NOSB NATIONAL LIST
FILE CHECKLIST

CROPS

MATERIAL NAME: **#21 Vitamin D3**

NOSB Database Form

References

MSDS (or equivalent)

TAP Reviews from: Gregg Young
(Additional TAP Review expected from: Donald Blakeney)

NOSB/NATIONAL LIST
COMMENT FORM
CROPS

Material Name: #21 Vitamin D3

Please use this page to write down comments, questions, and your anticipated vote(s).

COMMENTS/QUESTIONS:

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1. In my opinion, this material is:
_____ Synthetic _____ Non-synthetic.

2. This material should be placed on the proposed National List as:
_____Prohibited Natural _____Allowed Synthetic.

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

This file is due back to us by: September 19, 1995

Name of Material: Vitamin D3

Reviewer Name: _____

Is this substance Synthetic or non-synthetic? Explain (if appropriate)
NATURAL COMPOUND SYNTHETICALLY PRODUCED

If synthetic, how is the material made? (please answer here if our database form is blank)

This material should be added to the National List as:

X **Synthetic Allowed** ____ **Prohibited Natural**

or, ____ **Non-synthetic (This material does not belong on National List)**

Are there any use restrictions or limitations that should be placed on this material on the National List?
FOLLOW LABEL - USE OUT OF REACH OF NON-TARGET ORGANISMS

Please comment on the accuracy of the information in the file:
ADD: USE ON GOPHERS PENDING (1996)

Any additional comments? (attachments welcomed)

Do you have a commercial interest in this material? ____ **Yes;** X **No**

Signature Gregg A Yoo **Date** 9/13/95

Please address the 7 criteria in the Organic Foods Production Act:
(comment in those areas you feel are applicable)

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

NOT LIKELY - A BAIT NOT TO BE MIXED

(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment; LOOKS BETTER THAN ALL OTHER CHEMICAL RODENTICIDES + ORGANIC = STRYCHNINE

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

NOT LIKELY IF FOLLOWING LABEL

(4) the effect of the substance on human health;

NOT LIKELY TO CAUSE PROBLEMS

(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

IF USED IN BAIT STATIONS DESIGNED FOR TARGET SPECIES SHOULD BE SAFE TO NON-TARGET

(6) the alternatives to using the substance in terms of practices or other available materials; and TRAPPING STRYCHNINE (!)

(7) its compatibility with a system of sustainable agriculture.

LOOKS COMPATIBLE

NOSB Materials Database

Identification

Common Name **Vitamin D3**

Chemical Name 1-alpha-hydroxy ergocalciferol

Other Names Cholecalciferol, Quintox

Code #: CAS 54573-75-0

Code #: Other

N. L. Category Synthetic Allowed

MSDS no

Chemistry

Family

Composition

Properties

How Made

Made from cholesterol isolated from natural sources. The cholesterol is converted chemically into 7-dehydrocholesterol, which is then irradiated with ultraviolet light to form cholecalciferol. This is the same reaction that occurs in the skin upon exposure to sunlight.

Use/Action

Type of Use

Use(s) Crops

Rodent bait for mice and rats. GOPHERS + MOLES REGISTRATION PENDING ≈ 9/96

Action After ingestion, it induces mobilization of calcium resulting in hypercalcemia and mineralization of major organs.

Combinations

Status

OFPA

N. L. Restriction Allowed as a rodent bait

EPA, FDA, etc

Safety Guidelines

Directions

Registration

State Differences

Historical status

Internationl status

NOSB Materials Database

OFPA Criteria

2119(m)1: chemical interactions

2119(m)2: toxicity & persistence

Cholecalciferol breaks down readily by the same metabolic pathways as Vitamin D. While its toxicity to a variety of target species is known; there are few data on the effects of cholecalciferol on non-target species.

MSDS SHOWS VERY LOW ACUTE TOX. TO MALLARD DUCK

2119(m)3: manufacture & disposal consequences

2119(m)4: effect on human health

A NATURAL OCCURRING VITAMEN WHICH COULD BE TOXIC ONLY IF CONSUMED IN LARGE AMOUNTS

2119(m)5: agroecosystem biology

IF USED IN BAIT STATIONS DESIGNED FOR THE TARGET SPECIES SHOULD BE SAFE TO NON-TARGETS

2119(m)6: alternatives to substance

TRAPPING, STRYCHNINE (!)

2119(m)7: Is it compatible?

YES

References

Evaluation of Quintox for control of feral house mice. Twigg, L.E.; Kay, B.J. Journal of Wildlife Management, Wildlife Society, Bethesda, MD. January 1992, v. 56 (1) pp 174-185.

Marsh, R.E., and A.E. Koehler. 1990. A study of the potential secondary hazards of cholecalciferol when treated mice are consumed by gopher snakes. Bell Lab., Madison, WI 11pp.

Marsh, R.E. and A. Tunberg. 1986. Characteristics of cholecalciferol. Rodent Control: other options. Pest Control Tech. 14:43-45.

AU: Nowicki,-H-G; Myrtle,-J-F; Norman,-A-W
TI: Effects of organochlorine insecticides on metabolism of cholecalciferol (vitamin D3) in rachitic cockerel
SO: J-Agr-Food-Chem, Mar/Apr 1972, 20 (2): 380-384. Ref.
CN: DNAL 381-J8223

Quintox® RAT& MOUSE BAIT

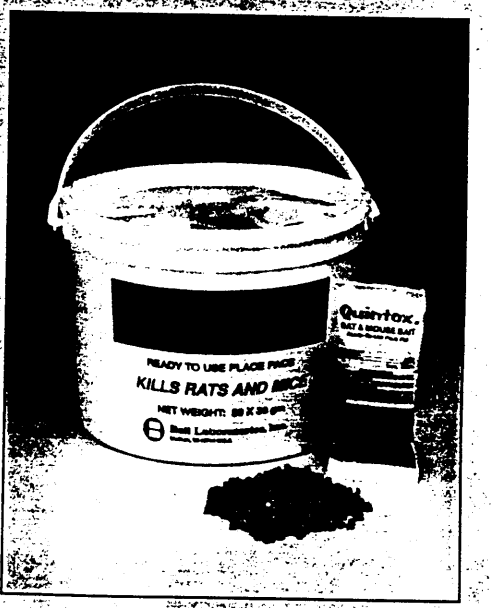
A Stop-Feed Rodenticide

QUINTOX Rat and Mouse Bait contains the active ingredient, Cholecalciferol, better known as Vitamin D_3, which takes a completely different biological pathway to killing rodents, including anticoagulant-resistant rodents.

Unlike anticoagulants, once a rodent eats a lethal dose of QUINTOX, all feeding stops. The toxicant mobilizes calcium from the rodent's bones into its bloodstream, producing hypercalcemia and heart failure. QUINTOX acts faster than anticoagulants, causing death in 2 to 4 days.

Rodents can consume a lethal dose of QUINTOX in a single day's feeding or accumulated in smaller, multiple feedings over a period of days. Just 1/10 oz. (2.8 grams) of QUINTOX can kill a mouse, while 1/4 oz. (7 grams) is a lethal dose for most rats. Bait shyness is not a problem with QUINTOX because toxic symptoms do not start until after a lethal dose is consumed.

Tests also show that no secondary hazards exist with QUINTOX. It is approved for use in and around homes, farms and commercial establishments.



Packaging: 5 1/2 lb. bulk plastic pails
pails of 50 x 30 g. place pacs – EPA REG. NO. 3240-42-12455

Specimen Label

DIRECTIONSFOR USE

is a violation of Federal law to use this product in a manner inconsistent with its labeling.

USE RESTRICTIONS: Treated baits must be placed in locations not accessible to children, pets, domestic animals, wildlife or placed in tamper-proof bait stations. Do not place baits in areas where there is a possibility of contaminating food or surfaces that come in direct contact with food.
For control of Norway rats, roof rats, and house mice in and around homes, industrial, commercial, agricultural, and poultry buildings, and similar manmade structures. QUINTOX may also be used inside transport vehicles (ships, trains, aircraft) and in and around related port or terminal buildings.

SELECTION OF TREATMENT AREAS: Determine areas where rats and/or mice will most likely find and consume the bait. Generally, these areas are along walls, by gnawed openings in or beside burrows, in corners and concealed places, between floors and walls or in locations where rodents or their signs have been observed. Protect bait from rain or snow. Remove as much food as possible.

APPLICATION DIRECTIONS

RATS: Apply 2 to 8 ounces of bait (usually at intervals of 15 to 30 feet) per placement. Maintain an uninterrupted supply of fresh bait for 15 days or until signs of rat activity cease.

HOUSE MICE: Apply 1/4 to 1/2 ounce of bait at intervals of 8 to 12 feet per placement. Larger placements (up to 1 ounce) may be needed at points of high mouse activity. Maintain an uninterrupted supply of fresh bait for 10 days or until all signs of mouse activity cease.

RATS & MICE: Replace contaminated or spoiled bait immediately. Collect and dispose of all dead animals and unconsumed bait properly. To prevent reinfestation eliminate food, water, and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish bait as needed.

Quintox®

RAT & MOUSE BAIT

KILLS RATS AND MICE

ACTIVE INGREDIENT:	Cholecalciferol	0.075%
INERT INGREDIENTS	.....	99.925%
	TOTAL	100.000%

KEEP OUT OF REACH OF CHILDREN
CAUTION

(See right for additional precautionary statements.)

Mfg. by:
Bell Laboratories, Inc.
Madison, WI 53704

EPA EST. NO. 12455-WI-1 EPA REG. NO. 12455-39

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Keep away from humans, domestic animals, and pets.

STATEMENT OF PRACTICAL TREATMENT: If swallowed, drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Avoid use of all oils.

NOTICE TO PHYSICIAN: If serum calcium levels are elevated, treatment with Calcitonin is effective in reducing calcium to normal levels. Continue monitoring serum calcium and treat as necessary for hypercalcemia (Reference, AMA Drug Evaluations, Third Edition (1977), Chapter 16, pp. 248-251).

ENVIRONMENTAL HAZARDS

Keep out of lakes, streams or ponds.

STORAGE AND DISPOSAL

STORAGE: Store only in original container, in a dry area inaccessible to children and pets.

DISPOSAL: Do not reuse empty container. Securely wrap original container in several layers of newspaper and discard in trash.

WARRANTY: Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.

QUINTOX®

MSDS
Date of Issue:
AUGUST 1992

MANUFACTURERS ADDRESS:	Prepared by:	TELEPHONE NO.:	EMERGENCY PHONE NO.:
BELL LABORATORIES, INC. 3699 KINSMAN BLVD., MADISON WI 53704	VJD	(608) 241-0202	Contact your local Poison Control Center.

PRODUCT NAME:	CAS NO.:
QUINTOX •	67-97-0

CHEMICAL FAMILY:	CHEMICAL NAME & SYNONYMS:
Sterol	9,10-Secocholesta-5,7,10 (19)-trien-3 betaol; activated 7 -dehydrocholesterol
CHEMICAL FORMULA:	TRADE NAME & SYNONYMS:
$C_{27}H_{44}O$	Cholecalciferol (Vitamin D_3)

SECTION I. HAZARDOUS INGREDIENTS

ACTIVE INGREDIENTS:	%	CURRENT TLV
Cholecalciferol	.075	N.E.

SECTION II. PHYSICAL DATA OF ACTIVE INGREDIENT

APPEARANCE & ODOR:	MOLECULAR WEIGHT:	MELT POINT:	SPECIFIC GRAVITY:
Odorless Crystal	384.62	84-85° C	NA
VAPOR DENSITY (AR=1):	**COLOR:**	**BULK DENSITY: (Finished Product)**	**BOILING POINT:**
NA	White	43 lbs./ft³	NA
VAPOR PRESSURE:	**SOLUBILITY:**	**WATER REACTIVE:**	**EVAPORATION RATE:**
NA	Insoluble in water.	NA	NA

SECTION III. FIRE & EXPLOSION DATA OF PRODUCT

FLASH POINT F (METHOD USED):	FLAMMABLE LIMIT:	AUTOIGNITION TEMP.:
NA	NA	NA

EXTINGUISHING MEDIA:
Extinguish with water, foam or inert gas.

SPECIAL FIRE FIGHTING PROCEDURES:
None

UNUSUAL FIRE OR EXPLOSION HAZARDS:
None

SECTION IV. REACTIVITY HAZARD DATA OF ACTIVE INGREDIENT

STABILITY:	CONDITIONS TO AVOID:
Stable.	None
POLYMERIZATION:	**CONDITIONS TO AVOID:**
Will not occur.	None

INCOMPATABILITY (MATERIALS TO AVOID):	HAZARDOUS DECOMPOSITION PRODUCTS:
None	None

SECTION V. TOXICITY DATA

LD50, ORAL (INGESTION): (100% AI)	LD50, DERMAL (SKIN CONTACT): (.075% Bait)	LD50, ORAL (INGESTION): (100% AI)
[Rat] 43.6 mg/kg	[Rabbit] greater than 2000 mg/kg	[Mice] 42.5 mg/kg
FISH, LC50 (LETHAL CONCENTRATION):	**LD50, ORAL:** (30% AI)	**8 DAY LC50:** (30% AI)
NE	[Mallard Duck] 2000 mg/kg	[Mallard Duck] 4000 ppm [Bobwhite Quail] 2000 ppm

SECTION VI. HEALTH HAZARD DATA OF PRODUCT

PRIMARY ROUTE OF ENTRY:	MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:	SIGNAL WORD:
☒ Ingestion ☐ Skin & eye contact ☐ Inhalation ☐ Skin absorption	None	Caution

HEALTH HAZARDS:	SIGNS & SYMPTOMS OF EXPOSURE:
1 - Caution	Hypercalcemia if ingested.

EMERGENCY FIRST AID PROCEDURES:
Eyes: Flush with water. **Skin:** Wash with soap &water. **Inhalation:** Non-hazardous.
Ingestion: Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Avoid use of all oils

SPECIAL PROTECTION INFORMATION:
If serum levels are elevated treatment with calcitonin is effective in reducing calcium to normal levels, continue monitoring serum calcium and treat as necessary for hypercalcemia. (Reference, AMA Drug Evaluations, Third Edition (1977), Chapter 16, pp. 248-251).

SECTION VII. CONTROL & PROTECTIVE MEASURES OF PRODUCT

RESPIRATOR TYPE:
None

EYE PROTECTION:	GLOVES:	VENTILATION:
None	Rubber gloves	None

OTHER PROTECTIVE MEASURES:
Wash hands after use.

SECTION VIII. SPILL OR LEAK PROCEDURE OF PRODUCT

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:
General clean-up.

WASTE DISPOSAL METHOD:
Wastes resulting from use may be disposed of on site or at an approved waste disposal facility.

SECTION IX. SPECIAL PRECAUTIONS & STORAGE DATA OF PRODUCT

STORAGE TEMERATURE:	AVERAGE SHELF LIFE:
Room temperature	Bait is stable for more than 1 year when stored properly.

SPECIAL SENSITIVITY (HEAT, LIGHT, MOISTURE):
Keep out of direct sunlight and away from high heat and moist conditions.

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING:
For best results store in a cool, dark, dry location. Store away from offensive odors.

SECTION X. SHIPPING DATA OF PRODUCT

D.O.T. SHIPPING NAME:	TECHNICAL SHIPPING NAME:
QUINTOX	Rodenticide containing Cholecalciferol (Vitamin D_3).

D.O.T. HAZARD CLASSIFICATION:	
Non-hazardous	
D.O.T. LABELS REQUIRED:	**FREIGHT CLASSIFICATION:**
None	Class 60

LIQUA-TOX II®

MSDS
Date of Issue:
NOVEMBER 1992

MANUFACTURERS ADDRESS:	Prepared by:	TELEPHONE NO.:	EMERGENCY PHONE NO.:
BELL LABORATORIES, INC. 3699 KINSMAN BLVD., MADISON WI 53704	VJD	(608) 241-0202	Contact your local Poison Control Center.

PRODUCT NAME:	CAS NO.:
LIQUA-TOX II®	82-66-6

CHEMICAL FAMILY:	CHEMICAL NAME & SYNONYMS:
Indandione	2-Diphenylacetyl -1, 3-Indandione, Sodium Salt
CHEMICAL FORMULA:	TRADE NAME & SYNONYMS:
$C_{23}H_{15}O_3Na$	Sodium Salt of Diphacinone

SECTION I. HAZARDOUS INGREDIENTS

ACTIVE INGREDIENTS:	%	CURRENT TLV
Sodium Salt of Diphacinone	.106	N.E.

SECTION II. PHYSICAL DATA OF ACTIVE INGREDIENT

APPEARANCE & ODOR:	MOLECULAR WEIGHT:	MELT POINT:	SPECIFIC GRAVITY:
Odorless liquid.	340.36	146-147° C	NA
VAPOR DENSITY (AR=1):	**COLOR:**	**BULK DENSITY: (Finished Product)**	**BOILING POINT:**
NA	Yellow	1.6 gm/ml	NA
VAPOR PRESSURE:	**SOLUBILITY:**	**WATER REACTIVE:**	**EVAPORATION RATE:**
NA	Soluble in water.	No reaction	NA

SECTION III. FIRE & EXPLOSION DATA OF PRODUCT

FLASH POINT F (METHOD USED):	FLAMMABLE LIMIT:	AUTOIGNITION TEMP.:
NA	NA	NA

EXTINGUISHING MEDIA:
Extinguish with water, foam or inert gas.

SPECIAL FIRE FIGHTING PROCEDURES:
None

UNUSUAL FIRE OR EXPLOSION HAZARDS:
None

SECTION IV. REACTIVITY HAZARD DATA OF ACTIVE INGREDIENT

STABILITY:	CONDITIONS TO AVOID:
Stable.	NA
POLYMERIZATION:	**CONDITIONS TO AVOID:**
Will not occur.	NA

INCOMPATABILITY (MATERIALS TO AVOID):	HAZARDOUS DECOMPOSITION PRODUCTS:
None	None

SECTION V. TOXICITY DATA

LD50, ORAL (INGESTION): (100% AI)	LD50, DERMAL (SKIN CONTACT): (.2% AI)	INHALATION: (.2% AI)
[Rat] 3.0 mg/kg	[Rabbit] > 1.8 g/kg	[Rat] > 5.13 mg/liter
FISH, LC50 (LETHAL CONCENTRATION):	**SKIN IRRITATION:** (.2% AI)	**EYE IRRITATION:** (.2% AI)
NE	[Rabbit] Not considered to be an irritant.	[Rabbit] Practically non irritating.

SECTION VI. HEALTH HAZARD DATA OF PRODUCT

PRIMARY ROUTE OF ENTRY:	MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE:	SIGNAL WORD:
☒ Ingestion ☐ Skin & eye contact ☐ Inhalation ☐ Skin absorption	None	Caution

HEALTH HAZARDS:	SIGNS & SYMPTOMS OF EXPOSURE:
1 - Caution: May be irritating.	May reduce clotting ability of the blood and cause bleeding.

EMERGENCY FIRST AID PROCEDURES:
Eyes: Flush with plenty of water. **Skin:** Wash with soap & water. **Inhalation:** None
Ingestion: Administer Vitamin K_1 intramuscularly or orally as indicated in bishydroxycoumarin overdoses. Repeat as necessary based on monitoring of prothrombin times.

SPECIAL PROTECTION INFORMATION:
None.

SECTION VII. CONTROL & PROTECTIVE MEASURES OF PRODUCT

RESPIRATOR TYPE:
None

EYE PROTECTION:	GLOVES:	VENTILATION:
None	None	None

OTHER PROTECTIVE MEASURES:
None

SECTION VIII. SPILL OR LEAK PROCEDURE OF PRODUCT

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:
General clean-up.

WASTE DISPOSAL METHOD:
Wastes resulting from use may be disposed of on site or at an approved waste disposal facility.

SECTION IX. SPECIAL PRECAUTIONS & STORAGE DATA OF PRODUCT

STORAGE TEMERATURE:	AVERAGE SHELF LIFE:
Room temperature.	Bait is stable for a minimum of 1 year when stored properly.

SPECIAL SENSITIVITY (HEAT, LIGHT, MOISTURE):
None

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING:
None

SECTION X. SHIPPING DATA OF PRODUCT

D.O.T. SHIPPING NAME:	TECHNICAL SHIPPING NAME:
Liqua-Tox II	Rodenticide containing Diphacinone

D.O.T. HAZARD CLASSIFICATION:	
Non-hazardous	
D.O.T. LABELS REQUIRED:	**FREIGHT CLASSIFICATION:**
None	Class 60

Identification

Common Name **Vitamin D3**

Chemical Name 1-alpha-hydroxy ergocalciferol

Other Names Cholecalciferol, Quintox

Code #: CAS 54573-75-0

Code #: Other

N. L. Category Synthetic Allowed

MSDS no

Chemistry

Family

Composition

Properties

How Made

Made from cholesterol isolated from natural sources. The cholesterol is converted chemically into 7-dehydrocholesterol, which is then irradiated with ultraviolet light to form cholecalciferol. This is the same reaction that occurs in the skin upon exposure to sunlight.

Use/Action

Type of Use Crops

Use(s) Rodent bait for mice and rats.

Action After ingestion, it induces mobilization of calcium resulting in hypercalcemia and mineralization of major organs.

Combinations

Status

OFPA

N. L. Restriction Allowed as a rodent bait

EPA, FDA, etc

Safety Guidelines

Directions

Registration

State Differences

Historical status

Internationl status

OFPA Criteria

2119(m)1: chemical interactions

2119(m)2: toxicity & persistence

Cholecalciferol breaks down readily by the same metabolic pathways as Vitamin D. While its toxicity to a variety of target species is known; there are few data on the effects of cholecalciferol on non-target species.

2119(m)3: manufacture & disposal consequences

2119(m)4: effect on human health

2119(m)5: agroecosystem biology

2119(m)6: alternatives to substance

2119(m)7: Is it compatible?

References

Evaluation of Quintox for control of feral house mice. Twigg, L.E.; Kay, B.J. Journal of Wildlife Management, Wildlife Society, Bethesda, MD. January 1992, v. 56 (1) pp 174-185.

Marsh, R.E., and A.E. Koehler. 1990. A study of the potential secondary hazards of cholecalciferol when treated mice are consumed by gopher snakes. Bell Lab., Madison, WI 11pp.

Marsh, R.E. and A. Tunberg. 1986. Characteristics of cholecalciferol. Rodent Control: other options. Pest Control Tech. 14:43-45.

AU: Nowicki,-H-G; Myrtle,-J-F; Norman,-A-W
TI: Effects of organochlorine insecticides on metabolism of cholecalciferol (vitamin D3) in rachitic cockerel
SO: J-Agr-Food-Chem, Mar/Apr 1972, 20 (2): 380-384. Ref.
CN: DNAL 381-J8223

United States
Environmental Protection
Agency

Office of Pesticides and Toxic Substances
Office of Pesticide Programs (TS-766C)
Washington, DC 20460

EPA

Pesticide Fact Sheet

PB87-115622

Name of Chemical: VITAMIN D3
Reason for Issuance:
Date Issued: December 1, 1984
Fact Sheet Number: 42

1. Description of chemical:

Generic name: Cholecalciferol, Activated 7-dehydrocholesterol, oleovitamin D_3, 9,10-secocholesta-5,7,10(19)-trien-3B-ol [NEW CHEMICAL]
Common name:
Trade name: Vitamin D_3
EPA Shaughessy code: 208700
Chemical Abstracts Service (CAS) number: 434-16-2
Year of initial registration: 1984
Pesticide type: rodenticide
Chemical family: sterol
U.S. and foreign producers: Phillips-Duphar (Netherlands)
Active ingredient
Bell Laboratories (Madison, WI)
Formulated product

2. Use patterns and formulations:

Application sites: in and around buildings, inside of transport vehicles
Pest species: norway rats, roof rats, and house mice
Type of formulations: granular (0.075% bait)
Type and method of application: topical, hand application
Application rates: 2-8 oz./15-30 ft. (rats)
1/4-1 oz./8-12ft. (mice)
Usual carriers: Confidential Business Information

3. Science findings:

Summary science statement:

Adequate studies are available to assess the acute toxicological hazards of technical and formulated Vitamin D_3. No toxicological hazards of concern were identified. Available studies indicate that Vitamin D_3 is of low toxicity to birds; studies on fish are inapplicable because Vitamin D_3 is virtually insoluble in water. The registration of this new active ingredient is conditioned on submittal of additional efficacy data by January 1976.

Chemical characteristics:

Technical Vitamin D_3 is a solid resin. The empirical formula is $C_{27}H_{44}O$, and the molecular weight is 384.62. The melting point is is 84-85°C. Vitamin D_3 is practically soluble in water, soluble in the usual organic solvents, and slightly soluble in vegetable oils.

Toxicological characteristics:

Currently available toxicology studies on Vitamin D_3 are as follows:

- Oral LD_{50} in rats: 352 mg/kg and 42 mg/kg for males and 619 mg/kg for females.
- Dermal LD_{50} in rabbits: >2000 mg/kg.
- Primary dermal irritation: not required because technical is a solid resin.
- Primary eye irritation: not required because technical is a solid resin.
- Inhalation LC_{50}: not required because technical is a solid resin.
- Acute, 60-day, Delayed Toxicity Study in rats: Acute dose, equal to accidental exposure, produced no elevated serum calcium levels and no abnormal long bone growth in young rats.
- Teratology in rats: not required because technical is a solid resin and Vitamin D_3, is a dietary supplement in the adult female diet.

Adequate studies are available to assess the acute toxicological effects of Vitamin D_3. No toxicological hazards of concern have been identified in the studies reviewed for this new pesticide.

Physiological and biochemical behavioral characteristics:

The registrant submitted a volume on the metabolism and function of Vitamin D_3. However, because Vitamin D_3 is a non-food use, is applied topically, and in small amounts, we did not review this submission of such information.

Environmental characteristics:

Because of the use pattern of this chemical (in and around buildings and inside of transport vehicles, we did not request any enviornmenal fate data.

Ecological characteristics:

Based on studies available to assess hazards to wildlife and aquatic organisms, Vitamin D_3 is characterized as being of low toxicity to birds. Because the chemical is virtually insoluable in water, we requested no aquatic toxicity data.

Results of currently available studies are as follows:

- avian oral LD_{50}: >2000 mg/kg (mallard duck)
- avian dietary LC_{50}: 4000 ppm (mallard duck)
  2000 ppm (bobwhite quail)
- fish LC_{50}: not required because technical is virtually insoluable in water.
- aquatic invertebrate LC_{50}: not required because technical is virtually insoluable in water.

Product Performance characteristics:

Because the Agency had suspended the efficacy requirements for this type of product, the company did not complete all the pre-suspension data. Subsequently, the Agency notified the company that it had re-instituted these data. The company will have a reasonable period of time (until January 1, 1986) to supply the missing laboratory and field data.

4. Summary of regulatory position and rationale:

The Agency has placed the one registered formulation in Toxicity Category III (CAUTION) and has classified this use pattern (in and around buildings and inside of transport vehicles for norway rats, roofs rats, and house mice) as "Unclassified". Such a product can be sold over-the-counter. The Agency has not identified a potential for adverse effects for man or the environment, based on the submitted toxicology and fish and wildlife data. Because of re-institution of the efficacy data requirements, the registration will be conditioned on the submittal of additional, acceptable laboratory and field efficacy data within fourteen months.

5. Summary of major data gaps:

-LD-50 tests on target species
-Laboratory, choice-test, efficacy data for target species
-Field efficacy data

All studies are to be submitted to the Agency by January 1, 1986.

6. Contact Person at EPA

William H. Miller
Product Manager (16)
Registration Division (TS-767C)
Insecticide-Rodenticide Branch
Environmental Protection Agency
Washington, DC 20460

Tel. No. (703) 557-2600