

Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

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

1.1 Product identifier

Trade name : Multivitamin (with Sunflower Oil) Formulation

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

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

20 Spartan Road

1619 Spartan, South Africa

Telephone : +27119239300

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

Specific target organ toxicity - repeated

exposure, Category 2

Long-term (chronic) aquatic hazard, Cat-

egory 3

H360D: May damage the unborn child.

H373: May cause damage to organs through pro-

longed or repeated exposure.

H412: Harmful to aquatic life with long lasting ef-

fects.

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.



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 Version
 Revision Date:
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 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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 propionate

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|----------------------------|---|---|--------------------------|
| Retinyl propionate | 7069-42-3 230-363-2 | Repr. 1A; H360D STOT RE 1; H372 (Liver) Aquatic Chronic 4; H413 | >= 2,5 - < 10 |
| (dl)-a-Tocopheryl acetate | 7695-91-2 231-710-0 | | >= 1 - < 10 |
| Benzyl alcohol | 100-51-6 202-859-9 603-057-00-5 | Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319 | >= 1 - < 10 |
| 2,6-Di-tert-butyl-p-cresol | 128-37-0 204-881-4 | Aquatic Acute 1; H400 Aquatic Chronic 1; H410 | >= 0,25 - < 1 |
| | | M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 | |



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 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

| 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 | >= 0,025 - < 0,1 |
|----------------|--------------------------------------|---|---------------------|
|----------------|--------------------------------------|---|---------------------|

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 ad-

vice 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 : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

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 : 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.



Multivitamin (with Sunflower Oil) Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 6599056-00009 Date of first issue: 15.10.2020 3.1

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

: Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- : Carbon oxides

ucts

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 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

Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Personal precautions

Follow safe handling advice (see section 7) and personal pro-

tective 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.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

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 Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

Clean up remaining materials from spill with suitable absor-

bent.

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 problem.

mine 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 : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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 mist or vapours.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

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

sessment

Keep container tightly closed.

Do not eat, drink or smoke when using this product.

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 contami-

nated 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



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---------------------------|-----------|-------------------------------|---------------------------|----------|
| (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 cm ² | 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 |
| Benzyl alcohol | Workers | Inhalation | Long-term systemic effects | 22 mg/m3 |
| | Workers | Inhalation | Acute systemic effects | 110 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 8 mg/kg bw/day |
| | Workers | Skin contact | Acute systemic effects | 40 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 5,4 mg/m3 |
| | Consumers | Inhalation | Acute systemic effects | 27 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 4 mg/kg bw/day |
| | Consumers | Skin contact | Acute systemic effects | 20 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 4 mg/kg bw/day |
| | Consumers | Ingestion | Acute systemic effects | 20 mg/kg bw/day |
| 2,6-Di-tert-butyl-p- cresol | Workers | Inhalation | Long-term systemic effects | 3,5 mg/m3 |
| | Workers | Dermal | Long-term systemic | 0,5 mg/kg |



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

| | | effects | bw/day |
|-----------|------------|----------------------------|----------------------|
| Consumers | Inhalation | Long-term systemic effects | 0,86 mg/m3 |
| Consumers | Dermal | Long-term systemic effects | 0,25 mg/kg bw/day |
| Consumers | Ingestion | Long-term systemic effects | 0,25 mg/kg bw/day |

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

| Substance name | Environmental Compartment | Value |
|----------------------------|----------------------------|-------------------|
| Retinyl propionate | Fresh water | 0,1 mg/l |
| | Freshwater - intermittent | 1 mg/l |
| | Marine water | 0,01 mg/l |
| | Sewage treatment plant | 10 mg/l |
| | Fresh water sediment | 2080 mg/kg dry |
| | | weight (d.w.) |
| | Soil | 735 mg/kg dry |
| | | weight (d.w.) |
| (dl)-a-Tocopheryl acetate | Fresh water | 0,27 mg/l |
| | Marine water | 0,027 mg/l |
| | Intermittent use/release | 0,27 mg/l |
| | Sewage treatment plant | 100 mg/l |
| | Fresh water sediment | 212000 mg/kg |
| | Marine sediment | 21200 mg/kg |
| | Soil | 74800 mg/kg |
| Benzyl alcohol | Fresh water | 1 mg/l |
| | Marine water | 0,1 mg/l |
| | Intermittent use/release | 2,3 mg/l |
| | Sewage treatment plant | 39 mg/l |
| | Fresh water sediment | 5,27 mg/kg |
| | Marine sediment | 0,527 mg/kg |
| | Soil | 0,456 mg/kg |
| 2,6-Di-tert-butyl-p-cresol | Fresh water | 0,199 μg/l |
| | Intermittent use/release | 0,02 μg/l |
| | Marine water | 0,02 μg/l |
| | Sewage treatment plant | 0,17 mg/l |
| | Fresh water sediment | 0,0996 mg/kg dry |
| | | weight (d.w.) |
| | Marine sediment | 0,00996 mg/kg |
| | | dry weight (d.w.) |
| | Soil | 0,04769 mg/kg |
| | | dry weight (d.w.) |
| | Oral (Secondary Poisoning) | 8,33 mg/kg food |

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.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.



Multivitamin (with Sunflower Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 6599056-00009 Date of first issue: 15.10.2020

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Organic vapour type (A)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : liquid Colour : transparent

amber

Odour : No data available Odour 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 : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

Relative density : No data available

Density : 0,925 g/cm³

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : Not applicable

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : Not applicable

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 : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

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 toxicological effects



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

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

Components:

Retinyl propionate:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Assessment: The substance or mixture has no acute oral tox-

icity

(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

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1.620 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6.000 mg/kg

Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Colecalciferol:

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

Acute inhalation toxicity : Acute toxicity estimate: 0,05 mg/l



Multivitamin (with Sunflower Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 6599056-00009 Date of first issue: 15.10.2020

Exposure time: 4 h

Test atmosphere: dust/mist Method: Expert judgement

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

Method: Expert judgement

Skin corrosion/irritation

Not classified based on available information.

Components:

Retinyl propionate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Mild skin irritation

(dl)-a-Tocopheryl acetate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Retinyl propionate:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

(dl)-a-Tocopheryl acetate:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 405



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

Result : Irritation to eyes, reversing within 21 days

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Remarks : Based on data from similar materials

Colecalciferol:

Species : Rabbit

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:

Retinyl propionate:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

(dl)-a-Tocopheryl acetate:

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

Benzyl alcohol:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

2,6-Di-tert-butyl-p-cresol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Species : Humans Result : negative

Colecalciferol:

Test Type : Maurer optimisation test

Exposure routes : Skin contact



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

Species : Guinea pig Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Retinyl propionate:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: 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

Remarks: Based on data from similar materials

(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

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

2,6-Di-tert-butyl-p-cresol:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

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

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- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

(dl)-a-Tocopheryl acetate:

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

Benzyl alcohol:

Species : Mouse Application Route : Ingestion



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

2,6-Di-tert-butyl-p-cresol:

Species : Rat
Application Route : Ingestion
Exposure time : 22 Months
Result : negative

Reproductive toxicity

May damage the unborn child.

Components:

Retinyl propionate:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Monkey

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

Positive evidence of adverse effects on development from

human epidemiological studies.

(dl)-a-Tocopheryl acetate:

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

test

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal 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 foetal develop-

ment

: Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

2,6-Di-tert-butyl-p-cresol:

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

Species: Rat



Multivitamin (with Sunflower Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 6599056-00009 Date of first issue: 15.10.2020

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

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:

Retinyl propionate:

Exposure routes : Ingestion Target Organs : Liver

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Remarks : Based on data from similar materials

2,6-Di-tert-butyl-p-cresol:

Assessment : No significant health effects observed in animals at concentra-

tions of 100 mg/kg bw or less.

Colecalciferol:

Exposure routes : Ingestion

Target Organs : Kidney, Blood, Bone

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

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

Components:

Retinyl propionate:

Species : Rat

LOAEL : > 1 - 10 mg/kg
Application Route : Ingestion
Exposure time : 3 Months

Remarks : Based on data from similar materials

(dl)-a-Tocopheryl acetate:

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

Benzyl alcohol:

Species : Rat



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

NOAEL : 1,072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

2,6-Di-tert-butyl-p-cresol:

Species : Rat
NOAEL : 25 mg/kg
Application Route : Ingestion
Exposure time : 22 Months

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.

Experience with human exposure

Components:

Retinyl propionate:

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:

Retinyl propionate:

Toxicity to fish : LL50 (Leuciscus idus (Golden orfe)): > 10.000 mg/l

Exposure time: 96 h Method: DIN 38412

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

Exposure time: 180 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



Multivitamin (with Sunflower Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 6599056-00009 Date of first issue: 15.10.2020

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 tox-

icity)

NOEC: 100 mg/l Exposure time: 28 d

Species: Oncorhynchus mykiss (rainbow trout)

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-

ic toxicity)

NOEC: 51 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

2,6-Di-tert-butyl-p-cresol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0,57 mg/l

Exposure time: 96 h

Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0,48 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

Toxicity to algae/aquatic

plants

: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0,24

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,24

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

1

Toxicity to microorganisms : EC50 : > 10.000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 0,053 mg/l Exposure time: 30 d

Species: Oryzias latipes (Japanese medaka)

Method: OECD Test Guideline 210

Toxicity to daphnia and other

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0,316 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

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

12.2 Persistence and degradability

Components:

Retinyl propionate:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 40 - 50 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

(dl)-a-Tocopheryl acetate:



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

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

2,6-Di-tert-butyl-p-cresol:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 4,5 % Exposure time: 28 d

Method: OECD Test Guideline 301C

Colecalciferol:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: <= 7 % Exposure time: 28 d

Method: OECD Test Guideline 301C

12.3 Bioaccumulative potential

Components:

Retinyl propionate:

Partition coefficient: n-

octanol/water

log Pow: 9,12

Remarks: Calculation

Benzyl alcohol:

Partition coefficient: n-

octanol/water

log Pow: 1,05

2,6-Di-tert-butyl-p-cresol:

Bioaccumulation : Species: Cyprinus carpio (Carp)

Bioconcentration factor (BCF): 330 - 1.800

Partition coefficient: n-

octanol/water

log Pow: 5,1

Colecalciferol:

Partition coefficient: n- : log Pow: > 6,2

octanol/water Method: OECD Test Guideline 107

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



Multivitamin (with Sunflower Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 6599056-00009 Date of first issue: 15.10.2020

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting poten-

tial

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.

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN 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



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

IMDG : Not regulated as a dangerous goodIATA : 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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

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

DSL : not determined

AICS : 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.
H302 : Harmful if swallowed.
H310 : Fatal in contact with skin.
H319 : Causes serious eye irritation.

H330 : Fatal if inhaled. H332 : Harmful if inhaled.

H360D : May damage the unborn child.



Multivitamin (with Sunflower Oil) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 04.04.2023

 3.1
 30.09.2023
 6599056-00009
 Date of first issue: 15.10.2020

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.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

STOT RE : Specific target organ toxicity - repeated exposure

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

Sheet

Sources of key data used to compile the Safety Data

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

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

Classification of the mixture:

Classification procedure:

Repr. 1A H360D Calculation method



Multivitamin (with Sunflower Oil) Formulation

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 6599056-00009 Date of first issue: 15.10.2020

STOT RE 2 H373 Calculation method Aquatic Chronic 3 H412 Calculation method

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