Reregistration Eligibility Decision (RED) Document for Pyrazon

September 2005

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data related to the risk assessments for the herbicide pyrazon. The enclosed Reregistration Eligibility Decision (RED), which was signed on September 1, 2005, contains the Agency's risk assessments for pyrazon and its conclusions concerning the potential human health and environmental risks of the current product uses, tolerance reassessment, and conditions under which these uses and products will be eligible for reregistration.

This RED also contains a generic and/or a product-specific Data Call-In(s) (DCI) that outline(s) further data requirements for this chemical. **Note**, **registrants of pyrazon must respond to DCIs issued by the Agency within 90 days of receipt of this letter. For Product Reregistration, the second set of required responses is due 8 months from receipt of this letter**. Registrants may avoid Agency enforcement action, specifically suspension of their pyrazon products registration(s), by submitting complete and timely responses.

In this RED, the Agency has determined that all uses of pyrazon will be eligible for reregistration provided that all of the data gaps identified in the Data Gaps section of this document are fulfilled.

A Notice of Availability for the Reregistration Eligibility Decision for pyrazon is being published in the *Federal Register*. To obtain a copy of the RED document, please contact the OPP Public Regulatory Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue NW, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet. See www.epa.gov/pesticides/reregistration/status.htm.

There will be a 60-day public comment period for this document, commencing on the day the Notice of Availability publishes in the Federal Register.

As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes.

Please note that the pyrazon risk assessments and the attached RED concern only this particular pesticide. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider

"available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyrazon and any other substances, and pyrazon does not appear to produce a toxic metabolite produced by other substances. For the purposes of this risk assessment action, therefore, EPA has not assumed that pyrazon has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Stephanie Plummer, at (703) 305-0076. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact the Product Reregistration Chemical Review Manager, Karen Jones, at (703) 308-8047.

Sincerely,

Debra Edwards, Ph.D.
Director
Special Review and Reregistration Division

Attachment

United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508C)

EPA 738-F-05-014
September 2005

Reregistration Eligibility Decision

Pyrazon

List [B]

Case No. 2570

Reregistration Eligibility Decision (RED) Document for Pyrazon

Approved by: _____

Debra Edwards, Ph. D.
Director
Special Review and Reregistration Division

Date: September 1, 2005

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
μg/g	Micrograms Per Gram
μg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter

MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Introduction

This document presents the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) decision regarding the reregistration eligibility of the registered uses of the herbicide pyrazon. The Agency made its reregistration eligibility determination based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered uses of pyrazon are eligible for reregistration.

Risks summarized in this document are those that result only from the use of pyrazon. The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." For the purposes of this risk assessment, therefore, EPA has not assumed that pyrazon has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs at http://www.epa.gov/pesticides/cumulative/.

Use Profile

Pyrazon [5-amino-4-chloro-2-phenyl-3(2H)-pyridazinone], also known as chloridazon, is an herbicide belonging to the pyridazinone class of pesticides. It works as an herbicide by blocking electron transport in photosystem II in green plants, thereby inhibiting photosynthesis. Pyrazon is registered for pre-plant, pre-emergence, and early post-emergence use on sugar beets and red table beets to control certain weeds. Approximately 10% of the U.S. sugar beet crop and 50% of the U.S. table beet crop are treated with pyrazon annually. Pyrazon is also registered for commercial use on ornamentals, including bulb crops and roses.

Human Health Risk Assessment

Toxicology

For more detailed information, see "*Pyrazon: HED Chapter of the Reregistration Eligibility Decision (RED) Document.*"; S. Stanton; 7/28/05.

The available toxicity data on pyrazon are adequate to assess the chemical's hazard potential. Pyrazon is an herbicide considered to be of low toxicity without highly specific responses in mammals. Technical pyrazon has low (category III/IV) acute toxicity via the oral, dermal, and inhalation routes of exposure. It is not an eye or skin irritant (category IV) and does not cause dermal sensitization. In longer-term studies, reduced body weight associated with reduced food consumption appears to be the most significant effect of pyrazon exposure in laboratory animals. At higher doses, conditions such as poor general appearance and some motor effects considered to be associated with

poor nutrition are noted in rats. In dogs, renal distal tubule vacuolation results at higher doses. No systemic effects resulted from dermal exposure to pyrazon.

In both the rat and rabbit prenatal developmental studies, pyrazon did not demonstrate any effects on the fetuses to indicate increased susceptibility. There were no effects on the reproductive performance of rats. Based on the lack of pre- and/or postnatal susceptibility resulting following exposure to pyrazon, and considering the lack of residual uncertainties for pre- and/or postnatal toxicity, no special FQPA safety factor is needed. Therefore, the special FQPA safety factor was reduced to 1X.

No neurobehavioral alterations or evidence of neuropathological effects were observed in the available rat and rabbit prenatal developmental toxicity studies or the rat multi-generation reproduction study. In addition, pyrazon is not considered to be neurotoxic from other guideline studies or in open literature reports. Some clinical signs suggesting neurotoxicity were noted at very high doses in the rat, but these were attributed to the weight loss and general poor condition of the rats. Based on the weight of evidence, a developmental neurotoxicity (DNT) study is not required for pyrazon.

Pyrazon may be classified as "not likely to be a carcinogen in humans" based on the lack of evidence of carcinogenicity in the rat and mouse carcinogenicity studies.

An acute reference dose (aRfD) was not established, since an endpoint attributable to a single exposure was not identified from the available database. A chronic reference dose (cRfD) of 0.18 mg/kg/day was established for pyrazon based on the NOAEL of 18 mg/kg/day in the rat chronic toxicity study and an uncertainty factor of 100 (10x for interspecies extrapolation and 10x for intraspecies variation). Decreased body weight and weight gain occurred in this study at the LOAEL of 60 mg/kg/day for females (88 mg/kg/day for males).

There are no available dermal absorption studies on pyrazon. Since no dermal exposure hazard was identified, no attempt to estimate a dermal absorption factor by comparing a LOAEL for a common endpoint, from common species from oral and dermal studies was made.

For the occupational assessment, only exposure from inhalation was used to assess short- and intermediate-term occupational risk. This is because systemic toxicity was not seen in a 21-day dermal toxicity study in rabbits (MRID 42331101) at the highest dose tested (1000 mg/kg/day). Inhalation risk was estimated using the NOAEL of 18 mg/kg/day from a rat chronic dietary toxicity study. The NOAEL was based upon female rate body weight effects. An inhalation factor of 100% was applied.

Table 1. Subchronic, Chronic, and Other Toxicity Profile for Pyrazon

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.3100 90-Day oral toxicity (rat)	41992701 (1990) Minimum. 0, 300, 1500 or 7500 ppm. 0, 65, 319 or 1756 mg/kg/day for males and 0, 91, 467 or 2316 mg/kg/day for females.	NOAEL = 65 mg/kg/day for males and 467 mg/kg/day for females. LOAEL = 319 mg/kg/day for males based on decreased body weight and gain, decreased food consumption and increased liver weight and decreased cholesterol and triglycerides. LOAEL = 2316 mg/kg/day for females based on slight decrease in body weight and gain, decreased food consumption and possibly decreased cholesterol and triglycerides.
870.3150. Subchronic toxicity- dogs	42903401 (1993) Acceptable/Guideline 0, 4000 or 5000 ppm. 0, 133 or 168 mg/kg/day.	NOAEL = Not established. LOAEL = 133 mg/kg/day based on vacuolation of the distal renal tubules of the females.
870.3200 21/28- Day dermal toxicity (rabbits)	42331101 (1992) Minimum 0 and 1000 mg/kg/day in 0.5% carboxy methylcellulose.	**Systemic:** NOAEL > 1000 mg/kg/day. LOAEL - not established. **Dermal:** At 1000 mg/kg/day - local dermal effects.
870.3700a. Prenatal developmental toxicity - rat	41992702 (1990) "Core-Guideline" 0, 10, 50 and 250 mg/kg/day in 0.5% carboxymethylcellulose.	**Maternal:** NOAEL = 10 mg/kg/day LOAEL = 50 mg/kg/day based on decreased body weight gains/ food consumption **Developmental:** NOAEL and LOAEL > 250 mg/kg/day. No effects at the highest dose tested.
870.3700b Prenatal developmental - rabbit	41507909 (1987) "Acceptable" 0, 55, 165 or 495 mg/kg/day in carboxymethylcellulose	**Maternal:** NOAEL = 55 mg/kg/day LOAEL = 165 mg/kg/day based on decreased body weight gains. **Developmental:** NOAEL and LOAEL > 495 mg/kg/day. No effects at the highest dose tested.
870.3800 Reproduction and fertility effects (rat)	42903407 (1993) Acceptable/Guideline 0, 100, 400 or 1600 ppm.	**Systemic (parental):** NOAEL and LOAEL > 1600 ppm (136 to 156 mg/kg/day). **Reproductive:** NOAEL and LOAEL > 1600 ppm. **Developmental:** NOAEL and LOAEL > 1600 ppm
870.4100a. Chronic toxicity - rats	42903404 (1993) Acceptable/Guideline Doses: 0, 100, 300, 1000 or 2000 ppm. 0, 4, 13, 43 or 88 mg/kg/day for males and 0, 6, 18, 60 or 125 mg/kg/day for females.	NOAEL = 18 mg/kg/day (females)/43 mg/kg/day (males). LOAEL = 60 mg/kg/day (females)/88 mg/kg/day (males) based on reduced body weight/gain.

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.4100b Chronic toxicity (dog)	42903403 (1993) Doses: 0, 6000 or 8000 ppm, 0, 186 or 241 mg/kg/day. Acceptable/Guideline	NOAEL = Not established LOAEL = 186 mg/kg/day based on vacuolization of the renal distal tubules (females), body weight decrease and lymphoreticular hyperplasia of the gastric mucosa (both sexes).
870.4100b Chronic toxicity (dog)	42903402 (1993) Doses: 0, 400, 1200 or 3600 ppm. 0, 11, 33 or 99 mg/kg/day. Acceptable/Guideline	NOAEL > 99 mg/kg/day. No effects at the highest dose tested. Studies in 42903403 and 42903402 combine to establish the NOAEL and LOAEL and satisfy the guideline requirement for chronic toxicity in dogs.
870.4200 Carcinogenicity (mouse)	42903406 (1993) Doses: 0, 200, 1000 or 5000 ppm. 0, 28, 146 or 762 mg/kg/day. Acceptable/Guideline.	NOAEL = 146 mg/kg/day LOAEL = 762 mg/kg/day based on body weight decreases. **No evidence of carcinogenicity.**
870.4300 Carcinogenicity (rat)	42903404 (1993) Acceptable when combined with the chronic feeding study (MRID No..: 42903404) Doses: 0, 100, 300 or 1000 ppm. 0, 4, 13 or 43 mg/kg/day for males and 0, 6, 17 or 59 mg/kg/day for females.	NOAEL = Not established. (males). LOAEL = > 43 mg/kg/day. [Note: hepatic focal necrosis was not considered a definite toxic response since it was not seen in the chronic study and did not show a clear dose response for increased severity. **No evidence of carcinogenicity.**
870.4300. Special carcinogenicity study (Interim report).	43815602 (1995) Acceptable/Non-Guideline Doses: 0, 3000 ppm (females) and 4000 ppm (males).	Interim report only. Study demonstrated poor survival and large body weight loss effects (29% in males and 32% in females for body weight and 38% for males and 52% for females for body weight gain).
870.5100. *Salmonella* and *Escherichia* gene mutation assay with metabolic activation.	41507910 (1989) "Acceptable" 20 to 5000 μg/plate.	Not mutagenic in any test strain. TA 98, TA 100, TA 1535 and TA 1537 strains of *Salmonella* and *E.coli* strain WP2 *uvrA*.
870.5395. *In vivo* mammalian cytogenetic assay.	41507911 (1987) "Acceptable" 0, 150, 300 or 600 mg/kg/day.	No evidence of increased micronucleated polychromatic erythrocytes at any dose due to pyrazon.
870.5550. Unscheduled DNA synthesis.	41507912 (1986) Unacceptable (needs verification of the test material and purity.	No evidence of induction of unscheduled DNA synthesis.

Guideline No./ Study Type	MRID No. (year)/ Classification /Doses	Results
870.7485. General metabolism	41992703 (1991) "Acceptable/Guideline"	The toxicokinetic data indicate that Pyrazon is readily absorbed by the rat gastro-intestinal tract. The major excretory route is via the urine with most being excreted in 24 hours for low doses and 48 hours for higher doses. Biliary excretion is significant but a minor route. Females may excrete Pyrazon at lower rates than males based on the 14 day repeat dose study. Tissue burden is low with up to only 3.28% remaining. A total of 10 fractions (nine metabolites and one isomer) in the urine and 5 fractions in the feces. were noted. The major urinary metabolites were sulfate and glucuronide conjugates and the major fecal metabolite was a p-hydroxy derivative of Pyrazon. The sulfate and glucuronide conjugates and p-hydroxy derivative of pyrazon were recognized as the biliary metabolites. Parent compound was detected only in small amounts in the urine and feces. Minor quantitative differences related to gender were identified.

The unscheduled DNA synthesis study (1986, MRID No.: 41507912) was classified as "unacceptable/upgradeable" because additional information on the percent purity and lot or batch number is needed to verify the identity of the test material. Therefore, another unscheduled DNA synthesis study will be required to fulfill the guideline.

Residue Chemistry

For more detailed information, see "*Pyrazon. Reregistration Eligibility Decision (RED). Summary of Analytical Chemistry and Residue Data*"; D. Soderberg; 7/28/05.

The available residue chemistry data are adequate to assess human dietary exposure to pyrazon from the consumption of treated food commodities. The residues of concern for tolerance enforcement and risk assessment are pyrazon, its desphenyl metabolite and their conjugates for plant commodities; and pyrazon, its hydroxy-pyrazon metabolite and their conjugates for livestock commodities. Adequate analytical methods are available for the enforcement of pyrazon tolerances.

The potential for accumulation of [^{14}C]pyrazon in rotational crops was investigated under outdoor and greenhouse-confined conditions. Pyrazon and its metabolites were identified in various crops and intervals and quantified at levels greater than 0.01 ppm. A limited field rotational crop study on wheat, leaf lettuce and potato has also been submitted. This limited trial shows that measurable pyrazon residues are found on some food or feed commodities for each of the three crops after a plant back interval of one year. Based upon this information, EPA, at the request of the registrant, intends to propose rotational crop tolerances for wheat, soybeans, dried beans, and corn. Based upon the limited field trials available, a one-year plant back restriction will be required. To confirm the appropriateness of these tolerance restrictions, a set of field accumulation

in rotational crop studies will be required. EPA may be contacted to discuss possible reduced sets of field trials to fulfill these requirements. Crops selected for these field trials should be selected on the basis of those crop rotations that the registrant intends to support.

Residue Analytical Method A9202, a modified version of Method I in PAM, Volume II, has been submitted with a supporting radiovalidation study. HED has determined that an Independent Laboratory Validation (ILV) study is required for Method A9202. The Registrant should also propose the method as an enforcement method.

Dietary Risk from Food

For more detailed information, see *"Pyrazon Chronic Dietary Exposure Assessment for the Reregistration Eligibility Decision"*; S. Stanton; D301080; 07/26/05

A chronic dietary risk assessment only was conducted for pyrazon, because an endpoint of concern attributable to a single dose was not identified. The chronic dietary assessment was conducted using the Lifeline Model Version 3.0 and the Dietary Exposure Evaluation Model (DEEM-FCID™), Version 2.03, which use food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998.

The Tier 1 chronic assessment assumed 100% crop treated, DEEM™ (Version 7.76) default processing factors, reassessed tolerance-level residues for all food commodities and screening level drinking water concentrations. Estimated exposures from pyrazon residues in food represent less than 0.1% of the cPAD for all population subgroups.

Dietary Risk from Drinking Water

For more detailed information, see *"Drinking Water Assessment for Pyrazon used on Table Beets and Sugar Beets"*; J. Breithaupt; 5/31/05.

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. Estimated drinking water concentrations were calculated for residues of parent pyrazon only in both surface and ground water, using the PRZM-EXAMS and SCI-GROW models, respectively. The modeling results are summarized below:

Table 2 Summary of Estimated Surface and Ground Water Concentrations for Pyrazon, *per se*.

Exposure Duration	Pyrazon (parent only)	
	Surface Water Conc., ppb [a]	Ground Water Conc., ppb [b]
Acute	465	5
Chronic (non-cancer)	428	5

[a] *From the PRZM-EXAMS - Index Reservoir model. Input parameters are based on spring application to sugar beets in MN at an application rate of 7.3 lb. a.i./a as a broadcast spray, an upper-bound aerobic soil metabolic half-life of 216 days, and an average K_{oc} value of 210.*

[b] *From the SCI-GROW model, based on spring application to sugar beets in MN and spring or fall application to sugar beets in CA at an application rate of 7.3 lb. a.i./a as a broadcast spray, the median K_{oc} of 220, and the average aerobic soil metabolic half-life of 121 days.*

Since the EDWCs for surface water were higher than those for ground water, the chronic surface water EDWC was used in the dietary assessment.

The residues of concern for risk assessment in drinking water include parent pyrazon and desphenyl pyrazon. Desphenyl pyrazon is found as a major degradate in environmental fate studies, accounting for up to 53% of the applied dose in the aerobic soil metabolism studies. EPA determined that an upper bound estimate of the combined residues of pyrazon and desphenyl pyrazon could be made by multiplying the model estimates for pyrazon only by a factor of 1.53. The resulting highly conservative, chronic EDWC of 655 ppb (1.53 x 428 ppb) was used as a point estimate in the dietary exposure assessment.

Nearly all (>99%) of the estimated dietary exposure to pyrazon is from drinking water. However, estimated exposures from drinking water are well below the Agency's level of concern, representing 25% or less of the cPAD for all population subgroups.

Residential Risk

There are currently no pyrazon products registered for homeowner use, and no residential exposure is expected from commercial uses of pyrazon; therefore, a residential risk assessment was not conducted.

Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water pathways) as well as exposures from non-occupational sources (e.g., residential uses). In the case of pyrazon, no residential exposures are expected, so the aggregate assessments include exposures via food and drinking water only. Furthermore, EPA conducted only a chronic aggregate risk assessment, because no acute endpoint was identified.

The chronic aggregate risk estimates for the U.S. population and all subgroups are well below the Agency's level of concern. The estimated chronic aggregate risk for

infants, the population subgroup with the highest estimated exposure, is 21% to 25% of the cPAD using the Lifeline and DEEM-FCID dietary models, respectively.

Estimated exposure to pyrazon in drinking water accounts for more than 99% of total aggregate risk for this chemical. Since the estimated drinking water concentration used in the assessment was a model-generated screening level value derived with conservative default input values, the resulting exposures likely overestimate actual risk from residues of pyrazon in drinking water.

Cumulative Risk

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to pyrazon and any other substances and pyrazon does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pyrazon has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs at http://www.epa.gov/pesticides/cumulative/.

Occupational Risk

For more detailed information, see *"Pyrazon: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document"*; W. Britton; 7/28/05.

Pesticide handlers are likely to be exposed during the occupational use of pyrazon in a variety of occupational environments. Since no chemical-specific handler exposure data are available for pyrazon, short- and intermediate-term inhalation exposures were assessed using data from the Pesticide Handlers Exposure Database (PHED) Version 1.1. PHED data were used with other Agency standard values for areas treated per day, body weight and the level of personal protective equipment (PPE) and engineering controls to assess handler exposures to pyrazon. Using these assumptions, the calculated occupational handler exposures do not exceed EPA's level of concern (i.e., MOEs > 100) for all exposure scenarios. Short- and intermediate-term inhalation MOEs range from 190 (mixing/loading liquids for aerial application to sugar beets) to more than 6,800 (aerial application to red table beets). Dermal exposure was not assessed, since a dermal endpoint of concern has not been identified for pyrazon.

Post-application exposure was not assessed because there is no dermal endpoint of concern and post-application inhalation exposure is expected to be negligible. However, per the Worker Protection Standard, a 12-hour restricted entry interval (REI) is required for chemicals classified as Toxicity Category III or IV. Pyrazon is classified in Toxicity Category III for acute oral and dermal Toxicity Category IV for acute inhalation and primary eye and skin irritation; therefore, the current REI of 12 hours is appropriate and will remain on labels.

Ecological Risk Assessment

For more detailed information, see *"Pyrazon Screening Level Ecological Risk Assessment for the Re-registration Decision"*; J. Martinez, et al; 8/16/2005.

Environmental Fate and Transport

The environmental fate characteristics of pyrazon indicate that it is mobile in a variety of soil types and is persistent in soil and in aquatic environments. On soil, the photolysis half-life is 69 days, with an aerobic soil metabolism half-life of 90-152 days, and an anaerobic soil metabolism half-life of 307 to 607 days, depending on the soil texture tested. Pyrazon has reported K_{oc} values in the range of 89 to 340 mL/g, indicating that this chemical will be mobile in soils. The most significant route of degradation of pyrazon in water appears to be photolysis, with a half-life of 12.5 days. Pyrazon is stable to hydrolysis at pH 5, 7 and 9. Based on fate characteristics, pyrazon has the potential for transport to surface water and ground water in the environment, resulting in contamination of water resources in areas where it has a tendency to persist.

Aquatic Organism Risk

For exposure to fish and aquatic invertebrates, EPA considers surface water only, since most aquatic organisms are not found in ground water. Surface water models are used to estimate exposure to freshwater aquatic animals, since monitoring data are generally not from studies targeted on small water bodies and primary streams, where many aquatic animals are found. In the case of pyrazon, EPA conducted Tier II surface water modeling using PRZM-EXAMS. The modeling results used in risk calculations for pyrazon are detailed in the Agency's environmental risk assessment.

Risk quotients (RQs) were calculated based on the available acute toxicity data and modeled surface water EECs. The acute RQ values for freshwater fish and invertebrates are all below the Agency's Level of Concern (LOC) for acute risk, acute restricted use, and acute endangered species risk. Chronic risks to freshwater fish and invertebrates could not be assessed, due to the lack of available data.

EPA assumed that the primary degradate, dephenylated pyrazon, will also not pose a significant risk to freshwater fish and invertebrates based available studies. Open literature and studies submitted by the technical registrant, BASF Corporation, suggest that, due to its apparent limited persistence in the environment and low toxicity, dephenylated pyrazon is substantially less toxic than pyrazon.

Some pyrazon may be used in coastal areas in California; thus, estuarine/marine organisms may be exposed. However, due to the lack of available toxicity data estuarine and marine organisms, risks to these organisms could not be assessed.

RQ values were also calculated for aquatic plants, and range from 0.0015 to 3.2 (listed and non-listed species). All RQs for non-listed aquatic plants fall below the LOC of 1, with the exception of the scenario modeled using the maximum application rate in Minnesota (7.3 lbs a.i./A). There are several RQs that exceed the LOC for listed species, for scenarios in California and Minnesota when application rates of 7.3 lbs a.i./A or 3.5 lbs a.i./A are assumed.

Terrestrial Organism Risk

The Agency assessed exposure to terrestrial organisms by first predicting the amount of pyrazon residues found on animal food items and then by determining the amount of pesticide consumed by using information on typical food consumption by various species of birds and mammals. The amount of residues estimated to be found on animal feed items are based on the Fletcher nomogram (a model developed by Fletcher, Hoerger, Kenaga, et al.) and the current maximum application rate for pyrazon.

Based on available studies, pyrazon is practically non-toxic to birds on an acute oral and dietary basis, and to mammals on an acute oral basis.

For birds, only acute risks were assessed, because no chronic toxicity data were available. The acute RQs for birds do not exceed the Agency's acute Level of Concern (0.5), but do exceed the endangered species Level of Concern (0.1) for all labeled use rates. Chronic risks were not assessed for birds, due to the lack of available chronic toxicity data.

For mammals, acute RQs do not exceed the Agency's acute LOC (0.5), but do exceed the endangered species LOC (0.1) for all labeled use rates, except the lowest (1.69 lbs. ai/A).

The Agency's assessment of chronic risks to non-target wild mammals is usually based on reproductive impairment. For pyrazon, a surrogate supplemental rat oral developmental study was used for risk quotient calculations. These calculations resulted in chronic RQs which exceed the LOC (1.0) for for all labeled uses. However, the EPA does not expect pyrazon to pose a significant chronic risk to mammals. The supplemental rat oral developmental study used for risk quotient calculations, resulted in a maternal NOAEL of 10 mg/kg/day and a maternal LOAEL of 50 mg/kg/day, based on reduced body weight gain and slightly reduced food consumption. The only effects demonstrated in the study were maternal with no effects on the developing fetuses. There was no indication of reproductive impairment in any of the studies submitted for the human health assessment. In addition, a 2-generation rat reproduction study in rats (MRID 42903407) showed no reproductive effects at 1,600 ppm, the highest dose tested (which is two orders of magnitude greater than the LOAEL from the oral developmental study). Therefore, the Agency does not believe non-listed mammals are at chronic risks from the current uses of pyrazon.

Based on modeled EECs and the available toxicity data, RQ values for all uses of pyrazon and all application scenarios exceed the LOC for listed and non-listed non-target terrestrial plants and terrestrial plants in semi-aquatic areas.

Endangered Species Concerns

The Agency's screening level ecological assessment for pyrazon resulted in a determination that pyrazon will have no direct acute effects on threatened and endangered freshwater aquatic animal species from its currently registered uses.

There are exceedances of the acute endangered species LOC for listed birds with every modeled maximum application rate use scenario. The RQ values range from 0.1 to 1.4. There are currently no acceptable chronic toxicity data available for birds; therefore, chronic risks to birds were not assessed. There is a potential concern for listed birds species for which the acute LOC is exceeded and for listed species that may be dependent upon birds with LOC exceedances. These concerns are limited to situations where exposure to the stressor actually occurs.

Acute RQs exceed the endangered species LOC for listed species of mammals for all the maximum use rate scenarios, except for the lowest rate (1.69 lbs a.i./A). The RQs range from 0.1 to 0.4. There are some chronic RQs that exceed the LOC for all the maximum use rate scenarios. RQs range from 1 to 76. There is potential concern for mammalian species for which the LOC is exceeded and for listed species for which there is dependency upon mammals with LOC exceedances. These concerns are limited to situations where exposure to the stressor actually occurs. EPA does not expect pyrazon to pose a significant chronic risk to mammals, though, because the RQs were calculated using a LOAEL of 50 mg/kg/day from a supplemental rat oral developmental study, based on reduced body weight gain and slightly reduced food consumption. A two-generation rat reproduction study showed no adverse reproductive effects at the 1600 ppm, the highest dose tested (which is two orders of magnitude greater than the LOAEL from the oral developmental study).

The LOC for listed aquatic plants (macrophytes) were not exceeded for most use rate scenarios. However, the LOC was exceeded for scenarios in California and Minnesota when application rates of 7.3 lbs a.i/A and 3.5 lbs. a.i./A were assumed. The LOC is exceeded for listed species of terrestrial plants and terrestrial plants in semi-aquatic areas for all maximum use rate scenarios. The RQ values range from 1 to 466. It is worth noting that the RQ of 466 is based on a worst case scenario, where the maximum application rate of 7.3 lbs a.i./A is used. In most cases, the application rate is much lower, and most RQs were less than 100. There is a potential concern for species within this taxonomic group for which RQs exceed the LOC and for listed species for which there is some sort of dependence upon plants with LOC exceedances. These concerns are limited to situations where exposure to the stressor actually occurs.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered

and threatened species, and to implement mitigation measures that address these impacts. The ESA requires federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. To analyze the potential of registered pesticide uses that may affect any particular species, EPA uses basic toxicity and exposure data developed for the REDs and considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, this analysis will consider regulatory changes recommended in this RED that are implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, or consultations with the Fish and Wildlife Service or National Marine Fisheries Service as appropriate. If the Agency determines use of pyrazon "may affect" listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402). Until that species specific analysis is completed, the risk mitigation measures being implemented through this RED will reduce the likelihood that endangered and threatened species may be exposed to pyrazon at levels of concern.

Risk Mitigation Summary

As with most herbicides, risks of concern associated with pyrazon were identified for listed and non-target terrestrial and semi-aquatic plants, and in some scenarios, endangered aquatic plants. Additionally, acute risks of concern, if exposures actually occur, were identified for endangered species of birds and mammals. Given that the pyrazon ecological risk assessment is a screening level analysis, EPA is not imposing any mitigation at this time. Should EPA's endangered species specific assessment indicate that use of pyrazon "may affect" listed species, changes to the registered uses of pyrazon may need to be modified (see section on "Endangered Species Concerns)".

Pyrazon is persistent and mobile in many types of soil, and therefore, has the potential to enter surface and ground water. To protect water sources, EPA will be requiring the following statements to be added to the labels for all pyrazon products:

"Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas."

"Pyrazon is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

Pyrazon end-use product labels currently include the following restriction: "Do not apply this product through any type of irrigation system." However, they also include directions for use with irrigation equipment; therefore, any directions for use with irrigation equipment must be removed from labels. Additionally, a restriction of not less than one year for rotational crop plant-back is required on all end-use product labels.

Tolerance Reassessment

For more detailed information, see "*Pyrazon. Reregistration Eligibility Decision (RED). Summary of Analytical Chemistry and Residue Data*"; D. Soderberg; 7/28/2005.

Tolerances have been established under 40 CFR §180.316 for combined residues of pyrazon and its metabolites (calculated as pyrazon) in or on: garden beet roots (0.1 ppm) and tops (1 ppm); sugar beet roots (0.1 ppm) and tops (1 ppm); and milk (0.01 ppm).

Several data deficiencies were identified in the residue chemistry chapter, as follows: 1) An Independent Laboratory Validation (ILV) study is required for Method A9202; 2) A set of field accumulation in rotational crop studies is being required; and 3) Reference analytical standards for pyrazon, its desphenyl metabolite, and its hydroxyl-metabolite should be submitted to the EPA National Pesticide Standards Repository. These data needs are explained in more detail in the "Data Requirements" section of this RED. Provided that these data deficiencies are addressed, adequate residue data have been submitted to reassess the established tolerances for sugar beets (tops and roots) and garden beets (tops and roots).

The available data indicate the current tolerances for residues of pyrazon and its metabolites in/on garden beet and sugar beet tops and roots, as well as milk, are not appropriate. EPA plans to revise the tolerances for sugar beet roots and tops, so that they will be 0.2 ppm and 3 ppm, respectively, and establish a tolerance for sugar beet molasses at 1.5 ppm. EPA also plans to revise the tolerances for garden beet roots and tops, so that they will be 0.9 ppm and 7 ppm, respectively. EPA plans to revise the tolerance for milk so that it will be 0.02 ppm. In addition, the Agency plans to set new meat tolerances, including tolerances in the livers of beef, sheep, goat and horse (0.15 ppm) and tolerances in the fat, meat and meat byproducts of beef, sheep, goat and horse (0.10 ppm).

Because residues in available rotational crop studies indicated measurable residues in rotated crops, full field trials must now be submitted for all crops to be rotated with sugar beets or garden beets. In the meantime, EPA will use the results of these limited field trials to propose establishment of tolerances in several rotational crops requested by the registrant: wheat, soybean, dried bean, and corn. The following tolerances will be proposed: wheat, forage (0.3 ppm); wheat, hay (0.2 ppm); wheat, straw (0.1 ppm); soybean, forage (0.5 ppm); soybean, hay (0.5 ppm); corn, field, forage (0.5 ppm); and corn, field, stover (0.5 ppm). However, because residues were determined in these limited field trials after a one year plant back interval, labels will be required to be adjusted to restrict rotation of crops to not less than one year plant back.

Data Gaps

Toxicology:

- 870.5550 – Unscheduled DNA Synthesis in Mammalian Cells in Culture

Residue Chemistry:

- 860.1340 - Independent Laboratory Validation (ILV) study for Method A9202

- 860.1900 – Field Accumulation in Rotational Crops Study

Ecological effects:

- None (72-3A) – Estuarine/marine Fish Acute Toxicity Test
- 850.1020 – Gammarid Acute Toxicity Test
- 850.1025 – Estuarine/marine Mollusk (Oyster) Acute Toxicity Test (Shell Deposition)
- None (72-3F) – Estuarine/marine Myside Acute Toxicity Test
- 850.1045 – Penaeid Acute Toxicity Test
- 850.1300 – Daphnid Chronic Toxicity Test
- 850.1350 – Mysid Chronic Toxicity Test
- 850.1400 – Early-life Stage, Freshwater Fish
- 850.1450 – Early-life Stage Estuarine Fish
- 850.1500 – Fish Life Cycle Study
- 850.2300 – Avian Reproduction Test, Bobwhite Quail
- 850.2300 – Avian Reproduction Test, Mallard Duck

Conclusions

The Agency is issuing this Reregistration Eligibility Document (RED) for pyrazon, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for complying with any required label changes for products containing pyrazon. The Agency has determined that all currently registered uses of pyrazon are eligible for reregistration.

The risk assessments for pyrazon are based on the best scientific data currently available to the Agency and are adequate for regulatory decision making.

There is a 60-day public comment period for this document.

Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in the Risk Mitigation Summary section. The following table describes how language on the labels should be amended.

Table 3. Summary of Labeling Changes for Pyrazon

Description	Amended Labeling Language	Placement on Label
End Use Products Intended for Occupational Use		
Handler PPE requirements established by the RED[1] for all pyrazon products	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are" (*registrant inserts correct chemical-resistant material*). "If you want more options, follow the instructions for category" *[registrant inserts A,B,C,D,E,F,G,or H]* "on an EPA chemical-resistance category selection chart." "All mixers, loaders, applicators, and other handlers must wear: - long-sleeved shirt, - long pants, - shoes and socks."	Precautionary Statements
User Safety Requirements	*If coveralls are not on label, use the following statement:* "Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

Description	Amended Labeling Language	Placement on Label
Engineering Controls	"Pilots must use an enclosed cockpit that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(6)]."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements)
User Safety Recommendations	"User Safety Recommendations Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing*. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)

Description	Amended Labeling Language	Placement on Label
Environmental Hazards	"Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate." "Do not contaminate water used for irrigation or domestic purposes." "Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas." "Pyrazon is known to leach through soil into ground water under certain conditions as a result of label use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment established by the RED.	For minimum early entry PPE use the following: "PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: * coveralls, * shoes plus socks, * chemical-resistant gloves made of any waterproof material"	Direction for Use Agricultural Use Requirements box

Description	Amended Labeling Language	Placement on Label
General Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Direction for Use directly above the Agricultural Use Requirements Box.
Other Application Restrictions (Risk Mitigation)	"Do not apply this product through any type of irrigation system." Delete any application instructions referring to use with irrigation equipment. "The following rotational crops may be planted 1 year after the last application of pyrazon: Beans, Corn, Soybeans and Wheat."	Directions for Use

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.
[2] If the product contains oil or bears instructions that will allow application with an oil-containing material, the "N" designation must be dropped.

Appendices

Appendix A. Use Patterns Subject to Reregistration for Pyrazon (Case 2570)					
Site Application Timing Application Type Application Equipment	Maximum Single Application Rate (lb a.i./A)	Maximum Number of Applications Per Year	Maximum Yearly Rate (lb a.i./A)	Restricted Entry Interval (Hours)	Use Directions and Limitations
Red Table Beet					
Early postemergence Soil band treatment/Soil broadcast treatment Band sprayer/Sprayer	3.7	NS	7.3	12	Do no apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system. Do not apply to sandy soils. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water intended for irrigation or domestic purposes.
Preemergence Soil band treatment/Soil broadcast treatment Band sprayer/Sprayer	3.7	NS	7.3	12 h	
Sugar Beet					
Postemergence Soil broadcast treatment Sprayer	3.7	NS	7.6	12 h (?)	See red table beet.
Preemergence Broadcast/Soil band treatmet/Soil broadcast treatment Band sprayer/Ground/Sprayer	7.6	NS	7.6	12 h Geographic allowable: CA, CO, ID, KS, MI, MN, MT, ND, NE, OH, OR, TX, UT, WA, WY	
Preplant Soil band treatment/Soil in-furrow treatment/Soil incorporated treatment Soil incorporation equipment	3.67	NS	7.6	12 (h) Incorporate to a depth of 2 inches	

Site Application Timing Application Type Application Equipment	Maximum Single Application Rate (lb a.i./A)	Maximum Number of Applications Per Year	Maximum Yearly Rate (lb a.i./A)	Restricted Entry Interval (Hours)	Use Directions and Limitations
Ornamental					
Pre-/Postemergence Ground sprayer or handheld (i.e., knapsack) equipment	1.7 to 5.0	NS	NS		Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply through any type of irrigation system.[1] Do not apply to sandy soils. Do not contaminate water by cleaning of equipment or disposal of equipment wash waters. Do not contaminate water intended for irrigation or domestic purposes.

NS = Not specified (on label)

Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the case Pyrazon covered by this RED. In contains generic data requirements that apply nitrapyrin in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following formats:

1. Data requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which is available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.

   A. Terrestrial food
   B. Terrestrial feed
   C. Terrestrial non-food
   D. Aquatic food
   E. Aquatic non-food outdoor
   F. Aquatic non-food industrial
   G. Aquatic non-food residential
   H. Greenhouse food
   I. Greenhouse non-food
   J. Forestry
   K. Residential
   L. Indoor food
   M. Indoor non-food
   N. Indoor medical
   O. Indoor residential

3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number is no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Appendix B. Data Supporting Guideline Requirements for the Reregistration of Pyrazon

New Guideline Number	Old Guideline Number	Description	Use Patterns	Citations
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	All	41891101
830.1600	61-2A	Description of materials used to produce the product	All	41891101
830.1620	61-2B	Description of production process	Al	40817301, 41891101
830.1670	61-2B	Formation of Impurities	All	41891101
830.1700	62-1	Preliminary Analysis	All	40817302, 41891102
830.1750	62-0	Certification of Limits	All	41891101, 41891102
830.1800	62-3	Analytical Method	All	40817303, 41891102
830.6302	63-2	Color	All	42027501, 41609801
830.6303	63-3	Physical State	All	42027501, 41609801
830.6304	63-4	Odor	All	42027501, 41609801
830.6313	63-13	Stability to normal and elevated temperatures, metals, and metal ions	All	41891104, 41609801
830.7000	63-12	pH	All	42027501, 41609801
830.7050	None	UV/Visible Absorption	All	Data gap
830.7200	63-5	Melting Point	All	41609801
830.7300	63-7	Density	All	42027501, 41609801
830.7370	63-10	Dissociation Constants in Water	All	42027501, 41609801
830.7550	63-11	Partition coefficient, shake flask method	All	40817304, 41609801
830.7840	63-8	Solubility	All	40817304, 41507901, 41891103, 41609801
830.7950	63-9	Vapor Pressure	All	40817304, 41507902, 41609801
ECOLOGICAL EFFECTS				
850.2100	71-1A	Avian Acute Oral Toxicity		41609802
850.2200	71-2A	Avian Dietary Toxicity – Quail		41609803
850.2200	71-2B	Avian Dietary Toxicity – Duck		41609804
850.2300	71-4A	Avian Reproduction - Quail		Data gap
850.2300	71-4B	Avian Reproduction – Duck		Data gap
850.1075	72-1A	Fish Toxicity Bluegill		41609805
850.1075	72-1C	Freshwater Fish Toxicity Rainbow Trout		41609806, 45628012
850.1075	72-1D	Freshwater Fish Toxicity Rainbow Trout – TEP		
850.1010	72-2A	Freshwater Invertebrate Toxicity		41609807, 45628011
850.1020	None	Gammarid Acute Toxicity Test		Data gap
850.1075	72-3A	Estuarine/Marine Toxicity – Fish		Data gap
850.1025	72-3B	Estuarine/Marine Toxicity – Mollusk		Data gap
850.1035	72-3C	Estuarine/Marine Toxicity – Shrimp		Data gap
850.1045	72-3	Panaeid Acute Toxicity Test		Data gap
850.1300	72-4A	Daphnid Chronic Toxicity Test		Data gap
850.1350	72-4B	Estuarine/Marine Invertebrate Life Cycle		Data gap

New Guideline Number	Old Guideline Number	Description	Use Patterns	Citations
850.1400	72-4C	Early-life Stage Freshwater Fish		Data gap
850.1450	72-4D	Estuarine/Marine Fish Early-Life Stage		Data gap
850.1500	72-5	Fish Life Cycle Toxicity		Data gap
850.4225	123-1A	Seedling Germination and Seedling Emergence, Tier 2		41681501
850.4250	123-1C	Vegetative Vigor, Tier 2		41681502
850.4400	123-2	Aquatic Plant Toxicity		41644801
850.5400	122-2B	Aquatic Plant Growth, Tier 2		41644801
850.6200	None	Earthworm Toxicity		45628009
TOXICOLOGY				
870.1100	81-1	Acute Oral Toxicity - Rat		41507903, 40282005, 42624907, 00047318, 00116308, 40126808
870.1200	81-2	Acute Dermal Toxicity – Rabbit/Rat		00116308, 41507904
870.1300	81-3	Acute Inhalation Toxicity – Rat		41507905
870.2400	81-4	Primary Eye Irritation - Rabbit		00116308, 41507906
870.2500	81-5	Primary Skin Irritation		41507907
870.2600	81-6	Dermal Sensitization		41507908
870.3100	82-1A	Subchronic Oral Toxicity: 90-Day Study Rodent		41992701
870.3150	82-1B	Subchronic Oral Toxicity: 90-Day Study Non-rodent		42903401
870.3200	82-2	21-Day Dermal – Rabbit/Rat		42331101
	83-1A	Chronic Feeding Toxicity - Rat		42903404
870.4100	83-1B	Chronic Feeding Toxicity – Non-rodent		42903402, 42903403
870.3700A	83-3A	Developmental Toxicity – Rat		41992702
870.3700B	83-3B	Developmental Toxicity – Rabbit		41507909
870.3800	83-4	2-Generation Reproduction – Rat		42903407
870.4100A	83-1A	Chronic Feeding Toxicity Study – Rat		42903404
870.4100B	83-1B	Chronic Feeding Toxicity Study - Non-rodent		42903402, 42903403
870.4200	83-2A	Carcinogenicity Rat		43815602
870.4200	83-2B	Carcinogenicity Mice		42903405, 42903406
870.4300	83-5	Combined Chronic Toxicity/Carcinogenicity: Rats		42903404, 43815602
870.5100	84-2	Bacterial Reverse Gene Mutation		41507910
870. 5395	84-2	In Vitro Mammalian Cytogenetics Tests		41507911
870.5550	84-2	Unscheduled DNA Synthesis in Mammalian Cells in Culture		Data gap
870.7485	85-1	General Metabolism		41992703
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis		41507913
835.2240	161-2	Photodegradation - Water		41507914
835.2410	161-3	Photodegradation - Soil		41507915, 42672301
835.4100	162-1	Aerobic Soil Metabolism		41507916, 42027502
835.4200	162-2	Anaerobic Soil Metabolism		41507917

New Guideline Number	Old Guideline Number	Description	Use Patterns	Citations
835.4400	162-3	Anaerobic Aquatic Metabolism		41507917
835.4300	162-4	Aerobic Aquatic Metabolism		41507916
835.1240	163-1	Leaching/Adsorption/Desorption		41507918, 42027503
835.6100	164-1	Terrestrial Field Dissipation		42230801, 42230802, 42458001
RESIDUE CHEMISTRY				
860.1300	171-4A	Nature of Residue – Plants		42672302
860.1300	171-4B	Nature of Residue – Livestock		42184101, 42546301, 42027504, 42027505, 42920709, 42964501, 43223501, 44047805
860.1340	171-4C	Residue Analytical Method – Plants		43223502, 44047801, 44047802
860.1340	171-4D	Residue Analytical Method - Livestock		44047803, 44047804
860.1380	171-4E	Storage Stability		
		Plant commodities		43635801, 44021801
		Animal commodities		42964501, 42920709, 43223501
860.1500	171-4K	Crop Field Trials		
		Garden beet		42920705, 42920706, 43302201, 43319701
		Sugar beet		42920701, 42920702, 42920703
860.1360	171-4M	Multi-residue Methods		42331102
860.1480	171-4J	Magnitude of Residue in Meat, Milk, Poultry and Eggs		44047806
850.1650	171-13	Analytical Reference Standards		Data gap
860.1850	165-1	Confined Accumulation in Rotational Crops		42627801, 43374301
860.1520	171-4L	Magnitude of Residue in Processed Food/Feed		42920708
860.1900	165-2	Field Accumulation in Rotational Crop Study		44047807, 44121601
OTHER				
885.4380	154A-24	Honey Bee Testing, Tier 1		41609811

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in Room 119, Crystal Mall 2, 1801 S. Bell Street, Arlington, VA. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4:30 PM.

The pyrazon docket contains this RED document and the supporting risk assessments. The documents can be accessed in the docket room or downloaded or viewed via the Internet at the following website:

http://www.epa.gov/pesticides/reregistration/status.htm.

These documents include:

HED Documents:

- Pyrazon: HED Chapter of the Reregistration Eligibility Decision Document (RED). (Stanton, Susan. 7/28/2005)

- Pyrazon RED – Reregistration Eligibility Decision. Product Chemistry Considerations. (Soderberg, David. 7/27/2005)

- Pyrazon. Reregistration Eligibility Decision (RED). Summary of Analytical Chemistry and Residue Data. (Soderberg, David. 7/28/2005)

- Pyrazon: Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document. (Britton, Wade. 7/28/2005)

- Review of Pyrazon Incident Reports. (Blondell, Jerome. 7/5/2005)

EFED Documents:

- Pyrazon Screening Level Ecological Risk Assessment for the Re-registration Decision. (Jenkins, Fred. 8/16/2005)

- Appendices to the "Pyrazon Screening Level Ecological Risk Assessment for the Re-registration Decision." (Jenkins, Fred. 8/16/2005) (Because the appendices are over 400 pages long, they are available upon request only. Anyone requesting a copy should contact the Chemical Review Manager for pyrazon.)

Appendix D. Citations Considered to be Part of the Database Supporting the Reregistration Eligibility Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selection from other sources, including published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them a s single studies.

3. IDENIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entrie s. This temporary identifying number is also used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix, which shows the relative position of the study within the volume.

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Appendix E. Generic Data Call-In

The Generic Data Call-In will be posted at a later date.

Appendix F. Product Specific Data Call-In

The product specific Data Call-In will be posted at a later date.

A**ppendix G. EPA's Batching of Nitrapyrin Products for Meeting Acute Toxicity Data Requirements for Reregistration**

EPA'S BATCHING OF NITRAPYRIN PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing pyrazon as the active ingredient, the Agency generally batches products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

A batching appendix for pyrazon was not performed. Considering both inert and active ingredients, none of the three product formulations evaluated were considered similar for purposes of sharing acute mammalian toxicity data. Notwithstanding the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product, should the need arise.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Appendix H. List of Registrants Sent This Data Call-In

A list of registrants sent this Data Call-In will be posted at a later date.

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:

http://www.epa.gov/opprd001/forms/

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet:
at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf

8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit www.epa.gov/pesticides/registrationkit/

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

   a. 83-3 Label Improvement Program – Storage and Disposal Statements
   b. 84-1 Clarification of Label Improvement Program
   c. 86-5 Standard Format for Data Submitted under FIFRA
   d. 87-1 Label Improvement Program for Pesticides Applied Through Irrigation Systems (Chemigation)
   e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
   f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
   g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
   h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires Acrobat reader.)

Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_NoticesPesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).

a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
b. EPA Form No. 8570-4, Confidential Statement of Formula
c. EPA Form No. 8570-27, Formulator's Exemption Statement
d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).

a. Registration Division Personnel Contact List
b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
c. Antimicrobials Division Organizational Structure/Contact List
d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)
f. 40 CFR Part 158, Data Requirements for Registration (PDF format)
g.. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)
5285 Port Royal Road
Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their website: ace.orst.edu/info/nptn.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

1. Date of receipt;
2. EPA identifying number; and
3. Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.

Documents Associated with this RED

The following documents are part of the Administrative Record for this RED document and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the respective Chemical Status Sheet.

1. Health Effects Division and Environmental Fate and Effects Division Science Chapters, which include the complete risk assessments and supporting documents.
2. Detailed Label Usage Information System (LUIS) Report.