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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: **Cholecalciferol:** Draft Ecological Risk Assessment for Registration Review

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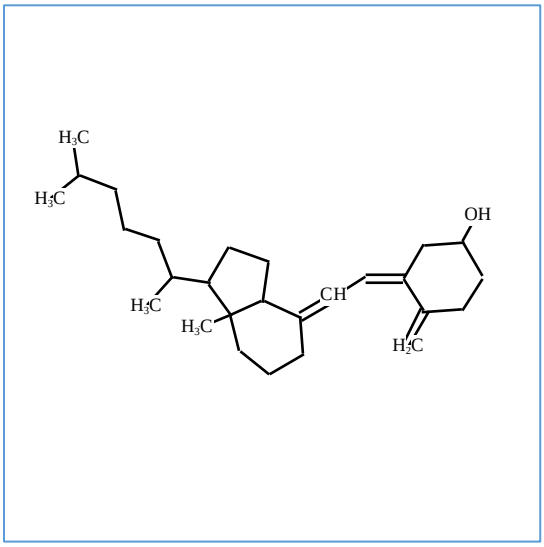
The Environmental Fate and Effects Division (EFED) has completed the draft environmental fate and ecological risk assessment in support of the Registration Review of the rodenticide cholecalciferol.

Draft Ecological Risk Assessment for the Registration Review of Cholecalciferol



Cholecalciferol; CAS No 67-97-0
USEPA PC Code: 202901

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1 Executive Summary

1.1 Overview

This document provides the draft risk assessment (DRA) for cholecalciferol. Cholecalciferol (3β,5*Z*,7*E*)-9,10-secocholesta-5,7,10(19)-trien-3-ol), a sterol also known as vitamin D_3, is used as a rodenticide and was first registered in the U.S. in 1984. Cholecalciferol is used to control Norway rats (*Rattus norvegicus*), roof rats (*Rattus rattus*), and house mice (*Mus musculus*). Ingestion results in hypercalcemia due to mobilization of calcium from bone matrix into blood plasma (Pelfrene, 1991) leading to metastatic calcification of soft tissues (Frazer, 1995).

1.2 Risk Conclusions Summary

This DRA examines the potential ecological risks associated with labeled uses of cholecalciferol as a rodenticide to non-target organisms not listed as Federally threatened or endangered species. The risk assessment uses a streamlined approach to focus on the taxa of primary risk concern based on previously completed risk assessments, and also taxa for which additional data have become available. Taxa of focus in this assessment include birds and mammals. Other non-target plants and animals, including aquatic organisms, terrestrial plants and terrestrial invertebrates are not expected to be at risk from use of cholecalciferol due to a lack of exposure.

Exposure to non-target birds and mammals is expected to be minimal when cholecalciferol is used according to label instructions (*i.e.*, mandatory placement of bait blocks inside tamper-proof bait stations or below-ground placement of pellets inside rodent burrows with mandatory retrieval of unconsumed bait). Although label language may help to reduce the likelihood of chronic exposure for non-target organisms (*e.g.*, birds and mammals), the label statements do not preclude such exposure. Since chronic toxicity data are not available, the likelihood of adverse effects from exposure to cholecalciferol cannot be fully characterized based on the available data.

Consistent with the use of the compound as a rodenticide, acute risk quotients (RQs) exceed the acute risk level of concern (LOC) of 0.5 for mammals. However, acute RQs for birds, which serve as surrogates for reptiles and terrestrial-phase amphibians, do not exceed the acute risk LOC. These risk conclusions are somewhat uncertain due to a lack of chronic toxicity data for birds and mammals.

Registrants of cholecalciferol have reported a substantial number of incidents of domestic animal poisoning for cholecalciferol. Between 1997 and 2019, there were 282 domestic animal incidents reported to EPA, although details are not available.

Risk to aquatic organisms was not assessed since the likelihood of exposure to cholecalciferol from the registered uses is considered low. Risks to terrestrial plants was not estimated due to the lack of toxicity data; however, the likelihood of exposure of terrestrial plants to cholecalciferol is expected to be low. Although pellets placed in rodent burrows may be near the root zones of terrestrial plants, it is uncertain as to the extent to which cholecalciferol will be taken up by plant roots. Similarly, risk to terrestrial invertebrates was not calculated due to the low likelihood of exposure given the use of cholecalciferol in bait stations or placement in rodent burrows where bees would not likely be attracted to the product. Although ground nesting bees could be potentially exposed, the likelihood that bees would be living in active rodent burrows is considered low. Potential risks to terrestrial invertebrates (*e.g.*, carrion beetles) through ingestion of residues in rodents killed by the compound is uncertain.

Table 1-1. Summary of Risk Quotients (RQs) across Taxonomic Groups from Current Uses of Cholecalciferol.

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Freshwater fish	Acute	Not calculated	No	Aquatic exposure is not expected based on the physical and chemical properties of cholecalciferol (such as low solubility) and its use pattern (mandatory use of tamper-proof bait stations or placement of pellets in underground burrows).
	Chronic			
Estuarine/ marine fish	Acute			
	Chronic			
Freshwater invertebrates	Acute			
	Chronic			
Estuarine/ marine invertebrates	Acute			
	Chronic			
Aquatic Plants	N/A			
Mammals	Acute	**2.3-24.4**	Yes	Dose-based acute RQs exceed the LOC for non-target mammals; dietary risks indicate <1% of daily diet to reach LD_{50}.
	Chronic	Not Calculated	--	No chronic toxicity data for mammals are available; however, the likelihood of exposure of non-target mammals to treated bait is expected to be low. However, it is possible for small mammals to potentially access bait stations or pellets placed in underground burrows or for larger mammals to feed on rodents killed by the compound (secondary exposure).

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Birds	Acute	<0.1	No	--
	Chronic	Not Calculated	--	No chronic toxicity data for birds are available; however, the likelihood of exposure for birds to treated bait is expected to be low. It is possible though for birds to access pellets placed in underground burrows or for larger birds to feed on rodents killed by the compound (secondary exposure).
Terrestrial invertebrates	Acute Adult	Not calculated	--	Acute oral toxicity data are available for adult bees; the compound is classified as practically non-toxic to bees. No additional data are available for acute contact or chronic oral toxicity for adult bees or acute/chronic toxicity to larval bees. Exposure for bees is expected to be low though due to placement of treated bait in bait stations. While placement of treated pellets in rodent burrows could serve as a route of exposure for ground-nesting bees, the likelihood of exposure is considered low since bees would not be attracted to the bait, label instructions stipulate that unconsumed bait be collected, and the likelihood that bees would nest in an active rodent burrow is considered low.
	Chronic Adult			
	Acute Larval			
	Chronic Larval			
Terrestrial plants	N/A	Not calculated	--	No data are available.

Level of Concern (LOC) Definitions:
Terrestrial Animals: Acute=0.5; Chronic=1.0; Terrestrial invertebrates: Acute=0.4; Chronic=1.0; Aquatic Animals: Acute=0.5; Chronic=1.0; Plants: 1.0
N/A: Not applicable
[1] RQs reflect exposure estimates for maximum application rates allowed on labels.

1.3 Environmental Fate and Exposure Summary

The environmental fate database is incomplete. However, while no data have been submitted, the estimated physical/chemical properties of cholecalciferol and its limited use (in bait stations or placement of pellets in underground burrows) indicate that its use is not expected to result in aquatic exposure. Thus, environmental fate data for use as inputs to aquatic exposure modeling are not needed for risk assessment at this time. Based on estimated environmental fate properties, cholecalciferol is a nonvolatile compound that is relatively immobile and

potential aquatic exposure is assumed to be negligible. Thus, risk to aquatic organisms was not assessed in this document.

1.4 Ecological Effects Summary

The toxicity profile for birds and mammals is incomplete. While acute toxicity data for birds and mammals are available, chronic toxicity data consistent with EPA study guidelines are lacking.

Cholecalciferol is highly toxic to rats on an acute oral exposure basis (MRID 42725701). Chronic mammalian guideline toxicity data are not available. Cholecalciferol is practically non-toxic to birds on an acute oral exposure basis (MRID 50844602 and 50844603). While chronic avian guideline toxicity data are not available, in an effort to limit chronic exposure, the label specifies that bait can only be placed in tamper-proof containers or well within rodent burrows and that unconsumed bait must be retrieved.

No toxicity data for aquatic organisms have been submitted for cholecalciferol. However, due to the low solubility of the compound and the registered uses in bait stations and within rodent burrows, the compound is unlikely to move into surface or ground water.

There are limited data to assess potential risk to predators or scavengers that may consume mammals containing cholecalciferol residues (secondary toxicity); however, additional information on secondary toxicity is available in the published literature indicating that the risk to birds and mammals from secondary poisoning with cholecalciferol is expected to be low.

Finally, no toxicity data are available for terrestrial plants. Cholecalciferol is practically non-toxic to honey bees (*Apis mellifera*) on an acute oral exposure basis.

1.5 Identification of Data Needs

In response to the Generic Data Call-in notice (GDCI-202901-1621) issued in support of the Registration Review of cholecalciferol, waiver requests for studies on avian sub-acute dietary toxicity (850.2200), avian reproduction toxicity (850.2300), mammalian metabolism and pharmacokinetics (*i.e.*, OCSPP 870.7485) and prenatal developmental toxicity (*i.e.*, OCSPP 870.3700) were submitted by the technical registrant BASF Corporation. For all of the waiver requests except the avian reproduction study, EFED believes that the waivers are supported by the scientific rationale provided by the registrant. As a result, at this time, only avian reproduction toxicity data are outstanding for cholecalciferol.

Also, in 2017, EFED identified a data gap for terrestrial invertebrates, and recommended a non-guideline study on the acute oral toxicity of cholecalciferol to adult honeybees. However, a

study has been identified in the peer-reviewed scientific literature which addresses the data gap and indicates that cholecalciferol is practically non-toxic to honeybees on an acute oral exposure basis. Therefore, EFED is no longer recommending honeybee acute oral toxicity data on cholecalciferol.

2 Introduction

This Draft Risk Assessment (DRA) examines the potential ecological risks associated with labeled uses of cholecalciferol on non-listed non-target organisms. Federally listed, threatened and/or endangered species ("listed") are not evaluated in this document. The DRA uses the best available scientific information on the use, environmental fate and transport, and ecological effects of cholecalciferol. The general risk assessment methodology is described in the *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs* ("Overview Document") (USEPA, 2004). Additionally, the process is consistent with other guidance produced by the Environmental Fate and Effects Division (EFED) as appropriate. When necessary, risks identified through standard risk assessment methods are further refined using available models and data. This risk assessment incorporates the available exposure and effects data and most current modeling and methodologies.

The Food Quality Protection Act (FQPA) requires EPA to screen pesticide chemicals for their potential to produce effects similar to those produced by estrogen in humans and gives EPA the authority to screen certain other chemicals and to include other endocrine effects. In response, EPA developed the Endocrine Disruptor Screening Program (EDSP), additional information on the EDSP is available in Error! Reference source not found..

3 Problem Formulation Update

The purpose of problem formulation is to provide the foundation for the environmental fate and ecological risk assessment being conducted for the labeled uses of cholecalciferol. The problem formulation identifies the objectives for the risk assessment and provides a plan for analyzing the data and characterizing the risk. As part of the Registration Review (RR) process, a detailed preliminary Problem Formulation (PF) (USEPA 2016) for this DRA was published to the docket in June of 2016.

In 2004, cholecalciferol was included in a comparative risk assessment conducted by EPA for nine rodenticides to evaluate the potential for rodenticide bait products to pose ecological risks to non-target birds and mammals (USEPA 2004). In that assessment, it was concluded that the likelihood of adverse effects on birds from direct exposure to baits was low; however, there were risks of concern for mammals from direct exposure to treated baits. For secondary risks (*i.e.*, through the consumption of residues in prey impaired or killed by cholecalciferol), there were insufficient data with which to support a risk conclusion. However, additional information

on secondary toxicity is available in the published literature indicating that the risk to birds and mammals from secondary poisoning with cholecalciferol is expected to be low.

In 2011, EFED completed an assessment for the federally listed endangered Salt Marsh Harvest Mouse (*Reithrodontomys raviventris*) (USEPA 2011). In that assessment, it was determined that acute and chronic direct and indirect effects to small mammals were likely to adversely affect (LAA) the listed mouse species; however, the assessment concluded that there was no potential adverse effects to birds, terrestrial invertebrates, terrestrial and aquatic plants from the use of cholecalciferol as a bait for rat and mouse control in and around buildings and in alleys and transport vehicles. In addition to direct adverse effects on the SMH mouse, the assessment also concluded that the use of cholecalciferol may adversely modify the habitat of the listed species by reducing the availability of nest sites on which the animal depends.

After the preliminary Problem Formulation (USEPA 2016), a Generic Data Call-In (GDCI-202901-1621) was issued and required several ecotoxicity studies for cholecalciferol that included:

- OCSPP 850.2100: Acute Avian Oral Toxicity with both an upland game bird, a waterfowl species and a passerine species:
- OCSPP 850.2200: Avian Dietary Toxicity with an upland game bird and a waterfowl species;
- OCSPP 850.2300: Reproductive Toxicity studies with an upland game bird and a waterfowl species;
- OCSPP 870.7485: Metabolism and Pharmacokinetics; and,
- OCSPP 870.3700 Prenatal Developmental Toxicity Study.

The preliminary Problem Formulation recommended an acute oral toxicity study with honey bees. However, after completion of the preliminary Problem Formulation, a study was identified in the peer-reviewed scientific literature (Booth *et al.*, 2004) indicating cholecalciferol is practically non-toxic to honey bees on an acute oral exposure basis. Therefore, the submission of an acute oral honey bee toxicity study was no longer required.

In response to EPA's request for data, the registrant submitted additional toxicity data for birds including:

- OCSPP 850.2100: Acute avian oral toxicity with bobwhite quail (MRID 50844602);
- OCSPP 850.2100: Acute avian oral toxicity with mallard duck (MRID 50844603); and,
- OCSPP 850.2200: Avian subacute dietary toxicity with mallard duck (MRID 50844604).

These new data are described in more detail in the Ecotoxicity Summary section (**Section 6)**.

However, avian reproduction toxicity data were not submitted.

For the two other Data Call-In (DCI) requirements (*i.e.*, metabolism and pharmacokinetics of mammals (OCSPP 870.7485) and prenatal developmental toxicity study (OCSPP 870.3700) a summary of available mammalian metabolism data was submitted and was considered sufficient for understanding the metabolism and chronic effects in mammals. Therefore, EFED recommended waiving the additional mammalian toxicity data.

As summarized in the preliminary Problem Formulation, based on previous risk assessments and the potential exposure pathways for non-target organisms, this assessment focuses on potential risks to birds and mammals; whereas, exposure and hence risk to all other non-target organisms are assumed to be low.

3.1 Mode of Action for Target Pests

Cholecalciferol (3β,5*Z*,7*E*)-9,10-secocholesta-5,7,10(19)-trien-3-ol), a sterol also known as vitamin D_3, is used as a rodenticide for commensal rodents (rats and mice). Its ingestion results in hypercalcemia from mobilization of calcium from bone matrix into blood plasma (Pelfrene, 1991) leading to metastatic calcification of soft tissues (Frazer, 1995). In mammals, cholecalciferol is metabolized (hydroxylated) in the liver to 25-hydroxycholecalciferol and is further metabolized (hydroxylated) in the kidney to form 1α, 25-dihydroxycholecalciferol (calcitriol) which is the most hormonally active form of the compound (Fraser 1995). Calcitrol in turn increases absorption of renal calcium ion, intestinal calcium ion, and phosphate ion. Death is from hypercalcemia, which results 3-4 days after ingestion of lethal dose; unlike many other rodenticides, cholecalciferol is not a blood anticoagulant (USEPA, 2015).

3.2 Label and Use Characterization

3.2.1 Label Summary

Cholecalciferol is a rodenticide registered for use in controlling commensal rodents [specifically Norway rats (*Rattus norvegicus*), roof rats (*Rattus rattus*), and house mice (*Mus musculus*)] and was first registered in the U.S. in 1984. Cholecalciferol is formulated into pellets and bait blocks. It must be placed inside tamper-proof bait stations if used above ground. In the pellet form it can also be used outdoors if placed in underground rat burrows, at least 6” inside the burrow entrance. Cholecalciferol is registered for use in and around homes, industrial and agricultural

structures, transportation vehicles, and 'man made structures' (*e.g.*, trash receptacles) (USEPA, 2015).

Cholecalciferol is currently formulated into 13 end-use products (each contains 0.075% cholecalciferol). Each of the products had their labels revised in 2012 and include the statement, "*Bait stations are mandatory for outdoor, above-ground use. Tamper-resistant bait stations must be used if children, pets, non-target mammals, or birds may access the bait*." As per label restrictions, cholecalciferol may not be applied by broadcast.

Label use directions specify:

- Outdoor use must be within 100 ft of man-made structures;
- For underground rodent burrows, the bait must be placed no less than 6 inches into burrows;
- May not be broadcast;
- 2 – 8 oz of bait per placement at intervals of 15 – 30 ft;
- Maintain uninterrupted supply for 7-15 days or until there is no sign of active feeding;
- Replace contaminated or spoiled bait immediately;
- Collect and dispose of all dead, exposed animals or leftover bait.

Also, the environmental hazard statement of the label indicates that the product is toxic to fish, birds and other wildlife and that predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait.

Regarding long-term exposure, while design restrictions of bait stations may limit the availability of the bait for non-target organisms on an acute exposure basis, potential exposure over a longer duration may occur. Several labels indicate the need to maintain fresh bait for at least 7 days and at least 15 days for some target pests or until there are no longer signs of new feeding by rodents. This suggests that bait may be available for longer periods and that prolonged exposure may occur through repeated applications. Also, it is possible that the bait may be placed in different structures in a given area over time which could allow for exposure over a longer time period.

Table 3-1. Summary of the Maximum Labeled Use Patterns for Cholecalciferol

Use Site/ Location	Form[1]	% a.i.	mg a.i./kg bait	Maximum Application Rate per Bait Placement[1]	Bait Placement Interval[2]
Bait for rats and mice in and around buildings, industrial and agricultural	Pellets and bait blocks	0.075	750	8 oz bait (170 mg a.i.) (rats)	15-30 ft (rats) 8-12 ft (mice)

Use Site/ Location	Form[1]	% a.i.	mg a.i./kg bait	Maximum Application Rate per Bait Placement[1]	Bait Placement Interval[2]
structures, transportation vehicles, and trash receptacles	in bait stations			1 oz bait (21.3 mg a.i.) (mice)	

[1] 1 oz bait = 28,350 mg *0.00075 = 21.3 mg a.i.

[2] The maximum amount of active ingredient per linear foot is 11.3 mg/ft for rats and 2.66 mg/ft for mice.

3.2.2 Usage Summary

The Biological and Economic Analysis Division (BEAD) Chemical Profile (BCP) indicates that there is no available usage information for cholecalciferol. (USEPA, 2015).

3.2.3 Label Uncertainties

Labels for cholecalciferol products do not limit the amount of product or active ingredient that may be applied per unit area, the number of applications that can be made per unit time, nor the minimal time interval between applications. Labels generally state the number of bait stations or bait blocks that may be placed in one location as well as the linear interval between placements. The linear interval is generally 15 to 30 feet for rats and 8 to 12 feet for mice. Also, labels don't limit the amount of pelleted bait placed in underground burrows or whether applicators must retrieve unconsumed pellets before placing fresh pellets.

4 Residues of Concern

The stressor of concern (*i.e.*, the compound introduced into the environment) for this assessment is defined as the parent compound only (*i.e.*, cholecalciferol). Since there are no environmental fate data, and estimations of the physical/chemical properties of the parent compound have been made, there are no data on potential environmental degradates of cholecalciferol.

5 Environmental Fate Summary

The environmental fate of cholecalciferol [(3β,5*Z*,7*E*)-9,10-secocholesta-5,7,10(19)-trien-3-ol] is not well-described as no environmental fate data have been submitted to the Agency for this pesticide. The physical/chemical properties of cholecalciferol were estimated using the quantitative structure-activity relationship (QSAR) Estimation Program Interface EPISuite™ (U.S. EPA, 2011) predictive models. A selection of the estimated environmental fate and transport properties of cholecalciferol is summarized **Table 5-1**. (See **Appendix B** for EpiSuite™ Output).

Cholecalciferol is a nonvolatile (2.4×10^{-9} Torr at 25 °C) compound that is essentially insoluble in water (2.2×10^{-5} mg/L at 25°C). With an estimated soil organic carbon-normalized partition coefficient (K_{oc}) of 1.5×10^{6} L/kg, the compound is expected to be immobile in soil based on the Food and Agriculture Organization (FAO) mobility classification scheme (FAO 2000). While volatilization from moist soil or water surfaces could be a more important fate process based on the estimated Henry's Law Constant of 2.3×10^{-4} atm-m^3/mole, the high tendency for sorption to soil would make this route of transport unlikely.

Environmental fate and degradation data are not available. Because cholecalciferol is not soluble and the compound readily sorbs to organic matter, and since the compound is applied as a bait only, the potential for runoff and spray drift is considered low.

Additionally, cholecalciferol bait pellets must be used inside rodent burrows (no broadcast treatment is allowed) or must be placed in bait stations. Therefore, the potential for contaminating surface water or groundwater is assumed to be low. Furthermore, since the active ingredient is often placed in highly hydrophobic, weather-resistant blocks, overall volatilization from the bait is also expected to be insignificant.

Table 5-1. Summary of Physical-Chemical, Sorption, and Bioconcentration Properties of Cholecalciferol.

Parameter	Value[1]	Source/ Study Classification/ Comment
Molecular Weight (g/mole)	384.64	--
Water Solubility at 25°C mg/L	2.2×10^{-5} mg/L	Estimated using EPISuite™ Ver 4.11.
Vapor Pressure (torr)	2.4×10^{-9} 25 °C	
Henry's Law constant at 25°C (atm-m^3/mole)	2.3×10^{-4}	
Log octanol-water partition coefficient (log K_{ow}) (unitless)	10.2	
Air-water partition coefficient (log K_{AW}) (unitless)	12.3	
Organic carbon normalized distribution coefficients (Koc in L/kg-organic carbon)	1.5×10^{6}	
Steady State Bioconcentration Factor (BCF) L/kg-wet weight fish or L/kg wet weight lipid	30	
Log Dissociation Constant (pKa)	N/A	

[1]All estimated values were calculated according to "*Guidance for Reporting on the Environmental Fate and Transport of the Stressors of Concern in Problem Formulations for Registration Review, Registration Review Risk Assessments, Listed Species Litigation Assessments, New Chemical Risk Assessments, and Other Relevant Risk Assessments*" (USEPA, 2010a).

6 Ecotoxicity Summary

Ecological effects data are used to estimate the toxicity of cholecalciferol to surrogate species. The toxicity profile for birds and mammals is not complete. While acute toxicity data for birds and mammals are available, chronic guideline toxicity data are lacking; however, data are available in the open literature to enable some characterization of chronic toxicity.

Ecotoxicity data for cholecalciferol and its associated products have been reviewed previously in multiple ecological risk assessments (USEPA, 2004) (USEPA, 2011) and in a preliminary Problem Formulation for Registration Review (USEPA, 2016, D431580). These data are summarized below. Various studies with birds exposed to cholecalciferol have been submitted since the preliminary Problem Formulation was issued in 2016; the results of these studies are described briefly in this section**.**

A search of the public ECOTOXicology (ECOTOX; https://cfpub.epa.gov/ecotox/) Knowledgebase in May 2019 did not yield any useful studies with relevant toxicity information on cholecalciferol.

Table 6-1 Error! Reference source not found. summarizes the most sensitive measured toxicity endpoints available across taxa. These endpoints are not likely to capture the most sensitive toxicity endpoint for a particular taxon but capture the most sensitive endpoint across tested species for each of the taxa. All studies in **Table 6-1** are classified as acceptable or supplemental. Non-definitive endpoints are designated with a greater than (>) or less than (<) value. Values that are based on newly submitted data are designated with an **N** footnote associated with the master record identification (MRID) number in tables.

6.1 Cholecalciferol Toxicity

Birds (surrogates for reptiles and terrestrial-phase amphibians)

Three acute avian toxicity studies have been submitted since the preliminary Problem Formulation. These studies include 2 acute oral toxicity studies with bobwhite quail and mallard ducks and 1 subacute dietary toxicity study.

There are two acute oral toxicity studies with birds available for cholecalciferol. In both studies with bobwhite quail (*Colinus virginianus*) and mallard ducks (*Anas platyrhynchos*), the 14-d LD_{50} values are >2,000 mg/kg bw and would classify cholecalciferol as practically non-toxic on an acute oral exposure basis (MRIDs 50844602, 50844603). For both of these studies, the data evaluation records (DERs) indicate that the purity of the test material was not specified; however, additional information provided recently by the technical registrant (email from BASF to EPA, 2/13/2020), indicates that pharmaceutical grade material (>97% active ingredient) was tested; therefore, the study classifications have been upgraded to supplemental and the data can be used quantitatively.

In a 1982 dietary toxicity study with bobwhite quail (Accession No. 00249059, MRID 00120350), the original DER indicated that the purity of the test material was not reported. However, additional information provided recently by the technical registrant BASF (MRID 50844605) indicated that the percent active ingredient (a.i.) of the test material was 30%. Therefore, the original LC_{50} value of 1,651 mg/kg-diet has been adjusted to reflect the percent a.i. resulting in an 8-day LC_{50} value of 495 mg a.i./kg-diet. This study has been upgraded to supplemental and the data can be used quantitatively. Based on these data, cholecalciferol is classified as highly toxic to birds on a sub-acute dietary exposure basis. In another sub-acute dietary toxicity study using mallard ducks, the 8-day LC_{50} value was 1,200 mg a.i./kg-diet (MRID 50844604) indicating that the compound is slightly toxic to mallard ducks on a subacute dietary exposure basis.

There are no chronic avian reproduction toxicity studies. However, the registrant has submitted information requesting a waiver from reproduction toxicity tests due to a lack of exposure, citing the mandatory bait stations for all above-ground placements and risk mitigation language stated on labels (MRID 50844601).

Mammals

With a rat LD_{50} of 11.8 mg a.i./kg bw, cholecalciferol is classified highly toxic to mammals on an acute oral exposure basis. In the study (MRID 42725701), rats (*Rattus norvegicus*) were dosed with a formulated bait (containing 0.075% cholecalciferol); however, it is not clear whether the test substance was similar to currently registered products containing cholecalciferol. Clinical observations of treated animals indicate thinness, lethargy, rough coat and occasional nasal bleeding. This study was reviewed by Health Effects Division (HED; TXR No. 0010276; 5/24/1993) and classified as acceptable.

HED identified a non-guideline oral toxicity study in which a single oral dose of 1.375 mg vitamin D_3/kg-bw did not produce adverse effects on blood serum calcium levels or on any growth parameters in young rats after 60 days of observation (Seefeld 1983 cited in the 2016 HED scoping document). Additionally, the registrant has submitted information from the published literature which address cholecalciferol toxicity (MRID 50844606). In prenatal

developmental and reproductive toxicity studies (McClain *et al*., 1980 and Seefeld, 1983), impairment of calcium homeostasis was established at elevated serum calcium levels ≥11.2 mg/dL. These levels are statistically significantly greater than serum calcium levels found in young rats treated with cholecalciferol and monitored for up to 60 days (uniformly <10 mg/dL). These reports show that quantitatively, based on extensive dissipation of cholecalciferol following oral administration (fecal elimination via bile, sequestration in adipose tissues, biotransformation to 25- hydroxycholecalciferol in liver, transport to kidney, conversion to calcitriol and inactive calcitroic acid in kidney, relatively short half-life of calcitriol), exposure to dose levels equivalent to ≥0.08 µg/kg calcitriol is not anticipated. Thus, for the purposes of hazard characterization, HED determined that additional developmental and/or reproductive toxicity studies on cholecalciferol are not likely to provide new and regulatorily meaningful data. Further, the 2016 Cholecalciferol Human Health Scoping Document in Support of Registration Review (US EPA 2016) also noted that the Prenatal Developmental Study (OPPTS 870.3700) would not be expected to provide a lower point of departure (POD) for human health risk assessment. The information provided by the registrant along with the information in the HED human health scoping document provide sufficient information for evaluating potential risk to non-target mammals.

Concerning potential secondary exposure, information is available from the published literature indicating that the risk to birds and mammals from secondary poisoning with cholecalciferol is expected to be low.

Terrestrial Invertebrates (Honey Bees)

A study by Booth *et al*. 2004 helps to address uncertainty surrounding the potential toxicity of cholecalciferol bait to terrestrial invertebrates. The study, conducted in New Zealand in 2004, was performed in accordance with the Organization for Economic Cooperation and Development (OECD) Test Guideline 213, *Honeybees, Acute Oral Toxicity Test*, (OECD, 1998). In addition to other organisms, the study evaluated the toxicity of cholecalciferol to honey bees. Honey bees were exposed to a suspension of cholecalciferol [prepared by emulsifying a 50:50 mix of cholecalciferol gel (0.8% ai) with sucrose water] containing 0, 300, 650, 1000, 1300, 2000, or 2650 µg a.i./mL cholecalciferol for 4 hours and then were assessed for mortality 24, 48 and 72 hours after exposure. The median lethal dose (LD_{50}) exceeded the highest level tested, *i.e.,* LD_{50}>265 µg a.i./bee. Based on these data, cholecalciferol is classified as practically non-toxic to honey bees on an acute oral exposure basis.

Aquatic Toxicity

No toxicity data for aquatic organisms have been submitted for cholecalciferol. However, due to the low solubility of the compound and the registered uses in bait stations and within rodent burrows, the likelihood that the compound will move into surface or groundwater is considered low.

Table 6-1. Terrestrial Toxicity Endpoints Selected for Evaluating Potential Risk for Cholecalciferol

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value	MRID or ECOTOX No./ Classification	Comments
Birds (surrogates for terrestrial amphibians and reptiles)					
Acute Oral (850.2100)	TGAI >97%	Bobwhite quail *(Colinus virginianus*)	LD_{50} >2,000 mg a.i./kg-bw	N50844602/ Supplemental	Doses were not verified analytically. However, the registrant has provided supplemental information indicating that the test material was pharmaceutical grade (>97% a.i.)
Acute Oral (850.2100)	TGAI (>97%)	Mallard duck (*Anas platyrhynchos*)	LD_{50} >2,000 mg a.i./kg-bw	N50844603/ Supplemental	Doses were not verified analytically. However, the registrant has provided supplemental information indicating that the test material was pharmaceutical grade (>97% a.i.)
Acute Dietary (850.2200)	Cholecalciferol oil concentrate (30%)	Mallard duck (*Anas platyrhynchos*)	LC_{50}: 1,178 mg a.i./kg diet	N50864404/ Supplemental	Dietary concentrations were not verified analytically.
Sub-acute Dietary (850.2200)	Cholecalciferol oil concentrate (30%)	Bobwhite quail (*Colinus virginianus*)	8-day LC_{50} = 495 mg a.i./kg-diet[1]	MRID 00120350/ Supplemental	Updated with information in MRID N50844605.
Mammals					
Acute Oral (870.1100)	Bait pellets (0.085%)	Wistar rat (*Rattus norvegicus*)	LD_{50} = 11.8 mg a.i./kg-bw	42725701/ Acceptable	Test substance was a suspension of formulated bait pellets.
Terrestrial Invertebrates					

Study Type	Test Substance (% a.i.)	Test Species	Toxicity Value	MRID or ECOTOX No./ Classification	Comments
Non-guideline/ OECD 213, Acute oral toxicity to honey bees	Cholecalciferol gel (0.8%)	Honey bee (*Apis mellifera*)	LD_{50}>265 µg a.i./bee	Booth, 2004	No effects observed. LD_{50} was greater than the highest dose tested.

TGAI=Technical Grade Active Ingredient; TEP= Typical end-use product; a.i.=active ingredient

[N] Studies submitted since the problem formulation was completed are designated with an N associated with the Master Record Identification (MRID) number.

[1] In additional information submitted by BASF (MRID 50844605; 2019), the test material was reported as containing 30% cholecalciferol, therefore, the original LC_{50} value of 1651 mg/kg-diet reported in the DER was adjusted by 30% to reflect this % a.i. resulting in an updated LC_{50}=495 mg a.i./kg-diet.

*Cited in the Health Effects Division (HED) Registration Review scoping document (USEPA 2016a)

6.2 Incident Data

The Incident Data System (IDS) is an Office of Pesticide Programs (OPP) database that houses ecological incidents that have been reported to the Agency. When available, IDS includes the date and location of an incident, type and magnitude of effects observed in various species, use(s) of pesticides known or suspected of contributing to the incident, and results of any chemical residue analysis or other analyses conducted during incident investigation. IDS incidents are categorized according to the certainty that the incident resulted from pesticide exposure. The current report summarizes the available incident information as of February 2020. The number of actual incidents associated with cholecalciferol may be higher than what is reported to the Agency. Incidents may go unreported and may not be associated with the use of the chemical. Although incident reporting is required under FIFRA Section 6(a)(2), the absence of reports in IDS does not indicate that the chemical has no effects on wildlife; rather, it is possible that incidents are unnoticed and unreported.

The Incident Data System (IDS) provides information on the available ecological pesticide incidents, including those that have been aggregately reported to the EPA that reported since registration to when the database was searched (February 2020).

Between January 1997 and September 2019, there were 282 separate domestic animal incidents reported to the Aggregate Incident Database (in 116 aggregate reports from registrants of cholecalciferol). Some of these incidents were reported when the tamper-proof bait stations were required for placement in any indoor or outdoor location to which children under six years of age, pets or non-target wildlife have access (implemented in 2008). Based on aggregate incident reports for cholecalciferol, domestic animal incidents continue to increase

despite mandatory mitigation measures (such as the required use of tamper-proof bait stations) implemented for cholecalciferol. **Figure 6-2** below provides a summary of the aggregate incident reports for cholecalciferol. It is difficult to determine if apparent trends in incidents are meaningful or not given that very few of the total incidents that occur are actually observed or reported to regulatory agencies. The cause(s) of the increase in the number of reported incidents over time is(are) unknown; it may be due in part to more systematic reporting or other factors. There were no reported aggregate incidents for wildlife or plants. (See **Appendix C** for IDS report).

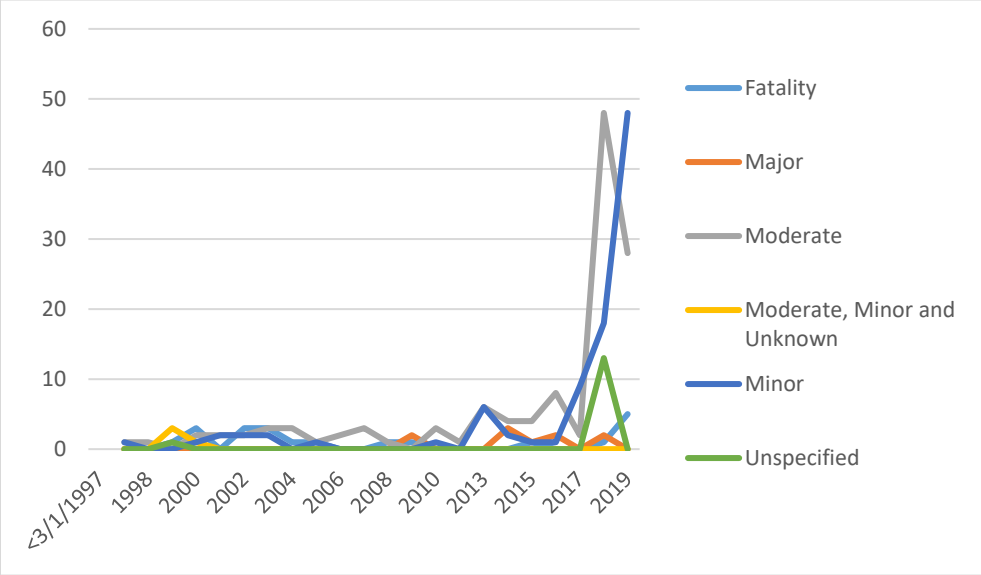

Figure 6-2. Domestic Animal Incidents Reported to EPA for Cholecalciferol (1997-2019)

Key

- DA – Death – if the domestic animal died or was euthanized;
- DB – Major – if the domestic animal exhibited or was alleged to have exhibited symptoms which may have been life-threatening or resulted in residual disability;
- DC – Moderate – if the domestic animal exhibited or was alleged to have exhibited symptoms which are more pronounced, more prolonged or of a more systemic nature than minor symptoms and included some treatment and return to pre-exposure state;
- DD – Minor – if the domestic animal was alleged to have exhibited symptoms, but they were minimally bothersome and resolved rapidly;
- DE – Unknown – if symptoms are unknown or not specified.

There was one wildlife incident in the database in which a juvenile female striped skunk was found in a dumpster in Corte Madera, California (I029093) in May 22, 2016. The affected animal was brought to a rehabilitation center and treated with fluids and antibiotics; however, it was later euthanized due to the severity of its condition (lethargic and inability to stand). Cholecalciferol was detected in the liver at >2.6 mg/kg.

Changes by EPA in the registrant reporting requirements for incidents in 1998 may account for a reduced number of non-aggregated reported incidents. Registrants are now only required to submit detailed information on "major" fish, wildlife, and plant incidents. Minor fish, wildlife, and plant incidents, as well as all other non-target incidents, are generally reported aggregately.

7 Analysis Plan

7.1 Overall Process

This assessment uses a weight-of-evidence approach that relies heavily, but not exclusively, on a risk quotient (RQ) method. The RQs are calculated by dividing an estimate environmental concentration (EEC) by a toxicity endpoint (*i.*e., EEC/toxicity endpoint). This is a way to determine if an estimated concentration is expected to be above or below the concentration associated with the toxicity endpoint. The RQs are compared to regulatory levels of concern (LOCs). The LOCs for non-listed species are meant to be protective of community-level effects. For acute and chronic risks to terrestrial and aquatic vertebrates, the LOCs are 0.5 and 1.0, respectively. The LOC for aquatic and terrestrial plants is 1.0 and the LOCs for acute and chronic risk to bees are 0.4 and 1.0, respectively. In addition to RQs, other available data (*e.g.*, incident data) can be used to help understand the potential risks associated with the use of the pesticide.

Exposure to aquatic organisms is not expected due to the mandatory use of bait stations or underground/burrow placement (pellets) for all cholecalciferol products. Further, considering the fate properties of cholecalciferol (low solubility and low volatility) it is expected that cholecalciferol transport to surface waters either via drift, volatility, or runoff is negligible. Thus, exposure for aquatic organisms (invertebrates, vertebrates and plants) is expected to be low; therefore, potential risks to aquatic organism is expected to be low.

Since neither drift nor runoff is anticipated for the registered uses, exposure for terrestrial plants is expected to be low and is not evaluated further.

Exposure and risk to terrestrial animals (birds and mammals) are assessed for animals that could directly consume bait (*i.e.*, primary exposure).

7.2 Modeling

Various models are typically used to calculate terrestrial EECs (see https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment). However, due to the use pattern for cholecalciferol (bait stations and

underground placement in rodent burrows), dietary ingestion estimates were obtained from the Wildlife Exposure Factors Handbook (USEPA 1993). The specific models used in this assessment are discussed further below in **Table 7-1**.

Table 7-1. List of the Models Used to Assess Risk.

Environment	Taxa of Concern	Exposure Media	Exposure Pathway	Model(s) or Pathway
Terrestrial	Vertebrate	Dietary items	Ingestion of bait	Dietary food intake values[1]

1. Wildlife Exposure Factor Handbook, USEPA 1993.

8 Terrestrial Vertebrate Risk Assessment

This assessment of the labeled uses of cholecalciferol relies on the deterministic RQ method to provide a metric of potential risks. The RQ provides a comparison of exposure estimates to toxicity endpoints (*i.e.*, estimated exposures divided by acute and/or chronic toxicity endpoints expressed in the same units as exposures, respectively). The resulting unitless RQ values are in turn compared to the Agency's LOCs. EPA uses the LOCs to indicate when the use of a pesticide, as directed by the label, has the potential to result in exposure levels sufficient to cause adverse effects to non-target organisms. A discussion of the RQ values for cholecalciferol and of other information that provides context for the interpretation of potential risk to various taxa are presented below.

Cholecalciferol risk to birds and mammals was evaluated under the assumption that birds and mammals can access cholecalciferol bait despite the requirement that all above-ground uses be inside tamper-proof bait stations.

8.1 Terrestrial Vertebrate Exposure Assessment

Primary exposure is assessed in this risk assessment and is defined as consumption of treated bait/pellets by target or non-target organisms. Secondary exposure in this assessment is defined as predation and consumption of exposed primary consumers. Exposure (food dry weight consumption) estimates were derived using allometric equations from USEPA's *Wildlife Exposure Factor Handbook* (USEPA 1993).

Primary exposure through cholecalciferol bait consumption was calculated using two methodologies. For the first method, cholecalciferol exposure was calculated as mg a.i./kg-

bw/day, where kg-bw is the weight of the consuming individual for three standard weight classes of mammals. Exposure (food dry weight consumption) estimates were derived using allometric equations from USEPA's *Wildlife Exposure Factor Handbook* (USPEA 1993). The allometric equations for birds and mammals were used to approximate those individuals with a high potential for consuming food and thus give the most conservative exposure estimates. Formulae for calculation of intake estimates are provided in **Table 8-1**, and cholecalciferol exposure estimates (on a dose basis) are provided in **Table 8-2**.

For the second method of exposure calculation, the amount of bait that a mammal (rodent) would have to consume to reach the LD_{50} can be calculated; this information was used to understand the amount of bait that a non-target mammal would need to consume to reach a lethal dose. This dietary exposure value can then be compared to the daily food intake for different sizes of mammals (15-1000 g). For birds, the amount of bait a bird would have to consume to reach the non-definitive LD_{50} (greater than 2000 mg a.i./kg-bw) value can be calculated, although the acute toxicity value is non-definitive.

The EEC for direct effects to birds and mammals was calculated based on EFED's default body weight classes for birds and mammals. For mammals the weight classes are small (15 g), medium (35 g), and large (1000 g).

Table 8-1. Formulas for Calculating Cholecalciferol Intake for Birds and Mammals Based on Consumption of Bait

Passeriform bird food intake (g, dry weight): FI (g dry-wt/day) = 0.398 * $Wt(g)^{0.850}$

Mammal food intake (g, dry weight): FI (g dry-wt/day) = 0.621 * $Wt(g)^{0.564}$

Cholecalciferol intake (mg a.i./kg-bwt/day) = FI (g dry-wt/day) * mg a.i./kg-bait / Wt(g)

Where: Wt (g) = weight (in grams) of the bird or mammal consumer

Food intake equation is from the Wildlife Exposure Factors Handbook (U.S. EPA, 1993)

Table 8-2. Expected Cholecalciferol Intake for Birds and Mammals Based on Primary Consumption of Bait

Species or Taxa	% a.i. in bait	Cholecalciferol Concentration in Bait (mg a.i./kg-bait)[1]	Body Weight (g)	Daily Food Intake (g/day)*	Cholecalciferol Intake (mg a.i./kg-bw/day)*
Birds	0.075	750	20	5	190
			100	20	150
			1000	141	106
Mammals			15	3	143
			35	5	99
			1000	31	23

*See **Table 8-1** for derivation
[1]1 kg of bait containing 0.075% ai contains 750 mg of cholecalciferol.

8.2 Terrestrial Vertebrate Risk Characterization

As described above, two methods are used to assess risks to birds and mammals from the use of cholecalciferol as a rodenticide. Since the bait is contained in tamper-proof bait stations, drift and runoff are not expected and are not considered exposure pathways.

Dose-based acute RQs from primary exposure of birds and mammals were calculated as the ratio of cholecalciferol intake (exposure) to the adjusted LD_{50} (toxicity). The risk analysis assumed that non-target birds and mammals are able to access cholecalciferol bait inside the bait station or to access bait pellets placed in underground rodent burrows.

For the acute risk analysis for birds, it was assumed that the non-definitive LD_{50} of >2,000 mg a.i./kg-bw was a definitive value (LD_{50}=2,000 mg a.i./kg-bw) in order to calculate acute RQs for birds. This approach results in a conservative estimate of acute risk to birds. For mammals, the definitive LD_{50} of 11.8 mg a.i./kg-bw was used to calculate acute RQs.

While acute risk estimates for birds do not exceed the acute risk LOC, RQ values (range: 1.34 – 24) exceed the acute risk LOC (0.5) for all sizes of mammals assessed (**Table 8-5**).

Table 8-3. Formulas for Calculation of Weight-Adjusted Mammalian Cholecalciferol Lethal Doses for 50% of the Animals Tested (LD_{50}).

Adjusted Mammalian LD_{50}

$$\text{Adj. } LD_{50} = LD_{50}\,(AW/TW)^{(0.25)}$$

Where:

Adj. LD_{50} = adjusted LD_{50} (mg a.i./kg-bw)
LD_{50} = endpoint reported from mammal study (11.8 mg a.i./kg-bw)
TW = body weight of tested animal (232 g rat, Wistar)
AW = body weight of assessed animal (g)

From: *Wildlife Exposure Factors Handbook* (U.S. EPA, 1993)

Table 8-4. Formulas for Calculation of Weight-Adjusted Avian Cholecalciferol LD_{50}'s

Adjusted Avian LD_{50}

$$\text{Adj. } LD_{50} = LD_{50}\ (AW/TW)^{(0.25)}$$

Where:

Adj. LD_{50} = adjusted LD_{50} (mg a.i./kg-bw)
LD_{50} = endpoint reported from avian study (2000 mg a.i./kg-bw)[1]
TW = body weight of tested animal (178 g Northern bobwhite)
AW = body weight of assessed animal (g)

From: *Wildlife Exposure Factors Handbook* (USEPA 1993)
[1] Assumes that LD_{50} >2,000 mg a.i./kg-bw =2000 mg a.i./kg-bw (MRID 50844602)

Table 8-5. Dose-based Acute Risk Quotients (RQs) for Primary Exposure of Birds and Small (Rodent) Mammals

Species or Taxa	Cholecalciferol Concentration in Bait (mg a.i./ kg-bait)	Weight (g)	Cholecalciferol Intake (mg a.i./ kg-bw/day)[1]	Adjusted LD_{50} (mg a.i./ kg-bw)[2]	Dose-based Acute RQ[3]
Birds	750	20	191	1158	<0.16
		100	150	1732	<0.09
		1000	106	3079	<0.03
Mammals		15	145	5.95	**24.0**
		35	99	7.35	**13.4**
		1000	23	17.0	**1.34**

[1] See **Table 8-1** for derivation.
[2] See **Table 8-3** and **8-4** for derivation. Used the body weight of the test animal for calculations of adjusted dose.
[3] RQ=Cholecalciferol Intake/Adjusted LD_{50}. **Bolded RQs** exceed the acute risk to non-listed species level of concern (LOC) of 0.5.

As described earlier, a second method to evaluate primary exposure was a dietary approach using the amount of cholecalciferol bait needed to be consumed to reach the LD_{50} dose which can then be compared to the daily food intake.

The amount of bait that a mammal would have to consume to reach the LD_{50} of 11.8 mg a.i./kg was calculated. Exposure (food dry weight consumption) estimates were derived using allometric equations from *The Wildlife Exposure Factors Handbook* (USEPA 1993). The allometric equations for passeriform birds and small mammals (rodents) were used as these would best approximate those individuals with high potential for consuming grain, and they would give the most conservative exposure estimates. Food dry weight was assumed equivalent to food wet weights as the expected water content of the bait would be minimal.

This analysis indicates that compared to the daily food intake for various sized mammals, a relatively small amount of bait (*e.g.,* 0.12 g for small mammals) is all that is needed to reach a lethal dose. For birds, no dose-based acute toxicity data are available. However, if it is assumed that the LD_{50} is 2,000 mg/kg-bw, the amount of bait that a bird would have to consume to reach that dose level can be calculated. Formulae for calculation of dose estimates are provided in **Tables 8-6** and **8-7** below. **Table 8-8** provides a summary of these estimates.

As can be seen in **Table 8-8**, for birds, the amount of bait (g) to be consumed to reach the LD_{50} exceeds the daily food intake by 6-29 fold, indicating it is unlikely that a bird would consume enough bait to result in potentially lethal effects. Further, according to the Wildlife Exposure Factors Handbook (USEPA 1993), the daily food intake for birds ranges from 5.1 to 141 g/day. In comparison, the LC_{50} from the acute dietary toxicity study with bobwhite quail was 495 mg a.i./kg-diet (MRID 00120350, updated with MRID 50844605) and is well above levels of daily food intake, indicating low likelihood of toxicity to birds on a subacute dietary exposure basis. However, for mammals, the amount of bait to be consumed to reach the LD_{50} is much less than the daily food intake, ranging from <1% for small mammals to about 74% of the daily food intake for larger mammals, indicating that it is much easier for small non-target mammals to consume a lethal dose.

Table 8-6. Formula for Calculation of Amount of Bait Consumed to Reach LD_{50} Dose for Mammals

Amount of Bait to be Consumed to Reach LD_{50} Dose (g bait/animal) =Adj. LD_{50} x AW / Concentration in Bait *Where:* Adj. LD_{50} = adjusted LD_{50} (mg a.i./kg-bw)[1] LD_{50} = endpoint reported from mammal study (11.8 mg a.i./kg-bw) AW = body weight of assessed animal (kg) Concentration a.i. in bait (mg a.i./g bait)

1. See **Table 8-5** for adjusted LD_{50} values.

Table 8-7. Formula for Calculation of Amount of Bait Consumed to Reach LD_{50} Dose for Birds

Amount of Bait to be Consumed to Reach LD_{50} Dose (g bait/animal) =Adj. LD_{50} x AW / Concentration in Bait *Where:* Adj. LD_{50} = adjusted LD_{50} (mg a.i./kg-bw)[1] LD_{50} = endpoint reported from avian study (2000 mg a.i./kg-bw) AW = body weight of assessed animal (kg) Concentration a.i. in bait (mg a.i./g bait)

1. See **Table 8-5** for adjusted LD_{50} values.

Table 8-8. Amount of Bait to be Consumed to Reach LD_{50} Dose for Birds and Mammals.

Species or Taxa	Cholecalciferol Concentration in Bait (mg a.i./ g-bait)	Weight (kg)	Adjusted LD_{50} (mg a.i./ kg-bw)[1]	Amount of Bait to be Consumed to Reach Adjusted LD_{50} (g bait)[2]	Daily food Intake (g)[3]	Percentage of Daily Food Intake
Birds	0.750	0.020	1158	31	5.1	608
		0.10	1732	230	20	1158
		1.0	3079	4105	141	2907
Mammals (rodents)		0.015	5.95	0.12	58	0.21
		0.035	7.35	0.34	94	0.36
		1	17	23	31	74

[1] See **Table 8-2** for adjusted LD_{50} values.
[2] See **Tables 8-6** and **8-7** for derivation.
[3] See **Table 8-1** for derivation.

Secondary Toxicity

There are limited data to assess potential risk to predators or scavengers that may consume mammals containing cholecalciferol residues (secondary exposure). However, the registrant has submitted information from the published literature which addresses the potential risk to birds exposed to insects that may feed on cholecalciferol bait (MRID 50844601). A study that examined invertebrates feeding on untreated baits used for vertebrate pest control in New Zealand under a worst-case scenario (*i.e*., aerial applications of cereal baits applied to a forest floor) concluded that only few of the invertebrate species likely to be present were found on baits and the total number of invertebrates found on baits was low compared to the number likely to be present (Spurr and Drew, 1999). In another study (Howald *et al*., 1999) rodent carcass location data using radio-tracked rats during a poisoning operation indicate that most poisoned rodents die below ground. However, even if some poisoned carcasses with cholecalciferol were available to predatory or scavenging birds, there would be low risk from secondary poisoning as no mortality or adverse effects were observed during a study where a predator and scavenger (1 red-tailed hawk (*Buteo jamaicensis*) and 2 turkey vultures (*Cathartes aura*), respectively) were fed 1 large or two small cholecalciferol-exposed rats for 10 days (USEPA, 2004). Eason *et al.* (2000) concluded that cholecalciferol is a lower risk to birds from

secondary poisoning when compared to other more acutely toxic rodenticides. Given that most rodent carcasses poisoned with rodenticides die below ground and that avian predators and scavengers tested are not very sensitive to cholecalciferol exposure, the risk to birds from secondary poisoning with cholecalciferol is expected to be low.

Regarding incidents, one ecological incident was reported in the OPP's incident database (2016) where a juvenile female striped skunk had to be euthanized due to the extent to which it was incapacitated. Cholecalciferol was detected in the liver at >2.60 mg/kg. However, between January 1997 and September 2019, there were 282 domestic animal incidents reported to the Aggregate Incident Database within 116 aggregate reports from registrants of cholecalciferol; details regarding the nature of these incidents and how the animals were actually exposed are not available.

Uncertainties in this assessment include the ability for non-target wildlife to access the bait that is contained in tamper-proof bait stations or pellets placed in underground burrows. Further, the potential for secondary exposure of birds and mammals from the use of cholecalciferol is uncertain, but is expected to be low.

9 Conclusions

Although environmental fate data are limited, cholecalciferol has a low solubility and is not expected to volatilize. Given the low solubility and K_{oc}, the compound is not expected to be mobile and based on its current uses (*i.e.*, as a bait in above ground bait stations or as pellets in rodent burrows), it is not expected to move to surface waters as a result of runoff of sediment-bound residues or through drift. Therefore, exposure and hence risk to aquatic organisms is presumed to be low. Similarly, exposure and hence risk to terrestrial plants is assumed to be low.

Exposure to non-target birds and mammals is expected to be minimal when cholecalciferol is used according to label instructions (i.e., mandatory placement of bait blocks inside tamper-proof bait stations or below-ground placement of pellets inside rodent burrows with mandatory retrieval of unconsumed bait). Although label language may help to reduce the likelihood of chronic exposure for non-target organisms (e.g., birds and mammals), label statements do not preclude such exposure. Since chronic toxicity data are not available, the likelihood of adverse effects from exposure to cholecalciferol cannot be fully characterized based on the available data.

Additionally, the registrant has submitted additional information from the published literature addressing mammalian prenatal and developmental toxicity and secondary toxicity to support a waiver request (MRID 50844601) for any additional chronic toxicity data. Although birds are sensitive to cholecalciferol on an acute dietary exposure basis, risk estimates for birds were below the LOC, and birds are unlikely to consume sufficient quantities of the product to result in acute risks.

Aquatic organisms are not expected to be at risk as aquatic exposure is assumed to be negligible. Likewise, terrestrial plants and terrestrial invertebrates, including pollinators, are not expected to be at risk due to a lack of significant exposure.

Given the uses of cholecalciferol as a rodenticide and the environmental fate properties of the compound, there is a low likelihood of exposure and risk to birds. While mammals are sensitive to cholecalciferol bait at very small amounts (0.12 gm for mammals to reach the LD_{50} dose), risks to non-target mammals are possible, but are reduced due to the mandatory use of bait stations and underground placement of pellets in rodent burrows. In general, when used in accordance with the label (bait blocks placed inside tamper-proof bait stations or placement of pellets in underground rodent burrows), it is unlikely that non-target wildlife will be exposed or at risk. However, incident data indicate that domestic animals are able to access the bait even when it is used according to label directions.

Prolonged exposure may occur through repeated applications as several labels direct users to replenish as needed and/or establish permanent bait stations for continuous source of pest infestation. However, chronic guideline toxicity data are lacking and the effects of long-term exposure on birds and mammals is unknown. While label language directing users on the use and placement of bait along with retrieving unconsumed bait is expected to reduce the likelihood of chronic exposure to non-target animals, the label language does not preclude the possibility of chronic exposure.

Table 9-1. Potential Environmental Fate Concerns Identified for Cholecalciferol

Bioconcentration/ Bioaccumulation[1]	Groundwater Contamination	Sediment	Persistence[2]	Residue of Concern	Secondary Exposure Concern?	Volatilization
No[1]	No[2]	No[3]	unknown	Parent Cholecalciferol	unknown	No

[1]Although the estimated log octanol-water coefficient (K_{ow}) of 10.9 suggests a potential to bioaccumulate; the compound is not expected to be transported to aquatic environments.

[2] Persistence classification is unknown since biotic and abiotic metabolism data are not available.

[3] Although the estimated organic carbon partition coefficient indicates that the compound will sorb to sediments, current uses of cholecalciferol limit the extent to which the compound will move into surface water.

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MRID 50844603: Jackson, D., *et al*. 1994. Cholecalciferol - Acute Oral Toxicity Test in Mallard Ducks. Unpublished study performed by Inveresk Research International, Tranent, Scotland. Laboratory Study No. 554956. Study sponsored by Sorex Limited, Widnes, Cheshire, England and submitted by BASF Corporation (Document Number 1994/1005291). Study initiated November 26, 1993 and completed May 30, 1994.

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MRID 50844605: Fletcher, D. (1982) 8-day Dietary LC_{50} Study with Cholecalciferol Oil Concentrate in Bobwhite quail: BLAL No. 82 DC 22. (Unpublished study received Dec 15, 1982 under 12455-60; prepared by Bio-Life Assoc., Ltd., submitted by Bell Laboratories, Madison, WI; CDL:249057-A). (Updated with purity information, 2019)

MRID 50844606: Chukwudebe, Amechi. 2019. Cholecalciferol: Prenatal Developmental, Reproductive and Fertility Effects Potential, Assessment and Waiver Request, Sponsor: BASF Corporation, BASF Registration Document Number:2019/7002594, May 14, 2019.

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Appendix A. Endocrine Disruptor Screening Program (EDSP)

As required by FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of the Draft Ecological Risk Assessment for Registration Review, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), cholecalciferol is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[1] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Cholecalciferol is not on List 1. For

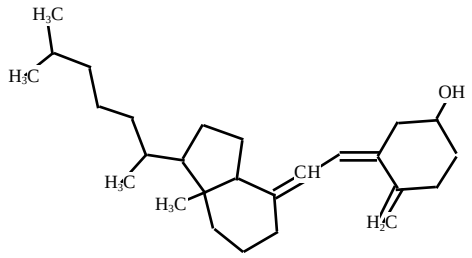
[1] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.

further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and Tier 1 screening battery, please visit EPA's web page[2].

[2] Available: http://www.epa.gov/endo/

Appendix B: EPISuite™ Output File for Cholecalciferol

EPI Suite Results For CAS 67-97-0




```
SMILES : OC1CC(C(=C)CC1)=CC=C2CCCC3(C2CCC3C(C)CCCC(C)C)C
CHEM   : cholecalciferol
MOL FOR: C27 H44 O1
MOL WT : 384.65
------------------------------ EPI SUMMARY (v4.11) --------------------------
Physical Property Inputs:
Log Kow (octanol-water):   ------
Boiling Point (deg C)  :   ------
Melting Point (deg C)  :   ------
Vapor Pressure (mm Hg) :   ------
Water Solubility (mg/L):   ------
Henry LC (atm-m3/mole) :   ------

Log Octanol-Water Partition Coef (SRC):
Log Kow (KOWWIN v1.68 estimate) =  10.24

Boiling Pt, Melting Pt, Vapor Pressure Estimations (MPBPVP v1.43):
Boiling Pt (deg C):  444.39  (Adapted Stein & Brown method)
Melting Pt (deg C):  168.98  (Mean or Weighted MP)
VP(mm Hg,25 deg C):  2.41E-009  (Modified Grain method)
VP (Pa, 25 deg C) :  3.22E-007  (Modified Grain method)
MP  (exp database):  84.5 deg C
Subcooled liquid VP: 8.96E-009 mm Hg (25 deg C, Mod-Grain method)
: 1.19E-006 Pa (25 deg C, Mod-Grain method)

Water Solubility Estimate from Log Kow (WSKOW v1.42):
Water Solubility at 25 deg C (mg/L):  2.224e-005
log Kow used: 10.24 (estimated)
no-melting pt equation used

Water Sol Estimate from Fragments:
Wat Sol (v1.01 est) =  0.00023488 mg/L
```

```
ECOSAR Class Program (ECOSAR v1.11):
Class(es) found:
Neutral Organics

Henrys Law Constant (25 deg C) [HENRYWIN v3.20]:
Bond Method :   2.30E-004  atm-m3/mole  (2.33E+001 Pa-m3/mole)
Group Method:   Incomplete
For Henry LC Comparison Purposes:
User-Entered Henry LC:  not entered
Henrys LC [via VP/WSol estimate using User-Entered or Estimated values]:
HLC:  5.484E-005 atm-m3/mole  (5.557E+000 Pa-m3/mole)
VP:   2.41E-009 mm Hg (source: MPBPVP)
WS:   2.22E-005 mg/L (source: WSKOWWIN)

Log Octanol-Air Partition Coefficient (25 deg C) [KOAWIN v1.10]:
Log Kow used:  10.24  (KowWin est)
Log Kaw used:  -2.027  (HenryWin est)
Log Koa (KOAWIN v1.10 estimate):  12.267
Log Koa (experimental database):  None

Probability of Rapid Biodegradation (BIOWIN v4.10):
Biowin1 (Linear Model)         :   0.5392
Biowin2 (Non-Linear Model)     :   0.0448
Expert Survey Biodegradation Results:
Biowin3 (Ultimate Survey Model):   2.2970  (weeks-months)
Biowin4 (Primary Survey Model) :   3.2688  (days-weeks  )
MITI Biodegradation Probability:
Biowin5 (MITI Linear Model)    :   0.0650
Biowin6 (MITI Non-Linear Model):   0.0122
Anaerobic Biodegradation Probability:
Biowin7 (Anaerobic Linear Model): -1.0733
Ready Biodegradability Prediction:   NO

Hydrocarbon Biodegradation (BioHCwin v1.01):
Structure incompatible with current estimation method!

Sorption to aerosols (25 Dec C)[AEROWIN v1.00]:
Vapor pressure (liquid/subcooled):  1.19E-006 Pa (8.96E-009 mm Hg)
Log Koa (Koawin est  ): 12.267
Kp (particle/gas partition coef. (m3/ug)):
Mackay model           :  2.51
Octanol/air (Koa) model:  0.454
Fraction sorbed to airborne particulates (phi):
Junge-Pankow model     :  0.989
Mackay model           :  0.995
Octanol/air (Koa) model:  0.973

Atmospheric Oxidation (25 deg C) [AopWin v1.92]:
Hydroxyl Radicals Reaction:
OVERALL OH Rate Constant = 269.6902 E-12 cm3/molecule-sec
Half-Life =     0.040 Days (12-hr day; 1.5E6 OH/cm3)
Half-Life =    28.555 Min
Ozone Reaction:
OVERALL Ozone Rate Constant =    41.616249 E-17 cm3/molecule-sec
Half-Life =     0.028 Days (at 7E11 mol/cm3)
Half-Life =     39.654 Min
Fraction sorbed to airborne particulates (phi):
0.992 (Junge-Pankow, Mackay avg)
0.973 (Koa method)
```

Note: the sorbed fraction may be resistant to atmospheric oxidation

Soil Adsorption Coefficient (KOCWIN v2.00):
Koc : 1.658E+006 L/kg (MCI method)
Log Koc: 6.220 (MCI method)
Koc : 1.506E+006 L/kg (Kow method)
Log Koc: 6.178 (Kow method)

Aqueous Base/Acid-Catalyzed Hydrolysis (25 deg C) [HYDROWIN v2.00]:
Rate constants can NOT be estimated for this structure!

Bioaccumulation Estimates (BCFBAF v3.01):
Log BCF from regression-based method = 2.537 (BCF = 344.5 L/kg wet-wt)
Log Biotransformation Half-life (HL) = 2.7847 days (HL = 609.1 days)
Log BCF Arnot-Gobas method (upper trophic) = 1.471 (BCF = 29.58)
Log BAF Arnot-Gobas method (upper trophic) = 5.097 (BAF = 1.251e+005)
log Kow used: 10.24 (estimated)

Volatilization from Water:
Henry LC: 0.00023 atm-m3/mole (estimated by Bond SAR Method)
Half-Life from Model River: 6.994 hours
Half-Life from Model Lake : 240.7 hours (10.03 days)

Removal In Wastewater Treatment:
Total removal: 94.04 percent
Total biodegradation: 0.78 percent
Total sludge adsorption: 93.26 percent
Total to Air: 0.00 percent
(using 10000 hr Bio P,A,S)

Level III Fugacity Model:

Mass Amount (percent)	Half-Life (hr)	Emissions (kg/hr)	
Air	0.0169	0.39	1000
Water	17.2	900	1000
Soil	80.8	1.8e+003	1000
Sediment	1.96	8.1e+003	0

Persistence Time: 1.09e+003 hr

Appendix C: Incident Data System Search Results for Cholecalciferol (2/19/2020)

Key:
DA=Domestic Animal Fatality
DB=Domestic Animal-Major
DC=Domestic Animal-Moderate
DCDE=Domestic Animal -Moderate, Minor and Unknown
DD=Domestic Animal-Minor
DE=Domestic Animal-Unspecified

Pkg & Seq.	Subm. Date	Reg#	Product Name	From Date	To Date	Package Description	Total Incident Count	HD	HE	DA	DB	DC	DCDE	DD	DE
032799 - 00016	########	007969-00382	SELONTRA RODENT BAIT	########	########	BASF: 17 aggregate summaries. October 17 - December 12, 2019. Includes brief backup reports. (JK)	2	0	0	0	0	1	0	1	0
032572 - 00030	10/4/2019	007969-00382	SELONTRA RODENT BAIT	7/18/2019	9/19/2019	BASF: 31 aggregate summaries. Jul 18 - Sep 19, 2019. Includes brief backup reports. (JK)	1	0	0	0	0	1	0	0	0
032572 - 00031	10/4/2019	007969-00383	TC 411	7/18/2019	9/19/2019	BASF: 31 aggregate summaries. Jul 18 - Sep 19, 2019. Includes brief backup reports. (JK)	1	0	0	1	0	0	0	0	0
032755 - 00023	12/3/2019	007969-00383-003282	D-CON XVI KILLS HOUSE MICE	7/1/2019	9/30/2019	Reckitt Benckiser: 25 aggregate summaries. July - September, 2019. (JK)	23	3	4	0	0	3	0	13	0
032755 - 00024	12/3/2019	007969-00384-003282	D-CON XVII KILLS HOUSE MICE	7/1/2019	9/30/2019	Reckitt Benckiser: 25 aggregate summaries. July - September, 2019. (JK)	5	1	0	0	0	1	0	3	0
032690 - 00009	########	012455-00106	TERAD3 BLOX (NON-SPECIFIC)	7/1/2019	9/30/2019	Bell Laboratories: 3rd qtr. 2019, 33 aggregate summaries. (JK)	1	0	0	0	0	0	0	1	0
032755 - 00025	12/3/2019		UNKNOWN PRODUCT	7/1/2019	9/30/2019	Reckitt Benckiser: 25 aggregate summaries. July - September, 2019. (JK)	1	0	0	0	0	1	0	0	0
032431 - 00024	8/26/2019	007969-00383-003282	D-CON XVI KILLS HOUSE MICE	4/1/2019	6/30/2019	SCR: 2nd qtr. 2019, 26 aggregate incident summaries. (JK)	19	0	0	2	0	6	0	11	0
032431 - 00025	8/26/2019	007969-00384-003282	D-CON XVII KILLS HOUSE MICE	4/1/2019	6/30/2019	SCR: 2nd qtr. 2019, 26 aggregate incident summaries. (JK)	4	0	0	0	0	3	0	1	0
032284 - 00033	7/9/2019	007969-00382	SELONTRA RODENT BAIT	4/1/2019	6/30/2019	BASF: 34 aggregate summaries. April - June, 2019. Includes brief backup reports. (JK)	1	0	0	0	0	0	0	1	0
032284 - 00034	7/9/2019	007969-00383	TC 411	4/1/2019	6/30/2019	BASF: 34 aggregate summaries. April - June, 2019. Includes brief backup reports. (JK)	1	0	0	1	0	0	0	0	0
032447 - 00018	8/28/2019	012455-00117	TERAD3 AG PELLETS	4/1/2019	6/30/2019	Bell: 51 aggregate summaries. April - June, 2019. (JK)	1	0	0	1	0	0	0	0	0
032447 - 00016	8/28/2019	012455-00106	TERAD3 BLOX	4/1/2019	6/30/2019	Bell: 51 aggregate summaries. April - June, 2019. (JK)	1	0	0	0	0	0	0	1	0

032447 - 00010	8/28/2019		TOMCAT CHOLECALCIFEROL 0.075% (NON-SPECIFIC)	4/1/2019	6/30/2019	Bell: 51 aggregate summaries. April - June, 2019. (JK)	1	0	0	0	0	0	0	1	0
032119 - 00011	5/23/2019	012455-00116-003240	AGRID3 BAIT CHUNX	1/1/2019	3/31/2019	Bell: 30 aggregate summaries. January - March, 2019. (JK)	2	0	0	0	0	1	0	1	0
032178 - 00023	6/4/2019	007969-00383-003282	D-CON XVI KILLS HOUSE MICE	1/1/2019	3/31/2019	Reckitt Benckiser: 24 aggregate summaries. January - March, 2019. (JK)	20	0	0	0	0	9	0	11	0
032178 - 00024	6/4/2019	007969-00384-003282	D-CON XVII KILLS HOUSE MICE	1/1/2019	3/31/2019	Reckitt Benckiser: 24 aggregate summaries. January - March, 2019. (JK)	1	0	0	0	0	1	0	0	0
032017 - 00021	4/18/2019	007969-00382	SELONTRA RODENT BAIT	1/1/2019	3/31/2019	BASF: 21 aggregate summaries. January - March, 2019. Includes brief backup reports. (JK)	4	0	0	0	0	1	0	3	0
031856 - 00011	2/21/2019	012455-00116-003240	AGRID3 BAIT CHUNX	10/1/2018	########	Bell: 40 aggregate summaries. October - December, 2018. (JK)	1	0	0	0	0	1	0	0	0
031843 - 00026	2/25/2019	007969-00383-003282	D-CON XVI KILLS HOUSE MICE	10/1/2018	########	Reckitt Benckiser: 28 aggregate summaries. October - December, 2018. (JK)	31	1	0	0	0	17	0	0	13
031843 - 00027	2/25/2019	007969-00384-003282	D-CON XVII KILLS HOUSE MICE	10/1/2018	########	Reckitt Benckiser: 28 aggregate summaries. October - December, 2018. (JK)	1	0	0	0	0	1	0	0	0
031738 - 00032	1/31/2019	007969-00382	SELONTRA RODENT BAIT	10/1/2018	########	BASF: 28 aggregate summaries. October - December, 2019. Includes brief backup reports.	1	0	0	0	0	1	0	0	0
031856 - 00010	2/21/2019	012455-00116	TERAD3 AG BLOX	10/1/2018	########	Bell: 40 aggregate summaries. October - December, 2018. (JK)	1	0	0	0	0	1	0	0	0
031856 - 00009	2/21/2019	012455-00106	TERAD3 BLOX	10/1/2018	########	Bell: 40 aggregate summaries. October - December, 2018. (JK)	1	0	0	0	0	0	0	1	0
031843 - 00028	2/25/2019		UNKNOWN PRODUCT	10/1/2018	########	Reckitt Benckiser: 28 aggregate summaries. October - December, 2018. (JK)	3	0	0	0	0	3	0	0	0
031612 - 00012	########	012455-00116-003240	AGRID3 BAIT CHUNX	7/1/2018	9/30/2018	Bell: 42 aggregate summaries. July - September, 2018.(JK)	2	0	0	0	0	2	0	0	0

031644 - 00026	12/3/2018	007969-00383-003282	D-CON XVI KILLS HOUSE MICE	7/1/2018	9/30/2018	Reckitt Benckiser: 27 aggregate summaries. July - September, 2018.	15	1	0	0	1	9	0	5	0
031644 - 00027	12/3/2018	007969-00384-003282	D-CON XVII KILLS HOUSE MICE	7/1/2018	9/30/2018	Reckitt Benckiser: 27 aggregate summaries. July - September, 2018.	3	0	0	0	0	1	0	2	0
031502 - 00044	########	007969-00382	SELONTRA RODENT BAIT	7/1/2018	9/30/2018	BASF; 44 aggregate summaries. July - September, 2018. Includes brief backup reports.	1	0	0	0	0	0	0	1	0
031612 - 00011	########	012455-00106	TERAD3 BLOX (NON-SPECIFIC)	7/1/2018	9/30/2018	Bell: 42 aggregate summaries. July - September, 2018.(JK)	1	0	0	0	0	0	0	1	0
031189 - 00031	7/5/2018	007969-00382	SELONTRA RODENT BAIT	4/19/2018	6/21/2018	BASF: aggregate summaries. April - June, 2018. Includes brief backup reports.	1	0	0	0	1	0	0	0	0
031309 - 00027	8/20/2018	007969-00383-003282	D-CON XVI KILLS HOUSE MICE	4/1/2018	6/30/2018	SRC: 2nd qtr. 2018, 31 aggregate summaries.	15	2	0	1	0	6	0	6	0
031309 - 00028	8/20/2018	007969-00384-003282	D-CON XVII KILLS HOUSE MICE	4/1/2018	6/30/2018	SRC: 2nd qtr. 2018, 31 aggregate summaries.	2	0	0	0	0	2	0	0	0
031070 - 00003	5/15/2018		CHOLECALCIFEROL (NON SPECIFIC)	1/1/2018	3/31/2018	Bell: 39 aggregate summaries. January - March, 2018.	1	0	0	0	0	1	0	0	0
031053 - 00028	5/29/2018	007969-00383-003282	D-CON XVI KILLS HOUSE MICE	1/1/2018	3/31/2018	SCR: 31 aggregate summaries. January - March, 2018.	6	2	0	0	0	2	0	2	0
031070 - 00007	5/15/2018	012455-00106	TERAD3 BLOX (NON-SPECIFIC)	1/1/2018	3/31/2018	Bell: 39 aggregate summaries. January - March, 2018.	1	0	0	0	0	1	0	0	0
030763 - 00013	2/9/2018	012455-00116-003240	AGRID3 BAIT CHUNX	10/1/2017	########	BELL LABORATORIES, INC.: 39 aggregate summaries. October - December, 2017.	2	0	0	0	0	0	0	2	0
030804 - 00029	3/5/2018	007969-00383-003282	D-CON	10/1/2017	########	SRC: 4th qtr. 2017, 34 aggregate incident summaries.	1	0	0	0	0	0	0	1	0
030575 - 00010	########	012455-00106	TERAD3 BLOX	7/1/2017	9/30/2017	Bell: Includes 3 H-C. Symptoms include Numbness, Polyuria, Heaviness in leg and feet, etc. 27 aggregate summaries. July - September 2017.	4	0	0	0	0	2	0	2	0
030310 - 00006	8/29/2017		QUINTOX	4/1/2017	6/30/2017	Bell: 38 aggregate summaries. April - June 2017.	1	0	0	0	0	0	0	1	0
030310 - 00013	8/29/2017	012455-00106	TERAD3 BLOX	4/1/2017	6/30/2017	Bell: 38 aggregate summaries. April - June 2017.	2	0	0	0	0	0	0	2	0

029958 - 00009	5/17/2017	012455-00106	TERAD3 BLOX	1/1/2017	3/31/2017	Bell Laboratories: Jan 1 - Mar 31 2017. 36 Aggregate Summaries	1	0	0	0	0	0	0	1	0
029684 - 00008	2/21/2017	012455-00116-003240	AGRID3 BAIT CHUNX	10/1/2016	########	Bell Labs: 4th qtr., 43 2016 aggregate incident summaries.	2	0	0	0	1	1	0	0	0
029684 - 00007	2/21/2017	012455-00106	TERAD3 BLOX	10/1/2016	########	Bell Labs: 4th qtr., 43 2016 aggregate incident summaries.	1	0	0	0	0	1	0	0	0
029412 - 00007	########	012455-00106	TERAD3 BLOX	7/1/2016	9/30/2016	Bell Labs: 3rd qtr. 2016, 41 aggregate incident summaries, 8 deaths due to bromethalin and diphacinone intoxication.	1	0	0	0	1	0	0	0	0
029175 - 00012	8/29/2016	012455-00116-003240	AGRID3 BAIT CHUNX	4/1/2016	6/30/2016	Bell: 2nd qtr. 2016, 43 aggregate incident summaries.	2	0	0	0	0	2	0	0	0
029175 - 00003	8/29/2016		CHOLECALCIFEROL (NON-SPECIFIC)	4/1/2016	6/30/2016	Bell: 2nd qtr. 2016, 43 aggregate incident summaries.	1	0	0	0	0	1	0	0	0
029175 - 00011	8/29/2016	012455-00106	TERAD3 BLOX	4/1/2016	6/30/2016	Bell: 2nd qtr. 2016, 43 aggregate incident summaries.	2	0	0	0	0	2	0	0	0
028894 - 00010	5/31/2016	012455-00116-003240	AGRID3 BAIT CHUNX	1/1/2016	3/31/2016	Bell Laboratories, Inc.: Aggregate Reports	1	0	0	0	0	0	0	1	0
028894 - 00008	5/31/2016	012455-00106	TERAD 3 BLOX	1/1/2016	3/31/2016	Bell Laboratories, Inc.: Aggregate Reports	1	0	0	0	0	1	0	0	0
028445 - 00012	2/23/2016	012455-00117-003240	AGRID3 PELLETED BAIT	10/1/2015	########	Bell: 4th qtr. 2015 aggregate incident reports.	1	0	0	0	0	1	0	0	0
028445 - 00011	2/23/2016	012455-00105	TERAD3 PELLETS	10/1/2015	########	Bell: 4th qtr. 2015 aggregate incident reports.	1	0	0	0	0	1	0	0	0
028236 - 00010	12/1/2015	012455-00106	TERAD3 BLOX	7/1/2015	9/30/2015	Bell: 3rd qtr. aggregate report	1	0	0	0	0	0	0	1	0
027952 - 00010	8/26/2015	012455-00106	TERAD3 BLOX	4/1/2015	6/30/2015	Bell: 2nd quarter 2015, 37 aggregate incident summaries.	1	0	0	0	0	1	0	0	0
027690 - 00014	5/26/2015	012455-00116-003240	AGRID3 BAIT CHUNX	1/1/2015	3/31/2015	Bell Laboratories: 36 aggregate summaries. Jan - Mar 2015. Includes human and domestic animal incidents.	1	0	0	1	0	0	0	0	0
027690 - 00013	5/26/2015	012455-00116	TERAD3 AG BLOX	1/1/2015	3/31/2015	Bell Laboratories: 36 aggregate summaries. Jan - Mar 2015. Includes human and domestic animal incidents.	1	0	0	0	1	0	0	0	0
027690 - 00012	5/26/2015	012455-00105	TERAD3 PELLETS	1/1/2015	3/31/2015	Bell Laboratories: 36 aggregate summaries. Jan - Mar 2015. Includes human	1	0	0	0	0	1	0	0	0

027443 - 00011	2/18/2015	012455-00116-003240	AGRID3 BAIT CHUNX	10/1/2014	########	and domestic animal incidents. Bell labs: Oct-Dec 2014, 50 aggregate incident summaries.	1	0	0	0	1	0	0	0	0
027443 - 00012	2/18/2015	012455-00117-003240	AGRID3 PELLETED BAIT	10/1/2014	########	Bell labs: Oct-Dec 2014, 50 aggregate incident summaries.	1	0	0	0	0	1	0	0	0
027218 - 00009	########	012455-00106	TERAD3 BLOX	7/1/2014	9/30/2014	Bell Laboratories: 37 aggregate summaries, July - Sept. 2014	1	0	0	0	0	1	0	0	0
026873 - 00008	8/28/2014	012455-00106	TERAD3 BLOX (NON-SPECIFIC)	4/1/2014	6/30/2014	Bell Laboratories: 37 aggregate summaries, Apr. - June 2014	1	0	0	0	1	0	0	0	0
026873 - 00021	8/28/2014	012455-00039-003240	TOMCAT VITAMIN D3 MOUSE POISON (DISCONTINUED)	4/1/2014	6/30/2014	Bell Laboratories: 37 aggregate summaries, Apr. - June 2014	1	0	0	0	0	0	0	1	0
026493 - 00013	5/30/2014	012455-00116-003240	AGRID3 BAIT CHUNX	1/1/2014	3/31/2014	Bell Laboratories: 41 aggregate summaries, Jan. - Mar. 2014 with human and domestic animal incidents	4	0	0	0	1	2	0	1	0
026152 - 00039	2/21/2014	003240-00028-012455	QUINTOX MOUSE SEED READY-TO-USE PLACE PAC (DISCONTINUTED)	10/1/2013	########	Bell Laboratories: 40 aggregate summaries, Oct. - Dec. 2013.	1	0	0	0	0	1	0	0	0
026152 - 00040	2/21/2014	003240-00042-012455	QUINTOX RAT AND MOUSE BAIT READY-TO-USE PLACE PAC (DISCONTINUED)	10/1/2013	########	Bell Laboratories: 40 aggregate summaries, Oct. - Dec. 2013.	1	0	0	0	0	1	0	0	0
026152 - 00009	2/21/2014	012455-00105	TERAD3 PELLETS	10/1/2013	########	Bell Laboratories: 40 aggregate summaries, Oct. - Dec. 2013.	1	0	0	0	0	0	0	1	0
025871 - 00009	########	012455-00106	TERAD 3 BLOX	7/1/2013	9/30/2013	Bell Laboratories: 36 aggregate summaries, July - Sept. 2013	1	0	0	0	0	0	0	1	0
025545 - 00012	8/20/2013	012455-00116-003240	AGRID3 BAIT CHUNX	4/1/2013	6/30/2013	Bell Laboratories: 40 aggregate summaries, Apr-June 2013.	2	0	0	0	0	1	0	1	0
025545 - 00040	8/20/2013	003240-00042-012455	QUINTOX RAT & MOUSE BAIT RTU PLACE PAC (DISCONTINUED)	4/1/2013	6/30/2013	Bell Laboratories: 40 aggregate summaries, Apr-June 2013.	1	0	0	0	0	0	0	1	0
025545 - 00010	8/20/2013	012455-00106	TERAD3 BLOX	4/1/2013	6/30/2013	Bell Laboratories: 40 aggregate summaries, Apr-June 2013.	1	0	0	0	0	0	0	1	0
025182 - 00008	5/16/2013	012455-00106	TERAD3 BLOX	1/1/2013	3/31/2013	Bell Laboratories: 33 aggregate summaries, Jan.- Mar. 2013. Includes human and domestic animal incidents.	3	0	0	0	0	2	0	1	0
025182 - 00007	5/16/2013	012455-00105	TERAD3 PELLETS	1/1/2013	3/31/2013	Bell Laboratories: 33 aggregate summaries, Jan.- Mar. 2013. Includes human	1	0	0	0	0	1	0	0	0

023713 - 00006	2/21/2012		QUINTOX (NON-SPECIFIC)	10/1/2011	########	and domestic animal incidents. Bell Labs: 40 aggregate summaries, Sept. - Dec. 2011. Includes 15 H-D, 1 D-A, 6 D-A, 56 D-C, and 82 D-D.	1	0	0	0	0	1	0	0	0
022471 - 00011	########	012455-00116-003240	AGRID 3 BAIT CHUNX	7/1/2010	9/30/2010	Bell Laboratories: 38 aggregate summaries, July-Sept. 2010. Incl. 17 H-D, 6 D-A, 8 D-B, 60 D-C, and 84 D-D.	1	0	0	0	0	0	0	1	0
022471 - 00012	########	012455-00117-003240	AGRID 3 PELLETED BAIT	7/1/2010	9/30/2010	Bell Laboratories: 38 aggregate summaries, July-Sept. 2010. Incl. 17 H-D, 6 D-A, 8 D-B, 60 D-C, and 84 D-D.	1	0	0	0	0	1	0	0	0
022471 - 00009	########	012455-00106	TERAD 3 BLOX	7/1/2010	9/30/2010	Bell Laboratories: 38 aggregate summaries, July-Sept. 2010. Incl. 17 H-D, 6 D-A, 8 D-B, 60 D-C, and 84 D-D.	1	0	0	0	0	1	0	0	0
022208 - 00005	8/31/2010		QUINTOX (NON-SPECIFIC)	4/1/2010	6/30/2010	Bell Labs: 38 aggregate summaries, Apr.-June 2010. Includes human and domestic animal incidents.	1	0	0	0	0	1	0	0	0
021675 - 00014	3/2/2010	012455-00117-003240	AGRID3 PELLETED BAIT	10/1/2009	########	Bell Laboratories: 40 aggregate summaries, Oct.-Dec. 2009, Incl. 11 H-D, 6 D-A, 18 D-B, 67 D-C, 110 D-D.	1	0	0	0	1	0	0	0	0
021675 - 00003	3/2/2010		CHOLECALCIFEROL	10/1/2009	########	Bell Laboratories: 40 aggregate summaries, Oct.-Dec. 2009, Incl. 11 H-D, 6 D-A, 18 D-B, 67 D-C, 110 D-D.	1	0	0	0	1	0	0	0	0
021422 - 00006	12/3/2009		QUINTOX (NON-SPECIFIC)	7/1/2009	9/30/2009	Bell Labs: 41 aggregate summaries Jul-Sep 2009. 15 H-D, 8 D-A, 4 D-B, 61 D-C, 99 D-D, 6 D-E. Multiple products.	1	0	0	1	0	0	0	0	0
020558 - 00004	2/27/2009		CHOLECALCIFEROL	10/1/2008	########	Bell Laboratories: 38 aggregate summaries, Oct. - Dec. 2008, Incl. 19 H-D, 21 D-A, 14 D-B, 67 D-C, 128 D-D.	2	0	0	1	0	1	0	0	0
018506 - 00004	5/29/2007		CHOLECALCIFEROL	1/1/2007	3/31/2007	Bell Labs: 37 aggregate summaries Jan.-Mar. 2007 14 H-D, 15 D-A, 12 D-B, 51	3	0	0	0	0	3	0	0	0

018267 - 00008	2/21/2007		QUINTOX (NON-SPECIFIC)	10/1/2006	########	D-C, 83 D-D. Tomcat Ultra. Hawk Bait Chunx. Contrac. Fastrac Bell Labs: 41 aggregate summaries Oct. - Dec. 2006 19 H-D, 14 D-A, 18 D-B, 96 D-C, 109 D-D. Hawk Bait Chunx, Tomcat, Jaguar, Fastrac, Rampage...	2	0	0	0	0	2	0	0	0
016887 - 00028	########		CHOLICALCIFEROL	7/1/2005	9/30/2005	Bell Labs: 29 aggregate summaries, July - Sept. 2005. Includes H-D minor human & domestic animal categories	1	0	0	1	0	0	0	0	0
016178 - 00022	5/11/2005		CHOLECALCIFEROL	1/1/2005	3/31/2005	Bell Labs: 24 aggregate summaries, 1/1/2005-3/31/2005: 5 H-D, 13 D-A, 4 D-B, 25 D-C, 38 D-D.	2	0	0	0	0	1	0	1	0
015028 - 00026	5/11/2004		CHOLICALCIFEROL	1/1/2004	3/31/2004	Bell Labs: 29 aggregate summaries; Jan - Mar 2004;82 incidents incl.4 H-D, 11 D-A, 34 D-C; 33 D-D	3	0	0	0	0	3	0	0	0
015028 - 00005	5/11/2004	012455-00057	QUINTOX MOUSE SEED	1/1/2004	3/31/2004	Bell Labs: 29 aggregate summaries; Jan - Mar 2004;82 incidents incl.4 H-D, 11 D-A, 34 D-C; 33 D-D	1	0	0	1	0	0	0	0	0
014738 - 00010	1/29/2004	012455-00057	QUINTOX MOUSE SEED (5 LB PAILS)	10/1/2003	########	Bell Labs.: 33 aggregate summaries, Oct. - Dec. 2003. Includes H-D, D-A, D-B, D-C, D-D	1	0	0	1	0	0	0	0	0
014738 - 00027	1/29/2004	003240-00028-012455	QUINTOX MOUSE SEED RTU PLACE PAC (10 GMS)	10/1/2003	########	Bell Labs.: 33 aggregate summaries, Oct. - Dec. 2003. Includes H-D, D-A, D-B, D-C, D-D	1	0	0	0	0	1	0	0	0
014633 - 00013	12/2/2003	012455-00057	QUINTOX MOUSE SEED (5 LB PAILS)	7/1/2003	9/30/2003	Bell Labs: 30 aggregate summaries, July - Sept. 2003. Incl. 11 H-D, 7 D-A, 2 D-B, 23 D-C, 32 D-D	1	0	0	0	0	0	0	1	0
014633 - 00025	12/2/2003	003240-00028-012455	QUINTOX MOUSE SEED READY-TO-USE PLACE PAC (10 GMS)	7/1/2003	9/30/2003	Bell Labs: 30 aggregate summaries, July - Sept. 2003. Incl. 11 H-D, 7 D-A, 2 D-B, 23 D-C, 32 D-D	2	0	0	0	0	1	0	1	0

013993 - 00028	5/20/2003		CHOLECALCIFEROL	1/1/2003	3/31/2003	Bell Labs: 33 Aggregate summaries: Jan-March 2003: incl. 86 incidents: 8 H-D, 14 D-A, 5 D-B, 26 D-C, 33 D-D.	1	0	0	1	0	0	0	0	0
013993 - 00024	5/20/2003	003240-00028-012455	QUINTOX MOUSE SEED RTU PLACE PACS (10 GMS)	1/1/2003	3/31/2003	Bell Labs: 33 Aggregate summaries: Jan-March 2003: incl. 86 incidents: 8 H-D, 14 D-A, 5 D-B, 26 D-C, 33 D-D.	1	0	0	0	0	1	0	0	0
013993 - 00005	5/20/2003	012455-00039	QUINTOX RAT & MOUSE BAIT (5.5 LB PAILS)	1/1/2003	3/31/2003	Bell Labs: 33 Aggregate summaries: Jan-March 2003: incl. 86 incidents: 8 H-D, 14 D-A, 5 D-B, 26 D-C, 33 D-D.	1	0	0	1	0	0	0	0	0
013486 - 00023	########		CHOLECALCIFEROL	7/1/2002	9/30/2002	Bell Lab: 26 Domestic and Human Aggregate summaries: 7/1/-9/30/2002: 5 H-D, 8 D-A, 2 D-B, 26 D-C, 38 D-D reports.	1	0	0	1	0	0	0	0	0
013204 - 00026	8/28/2002		CHOLICALCIFEROL	4/1/2002	6/30/2002	Bell Labs: 29 aggregate summaries, Apr. - June 2002. Incl H-D minor human and domestic animal effects	1	0	0	1	0	1	0	0	0
013204 - 00024	8/28/2002	003240-00028-012455	QUINTOX MOUSE SEED RTU PLACE PAC (10 GMS)	4/1/2002	6/30/2002	Bell Labs: 29 aggregate summaries, Apr. - June 2002. Incl H-D minor human and domestic animal effects	2	0	0	0	0	1	0	1	0
012903 - 00022	6/4/2002	003240-00028-012455	QUINTOX MOUSE SEED RTU PLACE PAC (10 GRMS)	1/1/2002	3/31/2002	Bell Labs: 25 aggregate summaries, Jan. - Mar. 2002. Includes 2 H-D, 6 D-A, 25 D-C, 20 D-D	1	0	0	0	0	0	0	1	0
012903 - 00021	6/4/2002	003240-00028	RAMPAGE MOUSE SEED PLACE PAC (10 GRMS) (VITAMIN D3)	1/1/2002	3/31/2002	Bell Labs: 25 aggregate summaries, Jan. - Mar. 2002. Includes 2 H-D, 6 D-A, 25 D-C, 20 D-D	1	0	0	1	0	0	0	0	0
012665 - 00026	3/22/2002		CHOLICALCIFEROL	10/1/2001	########	Bell Labs.: 28 aggregate summaries, Oct. - Dec. 2001. Includes H-D, domestic animal effects	1	0	0	0	0	0	0	1	0
012605 - 00012	3/6/2002		CHOLECALCIFEROL BAIT - OTHER/UNKNOWN	7/1/2001	9/30/2001	Bell Labs: 14 aggregate summaries, July-Sept. 2001: 25 incidents: 1 H-D, 5 D-A, 2 D-B, 11 D-C, 6 D-D.	1	0	0	0	0	1	0	0	0

011908 - 00023	8/20/2001		QUINTOX (NON-SPECIFIC)	4/1/2001	6/30/2001	Bell Labs: 23 aggregate summaries, Apr. - June 2001. Includes H-D, D-A, and other domestic animal effects	1	0	0	0	0	0	0	1	0
011474 - 00020	5/29/2001		CHOLECALCIFEROL	1/1/2001	3/31/2001	Bell Laboratories, Inc.: 01/01 - 03/01/2001 20 Aggregate Summaries, 6 H-D, 8 D-A, 2 D-B, 6 D-C 15 D-D.	1	0	0	0	0	1	0	0	0
011151 - 00017	2/19/2001	003240-00028-012455	QUINTOX MOUSE SEED RTU PLACE PAC	10/1/2000	########	Bell Labs: 20 Aggregate summaries. Includes H-D minor human, D-A, D-B, D-C,D,E domestic animal effects	1	0	0	0	0	0	0	1	0
011151 - 00018	2/19/2001	003240-00042-012455	QUINTOX RAT AND MOUSE BAIT PLACE PAC	10/1/2000	########	Bell Labs: 20 Aggregate summaries. Includes H-D minor human, D-A, D-B, D-C,D,E domestic animal effects	3	1	0	1	0	1	0	0	0
010898 - 00215	12/5/2000	012455-00053-000239	MOUSE-B-GON(TM) MOUSE KILLER	7/1/2000	9/30/2000	Scotts Co.: 78 indiv. incidents, H-C, P-A, mostly Oct. 2000. Also, 205 aggregate summaries, July-Sept. 2000 mostly H-D & P-B, also D-B, etc.	1	0	0	0	0	1	0	0	0
010862 - 00015	########	003240-00042-012455	QUINTOX RAT AND MOUSE BAIT PLACE PAC (30 GMS)	7/1/2000	9/30/2000	Bell Labs: 16 aggregate summaries, July - Sept. 2000. Includes 25 incidents H-D, DA, D-C, D-D	1	0	0	1	0	0	0	0	0
010862 - 00014	########	003240-00042	RAMPAGE MOUSE SED PLACE PAC	7/1/2000	9/30/2000	Bell Labs: 16 aggregate summaries, July - Sept. 2000. Includes 25 incidents H-D, DA, D-C, D-D	1	0	0	1	0	0	0	0	0
010211 - 00019	5/30/2000	003240-00028	RAMPAGE MOUSE SEED	1/1/2000	3/31/2000	Bell Labs, Inc.: 20 aggregate summaries, 1/00-3/00. H-D, D-A, D-B, D-C,D,E reports.	1	0	0	0	0	0	1	0	0
009875 - 00007	2/29/2000	012455-00057	QUINTOX MOUSE SEED	10/1/1999	########	Bell Labs: 21 Aggregate summary reports: 10/1 - 12/31/99: 35 Incidents: 2 H-D, 6 D-A, 2 D-B, 26 D-C/D/E	1	0	0	1	0	0	0	0	0
009875 - 00020	2/29/2000	003240-00028-012455	QUINTOX MOUSE SEED READY-TO-USE PLACE PAC	10/1/1999	########	Bell Labs: 21 Aggregate summary reports: 10/1 - 12/31/99:	2	0	0	0	0	0	2	0	0

009596 - 00013	########	003240-00042-012455	QUINTOX RAT AND MOUSE BAIT RTU PLACE PAC	7/24/1999	9/30/1999	35 Incidents: 2 H-D, 6 D-A, 2 D-B, 26 D-C/D/E Bell Laboratories: 13 Aggregate summary reports: a) 7/1 - 7/23/99, 1 D-C: b-m) 7/24 - 9/30/99, 2 H-D, 11 D-C/D/E, 2 D-A	1	0	0	0	0	0	1	0	0
008701 - 00009	6/8/1999	003240-00028-012455	QUINTOX MOUSE SEED RTU PLACE PAC (10 GMS)	1/1/1999	3/31/1999	Bell Labs. 11 aggregate summary reports: D-A, D-D,D-E, W-B for 1/99-3/99. One monthly report for H-B for 4/99	1	0	0	0	0	0	0	0	1
008374 - 00009	2/23/1999	012455-00039	QUINTOX RAT AND MOUSE BAIT (5.5 LB. PAILS)	10/1/1998	########	Bell Labs: 13 Aggregate reports: 10/1/98 - 12/31/98: D-B, D-C, D-D, D-E, W-B	1	0	0	0	0	1	0	0	0
005463 - 00242	7/2/1997	012455-00058-000239	RAT-B-GON RAT & MOUSE KILLER BAIT	5/1/1997	5/31/1997	Solaris compilation, May 1997: 914 brief reports: 531 human, 186 domestic animal and 197 plant incidents. Later reprocessed into 154 individual incidents plus 90 aggregate summaries.	1	0	0	0	0	0	0	1	0
005116 - 00128	4/30/1997	012455-00053-000239	MOUSE-B-GON(TM) MOUSE KILLER	3/1/1997	3/31/1997	Solaris: 473 brief human, domestic animal and plant incidents: March 1997. Reprocessed into 59 indiv. H-C reports & 70 aggregate summaries	1	0	0	0	0	1	0	0	0