according to the Hazardous Products Regulations



## **Betaine / Multivitamin Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/14/2025 4.0 06/18/2025 11513564-00005 Date of first issue: 02/24/2025

## **SECTION 1. IDENTIFICATION**

Product name : Betaine / Multivitamin Formulation

Product code : Supastock

Other means of identification : No data available

## Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

## GHS classification in accordance with the Hazardous Products Regulations

Skin sensitization : Category 1

## **GHS** label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements : Prevention:

P261 Avoid breathing dust.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P280 Wear protective gloves.

### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P333 + P313 If skin irritation or rash occurs: Get medical atten-

tion.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

## Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

according to the Hazardous Products Regulations



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## **Additional Labeling**

The following percentage of the mixture consists of ingredient(s) with unknown acute oral toxicity: 20 %

The following percentage of the mixture consists of ingredient(s) with unknown acute dermal toxicity: 20 %

The following percentage of the mixture consists of ingredient(s) with unknown acute inhalation toxicity: 20 %

## Other hazards

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

#### Components

Chemical name	Common	CAS-No.	Concentration (% w/w)
	Name/Synonym		
Starch	Sago starch	9005-25-8	>= 10 - < 30 *
3,7-Dimethyl 2,6-	2,6-Octadienal,	5392-40-5	>= 0.1 - < 1 *
octadienal	3,7-dimethyl-		>= 0.1 < 1
(dl)-a-Tocopheryl ace-	2H-1-	7695-91-2	
tate	Benzopyran-6-		
	ol, 3,4-dihydro-		
	2,5,7,8-		
	tetramethyl-2-		>= 0 - < 0.1 *
	(4,8,12-		
	trimethyl-		
	tridecyl)-, 6-		
	acetate		
Betaine hydrochloride	Methanamini-	590-46-5	
	um, 1-carboxy-		>= 0 - < 0.1 *
	N,N,N-trimethyl-		>= 0 - < 0.1
	, chloride		
Benzyl alcohol	Benzenemetha-	100-51-6	>= 0 - < 0.1 *
	nol		>= 0 < 0.1
Pyridoxine Hydrochlo-	3,4-	58-56-0	
ride	Pyridinedi-		
	methanol, 5-		>= 0 - < 0.1 *
	hydroxy-6-		>= 0 - < 0.1
	methyl-, hydro-		
	chloride		
Colecalciferol	Cyclohexanol,	67-97-0	
	3-[(2E)-2-		
	[(1R,3aS,7aR)-		
	1-[(1R)-1,5-		
	dimethylhex-		>= 0 - < 0.1 *
	yl]octahydro-7a-		/= 0 \ 0.1
	methyl-4H-		
	inden-4-		
	yli-		
	dene]ethylidene]		

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-4-methylene-,

Actual concentration or concentration range is withheld as a trade secret

**SECTION 4. FIRST AID MEASURES** 

General advice In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

If in eyes, rinse well with water. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur.

Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. May cause an allergic skin reaction.

Protection of first-aiders First Aid responders should pay attention to self-protection.

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES** 

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx) Chlorine compounds

Metal oxides

Oxides of phosphorus

according to the Hazardous Products Regulations



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Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment :

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable

container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation Advice on safe handling

Use only with adequate ventilation.

Do not get on skin or clothing.

Avoid breathing dust. Do not swallow.

Avoid contact with eyes.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Minimize dust generation and accumulation.

according to the Hazardous Products Regulations



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> Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

## Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m³	CA AB OEL
		TWA (Total dust)	10 mg/m³	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m³	CA BC OEL
		TWAEV (to- tal dust)	10 mg/m³	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
3,7-Dimethyl 2,6-octadienal	5392-40-5	TWAEV (in- halable frac- tion and va- pour)	5 ppm	CA QC OEL
		TWA (Inhalable fraction and vapor)	5 ppm	ACGIH
(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 ug/m3 (OEB 1)	Internal
Betaine hydrochloride	590-46-5	TWA	>= 100< 1000 µg/m3 (OEB2)	Internal
Pyridoxine Hydrochloride	58-56-0	TWA	OEB 3 (>= 10 < 100 μg/m3)	Internal
Colecalciferol	67-97-0	TWA	5 μg/m3 (OEB 4)	Internal
		Wipe limit	50 μg/100 cm <sup>2</sup>	Internal

# **Engineering measures**

The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance

according to the Hazardous Products Regulations



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Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from

stationary container, ventilated enclosure, etc.).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment. Essentially no open handling permitted.

Use closed processing systems or containment technologies.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

: Particulates type

Filter type

Hand protection

Material

Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : powder

according to the Hazardous Products Regulations



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Color : yellow

Odor : characteristic

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

handling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

according to the Hazardous Products Regulations



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Particle characteristics

Particle size : No data available

## **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

## Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

#### **Acute toxicity**

Not classified based on available information.

## **Components:**

#### Starch:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

# 3,7-Dimethyl 2,6-octadienal:

Acute oral toxicity : LD50 (Rat, female): 4,895 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.68 mg/l

Exposure time: 7 h
Test atmosphere: vapor

Acute dermal toxicity : LD50 (Rabbit): 2,250 mg/kg

## (dl)-a-Tocopheryl acetate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 3,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

according to the Hazardous Products Regulations



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П

Betaine hydrochloride:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Method: OECD Test Guideline 401

Remarks: The test was conducted according to guideline

Based on data from similar materials

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

**Pyridoxine Hydrochloride:** 

Acute oral toxicity : LD50 (Rat): 4,000 mg/kg

Colecalciferol:

Acute oral toxicity : LD50 (Rat, male): 35 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: 0.05 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: 50 mg/kg

Method: Expert judgment

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

3,7-Dimethyl 2,6-octadienal:

Species : Rabbit Result : Skin irritation

(dl)-a-Tocopheryl acetate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Betaine hydrochloride:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 439

Remarks : The test was conducted according to guideline

according to the Hazardous Products Regulations



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Result : No skin irritation

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

**Pyridoxine Hydrochloride:** 

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Starch:

Species : Rabbit

Result : No eye irritation

3,7-Dimethyl 2,6-octadienal:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

(dl)-a-Tocopheryl acetate:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Betaine hydrochloride:

Result : Irreversible effects on the eye

Benzyl alcohol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Pyridoxine Hydrochloride:

Species : Rabbit

Result : No eye irritation

Colecalciferol:

Species : Rabbit

Result : No eye irritation

according to the Hazardous Products Regulations



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## Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

## Respiratory sensitization

Not classified based on available information.

### Components:

#### Starch:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

# 3,7-Dimethyl 2,6-octadienal:

Test Type : Human repeat insult patch test (HRIPT)

Routes of exposure : Skin contact Result : positive

Assessment : Probability or evidence of skin sensitization in humans

## (dl)-a-Tocopheryl acetate:

Test Type : Draize Test
Routes of exposure : Skin contact
Species : Humans
Result : negative

## Betaine hydrochloride:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : The test was conducted according to guideline

# Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)

Routes of exposure : Skin contact
Species : Humans
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitization

rate in humans

# **Pyridoxine Hydrochloride:**

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

according to the Hazardous Products Regulations



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Result : negative

Colecalciferol:

Test Type : Maurer optimisation test

Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Starch:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

3,7-Dimethyl 2,6-octadienal:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: In vitro sister chromatid exchange assay in mam-

malian cells Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay)

Species: Mouse

Application Route: Ingestion

Result: negative

(dl)-a-Tocopheryl acetate:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay)

Species: Mouse

Application Route: Ingestion

according to the Hazardous Products Regulations



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Result: negative

Betaine hydrochloride:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: Directive 67/548/EEC, Annex V, B.13/14.

Result: negative

Remarks: The test was conducted according to guideline

Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: The test was conducted according to guideline

Based on data from similar materials

Test Type: Chromosome aberration test in vitro Method: Directive 67/548/EEC, Annex V, B.10.

Result: negative

Remarks: The test was conducted according to guideline

Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

Remarks: The test was conducted according to guideline

Based on data from similar materials

Benzyl alcohol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Pyridoxine Hydrochloride:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Colecalciferol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: equivocal

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

according to the Hazardous Products Regulations



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Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay)

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

Test Type: In vivo mammalian alkaline comet assay

Species: Rat

Application Route: Ingestion

Result: positive

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

### Carcinogenicity

Not classified based on available information.

## **Components:**

# 3,7-Dimethyl 2,6-octadienal:

Species : Mouse Application Route : Ingestion

Exposure time : 104 - 105 weeks

Result : negative

## (dl)-a-Tocopheryl acetate:

Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative

## Betaine hydrochloride:

Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks

Method : OECD Test Guideline 453

Result : negative

Remarks : The test was conducted equivalent or similar to guideline

Based on data from similar materials

## Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

according to the Hazardous Products Regulations



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Method : OECD Test Guideline 451

Result : negative

# Reproductive toxicity

Not classified based on available information.

#### Components:

## 3,7-Dimethyl 2,6-octadienal:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 443

Result: negative

Effects on fetal development : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 443

Result: negative

(dl)-a-Tocopheryl acetate:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Ingestion

Result: negative

Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development

Species: Mouse

Application Route: Ingestion

Result: negative

**Pyridoxine Hydrochloride:** 

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

according to the Hazardous Products Regulations



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## **STOT-single exposure**

Not classified based on available information.

#### STOT-repeated exposure

Not classified based on available information.

## Components:

#### Colecalciferol:

Routes of exposure : Ingestion

Target Organs : Kidney, Blood, Bone

: Shown to produce significant health effects in animals at con-Assessment

centrations of 10 mg/kg bw or less.

#### Repeated dose toxicity

## **Components:**

#### Starch:

Species : Rat

Application Route
Exposure time
Method >= 2,000 mg/kgSkin contact28 Days

Method : OECD Test Guideline 410

### 3,7-Dimethyl 2,6-octadienal:

Species : Rat, female LOAEL : 335 mg/kg Application Route : Ingestion : Rat, female Exposure time : 14 Weeks

# (dl)-a-Tocopheryl acetate:

: Rat Species : 500 mg/kg : Ingestion NOAEL Application Route Exposure time : 90 Days

#### Betaine hydrochloride:

**Species** : Rat

LOAEL : > 100 mg/kgApplication Route : Ingestion
Exposure time : 90 Days
Method : OECD Test Guideline 408

Remarks : The test was conducted according to guideline

Based on data from similar materials

## Benzyl alcohol:

Species Rat NOAEL 1.072 mg/l

Application Route inhalation (dust/mist/fume)

according to the Hazardous Products Regulations



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Exposure time 28 Days

Method **OECD Test Guideline 412** 

Colecalciferol:

Species Rat NOAEL

0.06 mg/kg LOAEL : 0.3 mg/kg Application Route : Ingestion Exposure time 90 Days

Method **OECD Test Guideline 408** 

**Aspiration toxicity** 

Not classified based on available information.

#### **SECTION 12. ECOLOGICAL INFORMATION**

## **Ecotoxicity**

#### **Components:**

3,7-Dimethyl 2,6-octadienal:

Toxicity to fish LC50 (Leuciscus idus (Golden orfe)): 6.78 mg/l

> Exposure time: 96 h Method: DIN 38412

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 6.8 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

: ErC50 (Desmodesmus subspicatus (green algae)): 103.8 mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 3 mg/l

Exposure time: 72 h

EC50 (activated sludge): 160 mg/l Toxicity to microorganisms

Exposure time: 30 min

Method: OECD Test Guideline 209

(dl)-a-Tocopheryl acetate:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

according to the Hazardous Products Regulations



# **Betaine / Multivitamin Formulation**

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NOEC (Pseudokirchneriella subcapitata (green algae)): >=

100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Oncorhynchus mykiss (rainbow trout)): 100 mg/l

Exposure time: 28 d

Toxicity to microorganisms : EC50: > 927 mg/l

Exposure time: 30 min Method: ISO 8192

Betaine hydrochloride:

Toxicity to daphnia and other : aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: The test was conducted according to guideline

Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: The test was conducted according to guideline

Based on data from similar materials

EC10 (Desmodesmus subspicatus (green algae)): > 1 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: The test was conducted according to guideline

Based on data from similar materials

Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

NOEC (Daphnia magna (Water flea)): 51 mg/l

Exposure time: 21 d

according to the Hazardous Products Regulations



# **Betaine / Multivitamin Formulation**

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Method: OECD Test Guideline 211 ic toxicity)

Pyridoxine Hydrochloride:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

**Colecalciferol:** 

LL50 (Danio rerio (zebra fish)): > 100 mg/l Toxicity to fish

Exposure time: 96 h

Method: OECD Test Guideline 203

aquatic invertebrates

Toxicity to daphnia and other : EL50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EL50 (Scenedesmus capricornutum (fresh water algae)): >

100 ma/l

Exposure time: 96 h

Method: OECD Test Guideline 201

## Persistence and degradability

#### **Components:**

3,7-Dimethyl 2,6-octadienal:

Biodegradability Result: Readily biodegradable.

Biodegradation: > 90 % Exposure time: 28 d

Method: Directive 67/548/EEC Annex V, C.4.D.

(dl)-a-Tocopheryl acetate:

Biodegradability Result: Not readily biodegradable.

Biodegradation: 21.7 - 31 %

Exposure time: 28 d

Method: OECD Test Guideline 301C

Benzyl alcohol:

Biodegradability Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d

**Pyridoxine Hydrochloride:** 

Biodegradability Result: Readily biodegradable.

> Biodegradation: 94 % Exposure time: 28 d

Method: OECD Test Guideline 301E

according to the Hazardous Products Regulations



# **Betaine / Multivitamin Formulation**

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**Colecalciferol:** 

Biodegradability : Result: Not readily biodegradable.

Biodegradation: <= 7 % Exposure time: 28 d

Method: OECD Test Guideline 301C

**Bioaccumulative potential** 

**Components:** 

3,7-Dimethyl 2,6-octadienal:

Partition coefficient: n-

: log Pow: 2.76

octanol/water

Betaine hydrochloride:

Partition coefficient: n-

: log Pow: -4.93

octanol/water

Remarks: Calculation

Benzyl alcohol:

Partition coefficient: n-

octanol/water

log Pow: 1.05

**Pyridoxine Hydrochloride:** 

Partition coefficient: n-

octanol/water

log Pow: 4.32

Colecalciferol:

Partition coefficient: n-

octanol/water

: log Pow: > 6.2

Method: OECD Test Guideline 107

Mobility in soil

No data available

Other adverse effects

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**SECTION 14. TRANSPORT INFORMATION** 

**International Regulations** 

**UNRTDG** 

Not regulated as a dangerous good

according to the Hazardous Products Regulations



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## **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

## Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **Domestic regulation**

#### **TDG**

Not regulated as a dangerous good

## Special precautions for user

Not applicable

### **SECTION 15. REGULATORY INFORMATION**

## The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average CA AB OEL / TWA : 8-hour Occupational exposure limit CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWAEV : Time-weighted average exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemi-

according to the Hazardous Products Regulations



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cal Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to

compile the Material Safety

Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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