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Safety Data Sheet

legal basis:

Commission regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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

1.1. Product identifier

Trade name: Orthosol pH+
Identifier: Contains:, Formic acid
Product code: 719545
UFI Code: 72E1-K0W0-G000-5886
Composition for label/Other name(s): COMPLEMENTARY FEED., Composition: Feed materials: Potassium chloride., Sodium chloride., Feed additives: Preservatives: Formic acid 1k236., (including sodium formate 1k237i). - 345 g/kg, Propionic acid 1k280. - 150 g/kg,

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

Identified uses

Uses:

Complementary feed.

Uses advised against:

other than named above

1.3. Details of the supplier of the safety data sheet

Name and address:

Orthovit BV
Sint Antoniusstraat 7B
6095 AK Baexem
Nederland
Phone: +31 475 2981
orthovitbv@gmail.com

Phone number:
e-mail address for a competent person
responsible for the safety data sheet:

1.4. Emergency telephone number

998 or 112, or contact with the nearest local Fire Department

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

General hazards

This product is classified as hazardous according to current regulations

Health hazards

Skin Corr. 1B	Skin corrosion, Category 1B	H314 Causes severe skin burns and eye damage
Eye Dam. 1	Serious eye damage, Category 1	H318 Causes serious eye damage

Physical hazards

not applicable

Environmental hazards

not applicable

2.2. Label elements

Hazard pictograms:



Signal Word:

Danger

Hazard statements:

H314 Causes severe skin burns and eye damage

EUH Phrases

EUH071 Corrosive to the respiratory tract

Precautionary statements:

P264b Wash body thoroughly after handling

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P310 Immediately call a POISON CENTER/doctor/...

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/...

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501a Dispose of contents/container to licensed waste disposal plant

2.3.Other hazards

This product does not fulfill the PBT or vPvB criteria according to Annex XIII to REACH Regulation (EC) 1907/2006

There is no evidence of endocrine disrupting properties.

SECTION 3:Composition/information on ingredients
3.2.Mixtures

Concentration value	Substance	CAS	EC	Index number	Hazard class	Specific concentration limits, the M-factors, ATE
10 - < 20 %	Propionic acid	79-09-4	201-176-3	607-089-00-0	Skin Corr. 1B H314 Flam. Liq. 3 H226 STOT SE 3 H335 Eye Dam. 1 H318	Skin Corr.1B, H314 >= 25 % Eye Irrit.2, H319 >= 10 - < 25 % Skin Irrit.2, H315 >= 10 - < 25 % STOT SE 3, H335 >= 10 %
20 - 30 %	Formic acid	64-18-6	200-579-1	607-001-00-0	Flam. Liq. 3 H226 Acute Tox. 4 H302 Acute Tox. 3 H331 Skin Corr. 1A H314 Eye Dam. 1 H318 EUH071	Skin Corr.1A, H314 >= 90 % Skin Corr.1B, H314 >= 10 - < 90 % Skin Irrit.2, H315 >= 2 - < 10 % Eye Irrit.2, H319 >= 2 - < 10 %

Remarks

See Section 16 for the full text of the H statements

SECTION 4:First aid measures
4.1.Description of first aid measures
Inhalation

Move the victim to fresh air. Keep at rest. Protect against heat loss. Ensure medical assistance. Symptoms of exposure may appear several hours later. In case of dyspnea qualified personnel should give oxygen.

Skin contact

Take off contaminated clothing and shoes immediately. If on skin, rinse well with water. Do not use soap nor neutralizing agents. Cover wound with sterile dressing. Ensure medical assistance.

Eye contact

Rinse immediately with plenty of water for at least 15 minutes. Immediately ensure a physician aid.

Ingestion

Clean mouth with water and drink afterwards plenty of water. Do NOT induce vomiting. Call a physician immediately.

4.2.Most important symptoms and effects, both acute and delayed
Symptoms and effects:
Symptoms and effects

no data available

4.3.Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5:Firefighting measures
5.1.Extinguishing media
Extinguishing media

Use extinguishing measures that are appropriate to surrounding fire.

5.2.Special hazards arising from the substance or mixture

During thermal decomposition may be released: carbon oxides.

5.3.Advice for firefighters

Containers exposed to fire or high temperature cool by spraying water from a safe distance. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. Prevent extinguishing media from entering the sewerage system, surface or ground water system.

Wear full protective suit. Use breathing apparatus isolating respiratory tract.

SECTION 6:Accidental release measures

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6.1. Personal precautions, protective equipment and emergency procedures

Avoid skin, eyes and clothing contamination. Avoid breathing vapour/fog/aerosol. Use personal protective equipment.

6.2. Environmental precautions

Prevent from entering the sewerage system, watercourses and soil. Protect drains. In case of environment contamination, inform appropriate services.

6.3. Methods and material for containment and cleaning up

Large spills should be collected mechanically (remove by pumping) for disposal. Cover residues with a non-combustible sorption material (e.g. sand, earth, universal binders), Collect into suitable container for disposal. Transfer for disposal. Flush with plenty of water. Washings should be collected and disposed of as a waste.

6.4. Reference to other sections

More information about suitable personal protective equipment is given in section 8.

Dispose of in accordance with the recommendations given in Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid eyes, skin and clothing contamination. Do not breathe vapours. Ensure suitable ventilation.

7.2. Conditions for safe storage, including any incompatibilities

Keep in tightly closed containers. Keep in a cool, well-ventilated place. Store away from incompatible materials (see section 10 of MSDS). Store in original packagings. Keep away from heat, flame sparks and other ignition sources. Protect from moisture.

7.3. Specific end use(s)

See section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL value

Propionic acid	DNEL value	for workers	inhalation	Short-term exposure	Systemic effects	62 mg/m ³
	DNEL value	for workers	inhalation	Short-term exposure	Local effects	62 mg/m ³
	DNEL value	for workers	inhalation	Long-term exposure	Systemic effects	31 mg/m ³
	DNEL value	for workers	inhalation	Long-term exposure	Local effects	31 mg/m ³
	DNEL value	for workers	dermal	Long-term exposure	Systemic effects	132 mg/kg
	DNEL value	for workers	dermal	Long-term exposure	Local effects	0,26 mg/cm ²

Formic acid	DNEL value	for workers	by inhalation	Long-term exposure	Local effects	9,5 mg/m ³
	DNEL value	for workers	by inhalation	Long-term exposure	Systemic effects	9,5 mg/m ³
	DNEL value	for consumers	by inhalation	Short-term exposure	Local effects	9,5 mg/m ³
	DNEL value	for consumers	by inhalation	Short-term exposure	Systemic effects	9,5 mg/m ³
	DNEL value	for consumers	by inhalation	Short-term exposure	Local effects	3 mg/m ³
	DNEL value	for consumers	by inhalation	Short-term exposure	Systemic effects	3 mg/m ³

PNEC value

Propionic acid	PNEC value	Fresh water	0,5 mg/l
	PNEC value	Marine water	0,05 mg/l
	PNEC value	Intermittent releases	5 mg/l
	PNEC value	Sediment (Fresh water)	1,86 mg/kg
	PNEC value	Sediment (Marine water)	0,186 mg/kg
	PNEC value	Soil	0,1258 mg/kg
	PNEC value	Sewage treatment plant (STP)	5 mg/l

Formic acid	PNEC value	Fresh water	2 mg/l
	PNEC value	Marine water	0,2 mg/l
	PNEC value	Intermittent releases	1 mg/l
	PNEC value	Sewage treatment plant (STP)	7,2 mg/l
	PNEC value	Sediment (Fresh water)	13,4 mg/kg
	PNEC value	Sediment (Marine water)	1,34 mg/kg
	PNEC value	Soil	1,5 mg/kg

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Occupational exposure limits

Propionic acid	NDS	30 mg/m ³
	NDSCH	45 mg/m ³
Formic acid	NDS	5 mg/m ³
	NDSCH	15 mg/m ³

Comments

Poland. OELs - Regulation of the Minister of Family, Labour and Social Policy, of 12 June 2018; Journal of Laws 2018, item 1286 as amended.

Biological limit values comments

not available

Recommended monitoring procedures

Regulation of the Minister of Health on tests and measurements applicable for hazardous substances and other adverse factors which are present in the workplace, of 2 February 2011 (Journal of Laws No33, item 166).

8.2.Exposure controls

Appropriate engineering controls

Provide adequate ventilation.

Individual protection measures

Respiratory protection

Use respirator with appropriate filter if vapours or aerosol are released. Combined acidic gas/vapour and organic vapour type

Eye /face protection

Safety glasses Safety goggles

Skin and hand protection

Acid-resistant protective gloves. in accordance with standard EN 374. Nitril rubber gloves Break through time >= 30 min Layer thickness 0,38mm

Other protection equipment

acid-resistant protective clothing

Reference to regulations

Individual protection measures should satisfy the requirements specified in the Regulation (EU) 2016/425 of the European Parliament and of the Council on basic requirements for personal protective equipment, of 9 March 2016.

General advice

When using do not eat or drink. Wash hands before every break and at the end of workday. Avoid eyes and skin contamination and inhaling of vapors/gases/mist.

Environ. exposure controls

Prevent entry into drains, waterways, sewers and soil.

SECTION 9:Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid	
Colour:	colorless	
Odour:	pungent	Odour threshold:
		No data available.
Melting point/freezing point:	No data available.	
Boiling point or initial boiling point and boiling range:	No data available.	
Flammability:	Not applicable.	
Lower and upper explosion limit:	No data available.	
Flash point:	No data available.	
Auto-ignition temperature:	No data available.	
Decomposition temperature:	No data available.	
pH:	ca. 3,3	5 % solution
Kinematic viscosity:	Not applicable.	
Solubility:	no data available	

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Partition coefficient: n-octanol/water (log value):	No data available.		
Vapour pressure:	No data available.		
Density and/or relative density:	Density	ca. 1,171 g/cm ³	20 °C
Relative vapour density:	No data available.		
Particle characteristics:	not applicable		

9.2. Other information

Information with regard to physical hazard classes:	no data available
Other safety characteristics:	no data available

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Reacts with: Bases. Exothermic reaction.

10.4. Conditions to avoid

Moisture. Sources of ignition.

10.5. Incompatible materials

Bases. Metals. Oxidizing agents.

10.6. Hazardous decomposition products

In case of fire hazardous decomposition products may be produced such as: Carbon oxides.

SECTION 11: Toxicological information

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

Acute oral toxicity

Propionic acid	LD50	3 500 - 5 160 mg/kg	Rat		
Formic acid	LD50	730 mg/kg	Rat	OECD Test Guideline 401	
Product	Acute toxicity estimate ATEmix	ca. 2 955 mg/kg			Based on available data, the classification criteria are not met.

Acute dermal toxicity

Propionic acid	LD50	496 mg/kg	Rabbit
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Acute inhalation toxicity

Propionic acid	LC50	> 4,9 mg/l	4 h		
Formic acid	LC50	7,85 mg/l	4 h	Rat	
Product	Acute toxicity estimate ATE	ca. 31,7 mg/l			Based on available data, the classification criteria are not met.

Acute toxicity - other exposure routes

No data available.

Skin corrosion/irritation

Product	corrosive causes burns	based on information on ingredients
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Serious eye damage/irritation

Product	corrosive Causes serious eye damage	based on information on ingredients
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Respiratory sensitisation

Based on available data, the classification criteria are not met.

Skin sensitisation

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Summary

Based on available data, the classification criteria are not met.

Carcinogenicity

Summary

Based on available data, the classification criteria are not met.

Reproductive toxicity

Summary

Based on available data, the classification criteria are not met.

STOT-single exposure

Summary

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Summary

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Information on likely routes of exposure

no data available

Symptoms related to the physical, chemical and toxicological characteristics

no data available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

no data available

11.2. Information on other hazards

Endocrine disrupting properties

There is no evidence of endocrine disrupting properties.

Other information

no data available

SECTION 12: Ecological information

12.1. Toxicity

Propionic acid	Toxicity to fish	LC50	> 10 000 mg/l	96 h	Leuciscus idus (Golden orfe)	DIN 38412	static test
	Toxicity to aquatic invertebrates	EC50	> 500 mg/l	48 h	Daphnia magna (Water flea)	84/449/EEC, C.2, static	static test
	Toxicity to aquatic plants	EC50	> 500 mg/l	72 h	Scenedesmus subspicatus	OECD Test Guideline 201	Biomass static test
	Toxicity to microorganisms	EC20	500 - 1 040 mg/l	30 min	activated sludge, domestic	DIN EN ISO 8192	

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Formic acid	Toxicity to fish	LC50	130 mg/l	96 h	Brachydanio rerio	ISO 7346	static test Based on test data for structurally similar materials.
	Acute toxicity to aquatic invertebrates	EC50	365 mg/l	48 h	Daphnia magna (Water flea)	OECD Test Guideline 202	static test Based on test data for structurally similar materials.
	Toxicity to algae	EC50	1 240 mg/l	72 h	Selenastrum capricornutum	OECD Test Guideline 201	static test Based on test data for structurally similar materials.
	Toxicity to bacteria	EC10	72 mg/l	13 days			
	Chronic toxicity to aquatic invertebrates		>= 100 mg/l	21 days	Daphnia magna (Water flea)	OECD Test Guideline 211	semi-static test
	Respiration inhibition of activated sludge	EC20	> 1 000 mg/l				

12.2. Persistence and degradability

Summary

Based on ingredients product is expected to rapidly biodegradable

12.3. Bioaccumulative potential

Summary

no data available

12.4. Mobility in soil

Summary

no data available

12.5. Results of PBT and vPvB assessment

This product does not fulfill the PBT or vPvB criteria according to Annex XIII to REACH Regulation (EC) 1907/2006

12.6. Endocrine disrupting properties

no data available

12.7. Other adverse effects

Causes change of pH in aqueous systems. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations, Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Comply with below named regulations:

Waste Disposal Law, of 14 December 2012 (Journal of Laws 2013, item 21), with further amendments. Law on packages and spent packages, of 13 June 2013 (Journal of Laws 2013, item 888) as amended.

Regulation of the Minister of Climate of 2 January 2020 on a catalog of waste (Journal of Laws 2020, item 10).

Suggested waste code: 16 03 05* Organic wastes containing dangerous substances.

Do not discharge to sewage systems, to soil or to water reservoirs. Dispose of in accordance with current legislation concerning Waste disposal. Waste packaging should be recycled. Packaging that can not be cleaned, should be disposed of like the product.

SECTION 14: Transport information

14.1. UN number or ID number

Transport type	UN Number
ADR	3265
RID	N/A
IMDG	N/A
ICAO	N/A
ADN	N/A

14.2. UN proper shipping name

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Transport type	UN proper shipping name
ADR	3265 Corrosive liquid, acidic, organic, n.o.s. (contains: Formic acid)
RID	not available
IMDG	not available
ICAO	not available
ADN	not available

14.3. Transport hazard class(es)

Transport type	Transport hazard class:	Classification code:	Hazard identification number:	Tunnel restriction code:	Labels numbers:
ADR	8	C3	80	E	8
RID	not available				
IMDG	not available				
ICAO	not available				
ADN	not available				



14.4. Packing group

Transport type	Packing group:
ADR	II
RID	not available
IMDG	not available
ICAO	not available
ADN	not available

14.5. Environmental hazards

The product does not pose a hazard to the environment in accordance with the criteria of the UN Model Regulations.

14.6. Special precautions for user

not available

14.7. Maritime transport in bulk according to IMO instruments

not available

SECTION 15:Regulatory information

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

ACT of 25 February 2011 on the chemical substances and their mixtures, with further amendments.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)

15.2. Chemical safety assessment

not applicable

SECTION 16:Other information

Changes of previous version

not applicable

Key or legend to abbreviations and acronyms used in the safety data sheet

Expl. - Explosive
 Flam. Gas - Flammable gas
 Flam. Aerosol - Flammable aerosol
 Ox. Gas - Oxidising gas
 Press. Gas - Gases under pressure
 Flam. Liq. - Flammable liquid
 Flam. Sol. - Flammable solid
 Self-react. - Self-reactive substance or mixture
 Pyr. Liq. - Pyrophoric liquid
 Pyr. Sol. - Pyrophoric solid
 Self-heat. - Self-heating substance or mixture
 Water-react. - Substance or mixture which in contact with water emits flammable gas
 Ox. Liq. - Oxidising liquid
 Ox. Sol. - Oxidising solid
 Org. Perox. - Organic peroxide

Met. Corr. - Substance or mixture corrosive to metals
Acute Tox. - Acute toxicity
Skin Corr. - Skin corrosion
Skin Irrit. - Skin irritation
Resp. Sens. - Respiratory sensitization
Skin Sens. - Skin sensitization
Muta. - Germ cell mutagenicity
Carc. - Carcinogenicity
Repr. - Reproductive toxicity, Category 1A
STOT SE - Specific target organ toxicity — single exposure
STOT RE - Specific target organ toxicity — repeated exposure
Asp. Tox. - Aspiration hazard
Aquatic Acute - Hazardous to the aquatic environment - Acute
Aquatic Chronic - Hazardous to the aquatic environment - Chronic
Ozone - Hazardous for the ozone layer
Lact. - Effects on or via lactation
NDS - Maximum permissible exposure level/concentration
NDSCH - Maximum short-term exposure level/concentration
NDSP - Maximum permissible ceiling exposure level/concentration
vPvB (Substance) - very persistent and very bioaccumulating
PBT (Substance) persistent, bioaccumulating and toxic
PNEC – Predicted No Effect Concentration
DNEL – Derived No Effect Level
LD50 - Lethal dose 50; dose/amount of a substance which kills 50 % of the test population
LC50 - Lethal concentration; concentration of a substance which kills 50 % of the test population
LOEC - Lowest Observed Effect Concentration
NOEL No Observed Effect Level
NOEC - No Observed Effect Concentration
ECX - Effective concentration; concentration of a substance which produces X % effect response
ADR – Agreement Concerning the International Carriage of Dangerous Goods by Road
ADN – Agreement Concerning the International Carriage of Dangerous Goods by Inland Waters
RID – Regulations Concerning the International Carriage of Dangerous Goods by Rail
IMDG – International Maritime Dangerous Goods Code
ICAO/IATA – International Civil Aviation Organization/International Air Transport Association
UVCB - Substances of Unknown or Variable composition, Complex reaction products or Biological materials

Key literature references and sources for data

This safety data sheet has been prepared based on the MSDS provided by the manufacturer or / and internet databases and current regulations.

Advice on any training appropriate for workers to ensure protection of human health and the environment

People involved in the handling of the product should be trained in the handling, safety and hygiene. The staff / drivers should be trained and obtain proper certification in accordance with the requirements of ADR.

List of relevant hazard statements and/or precautionary statements

EUH071 Corrosive to the respiratory tract
H226 Flammable liquid and vapour
H302 Harmful if swallowed
H314 Causes severe skin burns and eye damage
H318 Causes serious eye damage
H331 Toxic if inhaled
H335 May cause respiratory irritation
not applicable
P264b Wash body thoroughly after handling
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/...
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor/...
P501a Dispose of contents/container to licensed waste disposal plant

Other Information

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product in terms of safety requirements. These data can not be considered in any case describe the product (as product specification).
Producer/importer did not register the substance(s) under Reach (EC 1907/2006). Certain non- food/feed/pharma uses may however need a registration. It is in the responsibility of the downstream user to comply with REACH regulation in this respect.
Exposure scenarios are not required.
Conditions of use and suitability of the product for specific applications remain under user control
It is the user's responsibility to insure proper health, safety and other necessary information
Appropriate warnings and safe-handling procedures should be provided to handlers and users.
Calculation method was used for classification to hazard of acute toxicity.