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

1.1 Product identifier

Trade name : Ivermectin / Abamectin Liquid 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

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Acute toxicity, Category 4

Acute toxicity, Category 4

Acute toxicity, Category 4

Skin irritation, Category 2

H302: Harmful if swallowed.

H332: Harmful if inhaled.

H315: Causes skin irritation.

Eye irritation, Category 2

Reproductive toxicity, Category 1B

Specific target organ toxicity - single exH319: Causes serious eye irritation.
H360D: May damage the unborn child.
H371: May cause damage to organs.

posure, Category 2

Specific target organ toxicity - single ex-

posure, Category 3

Specific target organ toxicity - repeated

exposure, Category 2

Short-term (acute) aquatic hazard, Cate-

gory 1

Long-term (chronic) aquatic hazard, Cat-

H335: May cause respiratory irritation.

H373: May cause damage to organs through pro-

longed or repeated exposure. H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting

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egory 1 effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms :







Signal word : Danger

Hazard statements : H302 + H332 Harmful if swallowed or if inhaled.

H315 Causes skin irritation.

H319 Causes serious eye irritation.
 H335 May cause respiratory irritation.
 H360D May damage the unborn child.
 H371 May cause damage to organs.

H373 May cause damage to organs through prolonged

or repeated exposure.

H410 Very toxic 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

protection/ face protection.

Response:

P304 + P340 + P312 IF INHALED: Remove person to fresh

air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.

P308 + P311 IF exposed or concerned: Call a POISON

CENTER/ doctor.

P391 Collect spillage.

Hazardous components which must be listed on the label:

N-Methyl-2-pyrrolidone

Ivermectin

abamectin (combination of avermectin B1a and avermectin B1b) (ISO)

Restricted to professional users.

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.

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
N-Methyl-2-pyrrolidone	872-50-4 212-828-1 606-021-00-7	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Repr. 1B; H360D STOT SE 3; H335 ———————————————————————————————————	>= 20 - < 30
Ivermectin	70288-86-7 274-536-0	Acute Tox. 2; H300 Acute Tox. 3; H311 STOT SE 1; H370 (Central nervous system) STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——— M-Factor (Acute aquatic toxicity): 10,000 M-Factor (Chronic aquatic toxicity): 10,000	>= 1 - < 2.5
abamectin (combination of avermectin B1a and avermectin B1b) (ISO)	71751-41-2 606-143-00-0	Acute Tox. 2; H300 Acute Tox. 1; H330 Acute Tox. 3; H311 Repr. 2; H361fd STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity):	>= 1 - < 2.5

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			10,000 M-Factor (Chronic aquatic toxicity): 10,000 ————————————————————————————————	
(dl)-a	-Tocopheryl acetate	7695-91-2 231-710-0		< 0.1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Des	cription	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.

> If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

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

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.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

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4.2 Most important symptoms and effects, both acute and delayed

Risks : Harmful if swallowed or if inhaled.

Causes skin irritation.

Causes serious eye irritation.
May cause respiratory irritation.
May damage the unborn child.
May cause damage to organs.

May cause damage to organs through prolonged or repeated

exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

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

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

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).

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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

oarriers).

Retain and dispose of contaminated wash water.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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. 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 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 : 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. 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.

Already sensitised individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira-

tory irritants or sensitisers.

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

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

environment.

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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. Keep in a cool, well-ventilated place. Store in

accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
N-Methyl-2- pyrrolidone	872-50-4	TWA	10 ppm 40 mg/m3	GB EH40
			bed through the skin. The as	
	lead to systen		are concerns that dermal abs	sorption will
		STEL	20 ppm 80 mg/m3	GB EH40
		ose for which there	bed through the skin. The as are concerns that dermal abs	
		TWA	10 ppm 40 mg/m3	2009/161/EU
	Further inform skin, Indicative		possibility of significant uptak	te through the
		STEL	20 ppm 80 mg/m3	2009/161/EU
	Further inform skin, Indicative		possibility of significant uptak	e through the

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		TWA	10 ppm 40 mg/m3	2004/37/EC	
	Further inform	nation: Skin, Carcino	gens or mutagens		
		STEL	20 ppm 80 mg/m3	2004/37/EC	
	Further inform	nation: Skin, Carcino	gens or mutagens		
Ivermectin	70288-86-7	TWA	30 μg/m3 (OEB 3)	Internal	
	Further inform	Further information: Skin			
		Wipe limit	300 μg/100 cm2	Internal	
abamectin (combination of avermectin B1a and avermectin B1b) (ISO)	71751-41-2	TWA	15 μg/m3 (OEB 3)	Internal	
, , , , ,		Wipe limit	150 μg/100 cm ²	Internal	
(dl)-a-Tocopheryl acetate	7695-91-2	TWA	5000 ug/m3 (OEB 1)	Internal	

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
N-Methyl-2- pyrrolidone	Workers	Inhalation	Long-term systemic effects	14.4 mg/m3
	Workers	Inhalation	Long-term local ef- fects	40 mg/m3
	Workers	Skin contact	Long-term systemic effects	4.8 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	3.6 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	4.5 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2.4 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0.85 mg/kg bw/day
(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

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
N-Methyl-2-pyrrolidone	Fresh water	0.25 mg/l
	Freshwater - intermittent	5 mg/l
	Marine water	0.025 mg/l
	Sewage treatment plant	10 mg/l

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	Fresh water sediment	1.09 mg/kg dry weight (d.w.)
	Marine sediment	1.09 mg/kg dry weight (d.w.)
	Soil	0.07 mg/kg dry weight (d.w.)
(dl)-a-Tocopheryl acetate	Fresh water	0.27 mg/l
	Freshwater - intermittent	0.27 mg/l
	Marine water	0.027 mg/l
	Sewage treatment plant	100 mg/l
	Fresh water sediment	212000 mg/kg dry weight (d.w.)
	Marine sediment	21200 mg/kg dry weight (d.w.)
	Soil	74800 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less guick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task

being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance liquid Colour light yellow Odour characteristic Odour Threshold No data available

pН No data available

Melting point/freezing point No data available

Initial boiling point and boiling

range

> 100 °C Flash point

Evaporation rate No data available

Flammability (solid, gas) Not applicable

Upper explosion limit / Upper

flammability limit

No data available

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure No data available

Relative vapour density No data available

Relative density No data available

0.91 - 1.00 mg/l Density

Solubility(ies)

Water solubility Partition coefficient: n-

octanol/water

insoluble Not applicable

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

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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

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

Acute toxicity

Harmful if swallowed or if inhaled.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,031 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 1.84 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

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Components:

N-Methyl-2-pyrrolidone:

Acute oral toxicity : LD50 (Rat): 4,150 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.1 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

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

Ivermectin:

Acute oral toxicity : LD50 (Rat): 50 mg/kg

LD50 (Mouse): 25 mg/kg

LD50 (Monkey): > 24 mg/kg

Target Organs: Central nervous system Symptoms: Vomiting, Dilatation of the pupil Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 5.11 mg/l

Exposure time: 1 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): 406 mg/kg

LD50 (Rat): > 660 mg/kg

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Acute oral toxicity : LD50 (Rat): 24 mg/kg

LD50 (Mouse): 10 mg/kg

LDLo (Monkey): 24 mg/kg

Symptoms: Dilatation of the pupil

Acute inhalation toxicity : LC50 (Rat): 0.023 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): 330 mg/kg

LD50 (Rabbit): 2,000 mg/kg

(dl)-a-Tocopheryl acetate:

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

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

Assessment: The substance or mixture has no acute dermal

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toxicity

Skin corrosion/irritation

Causes skin irritation.

Components:

N-Methyl-2-pyrrolidone:

Result : Skin irritation

Ivermectin:

Species : Rabbit

Result : No skin irritation

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Species : Rabbit

Result : No skin irritation

(dl)-a-Tocopheryl acetate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

N-Methyl-2-pyrrolidone:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Ivermectin:

Species : Rabbit

Result : Mild eye irritation

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Species : Rabbit

Result : Mild eye irritation

(dl)-a-Tocopheryl acetate:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

Ivermectin:

Exposure routes : Dermal Species : Humans

Result : Does not cause skin sensitisation.

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Test Type : Maximisation Test Exposure routes : Skin contact

Result : Not a skin sensitizer.

(dl)-a-Tocopheryl acetate:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Hamster

Application Route: Ingestion Method: OECD Test Guideline 475

Result: negative

Ivermectin:

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

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro) Test system: human diploid fibroblasts

Result: negative

Test Type: Mouse Lymphoma

Result: negative

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster lung cells

Result: negative

Test Type: Alkaline elution assay

Result: negative

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

cytogenetic test, chromosomal analysis)

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

(dl)-a-Tocopheryl acetate:

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

Method: OECD Test Guideline 473

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

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Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

N-Methyl-2-pyrrolidone:

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

Species : Rat

Application Route : inhalation (vapour)

Exposure time : 2 Years
Result : negative

Ivermectin:

Species : Rat Application Route : Oral

NOAEL : 1.5 mg/kg body weight

Result : negative

Remarks : Based on data from similar materials

Species : Mouse Application Route : Oral

NOAEL : 2.0 mg/kg body weight

Result : negative

Remarks : Based on data from similar materials

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Species : Rat
Application Route : Oral
Exposure time : 105 weeks
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 93 weeks
Result : negative

(dl)-a-Tocopheryl acetate:

Species : Rat

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

Reproductive toxicity

May damage the unborn child.

Components:

N-Methyl-2-pyrrolidone:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: positive

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: inhalation (vapour)

Result: positive

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Ingestion

Result: positive

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

Ivermectin:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 0.6 mg/kg body weight

Result: Animal testing did not show any effects on fertility.

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse Application Route: Oral

Developmental Toxicity: NOAEL: 0.2 mg/kg body weight Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally

toxic doses

Test Type: Development

Species: Rat

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Application Route: Oral

Developmental Toxicity: LOAEL: 0.4 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-

spring were detected.

Remarks: The mechanism or mode of action may not be rele-

vant in humans.

Test Type: Development

Species: Rabbit Application Route: Oral

Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally

toxic doses

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Effects on fertility : Test Type: Fertility

Species: Rat, male Application Route: Oral Result: Effects on fertility

Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Oral

Early Embryonic Development: NOAEL: 0.12 mg/kg body

weight

Result: Fetotoxicity

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse Application Route: Oral

General Toxicity Maternal: NOAEL: 0.05 mg/kg body weight Developmental Toxicity: NOAEL: 0.2 mg/kg body weight

Result: Cleft palate

Remarks: Adverse developmental effects were observed

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 2 mg/kg body weight Result: Cleft palate, Teratogenic effects, Reduced embryonic

survival

Remarks: Adverse developmental effects were observed

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 1.6 mg/kg body weight

Result: Teratogenic effects

Reproductive toxicity - As-

sessment

: Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experi-

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ments.

(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-

Test Type: Embryo-foetal development Species: Rabbit ment

Application Route: Ingestion

Result: negative

STOT - single exposure

May cause respiratory irritation. May cause damage to organs.

Components:

N-Methyl-2-pyrrolidone:

Assessment May cause respiratory irritation.

Ivermectin:

Target Organs Central nervous system Assessment Causes damage to organs.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Ivermectin:

Target Organs : Central nervous system

: Causes damage to organs through prolonged or repeated Assessment

exposure.

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Exposure routes Ingestion

: Central nervous system Target Organs

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

N-Methyl-2-pyrrolidone:

Species Rat, male NOAEL 169 mg/kg

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LOAEL 433 mg/kg Application Route Ingestion Exposure time 90 Days

Method **OECD Test Guideline 408**

Species Rat NOAEL 0.5 mg/l Application Route
Exposure time LOAEL 1 mg/l

: inhalation (dust/mist/fume)

: 96 Days

: OECD Test Guideline 413 Method

LOAEL
LOAEL
Application Route
Exposure time Rabbit 826 mg/kg 1,653 mg/kg Skin contact Exposure time 20 Days

Ivermectin:

Species Doa NOAEL 0.5 mg/kg LOAEL 1 mg/kg Application Route Oral Exposure time 14 Weeks

Target Organs Central nervous system

Symptoms Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species Monkey 1.2 mg/kg NOAEL Application Route Oral Exposure time 2 Weeks

Remarks No significant adverse effects were reported

Species Rat NOAEL 0.4 mg/kg LOAEL 0.8 mg/kg Application Route : Oral Exposure time : 3 Months

: spleen, Bone marrow, Kidney Target Organs

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Species Rat NOAEL 1.5 mg/kg Application Route Oral Exposure time : 24 Months

Target Organs : Central nervous system

Symptoms Tremors, ataxia

Species Mouse NOAEL 4.0 mg/kg Application Route Oral Exposure time 24 Months

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Target Organs : Central nervous system

Symptoms : Tremors, ataxia

Species: DogNOAEL: 0.25 mg/kgLOAEL: 0.5 mg/kgApplication Route: OralExposure time: 53 Weeks

Target Organs : Central nervous system
Symptoms : Tremors, weight loss
Remarks : mortality observed

Species : Monkey
NOAEL : 1.0 mg/kg
Application Route : Oral
Exposure time : 14 Weeks

Target Organs : Central nervous system

(dl)-a-Tocopheryl acetate:

Species : Rat

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

N-Methyl-2-pyrrolidone:

Skin contact : Symptoms: Skin irritation

Ivermectin:

Skin contact : Remarks: Can be absorbed through skin.

Eye contact : Remarks: May irritate eyes.

Ingestion : Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vom-

iting, anorexia, Lack of coordination

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Ingestion : Symptoms: May cause, Tremors, Diarrhoea, central nervous

system effects, Salivation, tearing

SECTION 12: Ecological information

12.1 Toxicity

Components:

N-Methyl-2-pyrrolidone:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l

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Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 24 h Method: DIN 38412

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 600.5 mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 92.6 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC50 : > 600 mg/l

Exposure time: 30 min Method: ISO 8192

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 12.5 mg/l Exposure time: 21 d

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

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.000025 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

icity)

10,000

M-Factor (Chronic aquatic

toxicity)

10,000

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 3.2 μg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.6 μg/l

Exposure time: 96 h

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LC50 (Ictalurus punctatus (channel catfish)): 24 µg/l

Exposure time: 96 h

LC50 (Cyprinus carpio (Carp)): 42 µg/l

Exposure time: 96 h

LC50 (Cyprinodon variegatus (sheepshead minnow)): 15 μg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Americamysis): 0.022 µg/l

Exposure time: 96 h

EC50 (Daphnia magna (Water flea)): 0.34 μg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 100

mg/l

Exposure time: 72 h

M-Factor (Acute aquatic tox-

icity)

10,000

Toxicity to microorganisms : EC50 : > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.52 μg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.03 µg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

NOEC: 0.0035 µg/l Exposure time: 28 d

Species: Mysidopsis bahia (opossum shrimp)

M-Factor (Chronic aquatic

toxicity)

10,000

(dl)-a-Tocopheryl acetate:

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

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

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

mg/l

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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)

12.2 Persistence and degradability

Components:

N-Methyl-2-pyrrolidone:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 73 % Exposure time: 28 d

Method: OECD Test Guideline 301C

Ivermectin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 240 d

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Stability in water : Hydrolysis: 50 %(< 12 h)

(dl)-a-Tocopheryl acetate:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 21.7 - 31 %

Exposure time: 28 d

Method: OECD Test Guideline 301C

12.3 Bioaccumulative potential

Components:

N-Methyl-2-pyrrolidone:

Partition coefficient: n- : log Pow: -0.46

octanol/water Method: OECD Test Guideline 107

Ivermectin:

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Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-

octanol/water

: log Pow: 3.22

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Bioaccumulation : Bioconcentration factor (BCF): 52

Partition coefficient: n-

octanol/water

log Pow: 4

12.4 Mobility in soil

Components:

abamectin (combination of avermectin B1a and avermectin B1b) (ISO):

Distribution among environ-

mental compartments

: log Koc: > 3.6

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 Other adverse effects

Product:

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

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 : UN 3082

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ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(abamectin (combination of avermectin B1a and avermectin

B1b) (ISO), Ivermectin)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(abamectin (combination of avermectin B1a and avermectin

B1b) (ISO), Ivermectin)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(abamectin (combination of avermectin B1a and avermectin

B1b) (ISO), Ivermectin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(abamectin (combination of avermectin B1a and avermectin

B1b) (ISO), Ivermectin)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(abamectin (combination of avermectin B1a and avermectin

B1b) (ISO), Ivermectin)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

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Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 964

aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 964

ger aircraft)

Packing instruction (LQ) : Y964
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

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 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

Conditions of restriction for the fol-UK REACH List of restrictions (Annex 17)

lowing entries should be considered:

Number on list 3

Number on list 30: N-Methyl-2-

pyrrolidone

Number on list 71: N-Methyl-2-

pyrrolidone

Number on list 72: N-Methyl-2-

pyrrolidone

UK REACH List of restrictions (Annex 17)

JK REACH List of restrictions (Annex 17)

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.

Not applicable

UK REACH Candidate list of substances of very high N-Methyl-2-pyrrolidone

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained Not applicable Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) on substances that deplete the ozone Not applicable

layer

UK REACH List of substances subject to authorisation (Annex XIV)

GB Export and import of hazardous chemicals - Prior Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2

E1 **ENVIRONMENTAL** 200 t 100 t

HAZARDS

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

Full text of H-Statements

H300 : Fatal if swallowed.

H311 : Toxic in contact with skin. H315 : Causes skin irritation.

H319 : Causes serious eye irritation.

H330 : Fatal if inhaled.

H335 : May cause respiratory irritation. H360D : May damage the unborn child.

H361fd : Suspected of damaging fertility. Suspected of damaging the

unborn child.

H370 : Causes damage to organs if swallowed.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure STOT SE : Specific target organ toxicity - single exposure

2004/37/EC : Europe. Directive 2004/37/EC on the protection of workers

from the risks related to exposure to carcinogens or mutagens

at work

2009/161/EU : Europe. COMMISSION DIRECTIVE 2009/161/EU establishing

a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending

Commission Directive 2000/39/EC

GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

2004/37/EC / STEL : Short term exposure limit 2004/37/EC / TWA : Long term exposure limit 2009/161/EU / TWA : Limit Value - eight hours

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2009/161/EU / STEL : Short term exposure limit

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet

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

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

Classification of the mixture:

Classification procedure:

Acute Tox. 4	H302	Calculation method
Acute Tox. 4	H332	Calculation method
Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Repr. 1B	H360D	Calculation method
STOT SE 2	H371	Calculation method
STOT SE 3	H335	Calculation method

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STOT	RE 2	H373	Calculation method	
Aquati	ic Acute 1	H400	Calculation method	
Aquati	ic Chronic 1	H410	Calculation method	

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

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