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

1.1 Product identifier

Trade name : Butafosfan (<1%) Formulation

Product code : Prevensa Megabic, Megabic, Prevensa Megabic Parent

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

Use of the Sub-

stance/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)

Skin irritation, Category 2 H315: Causes skin irritation.

Serious eye damage, Category 1 H318: Causes serious eye damage.

## 2.2 Label elements

### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal word : Danger

Hazard statements : H315 Causes skin irritation.

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H318 Causes serious eye damage.

Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ eye protection/ face pro-

tection.

Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously

with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

P332 + P313 If skin irritation occurs: Get medical advice/

attention.

P362 + P364 Take off contaminated clothing and wash it

before reuse.

### Hazardous components which must be listed on the label:

Calcium diformate Phosphoric acid Formic acid

#### 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.

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

# **SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

Components

Components			
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
Calcium diformate	544-17-2	Eye Dam. 1; H318	>= 30 - < 50
	208-863-7		
Phosphoric acid	7664-38-2	Met. Corr. 1; H290	>= 10 - < 20
·	231-633-2	Acute Tox. 4; H302	
	015-011-00-6	Skin Corr. 1B; H314	

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Citrio poid	77.00.0	Eye Dam. 1; H318 EUH071  specific concentration limit Skin Corr. 1B; H314 >= 25 % Skin Irrit. 2; H315 10 - < 25 % Eye Irrit. 2; H319 10 - < 25 % EUH071 >= 25 %  Acute toxicity estimate  Acute oral toxicity: 2,000 mg/kg	
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	>= 1 - < 10
L-Malic acid	97-67-6 202-601-5	Eye Irrit. 2; H319	>= 1 - < 10
Fumaric acid	110-17-8 203-743-0 607-146-00-X	Eye Irrit. 2; H319	>= 1 - < 10
Formic acid	64-18-6 200-579-1 607-001-00-0	Flam. Liq. 3; H226 Met. Corr. 1; H290 Acute Tox. 4; H302 Acute Tox. 3; H331 Skin Corr. 1A; H314 Eye Dam. 1; H318 EUH071  specific concentration limit Skin Corr. 1A; H314 >= 90 % Skin Corr. 1B; H314 10 - < 90 % Skin Irrit. 2; H315 2 - < 10 % Eye Irrit. 2; H319 2 - < 10 % Flam. Liq. 3; H226 >= 85 %	>= 2 - < 3

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ersion 0	Revision Date: 14.04.2025	SDS Number: 11505013-00003	Date of last issue: 31.01.2025 Date of first issue: 22.01.2025	
			Eye Dam. 1; H318 >= 10 % EUH071 >= 10 %	
			Acute toxicity esti- mate	
			Acute oral toxicity: 500 mg/kg Acute inhalation tox- icity (vapour): 7.4 mg/l	
Butaf	osfan	17316-67-5 241-341-7		>= 0.1 - < 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 if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with plenty of water

for at least 15 minutes while removing contaminated clothing

and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention immediately.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

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Risks : Causes skin irritation.

Causes serious eye damage.

### 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 prod- :

ucts

Carbon oxides Metal oxides

Oxides of phosphorus

#### 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

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 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.

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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 deter-

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 : 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 : Use Advice on safe handling : De

Use only with adequate ventilation. Do not get on skin or clothing.

Do not breathe dust. Do not swallow.

Do not get in 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.

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 contami-

nated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment,

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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. 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

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**

dusts non-specific 4 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable

dust)

Basis: IE OEL

10 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable

dust)

Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Phosphoric acid	7664-38-2	TWA	1 mg/m3	2000/39/EC
	Further inform	nation: Indicative		
		STEL	2 mg/m3	2000/39/EC
	Further inform	nation: Indicative		
		OELV - 8 hrs (TWA)	1 mg/m3	IE OEL
		OELV - 15 min (STEL)	2 mg/m3	IE OEL
Formic acid	64-18-6	TWA	5 ppm 9 mg/m3	2006/15/EC
	Further information: Indicative			
		OELV - 8 hrs (TWA)	5 ppm 9 mg/m3	IE OEL

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Calcium diformate	Workers	Inhalation	Long-term systemic	337 mg/m3

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



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			effects	1
	Workers	Skin contact	Long-term systemic	4780 mg/kg
			effects	bw/day
	Consumers	Inhalation	Long-term systemic effects	83.2 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2390 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	23.9 mg/kg bw/day
Phosphoric acid	Workers	Inhalation	Long-term local ef- fects	1 mg/m3
	Workers	Inhalation	Acute local effects	2 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	0.73 mg/m3
Formic acid	Workers	Inhalation	Long-term systemic effects	9.5 mg/m3
	Workers	Inhalation	Long-term local ef- fects	9.5 mg/m3
	Consumers	Inhalation	Long-term systemic effects	6 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	6 mg/m3
	Consumers	Skin contact	Long-term systemic effects	3 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	3 mg/kg bw/day
Fumaric acid	Workers	Inhalation	Long-term systemic effects	42.32 mg/m3
	Workers	Skin contact	Long-term systemic effects	12 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	10.43 mg/m3
	Consumers	Skin contact	Long-term systemic effects	6 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	6 mg/kg bw/day

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

	. ,	· · · · · · · · · · · · · · · · · · ·
Substance name	Environmental Compartment	Value
Calcium diformate	Fresh water	2 mg/l
	Marine water	0.2 mg/l
	Intermittent use/release	10 mg/l
	Sewage treatment plant	2.21 mg/l
	Fresh water sediment	13.4 mg/l
	Marine sediment	1.34 mg/l
	Soil	1.5 mg/l
Citric acid	Fresh water	0.44 mg/l
	Marine water	0.044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34.6 mg/kg dry
		weight (d.w.)
	Marine sediment	3.46 mg/kg dry

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		weight (d.w.)
	Soil	33.1 mg/kg dry
		weight (d.w.)
Fumaric acid	Sewage treatment plant	30 mg/l

#### 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, dis-

posable 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 should conform to I.S. EN 14387

Filter type : Combined particulates, acidic, inorganic gas/vapour and or-

ganic vapour type (ABE-P)

### **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

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Initial boiling point and boiling

range

: No data available

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

dling 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

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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, han-

dling 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 : Inhalation

exposure Skin contact Ingestion

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: > 20 mg/l

Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

**Components:** 

Calcium diformate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

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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: Based on data from similar materials

Phosphoric acid:

Acute oral toxicity : LD50 (Rat): 2,000 mg/kg

Method: OECD Test Guideline 423

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Citric acid:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

L-Malic acid:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Remarks: Based on data from similar materials

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

Remarks: Based on data from similar materials

Fumaric acid:

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

Acute inhalation toxicity : LC50 (Rat): > 1.306 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Formic acid:

Acute oral toxicity : Acute toxicity estimate (Humans): 500 mg/kg

Method: Expert judgement

Acute inhalation toxicity : LC50 (Rat): 7.4 mg/l

Exposure time: 4 h
Test atmosphere: vapour

Assessment: Corrosive to the respiratory tract.

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

Remarks: Based on data from similar materials

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**Butafosfan:** 

Acute oral toxicity : LD50 (Mouse): 16,000 mg/kg

Skin corrosion/irritation

Causes skin irritation.

**Components:** 

Calcium diformate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Phosphoric acid:

Result : Corrosive after 3 minutes to 1 hour of exposure

Remarks : Based on national or regional regulation.

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

L-Malic acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Fumaric acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Formic acid:

Result : Corrosive after 3 minutes or less of exposure

Remarks : Based on extreme pH

Serious eye damage/eye irritation

Causes serious eye damage.

**Components:** 

**Calcium diformate:** 

Species : Rabbit

Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

Phosphoric acid:

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Species : Rabbit

Result : Irreversible effects on the eye

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

L-Malic acid:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days Remarks : Based on data from similar materials

Fumaric acid:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Formic acid:

Result : Irreversible effects on the eye Remarks : Based on skin corrosivity.

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

# **Components:**

### Calcium diformate:

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

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

L-Malic acid:

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

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

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Fumaric acid:

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

Method : OECD Test Guideline 406

Result : negative

Formic acid:

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

Method : OECD Test Guideline 406

Result : negative

### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

Calcium diformate:

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

Method: OECD Test Guideline 471

Result: negative

Genotoxicity in vivo : Test Type: Sex-linked recessive lethal test in Drosophila mel-

anogaster (in vivo)

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Phosphoric acid:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Citric acid:

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

Result: negative

Test Type: in vitro micronucleus test

Result: positive

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Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

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

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

L-Malic acid:

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

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Fumaric acid:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Formic acid:

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

Method: OECD Test Guideline 471

Result: negative

Genotoxicity in vivo : Test Type: Sex-linked recessive lethal test in Drosophila mel-

anogaster (in vivo)

Application Route: Ingestion Method: OECD Test Guideline 477

Result: negative

Carcinogenicity

Not classified based on available information.

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### **Components:**

Formic acid:

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

Remarks : Based on data from similar materials

### Reproductive toxicity

Not classified based on available information.

#### **Components:**

Calcium diformate:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

Remarks: Based on data from similar materials

Phosphoric acid:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Effects on foetal develop-

ment

Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Citric acid:

Effects on foetal develop-

ment

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

#### L-Malic acid:

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



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

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: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Formic acid:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

Remarks: Based on data from similar materials

### STOT - single exposure

Not classified based on available information.

### **Components:**

### Citric acid:

Assessment : May cause respiratory irritation.

## STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

### **Components:**

#### Calcium diformate:

Species : Rat

NOAEL : 3,000 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Method : OECD Test Guideline 408

Remarks : Based on data from similar materials

### Phosphoric acid:

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



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Species : Rat

NOAEL : 250 mg/kg
Application Route : Ingestion
Exposure time : 40 - 52 Days

Method : OECD Test Guideline 422

Citric acid:

Species : Rat

NOAEL : 4,000 mg/kg
LOAEL : 8,000 mg/kg
Application Route : Ingestion
Exposure time : 10 Days

L-Malic acid:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 104 Weeks

Remarks : Based on data from similar materials

Fumaric acid:

Species : Rat

NOAEL : 600 mg/kg Application Route : Ingestion Exposure time : 2 yr

Formic acid:

Species : Rat
NOAEL : 400 mg/kg
Application Route : Ingestion
Exposure time : 52 Weeks

Remarks : Based on data from similar materials

### **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 consid-

ered 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.

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



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### **SECTION 12: Ecological information**

## 12.1 Toxicity

#### Components:

Calcium diformate:

Toxicity to fish LC0 (Danio rerio (zebra fish)): >= 1,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 1,000 mg/l

Exposure time: 48 h Method: EPA-660/3-75-009

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): >

1,000 mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 500

mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

Toxicity to microorganisms NOEC: >= 22.1 mg/l

Exposure time: 28 d

Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: >= 100 mg/lExposure time: 21 d

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

Remarks: Based on data from similar materials

Phosphoric acid:

Toxicity to fish LC50 (Oryzias latipes (Japanese medaka)): > 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 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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

Exposure time: 72 h

Method: OECD Test Guideline 201

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



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Toxicity to microorganisms : EC50 : > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

Citric acid:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,535 mg/l

Exposure time: 24 h

L-Malic acid:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

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

mg/l

Exposure time: 72 h

Test substance: Neutralised product Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Neutralised product Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 (activated sludge): > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

Fumaric acid:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 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 : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

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



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plants 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 : > 300 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Formic acid:

Toxicity to fish LC50 (Danio rerio (zebra fish)): 130 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 365 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): 1,240

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): 295

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC: 72 mg/l Toxicity to microorganisms

Exposure time: 13 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: > 100 ma/l

Exposure time: 21 d

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

**Butafosfan:** 

**Ecotoxicology Assessment** 

Toxic effects cannot be excluded Acute aquatic toxicity

Chronic aquatic toxicity Toxic effects cannot be excluded

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



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### 12.2 Persistence and degradability

# **Components:**

Calcium diformate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 86 % Exposure time: 28 d

Method: OECD Test Guideline 306

Remarks: Based on data from similar materials

Citric acid:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Fumaric acid:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 67.5 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Formic acid:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 100 % Exposure time: 28 d

Method: OECD Test Guideline 301C

#### 12.3 Bioaccumulative potential

### **Components:**

Calcium diformate:

Partition coefficient: n- : log Pow: -2.3 - -1.9

octanol/water Remarks: Based on data from similar materials

Citric acid:

Partition coefficient: n-

: log Pow: -1.72

octanol/water L-Malic acid:

Partition coefficient: n-

: log Pow: -1.68

octanol/water

Remarks: Calculation

Fumaric acid:

Partition coefficient: n-

octanol/water

log Pow: 0.46

Formic acid:

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



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Partition coefficient: n-

octanol/water

: log Pow: -2.1

### 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 consid-

ered 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 han-

dling 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 : UN 3453
ADR : UN 3453
RID : UN 3453
IMDG : UN 3453
IATA : UN 3453

#### 14.2 UN proper shipping name

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



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ADN : PHOSPHORIC ACID, SOLID, MIXTURE

ADR : PHOSPHORIC ACID, SOLID, MIXTURE

RID : PHOSPHORIC ACID, SOLID, MIXTURE

IMDG : PHOSPHORIC ACID, SOLID, MIXTURE

IATA : Phosphoric acid, solid, Mixture

### 14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 8
ADR : 8
RID : 8
IMDG : 8
IATA : 8

### 14.4 Packing group

## ADN

Packing group : III
Classification Code : C2
Hazard Identification Number : 80
Labels : 8

#### **ADR**

Packing group : III
Classification Code : C2
Hazard Identification Number : 80
Labels : 8
Tunnel restriction code : (E)

#### RID

Packing group : III
Classification Code : C2
Hazard Identification Number : 80
Labels : 8

### **IMDG**

Packing group : III
Labels : 8

EmS Code : F-A, S-B

### IATA (Cargo)

Packing instruction (cargo : 864

aircraft)

Packing instruction (LQ) : Y845
Packing group : III

Labels : Corrosive

#### IATA (Passenger)

Packing instruction (passen: 860

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



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ger aircraft)

Packing instruction (LQ) Y845 Packing group Ш Labels Corrosive

14.5 Environmental hazards

Environmentally hazardous no

Environmentally hazardous no

Environmentally hazardous no

**IMDG** 

Marine pollutant no

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

### 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)

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).

Regulation (EU) No 2024/590 on substances that de-

plete the ozone layer

Not applicable

Not applicable

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



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Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia-

ment and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

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

### 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

Not applicable

lines.

#### **Full text of H-Statements**

H226 : Flammable liquid and vapour. H290 : May be corrosive to metals.

H302 : Harmful if swallowed.

H314 : Causes severe skin burns and eye damage.

H318 : Causes serious eye damage. H319 : Causes serious eye irritation.

H331 : Toxic if inhaled.

H335 : May cause respiratory irritation. EUH071 : Corrosive to the respiratory tract.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Eye Dam. : Serious eye damage

Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Met. Corr. : Corrosive to metals
Skin Corr. : Skin corrosion

STOT SE : Specific target organ toxicity - single exposure

2000/39/EC : Europe. Commission Directive 2000/39/EC establishing a first

list of indicative occupational exposure limit values

2006/15/EC : Europe. Indicative occupational exposure limit values

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

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



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and 2

2000/39/EC / TWA Limit Value - eight hours Short term exposure limit 2000/39/EC / STEL 2006/15/EC / TWA Limit Value - eight hours

IE OEL / OELV - 8 hrs (TWA) Occupational exposure limit value (8-hour reference period) IE OEL / OELV - 15 min Occupational exposure limit value (15-minute reference peri-

(STEL)

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

compile the Safety Data

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

### Classification of the mixture:

### Classification procedure:

Skin Irrit. 2 H315 Calculation method Eye Dam. 1 H318 Calculation method

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



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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.

IE / EN