

SAFETY DATA SHEET

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



Diflubenzuron (25%) Formulation

Version 2.1 Revision Date: 30.09.2023 SDS Number: 10876890-00005 Date of last issue: 24.02.2023
Date of first issue: 26.10.2022

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

1.1 Product identifier

Trade name : Diflubenzuron (25%) Formulation

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 sensitisation, Category 1	H317: May cause an allergic skin reaction.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



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Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
P280 Wear protective gloves.

Response:
P314 Get medical advice/ attention if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Hazardous components which must be listed on the label:

N-[[[4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide
(R)-p-mentha-1,8-diene
N,N'-Methylenebis[N'-[3-(hydroxymethyl)-2,5-dioximidazolidin-4-yl]urea]

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.

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-[[[4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide	35367-38-5 252-529-3	STOT RE 2; H373 (Blood, spleen, Liver) Aquatic Acute 1; H400 Aquatic Chronic 1;	>= 25 - < 30

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		H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1,000	
Sulfurous acid, monosodium salt, reaction products with (cresol, formaldehyde, nonylphenol) polymer	115535-44-9	Aquatic Chronic 3; H412	$\geq 2.5 - < 10$
(R)-p-mentha-1,8-diene	5989-27-5 227-813-5 601-096-00-2	Flam. Liq. 3; H226 Skin Irrit. 2; H315 Skin Sens. 1B; H317 Asp. Tox. 1; H304 Aquatic Acute 1; H400 Aquatic Chronic 3; H412 M-Factor (Acute aquatic toxicity): 1	$\geq 1 - < 2.5$
N,N'-Methylenebis[N'-[3-(hydroxymethyl)-2,5-dioximidazolidin-4-yl]urea]	39236-46-9 254-372-6	Skin Sens. 1B; H317 Aquatic Chronic 3; H412	$\geq 0.1 - < 0.25$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

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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

Risks : May cause an allergic skin reaction.
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 products : Carbon oxides
Chlorine compounds
Nitrogen oxides (NO_x)
Fluorine compounds
Metal oxides
Sulphur oxides

5.3 Advice for firefighters

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

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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

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flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
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-[[[4-chloro-phenyl)amino]carbonyl]-2,6-difluorobenzamide	35367-38-5	TWA	100 µg/m ³ (OEB 2)	Internal
Propylene glycol	57-55-6	OELV - 8 hrs (TWA) (particles)	10 mg/m ³	IE OEL
		OELV - 8 hrs (TWA) (total (vapour and particles))	150 ppm 470 mg/m ³	IE OEL

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m ³
	Workers	Inhalation	Long-term systemic effects	168 mg/m ³
	Consumers	Inhalation	Long-term local effects	10 mg/m ³

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	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
(R)-p-mentha-1,8-diene	Workers	Inhalation	Long-term systemic effects	66.7 mg/m3
	Workers	Skin contact	Acute local effects	9.5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	16.6 mg/m3
	Consumers	Skin contact	Acute local effects	4.8 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4.8 mg/kg bw/day
N,N''-Methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]	Workers	Inhalation	Long-term systemic effects	24.5 mg/m3
	Workers	Inhalation	Acute systemic effects	45.5 mg/m3
	Workers	Skin contact	Long-term systemic effects	2.8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	160 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	1.4 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)
(R)-p-mentha-1,8-diene	Fresh water	0.014 mg/l
	Marine water	0.0014 mg/l
	Sewage treatment plant	1.8 mg/l
	Fresh water sediment	3.85 mg/kg dry weight (d.w.)
	Marine sediment	0.385 mg/kg dry weight (d.w.)
	Soil	0.763 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	133 mg/kg food
N,N''-Methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]	Fresh water	0.00578 mg/l
	Freshwater - intermittent	0.0578 mg/l
	Marine water	0.00058 mg/l

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	Sewage treatment plant	20 mg/l
	Fresh water sediment	0.08878 mg/kg dry weight (d.w.)
	Marine sediment	0.00888 mg/kg dry weight (d.w.)
	Soil	0.01435 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 quick 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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 14387

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : suspension

Colour : off-white

Odour : No data available

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Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity
Viscosity, kinematic : 1300 - 2400 mm²/s

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : 1.09 - 1.19

Density : No data available

Relative vapour density : No data available

Particle characteristics
Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

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Evaporation rate : No data available

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 : 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 hazard classes as defined in Regulation (EC) No 1272/2008

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

Acute toxicity

Not classified based on available information.

Components:

N-[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide:

Acute oral toxicity : LD50 (Rat): 4,640 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 2.49 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Method: OECD Test Guideline 402

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(R)-p-mentha-1,8-diene:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg
Remarks: Based on data from similar materials

N,N''-Methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

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

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 8,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

N-[[4-(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide:

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

(R)-p-mentha-1,8-diene:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation

N,N''-Methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

N-[[4-(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide:

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

(R)-p-mentha-1,8-diene:

Species : Rabbit
Method : OECD Test Guideline 405

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Result : No eye irritation

N,N''-Methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

N-[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide:

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

(R)-p-mentha-1,8-diene:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

N,N''-Methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

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

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

N-[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

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Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

(R)-p-mentha-1,8-diene:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

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

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: In vivo mammalian alkaline comet assay
Species: Rat
Application Route: Ingestion
Result: negative

N,N"-Methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Test Type: Unscheduled DNA synthesis (UDS) test with
mammalian liver cells in vivo
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 486
Result: negative
Remarks: Based on data from similar materials

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Carcinogenicity

Not classified based on available information.

Components:

N-[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide:

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

(R)-p-mentha-1,8-diene:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

N-[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

(R)-p-mentha-1,8-diene:

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

N,N''-Methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]:

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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Components:

N-[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide:

Exposure routes : Ingestion
Target Organs : Blood, spleen, Liver
Assessment : Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

Exposure routes : inhalation (dust/mist/fume)
Target Organs : Blood, spleen, Liver
Assessment : Shown to produce significant health effects in animals at concentrations of >0.02 to 0.2 mg/l/6h/d.

Exposure routes : Skin contact
Target Organs : Blood, spleen, Liver
Assessment : Shown to produce significant health effects in animals at concentrations of >20 to 200 mg/kg bw.

(R)-p-mentha-1,8-diene:

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

Repeated dose toxicity

Components:

N-[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide:

Species : Rat
LOAEL : 81 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Species : Rabbit
NOAEL : > 322 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Species : Rat
NOAEL : > 0.1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days

(R)-p-mentha-1,8-diene:

Species : Rat, male
NOAEL : 5 mg/kg
LOAEL : 30 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

N,N''-Methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]:

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Species : Rat, male
NOAEL : 672 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Aspiration toxicity

Not classified based on available information.

Components:

(R)-p-mentha-1,8-diene:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

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

SECTION 12: Ecological information

12.1 Toxicity

Components:

N-[[[(4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide:

Toxicity to fish : LC50 (Cyprinodon variegatus (sheepshead minnow)): > 0.13 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.0026 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornutum (green algae)): > 0.2 mg/l
Exposure time: 72 h
Remarks: No toxicity at the limit of solubility

M-Factor (Acute aquatic toxicity) : 100

Toxicity to fish (Chronic toxicity) : NOEC: 0.2 mg/l
Exposure time: 21 d
Species: Oncorhynchus mykiss (rainbow trout)

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.00004 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity) : 1,000

Sulfurous acid, monosodium salt, reaction products with (cresol, formaldehyde, nonylphenol) polymer:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10 - 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

(R)-p-mentha-1,8-diene:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 0.720 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 307 µg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.25 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): 0.14 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50 : > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : EC10: 0.37 mg/l
Exposure time: 8 d
Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10: 0.153 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

N,N''-Methylenebis[N'-(3-(hydroxymethyl)-2,5-dioximidazolidin-4-yl)urea]:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 220 mg/l
Exposure time: 96 h

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10 - 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l
Exposure time: 72 h
Method: Directive 67/548/EEC, Annex V, C.3.
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): > 1 - 10 mg/l
Exposure time: 72 h
Method: Directive 67/548/EEC, Annex V, C.3.
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

12.2 Persistence and degradability

Components:

N-[[[4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide:

Biodegradability : Result: Not readily biodegradable.
Method: OECD Test Guideline 301

(R)-p-mentha-1,8-diene:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 71.4 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

N,N''-Methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 37.4 - 42.7 %
Exposure time: 25 d

12.3 Bioaccumulative potential

Components:

N-[[[4-chlorophenyl)amino]carbonyl]-2,6-difluorobenzamide:

Bioaccumulation : Bioconcentration factor (BCF): 320

Partition coefficient: n-octanol/water : log Pow: 3.89

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(R)-p-mentha-1,8-diene:

Partition coefficient: n-octanol/water : log Pow: 4.38

N,N"-Methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]:

Partition coefficient: n-octanol/water : log Pow: < 4
Remarks: Expert judgement

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

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

12.6 Endocrine disrupting properties

Product:

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

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN : UN 3082
ADR : UN 3082

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

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(N-[[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide, (R)-p-mentha-1,8-diene)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(N-[[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide, (R)-p-mentha-1,8-diene)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(N-[[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide, (R)-p-mentha-1,8-diene)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(N-[[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide, (R)-p-mentha-1,8-diene)

IATA : Environmentally hazardous substance, liquid, n.o.s.
(N-[[[4-chlorophenyl]amino]carbonyl]-2,6-difluorobenzamide, (R)-p-mentha-1,8-diene)

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
Tunnel restriction code : (-)

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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 aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
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 Maritime transport in bulk according to IMO instruments

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 mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 75, 3

If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1	Quantity 2
		100 t	200 t

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where 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.

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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

H226 : Flammable liquid and vapour.
H304 : May be fatal if swallowed and enters airways.
H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H373 : May cause damage to organs through prolonged or repeated exposure.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.
H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Asp. Tox. : Aspiration hazard
Flam. Liq. : Flammable liquids
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
IE OEL : List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour 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; AIIIC - 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 sub-

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stance; 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

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

Classification of the mixture:

Skin Sens. 1	H317
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

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