SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Multivitamin (with Rice Flour) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 24.02.2025
2.0	14.04.2025	11513708-00002	Date of first issue: 24.02.2025

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Multivitamin (with Rice Flour) Formulation

Product code : Growmix Shrimp

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1A	H360D: May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements : H360D May damage the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Retinyl acetate
Colecalciferol

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)

(dl)-a-Tocopheryl acetate	7695-91-2 231-710-0		>= 1 - < 10
Nicotinic acid	59-67-6 200-441-0	Eye Irrit. 2; H319	>= 1 - < 10
Retinyl acetate	127-47-9 204-844-2	Repr. 1A; H360D STOT RE 1; H372 (Liver) Aquatic Chronic 3; H412	>= 0,3 - < 1
Menadione sodium bisulfite	130-37-0 204-987-0 607-618-00-5	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 _____ M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 0,25 - < 1
Colecalciferol	67-97-0 200-673-2 603-180-00-4	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 2; H310 STOT RE 1; H372 (Kidney, Blood, Bone) Aquatic Chronic 4; H413 _____ specific concentration limit STOT RE 1; H372 >= 3 % STOT RE 2; H373 0,3 - < 3 % _____ Acute toxicity estimate Acute oral toxicity: 35 mg/kg Acute inhalation toxicity (dust/mist): 0,05 mg/l Acute dermal toxicity: 50 mg/kg	>= 0,3 - < 1
Pyridoxine hydrochloride	58-56-0 200-386-2		>= 0,1 - < 1
Substances with a workplace exposure limit :			

Ascorbic acid	50-81-7 200-066-2		>= 1 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

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.

In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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 products : Carbon oxides
Nitrogen oxides (NOx)
Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe 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 Keep container tightly closed. Minimize dust generation and accumulation. 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.
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. 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Dust
5 mg/m3
Value type (Form of exposure): TWA (respirable dust)
Basis: FOR-2011-12-06-1358

10 mg/m3
Value type (Form of exposure): TWA (total dust)
Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ascorbic acid	50-81-7	TWA	5000 µg/m3 (OEB 1)	Internal
(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 ug/m3 (OEB 1)	Internal
Colecalciferol	67-97-0	TWA	5 µg/m3 (OEB 4)	Internal
		Wipe limit	50 µg/100 cm²	Internal
Pyridoxine hydro-chloride	58-56-0	TWA	OEB 3 (>= 10 < 100 µg/m3)	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
(dl)-a-Tocopheryl acetate	Workers	Inhalation	Long-term systemic effects	73,5 mg/m3
	Workers	Skin contact	Long-term systemic effects	416,6 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	21,7 mg/m3
	Consumers	Skin contact	Long-term systemic effects	250 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	12,5 mg/kg bw/day
Nicotinic acid	Workers	Inhalation	Long-term systemic	0,5 mg/m3

			effects	
	Workers	Skin contact	Long-term systemic effects	0,14 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0,25 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0,14 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,14 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
(dl)-a-Tocopheryl acetate	Fresh water	0,27 mg/l
	Freshwater - intermittent	0,27 mg/l
	Marine water	0,027 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	212000 mg/kg dry weight (d.w.)
	Marine sediment	21200 mg/kg dry weight (d.w.)
	Soil	74800 mg/kg dry weight (d.w.)
Nicotinic acid	Fresh water	0,077 mg/l
	Freshwater - intermittent	0,77 mg/l
	Marine water	0,008 mg/l
	Sewage treatment plant	8,8 mg/l
	Fresh water sediment	0,122 mg/kg dry weight (d.w.)
	Marine sediment	0,012 mg/kg dry weight (d.w.)
	Soil	0,043 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

Eye/face 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.

Hand protection

Material : Chemical-resistant gloves

Remarks	:	Consider double gloving.
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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to NS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	White to light yellow
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
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
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity		

Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	Not applicable
Particle characteristics		
Particle size	:	No data available

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	Not applicable
Molecular weight	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

(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

Nicotinic acid:

Acute oral toxicity : LD50 (Rat, female): 4.500 mg/kg
Method: OECD Test Guideline 401
Remarks: The test was conducted equivalent or similar to guideline

Acute inhalation toxicity : LC50 (Rat): > 3,8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 436
Remarks: The test was conducted according to guideline

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Remarks: The test was conducted according to guideline

Retinyl acetate:

Acute oral toxicity : LD50 (Rat): 4.790 mg/kg

Menadione sodium bisulfite:

Acute oral toxicity : LD50 (Rat): > 2.000 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 judgement

Acute dermal toxicity : Acute toxicity estimate: 50 mg/kg
Method: Expert judgement

Pyridoxine hydrochloride:

Acute oral toxicity : LD50 (Rat): 4.000 mg/kg

Ascorbic acid:

Acute oral toxicity : LD50 (Rat): 11.900 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

(dl)-a-Tocopheryl acetate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Nicotinic acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : The test was conducted equivalent or similar to guideline

Retinyl acetate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Mild skin irritation

Menadione sodium bisulfite:

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Remarks : The test was conducted according to guideline
Based on data from similar materials

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439
Remarks : The test was conducted according to guideline
Based on data from similar materials

Result : Skin irritation

Pyridoxine hydrochloride:

Species : Rabbit
Result : No skin irritation

Ascorbic acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

(dl)-a-Tocopheryl acetate:

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation

Nicotinic acid:

Species : Rabbit
Method : OECD Test Guideline 405
Result : Irritation to eyes, reversing within 21 days
Remarks : The test was conducted according to guideline

Retinyl acetate:

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation

Menadione sodium bisulfite:

Species : Bovine cornea
Method : OECD Test Guideline 437
Remarks : The test was conducted according to guideline
Based on data from similar materials

Species : Tissue Culture

Method : OECD Test Guideline 492
Remarks : The test was conducted according to guideline
Based on data from similar materials

Result : Irritation to eyes, reversing within 21 days

Colecalciferol:

Species : Rabbit
Result : No eye irritation

Pyridoxine hydrochloride:

Species : Rabbit
Result : No eye irritation

Ascorbic acid:

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

(dl)-a-Tocopheryl acetate:

Test Type : Draize Test
Exposure routes : Skin contact
Species : Humans
Result : negative

Nicotinic acid:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : The test was conducted equivalent or similar to guideline

Retinyl acetate:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Colecalciferol:

Test Type	:	Maurer optimisation test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Pyridoxine hydrochloride:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

Ascorbic acid:

Test Type	:	Maurer optimisation test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Germ cell mutagenicity

Not classified based on available information.

Components:

(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 Result: negative

Nicotinic acid:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: The test was conducted according to guideline Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Remarks: The test was conducted according to guideline

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: The test was conducted according to guideline

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 475
Result: negative
Remarks: The test was conducted according to guideline

Retinyl acetate:

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: Ingestion
Method: OECD Test Guideline 474
Result: negative

Menadione sodium bisulfite:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: The test was conducted according to guideline
Based on data from similar materials

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
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.

Pyridoxine hydrochloride:

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

Ascorbic acid:

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

(dl)-a-Tocopheryl acetate:

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

Ascorbic acid:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	2 Years
Result	:	negative

Reproductive toxicity

May damage the unborn child.

Components:

(dl)-a-Tocopheryl acetate:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: negative

Nicotinic acid:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: The test was conducted according to guideline

Retinyl acetate:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Monkey
Application Route: Ingestion
Result: positive
Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

Pyridoxine hydrochloride:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Ascorbic acid:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Nicotinic acid:

Assessment	:	No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Retinyl acetate:

Exposure routes	:	Ingestion
Target Organs	:	Liver
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

Colecalciferol:

Exposure routes	:	Ingestion
Target Organs	:	Kidney, Blood, Bone
Assessment	:	Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

(dl)-a-Tocopheryl acetate:

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

Nicotinic acid:

Species	:	Rat
NOAEL	:	50 mg/kg
LOAEL	:	250 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days
Method	:	OECD Test Guideline 407
Remarks	:	The test was conducted according to guideline

Retinyl acetate:

Species	:	Rat
NOAEL	:	1,43 - 3,47 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

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

Ascorbic acid:

Species : Rat, male
NOAEL : >= 8.100 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Retinyl acetate:

Ingestion : Symptoms: liver impairment
Remarks: Based on data from similar materials
Symptoms: Embryo-foetal toxicity
Remarks: Based on data from similar materials

SECTION 12: Ecological information

12.1 Toxicity

Components:

(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

NOEC (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : > 927 mg/l
Exposure time: 30 min
Method: ISO 8192

Toxicity to fish (Chronic toxicity) : NOEC: 100 mg/l
Exposure time: 28 d
Species: Oncorhynchus mykiss (rainbow trout)

Nicotinic acid:

Toxicity to fish : LC50 (Salmo trutta (brown trout)): 520 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: The test was conducted according to guideline

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 77 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: The test was conducted equivalent or similar to guideline

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): 37,356 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: The test was conducted equivalent or similar to guideline

EC10 (Desmodesmus subspicatus (green algae)): 12,098 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: The test was conducted equivalent or similar to guideline

Toxicity to microorganisms : EC10 (Pseudomonas putida): 88 mg/l
Exposure time: 16 h
Method: OECD Test Guideline 209
Remarks: The test was conducted equivalent or similar to guideline

Retinyl acetate:

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): 46 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50 (activated sludge): > 1.000 mg/l

Exposure time: 180 min
Method: OECD Test Guideline 209

Menadione sodium bisulfite:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 0,1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 0,1 - 1 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)): >0,01 - 0,1
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: The test was conducted according to guideline
Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): >0,001 - 0,01
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: The test was conducted according to guideline
Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 1

M-Factor (Chronic aquatic toxicity) : 1

Colecalciferol:

Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : 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 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 201

Pyridoxine hydrochloride:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Ascorbic acid:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 1.020 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to microorganisms : EC50 : 140 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

12.2 Persistence and degradability

Components:

(dl)-a-Tocopheryl acetate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 21,7 - 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Nicotinic acid:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 100 %
Exposure time: 14 d
Method: OECD Test Guideline 301E
Remarks: The test was conducted according to guideline

Retinyl acetate:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 15 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Menadione sodium bisulfite:

Biodegradability : Result: Not readily biodegradable.
Method: OECD Test Guideline 302C
Remarks: The test was conducted according to guideline
Based on data from similar materials

Colecalciferol:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: <= 7 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Pyridoxine hydrochloride:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 94 %
Exposure time: 28 d
Method: OECD Test Guideline 301E

Ascorbic acid:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 5 d
Method: OECD Test Guideline 302

12.3 Bioaccumulative potential

Components:

Nicotinic acid:

Partition coefficient: n-octanol/water : log Pow: -2,34
Method: OECD Test Guideline 117
Remarks: The test was conducted according to guideline

Retinyl acetate:

Partition coefficient: n-octanol/water : log Pow: 9,4
Method: OECD Test Guideline 117

Menadione sodium bisulfite:

Partition coefficient: n-octanol/water : log Pow: -1,56
Remarks: Calculation

Colecalciferol:

Partition coefficient: n-octanol/water : log Pow: > 6,2
Method: OECD Test Guideline 107

Pyridoxine hydrochloride:

Partition coefficient: n-octanol/water : log Pow: 4,32

Ascorbic acid:

Partition coefficient: n-octanol/water : log Pow: -1,85

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Do not dispose of waste into sewer.

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

14.1 UN number or ID number

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.4 Packing group

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor. Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Colecalciferol

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.
Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H300	:	Fatal if swallowed.
H310	:	Fatal in contact with skin.
H315	:	Causes skin irritation.
H319	:	Causes serious eye irritation.
H330	:	Fatal if inhaled.
H360D	:	May damage the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H412	:	Harmful to aquatic life with long lasting effects.
H413	:	May cause long lasting harmful effects to aquatic life.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard

Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Irrit.	:	Eye irritation
Repr.	:	Reproductive toxicity
Skin Irrit.	:	Skin irritation
STOT RE	:	Specific target organ toxicity - repeated exposure
FOR-2011-12-06-1358	:	Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA	:	Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Chemical 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Classification of the mixture:		**Classification procedure:**
Repr. 1A	H360D	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Chronic 3	H412	Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NO / EN