Photolysis of 14C-BAS 320 I on Soil: Final Report. Project Number:

835.3110 Ready biodegradability

MRID	Citation Reference
46807706	Damon, A.; Heim, D.; Rice, P. (2002) BAS 320 I: Ready Biodegradation Study. Project Number: 85675, 46798, 2002/7010966. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 52 p.

Non-Guideline Study

MRID		Citation Reference
46264404	2025680	Paulick, R.; Jackson, S. (2004) Environmental Fate Summary for BAS 320 I. Project Number: 2004/5000150. Unpublished study prepared by BASF Corporation. 14 p
46294001	Reduced-Risk Rationale	Aldridge, K.; Anderson, T.; Canez, V.; et. al. (2004) Reduced-Risk Pesticide Rationale for BAS 320 I. Project Number: 2004/5000465. Unpublished study prepared by BASF Corporation. 449 p.
46264225	2065681	Saha, M.; Gooding, R. (2003) Validation of BASF Method No. D0301: The Determination of Residues of BAS 320 I and its Metabolites M320I04 (Reg. no. 4096485), M320I06 (Reg. no. 121464), and M320I23 (Reg. no. 4984051) in Soil Using LC-MS/MS. Project Number: 83435, 2003/5000302, D0301. Unpublished study prepared by BASF Corporation. 100 p.
46264226	2065682	Perez, R. (2004) Independent Laboratory Validation of BASF Analytical Method D0301: "The Determination of Residues of BAS 320 I and its Metabolites, M320I04 (Reg No. 4096485), M320I06 (Reg. No. 121464), and M320I23 (Reg. No. 4984051) in Soil Using LC-MS/MS". Project Number: 83437, 2003/5000437, ADPEN/903/ 2K30818. Unpublished study prepared by Adpen Labs. 76 p.
46264227	2065683	Zangmeister, W. (2003) Validation of Analytical Method 534/0: Method for the Determination of BAS 320 I, E-isomer (Reg. no. 4102472), BAS 320 I, Z-isomer (Reg.no.4102572) M320I04 (Reg.no.4096485) and M320I23 (Reg.no.4984051) in Tap- and Surface Water: Final Report. Project Number: 93005, 2003/1009280, 534/0. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng. 65 p.
46264410	2025686	Ta, C. (2004) Freezer Storage Stability Study of BAS 320 I and Its Metabolites, M320I04, M320I06 and M320I23 in Soil. Project Number: 131228, 2004/5000038. Unpublished study prepared by BASF Corporation. 42 p.
46540414	2025690 2053609	Malinsky, D. (2005) Freezer Storage Stability Study of BAS 320 I (E and Z Isomers) and its Metabolites (M320I04, M320I06 and M320I23) in Soil: Final Report. Project Number: 2004/5000781, 121739, 2003001. Unpublished study prepared by BASF Agro Research. 104 p.

46807707 Hassink, J. (2003) Volatilization of BAS 320 I After Application of BAS 320 00 I on Soil and on Plant Surfaces. Project Number: 2003/1009247, 82195. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng). 29 p.

46807708 Hassink, J. (2004) Photochemical Oxidative Degradation of BAS 320 I (QSAR Estimates). Project Number: JH/04/08, 2004/1015196. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng). 11 p.

46264409 Malinsky, S. (2004) Freezer Storage Stability Study of BAS 320 I (E and Z Isomers) and Its Metabolites (M320I04, M320I06 and M320I23) in Soil. Project Number: 121739, 2003/5000554. Unpublished study prepared by BASF Corporation. 88 p.

Ecological Effects Studies

850.1010 72-2 Aquatic invertebrate acute toxicity, test, freshwater daphnids

MRID	Citation Reference
46264505	Aufderheide, J.; Lucash, K.; Olivieri, C. (2001) Acute Toxicity of BAS 320 I to Daphnia magna, under Flow-Through Test Conditions: Final Report. Project Number: EXT/00/296, HC/521/001, 46275. Unpublished study prepared by BASF Agro Research, American Cyanamid Co. and ABC Laboratories, Inc. 71 p.
46264538	Hughes, C.; Holmes, C. (2004) Acute Toxicity of BAS 320 00I to the Water Flea, Daphnia magna, Under Flow-Through Test Conditions: Final Report. Project Number: 85683, 48597, 2004/5000058. Unpublished study prepared by ABC Laboratories, Inc. and BASF Aktiengesellschaft. 34 p.
46623309	Funk, M. (2004) Effect of Reg. No. 4096485 (Metabolite of BAS 320 I) on the Immobility of Daphnia Magna STRAUS in a 48 Hours Static, Acute Toxicity Test. Project Number: 64928, 2004/1003948. Unpublished study prepared by BASF Aktiengesellschaft. 28 p.
46623310	Funk, M. (2004) Effect of Reg. No. 4984051 (Metabolite of BAS 320 I) on the Immobility of Daphnia Magna STRAUSS in a 48-Hours Static, Acute Toxicity Test. Project Number: 66916, 2004/1025184. Unpublished study prepared by BASF Aktiengesellschaft. 22 p.
46623311	Funk, M. (2004) Effect of Reg. No. 121464 (Metabolite of BAS 320 I) on the Immobility of Daphnia Magna STRAUSS in a 48-Hours Static, Acute Toxicity Test. Project Number: 66918, 2004/1025185. Unpublished study prepared by BASF Aktiengesellschaft. 21 p.
46623312	Funk, M. (2004) Effect of Reg. No. 43455 (Metabolite of BAS 320 I) on the Immobility of Daphnia Magna STRAUSS in a 48 Hours Static, Acute Toxicity Test. Project Number: 133946, 2004/1025186. Unpublished study prepared by BASF Aktiengesellschaft. 21 p.

72-3 Acute Toxicity to Estuarine/Marine Organisms

MRID	Citation Reference
46264519	Aufderheide, J.; Lucash, K.; Mitchell, G. (2002) Acute Effect of BAS 320 I on New Shell Growth of the Eastern Oyster, Crassostrea virginica, Under Flow-Through Test Conditions: Final Report. Project Number: 85625, 46460, 2002/5004774. Unpublished study prepared by BASF Agro Research, ABC Laboratories, Inc., and American Cyanamid Co. 79 p.

46264521 Aufderheide, J.; Lucash, K.; Olivieri, C. (2001) Acute Toxicity of BAS 320 I to Sheepshead Minnow, Cyprinodon variegatus, under Flow-Through Test Conditions: Final Report. Project Number: 85639, HC/511/003, 46459. Unpublished study prepared by: ABC Laboratories, Inc., BASF Agro Research, and American Cyanamid Co. 69 p.

850.1035 Mysid acute toxicity test

MRID	Citation Reference
46264520	Aufderheide, J.; Lucash, K.; Olivieri, C. (2001) Acute Toxicity of BAS 320 I to Mysid Shrimp, Mysidopsis bahia, Under Flow-Through Test Conditions: Final Report. Project Number: EXT/00/297, HC/511/001, 46276. Unpublished study prepared by ABC Laboratoiries, Inc., BASF Agro Research, and American Cyanamid Co. 76 p.

72-4 Fish Early Life Stage/Aquatic Invertebrate Life Cycle Study

MRID	Citation Reference
46264501	Aufderheide, J.; Lucash, K.; Mitchell, G. (2002) Toxicity of BAS 320 I to Early Stages of Rainbow Trout, Oncorhynchus mykiss, Determined Under Flow-Through Test Conditions: Final Report. Project Number: 85617, 46464, 2002/5004776. Unpublished study prepared by BASF Agro Research, American Cyanamid Co and ABC Laboratories, Inc. 84 p.
46264502	Madsen, T.; Mitchell, G. (2002) Toxicity of BAS 320 I to Early Life Stages of Sheepshead Minnow, Cyprinodon variegatus, Determined Under Flow-Through Test Conditions: Final Report. Project Number: 85615, 46755, 2002/5004775. Unpublished study prepared by BASF Agro Research, American Cyanamid Co and Analytical Bio-Chemistry Labs, Inc. 80 p.
46264506	Aufderheide, J.; Lucash, K.; Mitchell, G. (2002) Toxicity of BAS 320 I to Mysidopsis bahia During a Life-Cycle Exposure Conducted Under Flow-Through Test Conditions: Final Report. Project Number: 85623, 46462, 2002/5004778. Unpublished study prepared by BASF Agro Research and American Cyanamid Co and ABC Laboratories, Inc. 82 p.

850.1075 72-1 Fish acute toxicity test, freshwater and marine

MRID	Citation Reference
46264435	Aufderheide, J.; Lucash, K.; Olivieri, C. (2001) Acute Toxicity of BAS 320 I to Rainbow Trout, Oncorhynchus mykiss, Under Flow-Through Test Conditions: Final Report. Project Number: EXT/00/295, HC/511/004. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 74 p.

46264436 Aufderheide, J.; Lucash, K.; Olivieri, C. (2001) Acute Toxicity of BAS 320 I to Bluegill Sunfish, Lepomis macrochirus, Under Flow-Through Test Conditions: Final Report. Project Number: EXT/00/294, HC/511/002, 46274. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 72 p.

46264437 Aufderheide, J.; Holmes, C. (2004) Acute Toxicity of BAS 320 I to Common Carp, Cyprinus carpio, Determined under Static Test Conditions in a Sediment-Water System. Project Number: 131861, 48500, 2004/5000075. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 44 p.

46264438 Aufderheide, J.; Holmes, C. (2004) Acute Toxicity of BAS 320 I to Channel Catfish, Ictalurus punctatus, Determined Under Static Test Conditions in a Sediment-Water System. Project Number: 131864, 48501, 2004/5000074. Unpublished study prepared by Analytical Bio-Chemistry Labs., Inc. 43 p.

46264537 Hughes, C.; Holmes, C. (2004) Acute Toxicity of BAS 320 00I to the Rainbow Trout, Oncorhynchus mykiss, Determined Under Flow-Through Test Conditions: Final Report. Project Number: 856687, 48596, 2004/5000072. Unpublished study prepared by ABC Laboratories, Inc. and BASF Aktiengesellschaft. 33 p.

46623313 Jatzek, J. (2005) Reg. No. 4096485 (Metabolite of BAS 320 I): Acute Toxicity Study on the Rainbow Trout (Oncorhynchus mykiss) in a Semistatic System Over 96 Hours. Project Number: 2005/1004842, 12F0196/035017. Unpublished study prepared by BASF Aktiengesellschaft. 50 p.

46623314 Jatzek, J. (2004) Reg. No. 4984951 (Metabolite of BAS 320 I): Acute Toxicity Study on the Rainbow trout (Oncorhynchus mykiss) in a Static System Over 96 Hours. Project Number: 12F0670/025070, 2004/1025190. Unpublished study prepared by BASF Aktiengesellschaft. 34 p.

46623315 Jatzek, J. (2004) Reg. No. 121464 (Metabolite of BAS 320 I): Acute Toxicity Study on the Rainbow Trout (Oncorhynchus mykiss) in a Static System Over 96 Hours. Project Number: 12F0193/045048, 2004/1025187. Unpublished study prepared by BASF Aktiengesellschaft. 34 p.

46623316 Jatzek, J. (2004) Reg. No. 43455 (Metabolite of BAS 320 I) Acute Toxicity Study on the Rainbow Trout (Oncorhynchus mykiss). Project Number: 12F0191/045028, 2004/1025188. Unpublished study prepared by BASF Aktiengesellschaft. 34 p.

850.1300 Daphnid chronic toxicity test

MRID	Citation Reference
46264507	Hicks, S.; Lucash, K.; Olivieri, C.; et al. (2001) Chronic Toxicity of BAS 320 I During the Complete Life-Cycle of Daphnia magna under Flow-Through Test Conditions: Final Report. Project Number: 85613, 46463, HC/523/001. Unpublished study prepared by BASF Agro Research, American Cyanamid Co., and ABC Laboratories, Inc. 89 p.

850.1400 72-5 Fish early-life stage toxicity test

MRID Citation Reference

46264503	Shaefers, C. (2004) BAS 320 0 I: Zebrafish (Danio rerio), Static Full Life Cycle Test With Sediment: Final Report. Project Number: BAS/018/4/61, 2004/1004383. Unpublished study prepared by Fraunhofer-Institute for Molecular Biology and Applied Ecology. 138 p.
46623317	Schafers, C. (2004) BAS 320 00 I: Rainbow Trout, Static Full Life Cycle Test with Sediment (Including Amendment 1): Final Report. Project Number: BAS/018/4/61, 2004/7010580. Unpublished study prepared by Fraunhofer Institute for Molecular Biology and Applied Ecology. 152 p.

850.1730 Fish BCF

MRID	Citation Reference
46264504	Afzal, J. (2004) Uptake, Depuration, Bioconcentration and Metabolism of (Carbon-14) Labeled BAS 320 I in Bluegill Sunfish (Lepomis macrochirus) Under Flow-Through Conditions: Final Report. Project Number: 130145, 47149, 2003/5000528. Unpublished study prepared by BASF Agro Research and ABC Laboratories, Inc. 151 p.
46264522	Funk, M. (2004) Bioaccumulation of BAS 320 00I in an Aquatic Ecosystem: Final Report. Project Number: 131198, 2004/1003965. Unpublished study prepared by BASF Aktiengesellschaft. 222 p.

850.2100 71-1 Avian acute oral toxicity test

MRID	Citation Reference
46264425	Moranz, M.; Kaczor, M.; Admed, S. (2001) Avian Acute Oral Toxicity Test with BAS 320 I in the Northern Bobwhite (Colinus Virginianus): Final Report. Project Number: EXT/00/190, HC/505/001. Unpublished study prepared by Ecotoxicology and Biosystems Associ. 61 p.
46264426	Moranz, M.; Kaczor, M.; Ahmed, S. (2001) Avian Acute Oral Toxicity Test with BAS 320 I in the Mallard Duck (Anas platyrhynchos): Final Report. Project Number: EXT/00/191, HC/505/002. Unpublished study prepared by Ecotoxicology and Biosystems Associ. 61 p.

850.2200 71-2 Avian dietary toxicity test

MRID	Citation Reference
46264427	Gallagher, S.; Grimes, J.; Beavers, J.; et. al. (2003) Avian Dietary Toxicity Test with BAS 320 I in the Northern Bobwhite Quail (Colinus virinianus): Final Report. Project Number: 1131/02, 147/205A, 2003/5000289. Unpublished study prepared by Wildlife International, Ltd. 84 p.

46264428	Gallagher, S.; Grimes, J.; Beavers, J.; et al. (2003) Avian Dietary Toxicity Test with BAS 320 I in the Northern Mallard Duck (Anas platyrhynchos): Final Report. Project Number: 1131/05, 147/206, 2003/5000290. Unpublished study prepared by Wildlife International, Ltd. 80 p.
49576201	Zok S. (2009) BAS 320 041 (Siesta) - Avian Dietary Test in the Bobwhite quail (Colinus virginianus). Project Number: 94W0093/045096, 2008/1086272. Unpublished study prepared by BASF SE. 76p.

850.2300 71-4 Avian reproduction test

MRID	Citation Reference
46264429	Gallagher, S.; Beavers, J.; Jaber, M.; et al. (2002) Sub-Acute Dietary Toxicity Study with BAS 320 I in the Northern Bobwhite (Colinus virginianus): Final Report. Project Number: 147/207, 64544, 2002/5003826. Unpublished study prepared by Wildlife International, Ltd. 164 p.
46264430	Zok, S. (2004) BAS 320 I - 1-Generation Reproduction Study on the Bobwhite Quail (Colinus virginianus) by Administration in the Diet: Final Report. Project Number: 71W0071/015111, 2004/1003988, 2004/1004399. Unpublished study prepared by BASF Aktiengesellschaft. 425 p.
46264431	Zok, S. (2004) BAS 320 I - 1-Generation Reproduction Study on the Bobwhite Quail (Colinus virginianus) by Administration in the Diet: Final Report. Project Number: 81W0071/015122, 2004/1004361, 2004/1004400. Unpublished study prepared by BASF Aktiengesellschaft. 399 p.
46264432	Gallagher, S.; Beavers, J.; Jaber, M.; et al. (2002) Sub-Acute Dietary Toxicity Study with BAS 320 I in the Mallard (Anas platyrhynchos): Final Report. Project Number: 147/208, 64546, 2002/5003827. Unpublished study prepared by Wildlife International, Ltd. 143 p.
46264433	Zok, S. (2004) BAS 320 I 1-Generation Reproduction Study on the Mallard Duck (Anas platyrhynchus) by Administration in the Diet: Final Report. Project Number: 72W0071/015112, 2004/1003986, 2004/1004397. Unpublished study prepared by BASF Aktiengesellschaft. 321 p.
46264434	Zok, S. (2004) BAS 320 I - 1-Generation Reproduction Study on the Mallard Duck (Anas platyrhynchus) by Administration in the Diet: Final Report. Project Number: 72W0071/015121, 2004/1003987, 2004/1004398. Unpublished study prepared by BASF Aktiengesellschaft. 368 p.
46623318	Tilting, N. (2004) Determination of BAS 320 I Residues in Eggs of Virginian Quail from an Avian Reproduction Study with Modified Dosing Regime. Project Number: 159793A, 2004/1013353. Unpublished study prepared by BASF Aktiengesellschaft. 51 p.
46623319	Tilting, N. (2004) Determination of BAS 320 I Residues in Eggs of Bobwhite Quail from an Avian Reproduction Study. Project Number: 159793, 2004/1013354. Unpublished study prepared by BASF Aktiengesellschaft. 53 p.

46623320	Tilting, N. (2004) Determination of BAS 320 I Residues in Eggs of Mallard Ducks from an Avian Reproduction Test. Project Number: 159796A, 2004/1013355. Unpublished study prepared by BASF Aktiengesellschaft. 52 p.
46623321	Tilting, N.; Mackenroth, C. (2004) Determination of BAS 320 I Residues in Eggs of Mallard Ducks from an Avian Reproduction Test. Project Number: 159796, 2004/1020820. Unpublished study prepared by BASF Aktiengesellschaft. 43 p.

850.2500 Field testing for terrestrial wildlife

MRID	Citation Reference
46696501	Hafemann, C. (2004) Bioaccumulation Study of BAS 320 I in Earthworms: (Final Report). Project Number: 2004/1010339, 131192. Unpublished study prepared by BASF Ag Research Station (Basf Aktieng.). 28 p.

850.3020 Honey bee acute contact toxicity

MRID	Citation Reference
46264517	Aufderheide, J.; Gagne, J. (2004) Acute Contact Toxicity Test with BAS 320 I Technical in the Honeybee, Apis mellifera: Final Report. Project Number: 131441, 48260, 2004/500033. Unpublished study prepared by Chem Service, Inc., BASF Agro Research and ABC Laboratories, Inc. 25 p.
46623322	Kling, A. (2003) Assessment of Side Effects of BAS 320 00 I to the Honey Bee, Apis Mellifera L. in the Laboratory: Final Report. Project Number: 20021334/01/BLEU, 2003/1001084. Unpublished study prepared by Arbeitsgemeinschaft GAB Biotechnologie. 33 p.

850.3040 Field testing for pollinators

MRID	Citation Reference
46623323	Schmitzer, S. (2003) Toxicity Testing of BAS 320 00 I on Honey Bees (Apis mellifera L.) in the Cage under Field Conditions. Project Number: 131372, 16931038, 2003/1021623. Unpublished study prepared by Institut fuer Biologische Analytik und Consulting IBACON. 38 p.

860.1850 Residue Chemistry Tests

MRID	Citation Reference
46264401	Hofs, R. (2004). BAS 320 I (AC 836519): Confined Accumulation Study of (Carbon 14) BAS 320 I in Rotational Crops. Laboratory Project Identification: M01P519DE1. BASF Registration Document Number: 2004/1000741.

	Unpublished study prepared by BASF Ag Research Station (Limburgerhof, Germany). 180 p.
46264402	Hofs, R. (2004). Additional Trials to the Confined Rotational Crop Study with ^{14}C-BAS 320 I. Laboratory Project Identification: 130967. BASF Registration Document Number: 2004/1000742. Unpublished study prepared by BASF Ag Research Station (Limburgerhof, Germany). 127 p.
46264403	MRID 46264403. Johnston, R.; Panek, M. (2004). Limited Rotational Crop Study for the Use of BAS 320 I in Tomatoes. Study Number: 130308. BASF Registration Document Number: 2003/5000435. Unpublished study prepared by BASF Agro Research (Research Triangle Park, NC). 146 p.

870.1100 Acute oral toxicity

MRID	Citation Reference
46264231	Gamer, A. (2002) M320I02 (Z-Isomer of BAS 320 I) - Acute Oral Toxicity Study in Sprague Dawley Rats: Final Report. Project Number: 10A677/011104, 2002/1010403. Unpublished study prepared by BASF Aktiengesellschaft. 23 p.
46264232	Lowe, C. (2001) Oral LD50 Study in Albino Rats with BAS 320 I: Final Report. Project Number: T/1232, HC/411/001. Unpublished study prepared by BASF Agro Research. 18 p.
46264233	Gamer, A.; Leibold, E. (2003) Reg. No 4984051 (Metabolite of BAS 320 I) - Acute Oral Toxicity Study in Rats: Final Report. Project Number: 10A0670/021070, 2003/1020046. Unpublished study prepared by BASF Aktiengesellschaft. 20 p.
46264234	(2001) Oral LD50 Study in Albino Mice with BAS 320 I: Final Report. Project Number: T/1240, HC/411/002. Unpublished study prepared by BASF Agro Research. 17 p.
46264528	Gamer, A.; Leibold, E. (2003) BAS 320 00 I - Acute Oral Toxicity Study in Rats: Final Report. Project Number: 10A0244/021065, 2003/1018186. Unpublished study prepared by BASF Aktiengesellschaft. 20 p.
46395805	Cerven, D. (2004) Acute Oral Toxicity/LD50 in Rats: 15% w/v R-28153/15% w/v Amitraz Spot-On. Project Number: MB/03/11648/01, 1000/01, 0817/T/US/07/03. Unpublished study prepared by MB Research Laboratories. 17 p.
46437603	Cerven, D. (2004) Acute Oral Toxicity (in Rats) - Up and Down Procedure (UDP): 20% w/v R-28153 Spot-On: Amended Final Report. Project Number: MB/04/12416/01, 1010/01, 0817/T/US/19/04. Unpublished study prepared by MB Research Laboratories. 14 p.

46548807	Gamer, A. (2004) BAS 320 04 I - Acute Oral Toxicity Study in Rats. Project Number: 10A0093/041019, 2004/1025755. Unpublished study prepared by BASF Aktiengesellschaft. 21 p.
46623303	Gamer, A.; Leibold, E. (2004) Reg. No. 4984051 (Metabolite of BAS 320 I) - Acute Oral Toxicity Study in Rats: Final Report. Project Number: 10A0670/021070, 2004/7010575. Unpublished study prepared by BASF Aktiengesellschaft. 27 p.
47389903	Gilotti, A. (2007) Acute Oral Toxicity-Up and Down Procedures (UDP) (15% w/v Metaflumizone). Project Number: MB/07/15760/01, 1010/01. Unpublished study prepared by MB Research Laboratories. 17 p.

870.3800 Reproduction and fertility effects

MRID	Citation Reference
46264315	Schneider, S.; Deckardt, K.; Hellwig, J.; et al. (2004) BAS 320 I - Two-Generation Reproduction Toxicity Study in Wistar Rats Oral Administration (Gavage): Final Report. Project Number: 73R0071/01058, 2004/1009123. Unpublished study prepared by BASF Aktiengesellschaft. 1129 p.
46623304	Schneider, S.; Deckardt, K.; Hellwig, J.; et. al. (2005) BAS 320 I - Two-Generation Reproduction Toxicity Study in Wistar Rats: Oral Administration (Gavage): Final Report. Project Number: 73R0071/01058, 2005/7002823. Unpublished study prepared by BASF Aktiengesellschaft. 1138 p.

Appendix A: Environmental Fate and Transport Characterization

A summary of important physicochemical properties of metaflumizone is provided in **Table A-1**.

Table A-1 Summary of the physical and chemical properties of metaflumizone

Property	*Description or Value*	*Reference*
CAS Name	2-[2-(4-Cyanophenyl)-1-[3-trifluoromethyl)-phenyl]-ethylidene]-N-[4-trifluoromethoxy)-phenyl]-hydrazinecarboxamide (E/Z). E:Z Isomer Ratio ≈12:1	
CAS number	139968-49-3	
IUPAC Name	(E+Z)-2-[2-(4-Cyanophenyl)-1-[3 (trifluoromethyl)phenyl]ethylidene] -N-[4-(trifluoromethoxy) phenyl]-hydrazinecarboxamide. E:Z Isomer Ratio ≈12:1	
Molecular Wt.	506.4 grams	462642-01
Solubility (ppb)	**Ionized water: 1.79** at 20℃**; 1.35** @ pH 5; **1.81** @ pH 7 & **1.73** @ pH 9 **Ethyl acetate: 1.8 x 10 ^{8}; Methanol: 1.4 x 10 ^{7}; Acetone: 1.5 x 10 ^{8};** In Toluene: **4.0 x 10 ^{6};** In Dichloromethane: **9.9 x 10 ^{7};** In *n*-Hexane: **8.5 x 10 ^{3}** In Acetonitrile: **6.3 x 10 ^{7}**	462642-08 462642-12
Vapor pressure	9.3 x 10^{-11} torr at 20℃	462642-06
Henry's Law Constant	3.5 x 10^{-8} atm m^3 $mole^{-1}$	Calculated
K_{ow}	**E isomer= 125, 893** (Log K_{ow} = 5.1) and for the **Z isomer = 25,119** (Log K_{ow} = 4.4)	462642-13

A shown in **Table A-1**, metaflumizone is a high molecular weight compound consisting of a mixture of two isomers: the main E isomer and the Z isomer in a ratio of ≈12:1. Laboratory studies indicated that metaflumizone is insoluble in water (1.79 ppb) and much more soluble in most organic solvents (nearly 5 to 8 orders of magnitude more soluble than in de-ionized water; MRID 462642-12). The chemical is characterized by its low vapor pressure and Henry's Law Constant and by its lipophilic property (K_{ow} range: 125, 893 to 25,119 for the E and Z isomers, respectively). Therefore, metaflumizone is not expected to partition into the air but can bio-accumulate/ bio-concentrate in organisms such as fish. In a fish bio-concentration study, calculated BCF values for metaflumizone were 3,500 (edible) and 12,000 (non-edible) (MRID 462645-04; **Table A-4**, below).

Based on the low solubility of metaflumizone, the chemical is expected to be, at least partly and at some stage, present in the aquatic environment in an insoluble form (referred to as the insoluble pool) when concentrations reaching these systems are much higher than its reported solubility (on the assumption that its solubility in the end use product and in natural waters is equal to its reported solubility in de-ionized water). For currently registered bait products, the maximum single rate is very low (0.001 lb. a.i/A) and its expected concentration in the top 2" of the soil is near its solubility (1.47 ppb) suggesting that most of the applied chemical will probably be in the soluble pool.

The fate and transport properties of metaflumizone are summarized, hereunder.

(a) Abiotic Degradation Studies

Metaflumizone labeled at both the [benzonitrile-U-^{14}C] and the [trifluoromethoxyphenyl-U-^{14}C] was used in conducting hydrolysis and photolysis studies (MRIDs 462644-19/20). In the hydrolysis study, the chemical was shown to be practically stable in neutral/alkaline aqueous buffered solutions (t½ range= 217-630 days at pH 9 and 7) and to degrade rapidly when the pH is acidic (t½ range= 6-31 days at pH 4 and 5).

The chemical was also shown to degrade rapidly by aqueous photolysis (t½= 4.6 days at pH 9) and was more resistant to degradation by photolysis on soil surfaces subjected to sunlight (t½= 54 days, MRID 462644-06). Results indicate that hydrolysis and direct photolysis is important in metaflumizone dissipation in acidic media and in clear/shallow surface water, respectively. Photolysis on soil is expected to be unimportant. A summary of abiotic properties for metaflumizone is included in **Table A-2**.

Table A-2 Summary of abiotic fate properties of metaflumizone

***Property*[1]**	***Description or Value*[2]**	***MRID*[3]**
Hydrolysis t ½ (**EOS**= 30 days; **L1 & L3 @ 25** °C)	**<u>Combined two Labels (Range)</u>**: pH 4= **6 (6-6)** days; pH 5= **29 (27-31)** days; pH 7= **416 (301-630)** days; and pH 9= **231** (**217-248**) days; ***Major Degradation products:*** **M320 I 04:** Max. 50 and 90% @ EOS **and M320 I 08:** Max. 34 and 74% @ EOS **for pH 5 and 4** ***Minor Degradation products:*** **M320 I 04**: Max. 4-5% @ EOS **for pH 7 and 9**	462644-19 A
Aqueous photolysis t ½ (**EOS**= 15 days; **L1 & L3@ 22** °C)	**4.6** days in sterile pH 9 buffer ***Major Degradation products:*** **M320 I 05:** Max. 23% @ EOS (21% volatilized into the trap); **M320 I 06:** Max. 27% @ EOS ***Minor Degradation products:*** **M320 I 04:** Max. 8% @ 1 d declined to 4% @ EOS**; M320 I 08** Max. 4% @ 2-3 d declined to 2% @ EOS**; M320 I 09:** Max. 6% @ EOS ***Mineralization to CO_2:*** 2-6% @ EOS	462644-20 A
Soil photolysis t ½ (**EOS**= 15 days; **L1 & L3 @ 22** °C)	**54** days on a NJ sandy loam soil (pH 6.9 & Organic matter= OM= 1.7%) ***Minor Degradation products:*** **M320 I 04:** Max. 1% @ EOS**; M320 I 05:** Max. ≤1%@ EOS**; M320 I 06:** Max. 8% @ 10 d declined to 6% @ EOS**; M320 I 07:** Max. 5% @ 1 d declined to 1% @ EOS ***Mineralization to CO_2:*** 0.4-2% @ EOS; Un-extracted Residues: 10-14% @ EOS	462644-06 A 468077-03 U

[1] Abbreviations: **EOS**= End of Study= Length of study in days; L1, L2 and L3 refer to radiolabel position on metaflumizone structure: **L1**= Trifluoromethoxyphenyl ring; **L2**= Trifluoromethylphenyl ring; **L3**= Benzonitrile ring
[2] Maximum degradate formation in % regardless of the radiolabel position;
[3] Study Classification: A= Acceptable and U= Unacceptable

(a) Metabolism Studies

Metaflumizone can be characterized by relative persistence in the aerobic soil system. Calculated half-lives from four aerobic soil studies were in the range of 73 to 110 days (four soils from ID, MN, NJ and PA with [benzonitrile-U-^{14}C]-label, MRID 462644-07); 194 days in one soil from NJ with [trifluoromethoxyphenyl-U-^{14}C] and [Benzonitrile-^{14}C] labels (MRID 462644-05); and 204 to 408 days in three German soils with [trifluoromethoxyphenyl-U-^{14}C] label (MRID 468077-04). Although differences in the range of half-lives may be related to varied soils, it is important to point out variations in biomass and incubation temperatures may have also been a factor. It is also noted that the extraction systems used in the various soils were somewhat different although it was based on acetonitrile and/or methanol.

It appears that the extraction systems used were efficient in most soils with the exception of the systems used in the NJ sandy loam soil (MRID 462644-05) and in the soils from ID, MN, NJ, and PA (MRID 462644-07). In these soils the unidentified un-extracted residues were >30%. No explanation was offered for such unacceptable high un-extracted residues. For this, the registrant is referred to EFED Un-extracted residues guidance[3] to verify the appropriateness of the extraction systems used in these studies.

In contrast to the aerobic conditions, much longer half-lives were calculated for one loamy soil from WI incubated under anaerobic conditions (353 to 365 days; MRID 66233-41).

For water/sediment systems, three aquatic studies were submitted: two under aerobic conditions (MRID 466233-43 and 466233-42) and one under anaerobic conditions (MRID 462644-22). Sediment and total system half-lives, in the two aerobic systems were >100 days and were >378 days in the anaerobic system suggesting relatively high persistence of metaflumizone in the aerobic lake/pond water/sediment systems and in the anaerobic lake system, respectively. In contrast, half-lives of metaflumizone in the water column of these systems were short as a direct result of the chemical high affinity to adsorption to the solid phase.

A summary of the biotic fate properties for metaflumizone is included in **Table A-3**.

[3] Un-extracted Residues Guidance, URL: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-addressing-unextracted-pesticide-residues

Table A-3 Summary of biotic fate properties of metaflumizone

Property[1]	*Description or Value*[2]	*MRID*
Aerobic soil metabolism t ½ (German soils: **EOS**= 122 days; **L2**; One PA soil: **EOS**= 364 days; **L1 & L3**); The four US soils: **EOS**= 365 days; **L3**)	**408 days** (Sandy Loam, Germany: OM= 4.7%, pH= 8.2 @ 20 ºC)); **347 days** (Loam, Germany: OM= 4.2%, pH= 7.7 @ 20 ºC)); and **204 days** (Loamy Sand, Germany: OM= 4.1%, pH= 5.9 @ 20 ºC)). ***Minor Degradation products:*** **M320 I 04:** Max. 2% @ 3d declined to <1% @ EOS**;** **M320 I 09:** Max. 0.1%**; M320 I 23:** Max. 2-3% @ EOS**; M320 I 29:** Max. <1% ***Mineralization to CO_2:*** 2-15% @ EOS; ***Un-extracted Residues:*** 6-13% @ EOS	468077-04 S
	194 days (Sandy Loam, NJ: OM= 1.7%, pH= 6.9, CEC= 6.7 @ 20 ºC) ***Minor Degradation products:*** **M320 I04:** Max. 1% declined**; M320 I 07:** Max. 1-3% after d 14**; M320 I 08:** Max. <1% @**; M320 I 23:** Max.7-8% @ **EOS** ***Mineralization to CO_2:*** 8-29% @ EOS; ***Un-extracted Residues:*** 17% at 6 months and increased to **21-38%** @ EOS ***Un-Knowns:*** One degradate with a Max. of <1-3%	462644-05 (For PA Sandy loam soil) A
	075 days (Loamy Sand, ID: OM= 1.1%, pH= 6.8, CEC= 11.0, @ 27 ºC); **086 days** (Clay loam, MN: OM= 6.9%, pH= 6.2, CEC= 23.6, @ 27 ºC); **073 days** (Silt loam, NJ: OM= 2.4%, pH= 6.7, CEC= 9.6, @ 27 ºC); **110 days** (Loam, PA: OM= 3.0%, pH= 7.1, CEC= 9.9 @ 27 ºC); ***Minor Degradation products:*** **M320 I04:** Max. 1-3% @ 61 d declined to <1% @ EOS**;** **M320 I 09:** Max. 1-2%**; M320 I 23:** Max. 5-6% @ EOS; ***Mineralization to CO_2:*** 46-54% @ EOS; ***Un-extracted Residues:*** 2-3.% at 0 d to **23-38%** at 6-9 months and were **25-34%** @ EOS	462644-07 (For ID, MN, NJ & PA) A
Anaerobic soil t ½	**353 and 365 days** for two labels (Loamy Sand, WI: OM= 2.6%, pH= 6.3 @ 20 ºC) ***Major & Minor Degradation products:*** **None; Max. CO_2= 2%**	466233-41 A
Aerobic aquatic (t ½ **EOS**= 100 days; **L1, L2 & L3 @ 20**ºC)	**Lake water** (pH 6 and O.C 36 mg/L)/ **sandy loam sediment system from the UK:** **>100** days in the total system (t ½ could not be determined, short duration study) ***Minor Degradation products:*** **M320 I 04:** Max. 5-6% @ 1 d declined to <LOD**; M320 I 23:** Max. 7.5% @ EOS; ***Mineralization to CO_2:*** 3-8% @ EOS; ***Un-extracted Residues:*** 4-13% @ EOS; **Pond water**/(pH 7.6 and O.C 9.6 mg/L)/ **clay loam sediment** (pH 7.3-7.7 and O.M 13.9%)/ **system from the UK:** **>100** days in the total system (t ½ could not be determined, short duration study) ***Major & Minor Degradation products:*** **None** ***Mineralization to CO_2:*** <1-4% @ EOS; ***Un-extracted Residues:*** 4-9% @ EOS	466233-42 A
	Pond water/sand sediment system from SD: **>100** days in sediment and total system (t ½ could not be determined, short duration) ***Minor Degradation products:*** **M320 I 04:** Max. 1-2% throughout to EOS**; M320 I 05:** Max. <0.1%**; M320 I 06:** Max. <0.2%**; M320 I 08:** Max. 3% @ 3 d declined to <0.1% @ EOS**; M320 I 09:** Max. 1% @ 7 d declined to <0.1% @ EOS**; M320 I 29:** Max. <0.1% throughout; ***Mineralization to CO_2:*** 2-4% @ EOS; ***Un-extracted Residues:*** 5-10% @ EOS	466233-43 A
Anaerobic aquatic t ½ **(EOS**= 378 days; **L1 & L3** @ 25 ºC)	**Lake water/sandy loam sediment system from SD :> 378** days in the total system (reservoir water: pH 8.4/Sandy Loam sediment: pH 8.5 and OM 0.6%) ***Minor Degradation products:*** **M320 I04:** Max. 4% @ 120 d declined to 2% @ EOS; **M320 I 23:** <1% in water; Max. 4-5% @ **M320 I09:** Max. 2-4% @ 91 d declined to 1-2% @ EOS; **M320 I 05:** <0.1% in water; ***Mineralization to CO_2:*** <1% @ EOS; ***Un-extracted Residues:*** 6-14.% @ EOS	462644-22 A

[1] Abbreviations: **EOS**= End of Study= Length of study in days; L1, L2 and L3 refer to radiolabel position on metaflumizone structure: **L1**= Trifluoromethoxyphenyl ring; **L2**= Trifluoromethylphenyl ring; **L3**= Benzonitrile ring; [2] Maximum degradate formation in % regardless of the radiolabel position; [3] Study Classification: A= Acceptable and S= Supplemental

(b) Transport and Mobility Studies

Metaflumizone is not expected to partition into the air from dry and/or moist soil because of its relatively low vapor pressure/Henry's Law Constant. In the soil system, mobility of the chemical is govern by its very low solubility (1.79 ppb) and its high affinity to solid phase (K_{oc} ranged from16,534 to 51,031 L Kg^{-1} with an average of 30,753 L Kg^{-1} in seven different soils, MRIDs 462644-11/12) (**Table A-3**). Metaflumizone low solubility limits its concentration, in the in the soil pore water to near solubility thus limiting amounts available for leaching and/or run-off in the water phase. Any additional amount present in these systems may stay insoluble. Soluble amounts of the chemical is expected to be affected by its high affinity to the solid phase (i.e., soil/sediment particles) as it becomes adsorbed and not available for leaching. Therefore, metaflumizone is classified as immobile in soil systems and leaching to lower soil horizons and groundwater is expected to be limited. However, metaflumizone is expected to be transported by run-off adsorbed to the sediment phase.

(c) Field Studies

Metaflumizone suspension concentrate formulation was surface applied at a nominal rate of 0.25 lb. a.i/A on single bare-ground plots in Florida (sandy soil) and California (sandy loam soil) and in separate bare-ground and cropped plots in Texas (sandy loam soil) and Idaho (loam/clay loam soil) (MRID 462644-08). The active ingredient dissipated from the top soil (0-7.5 cm) with a field calculated first order half-lives ranging from 60 to 101 days for bare-ground plots and 151 to 240 days for plots planted with cotton and potatoes, respectively. The bi-phasic nature of metaflumizone field dissipation was observed only in bare-ground plots with shorter half-lives for the first phase (range from 7 to 31 days within the first 21-63 days of the experiments). Much longer half-lives in the range of 65-151days were observed for the second phase with most of the chemical dissipating during the first phase. Dissipation of the chemical was not bi-phasic in the cropped plots. Metaflumizone was mainly detected in the top 7.5 cm with sporadic detection in the 7.5-15 cm subsurface and no detection below the depth of 45 cm, therefore, confirming immobility suggested by laboratory adsorption/desorption studies. It is also noted that, on the average, field dissipation half-lives are similar to aerobic soil half-lives. In these field dissipation studies, M320 I 23 was the only identified degradate among the three degradates tracked, namely, M320 I 04/06/23. The maximum observed concentration of M320 I 23 ranged from 2-5% of the total amount of four parent applications. The observed concentrations of this degradate were in the top 7.5 cm of the soil and were either sporadic or maintained throughout the study period.

Two one-year terrestrial field dissipation studies, were also submitted for eight soils in the continental Europe with bare-ground plots (MRIDs 468077-05 and 466233-44). Results suggest that the nature of metaflumizone dissipation was bi-phasic and was generally similar to results obtained for US bare-ground plots. In six of these soils, first order half-lives for all data points ranged from 39 to 116 days with first phase half-lives ranging from 9 to 36 days in the first 28-122 days of the experiments. Much shorter first order half-lives (5 and 8 days) were observed in two of the soils (MRID 466233-44) even when all of the data points were used (r^2 ranged from

0.72-0.90). Degradates M320 I 04/06 were tracked in all of the eight soils but was observed, above the detection limit, in only two separate soils. In the first soil, M320 I 04 was observed, within the first week, at a maximum concentration of 19% of the applied parent while M320 I 06 was observed in the second soil, within the same time period, at a maximum concentration of 12% of the applied parent. Degradates M320 I 04/06 declined to below detection following the above stated maximums suggesting field none persistence. In contrast, the degradate M320 I 23 was tracked in only two soils but was not observed (appear not to form) (**Table A-4**).

Table A-4 Summary of the transport/bio-concentration/field properties of metaflumizone

Property	***Description or Value***	***MRID[1]***
Adsorption coefficient (Koc) L Kg -1	**21,378 (Loamy sand soil, O.C= 1.4% and pH= 5.6);** **43,762 (Loamy sand soil, O.C= 0.8% and pH= 6.1);** **24,181 (Silt loamy soil, O.C= 1.9% and pH= 6.4);** **16,534 (Loamy sand soil, O.C= 2.3% and pH= 7.0); and** **30,123 (Loam soil, O.C= 1.9% and pH= 7.3)**	EU soils 462644-11 A
	28,262 (Loam soil, ID, O.C= 3.7% & pH= 6.7); and **51,031 (Sandy Loam, NC, O.C= 1.2% & pH= 5.7)**	US soils 462644-12 A
Terrestrial field dissipation half-lives	**061 days** (FL bare-ground Sandy soil, O.M= 1.4%, pH 7.6, CEC= 05 meq/100g); **083 days** (CA bare-ground Sandy loam soil, O.M= 0.9%, pH 8.5, CEC= 07 meq/100g); **060 days** (TX bare-ground Sandy loam soil, O.M= 0.8%, pH 7.7, CEC= 10 meq/100g); **101 days** (ID bare-ground Loam/Clay loam; O.M= 2.0%, pH 6.3, CEC= 17 meq/100g); **151 days** (TX same soil but planted cotton); **240 days** (ID same soil but planted potatoes) ***Minor Degradation products:* M320 I 23:** Max. 4-5% **(tracked M320 I 04/06/23**) Maximum observed ranged from 2-5% of the total amount of four parent applications. **M320 I 23** concentrations were <u>either</u> sporadic <u>or</u> maintained throughout the study	462644-08 A
	078 days (UK-1, bare-ground Sandy clay loam soil); bi-phasic; **089 days** (UK-2, bare-ground Sandy clay loam soil); bi-phasic; **116 days** (Germany-1, bare-ground Silty loam soil); bi-phasic; **091 days** (Germany-2, bare-ground Sandy loam soil); bi-phasic; **005 days** (Spain-1, bare-ground Sand soil; **053 days** (Italy, bare-ground Sandy clay loam soil); bi-phasic; **008 days** (France, bare-ground Sandy loam soil; **039 days** (Spain-2, bare-ground Sandy loam soil); bi-phasic ***Major Degradation products:* M320 I 04** in UK-1 and Germany-1 soils; **None** in all other soils	468077-05 S and 466233-44 S
Fish Bio-concentration	Bluegill sunfish **Max. BCFs= 3,500** (edible) and **12,000** (non-edible) Max. Observed at **42** days of exposure (at termination of exposure) **≥85%** of Max. **depurated** after **56** days ***<u>Transformation products:</u>*** ≤0.1% of the total radioactive residue were **M320 I 04/07** which were isolated from water and fish tissues	462645-04 A

[1] Study Classification: A= Acceptable and S= Supplemental

(d) Metaflumizone Isomers

Metaflumizone parent consists of two isomers, E and Z, with an isomer ratio of 12:1 **(E=92.3%** and Z=7.7%). This assessment was based on exposure for the total parent on the assumption of similar toxicity of Z and E isomers. Examination of available physical, chemical and fate properties of the two isomers and changes in their ratios in submitted fate reveals the following:

- Hydrolysis at pH 7 and 9 (Z-isomer is less stable than the E-isomer) caused a slight increase in the E:Z ratios with the ***Z% decreasing*** below original (% at time-zero);

- Aerobic soil bio-degradation (From maximum: Z-isomer is generally more stable than E-isomer):

    - 4 out of 5 soils: E: Z ratios ***increased*** up to nearly three times its original value then start to decrease after 200 days to reach its original value after one year. This was accompanied by the ***Z% decreasing*** below original (% at time-zero);

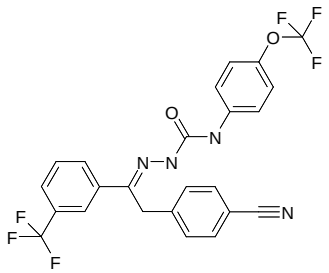
    - One soil (two labels): E: Z ratios ***decreased*** gradually from its original value to nearly <1:1 after one year. This was accompanied by the ***Z% Increasing*** slightly by 3% over its original (% at time-zero) then decreasing to its original value after one year.

- Photolysis (From Maximum: Z-isomer is more stable than the E-isomer) caused a sharp decrease in the E: Z ratios (within one day) with the ***Z% Increasing*** over its original (% at time-zero) to a maximum range of 30% on soil to 48% in water; followed by gradual decrease in Z% to slightly higher than it original value on soils or to its original value in water.

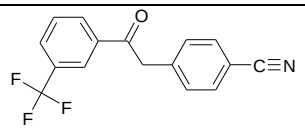
(e) Metaflumizone Degradation Products

Based on submitted fate data for metaflumizone, major quantities of degradates (>10%) were only formed in abiotic acid hydrolysis (degradates M320 I04 and M320 I08) and aqueous photolysis (degradates M320 I05 and M320 I06). In contrast only minor quantities of degradates (<10%) were formed in the aerobic soil and the aerobic aquatic systems. **Table A-5** contains reported parent structure along with structures, physical and chemical properties for the eight degradation products that were identified/quantified in various laboratory abiotic/biotic studies. Identified degradation products varied with the position of the label in metaflumizone structure. Furthermore, **Table A-6** contains a summary of the observed maximum quantities of metaflumizone degradation products along with observed change occurring with time (i.e., decline, no decline or no clear decline).

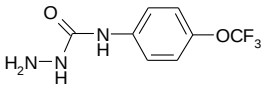
Table A-5 Reported physical and chemical properties of metaflumizone degradates



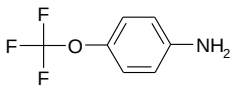
Metaflumizone Parent



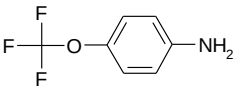
M320 I04 (Ketone Metabolite): 4-[2-Oxo-2-(3-trifluoromethylphenyl)ethyl] benzonitrile; **CAS No.:** 146653-56-7; **M. Wt.=** 289.3 g mole^{-1}**; Solubility: 4.72x10^{3} ppb**



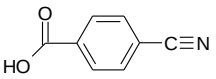
M320 I08: N-[4-(trifluoromethoxy) phenyl] hydrazinecarboxamide; **CAS No.:** 144172-28-1; **M. Wt.=** 235 g mole^{-1}



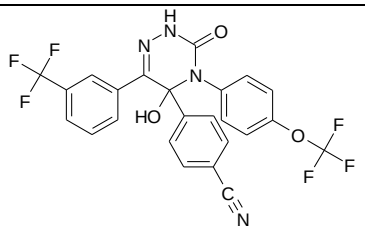
M320 I05 (Aniline Metabolite): 4-(Trifluoromethoxy)aniline; **CAS No.:** 461-82-5; **M. Wt.=** 177 g mole^{-1}



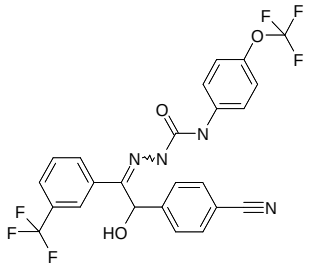
M320 I09: 4-(2-Hydrazono-2-[3-(trifluoromethyl)phenyl] ethyl)benzonitrile **CAS No.:** 139972-23-9; **M. Wt.=** 303.3 g mole^{-1}



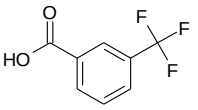
M320 I06: 4-Cyanobenzoic acid**; CAS No.:** 619-65-8; **M. Wt.=** 147 g mole^{-1}**; Solubility: 1.53x10^{5} ppb**



M320 I23 (Cyclic Parent): 4-(5-Hydroxy-3-oxo-4-[4-(trifluoromethoxy)phenyl]-6-[3-(trifluoromethyl)phenyl]-2,3,4,5-tetrahydro-1,2,4-triazin-5-yl)benzonitrile; **CAS No.:** 139968-49-3; M. Wt.= 520.4



M320 I07: Name: 4-{(2Z/E)-1-Hydroxy-2-[({[4-(trifluoromethoxy) phenyl]amino}carbonyl)-hydrazono]-2-[3-(trifluoromethyl) phenyl]ethyl} benzonitrile.; **CAS No.: Not reported; M. Wt.= 523/524** g mole^{-1}



M320 I29: 3-Trifluoromethyl benzoic acid**; CAS No.:** 454-92-2; **M. Wt.=** 190.1 g mole^{-1}

Table A-6 Summary of the maximum quantities/change with incubation time of degradates formed in various fate studies[1]

Degradate	Hydrolysis		Photolysis		Aerobic		Anaerobic Aquatic
	pH 4 & 5	pH 7 & 9	Aqueous	On Soil	Soil	Aquatic[2]	
M320 I04	**90% & 50%** (No-Decline)	**4 & 5%** (No-Decline)	**10%** (Declined)	**1%** (Declined)	**3%** (Declined)	**6%** (Declined)	**4%** (Declined)
M320 I05			**23%** (Volatilized)	**1%** (Not Clear)		**<0.1%** (Not Clear)	**<0.1%** (Not Clear)
M320 I06			**27%** (No-Decline)	**8%** (Slight Decline)		**<0.2%** (Not Clear)	
M320 I07				**5%** (Declined)			
M320 I08	**74 & 34%** (No-Decline)		**4%** (Declined)		**<1%** (Not Clear)	**3%** (Declined)	
M320 I09			**6%** (No-Decline)		**2%** (Not Clear)	**1%** (Declined)	**4%** (Not Clear)
M320 I23					**8%** (No-Decline)	**8%** (No-Decline)	**5%** (No-Decline)
M320 I29					**<1%** (Not Clear)	**<0.1%** (Not Clear)	

[1] **Maximum degradate quantities** reported in this **Table** in % of applied radioactivity are the highest maximum taken from data representing one system with more than one label or one/more than one system with one/more than one label;

[2] **Maximums** are for the **UK lake and SD pond systems** noting that no degradates were observed in the UK pond water system;

Degradate Not Observed

Finally, fate and transport data were also submitted for degradates **M320 I 04/06/29/23** (**Table A-7**). In these studies, degradates were the test substance.

Table A-7 Summary of the fate and transport properties of metaflumizone degradates **M320 I 04/06/I29/123**.

Property	*Description and Value*			
Aerobic soil metabolism (t ½)		*Metaflumizone Degradation Products t ½ (days)*		
		M320 I06	*M320 I29*	*M320 I23*
	Soil	*MRID: 465404-15*	*MRD: 465404-17*	*MRD: 465404-16*
	Loam soil (Germany)	**16**	**8**	**770**
	Sandy Loam soil (Germany)	**15**	**6**	
	Sandy Loam soil (ID, USA)	**7**		**Not Determined**
	Silt Loam (NJ, USA)	**18**	**Not Determined**	
	Sand (Germany)	**Not Determined**		**2,311**
	Loamy Sand (Germany)		**6**	**1,733**
	Major & Minor Degradates	**None**		
Adsorption coefficient (K_{oc})		*K_{oc} for Metaflumizone Degradation Products (L kg $^{-1}$)*			
		M320 I 06	*M320 I 29*	*M320 I 04*	*M320 I 23*
	Soil Name/Location (Soil Texture)[1]	*MRID: 462644-13/14*	*MRID: 466233-40*	*MRID: 462644-17/18*	*MRID: 462644-15/16*
	Borgeby/EU (**LS**)	**9**	**106**	**1,949**	**15,279**
	Birnbaum/EU (**LS**)	**4**	**7**	**1,135**	**9,402**
	Sora/EU (**SiL**)	**4**	**11**	**1,155**	**5,312**
	(Bruch West (**LS**)	**3**	**6**	**559**	**3,052**
	LUFA 3 A/EU (**L**)	**5**	**10**	**895**	**5,295**
	ID, USA(**L**)	**3**	**5**	**867**	**3,857**
	NC, USA (**SL**)	**56**		**957**	**2,301**
	LUFA 2.2/EU **(LS)**		**28**	**Not Determined**	
	Average	**12**	**25**	**1,074**	**6,357**
	FAO Mobility Class	**Mobile**		**Slightly mobile**	**Moderately mobile**
	[1] **Soil Textural Class Abbreviations: LS**= Loamy Sand; **L**= Loam; **SiL**= Silt Loam				

Appendix B: SIP output for Metaflumizone

Table 1. Inputs

Parameter	**Value**
Chemical name	Metaflumizone
Solubility (in water at 25oC; mg/L)	0.00179
Mammalian LD50 (mg/kg-bw)	2025
Mammalian test species	laboratory rat
Body weight (g) of "other" mammalian species	
Mammalian NOAEL (mg/kg-bw)	20
Mammalian test species	laboratory rat
Body weight (g) of "other" mammalian species	
Avian LD50 (mg/kg-bw)	156
Avian test species	mallard duck
Body weight (g) of "other" avian species	
Mineau scaling factor	1.15
Mallard NOAEC (mg/kg-diet)	0
Bobwhite quail NOAEC (mg/kg-diet)	7.6
NOAEC (mg/kg-diet) for other bird species	0
Body weight (g) of other avian species	
NOAEC (mg/kg-diet) for 2nd other bird species	0
Body weight (g) of 2nd other avian species	

Table 2. Mammalian Results		
Parameter	Acute	Chronic
Upper bound exposure (mg/kg-bw)	**0.0003**	**0.0003**
Adjusted toxicity value (mg/kg-bw)	1557.5501	15.3832
Ratio of exposure to toxicity	0.0000	0.0000
Conclusion*	**Drinking water exposure alone is NOT a potential concern for mammals**	**Drinking water exposure alone is NOT a potential concern for mammals**

Table 3. Avian Results				
Parameter	Acute	Chronic		
Upper bound exposure (mg/kg-bw)	**0.0014**	**0.0014**		
Adjusted toxicity value (mg/kg-bw)	80.9992	0.8079		
Ratio of exposure to acute toxicity			0.0000	0.0018
Conclusion*	**Drinking water exposure alone is NOT a potential concern for birds**	**Drinking water exposure alone is NOT a potential concern for birds**		

*Conclusion is for drinking water exposure alone. This does not combine all routes of exposure. Therefore, when aggregated with other routes (*i.e.*, diet, inhalation, dermal), pesticide exposure through drinking water may contribute to a total exposure that has potential for effects to non-target animals.

Appendix C: STIR output for Metaflumizone

Welcome to the EFED

Screening Tool for Inhalation Risk

This tool is designed to provide the risk assessor with a rapid method for determining the potential significance of the inhalation exposure route to birds and mammals in a risk assessment.

Input

Application and Chemical Information

Enter Chemical Name	Metaflumizone	
Enter Chemical Use	Insecticide	
Is the Application a Spray? (enter y or n)	n	
If Spray What Type (enter ground or air)	ground	
Enter Chemical Molecular Weight (g/mole)	506.4	
Enter Chemical Vapor Pressure (mmHg)	9.30E-11	
Enter Application Rate (lb a.i./acre)	1.5	

Toxicity Properties

Bird

Enter Lowest Bird Oral LD_{50} (mg/kg bw)	7.6	
Enter Mineau Scaling Factor	1.15	
Enter Tested Bird Weight (kg)	0.178	

Mammal

Enter Lowest Rat Oral LD_{50} (mg/kg bw)	2025	
Enter Lowest Rat Inhalation LC_{50} (mg/L)	0.03	
Duration of Rat Inhalation Study (hrs)	4	
Enter Rat Weight (kg)	0.35	

Output

Results Avian (0.020 kg)

Maximum Vapor Concentration in Air at Saturation (mg/m^3)	2.53E-06	
Maximum 1-hour Vapor Inhalation Dose (mg/kg)	3.19E-07	
Adjusted Inhalation LD_{50}	6.28E-04	
Ratio of Vapor Dose to Adjusted Inhalation LD_{50}	5.07E-04	**Exposure not Likely Significant**
Maximum Post-treatment Spray Inhalation Dose (mg/kg)	not applicable	
Ratio of Droplet Inhalation Dose to Adjusted Inhalation LD_{50}	not applicable	not applicable

Results Mammalian (0.015 kg)

Maximum Vapor Concentration in Air at Saturation (mg/m^3)	2.53E-06	
Maximum 1-hour Vapor Inhalation Dose (mg/kg)	4.00E-07	

Adjusted Inhalation LD_{50}	1.79E+00	
Ratio of Vapor Dose to Adjusted Inhalation LD_{50}	2.24E-07	**Exposure not Likely Significant**
Maximum Post-treatment Spray Inhalation Dose (mg/kg)	not applicable	
Ratio of Droplet Inhalation Dose to Adjusted Inhalation LD_{50}	not applicable	not applicable