

SAFETY DATA SHEET

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



Amitraz (12.5%) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.1	30.09.2023	1829291-00017	Date of first issue: 11.07.2017

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

1.1 Product identifier

Trade name : Amitraz (12.5%) 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)

Acute toxicity, Category 4	H302: Harmful if swallowed.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1B	H360F: May damage fertility.
Specific target organ toxicity - single exposure, Category 3	H336: May cause drowsiness or dizziness.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard, Category 1	H304: May be fatal if swallowed and enters airways.
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.

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements :

- H302 Harmful if swallowed.
- H304 May be fatal if swallowed and enters airways.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness.
- H360F May damage fertility.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

Supplemental Hazard Statements : EUH066 Repeated exposure may cause skin dryness or cracking.

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:

- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P391 Collect spillage.

Hazardous components which must be listed on the label:

Hydrocarbons, C10, aromatics, <1% naphthalene
4-Nonylphenol, branched, ethoxylated
amitraz (ISO)
Bis(2,6-diisopropylphenyl)carbodiimide

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: This substance/mixture contains components considered to have endocrine disrupting properties for environment, according to REACH Article 57(f), Commission Regulation (EU) 2018/605 or Commission Delegated Regulation (EU) 2017/2100.

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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)
Hydrocarbons, C10, aromatics, <1% naphthalene	64742-94-5	STOT SE 3; H336 Asp. Tox. 1; H304 Aquatic Chronic 2; H411 EUH066	>= 50 - < 70
4-Nonylphenol, branched, ethox- ylated	127087-87-0	Acute Tox. 4; H302 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 10 Acute toxicity esti- mate Acute oral toxicity: 300.03 mg/kg	>= 10 - < 20
amitraz (ISO)	33089-61-1 251-375-4 612-086-00-2	Acute Tox. 4; H302 Skin Sens. 1B; H317 STOT RE 2; H373 (Liver, Central nerv- ous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 10 - < 20

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Bis(2,6-diisopropylphenyl)carbodiimide	2162-74-5 218-487-5	Acute Tox. 4; H302 Repr. 1B; H360F STOT RE 1; H372 (Kidney, Heart, Gas- trointestinal tract, Lymph nodes) Aquatic Chronic 4; H413 Acute toxicity esti- mate Acute oral toxicity: 300.03 mg/kg	>= 1 - < 2.5
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For explanation of abbreviations see section 16.

Alternative CAS Numbers for some regions

Chemical name	Alternative CAS Number(s)
4-Nonylphenol, branched, ethoxylated	68412-54-4

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.
- 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 : 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.
If vomiting occurs have person lean forward.
Call a physician or poison control centre immediately.
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.
May be fatal if swallowed and enters airways.
May cause an allergic skin reaction.
Causes serious eye irritation.
May cause drowsiness or dizziness.
May damage fertility.
May cause damage to organs through prolonged or repeated exposure.
Repeated exposure may cause skin dryness or cracking.

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
Nitrogen oxides (NO_x)

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

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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 : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe the 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 assessment
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working

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place. When using do not eat, drink or smoke. 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 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
Hydrocarbons, C10, aromatics, <1% naphthalene	64742-94-5	OELV - 8 hrs (TWA) (inhalable fraction)	5 mg/m ³	IE OEL
amitraz (ISO)	33089-61-1	TWA	10 µg/m ³ (OEB 3)	Internal
		Wipe limit	1250 µg/100 cm ²	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Bis(2,6-diisopropylphenyl)carbodiimide	Workers	Inhalation	Long-term systemic effects	0.094 mg/m ³
	Workers	Skin contact	Long-term systemic effects	0.013 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0.023 mg/m ³
	Consumers	Skin contact	Long-term systemic effects	0.007 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg

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			fects	bw/day
	Consumers	Ingestion	Long-term systemic effects	0.007 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	0.021 mg/kg bw/day
Hydrocarbons, C10, aromatics, <1% naphthalene	Workers	Inhalation	Long-term systemic effects	151 mg/m3
	Workers	Skin contact	Long-term systemic effects	12.5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	32 mg/m3
	Consumers	Skin contact	Long-term systemic effects	7.5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	7.5 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Bis(2,6-diisopropylphenyl)carbodiimide	Fresh water	0.0001 mg/l
	Marine water	0.00001 mg/l
	Intermittent use/release	0.001 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	5.461 mg/kg dry weight (d.w.)
	Soil	4.445 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.

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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	:	liquid
Colour	:	yellow
Odour	:	characteristic, aromatic, hydrocarbon-like
Odour Threshold	:	No data available
Melting point/freezing point	:	Not applicable
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	106 °C
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Solubility(ies)	:	

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Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Vapour pressure : No data available

Relative density : No data available

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.

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.

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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

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,505 mg/kg
Method: Calculation method

Components:

Hydrocarbons, C10, aromatics, <1% naphthalene:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 420
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 4.778 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 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

4-Nonylphenol, branched, ethoxylated:

Acute oral toxicity : LD50 (Rat): > 300 - 2,000 mg/kg
Remarks: Based on data from similar materials

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

amitraz (ISO):

Acute oral toxicity : LD50 (Rat): > 400 mg/kg
LD50 (Mouse): > 1,085 mg/kg
LD50 (Guinea pig): > 400 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rat): > 1,600 mg/kg

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Bis(2,6-diisopropylphenyl)carbodiimide:

Acute oral toxicity : LD50 (Rat): > 300 - 2,000 mg/kg
Method: OECD Test Guideline 423

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Repeated exposure may cause skin dryness or cracking.

Components:

Hydrocarbons, C10, aromatics, <1% naphthalene:

Assessment : Repeated exposure may cause skin dryness or cracking.

amitraz (ISO):

Species : Rabbit
Result : No skin irritation

Bis(2,6-diisopropylphenyl)carbodiimide:

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

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Hydrocarbons, C10, aromatics, <1% naphthalene:

Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

4-Nonylphenol, branched, ethoxylated:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

amitraz (ISO):

Species : Rabbit
Result : No eye irritation

Bis(2,6-diisopropylphenyl)carbodiimide:

Species : Rabbit
Method : OECD Test Guideline 405

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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:

Hydrocarbons, C10, aromatics, <1% naphthalene:

Test Type	: Maximisation Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative
Remarks	: Based on data from similar materials

4-Nonylphenol, branched, ethoxylated:

Test Type	: Human repeat insult patch test (HRIPT)
Exposure routes	: Skin contact
Result	: negative
Remarks	: Based on data from similar materials

amitraz (ISO):

Test Type	: Maximisation Test
Exposure routes	: Dermal
Species	: Guinea pig
Result	: Sensitiser

Bis(2,6-diisopropylphenyl)carbodiimide:

Test Type	: Maximisation 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:

Hydrocarbons, C10, aromatics, <1% naphthalene:

Genotoxicity in vitro	: Test Type: In vitro sister chromatid exchange assay in mammalian cells Result: negative Remarks: Based on data from similar materials
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Genotoxicity in vivo	: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
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Species: Rat
Application Route: inhalation (vapour)
Result: negative
Remarks: Based on data from similar materials

4-Nonylphenol, branched, ethoxylated:

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

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

amitraz (ISO):

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

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Bis(2,6-diisopropylphenyl)carbodiimide:

Genotoxicity in vitro : 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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

4-Nonylphenol, branched, ethoxylated:

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

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Result : negative
Remarks : Based on data from similar materials

amitraz (ISO):

Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : > 10.18 mg/kg body weight
Result : negative

Species : Mouse
Exposure time : 2 Years
LOAEL : 2.3 mg/kg body weight
Result : positive
Target Organs : Liver, Stomach

Reproductive toxicity

May damage fertility.

Components:

Hydrocarbons, C10, aromatics, <1% naphthalene:

Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: inhalation (vapour)
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

amitraz (ISO):

Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: NOAEL: > 4.8 mg/kg body weight
Result: No significant adverse effects were reported

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 3 mg/kg body weight
Remarks: No significant adverse effects were reported

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 5 mg/kg body weight

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Result: Effects on foetal development

Bis(2,6-diisopropylphenyl)carbodiimide:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 421
Result: positive

Test Type: Fertility
Species: Rat
Application Route: Ingestion
Result: positive

Effects on foetal development : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 421
Result: equivocal

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT - single exposure

May cause drowsiness or dizziness.

Components:

Hydrocarbons, C10, aromatics, <1% naphthalene:

Assessment : May cause drowsiness or dizziness.
Remarks : Based on data from similar materials

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

amitraz (ISO):

Target Organs : Liver, Central nervous system
Assessment : May cause damage to organs through prolonged or repeated exposure.

Bis(2,6-diisopropylphenyl)carbodiimide:

Exposure routes : Ingestion
Target Organs : Kidney, Heart, Gastrointestinal tract, Lymph nodes
Assessment : Causes damage to organs through prolonged or repeated exposure.

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Repeated dose toxicity

Components:

Hydrocarbons, C10, aromatics, <1% naphthalene:

Species : Rat
NOAEL : 300 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks
Remarks : Based on data from similar materials

4-Nonylphenol, branched, ethoxylated:

Species : Rat
LOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Remarks : Based on data from similar materials

amitraz (ISO):

Species : Mouse
NOAEL : 3 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Liver

Species : Dog
NOAEL : 0.25 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Central nervous system, Liver

Bis(2,6-diisopropylphenyl)carbodiimide:

Species : Rat
NOAEL : 4 mg/kg
LOAEL : 16 mg/kg
Application Route : Ingestion
Exposure time : 28 Days
Method : OECD Test Guideline 407

Aspiration toxicity

May be fatal if swallowed and enters airways.

Product:

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.

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Components:

Hydrocarbons, C10, aromatics, <1% naphthalene:

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.

Experience with human exposure

Components:

amitraz (ISO):

Ingestion : Target Organs: Central nervous system

SECTION 12: Ecological information

12.1 Toxicity

Components:

Hydrocarbons, C10, aromatics, <1% naphthalene:

Toxicity to fish : LL50 (Oncorhynchus mykiss (rainbow trout)): 2 - 5 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): 3 - 10 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 3 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

4-Nonylphenol, branched, ethoxylated:

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- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 0.1 - 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): > 0.1 - 1 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : ErC50 (Selenastrum capricornutum (green algae)): > 1 - 10 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
- EC10 (Selenastrum capricornutum (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
- M-Factor (Acute aquatic toxicity) : 1
- Toxicity to fish (Chronic toxicity) : NOEC: > 0.1 - 1 mg/l
Exposure time: 100 d
Species: Oryzias latipes (Japanese medaka)
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 0.001 - 0.01 mg/l
Exposure time: 28 d
Species: Mysidopsis bahia (opossum shrimp)
Remarks: Based on data from similar materials
- M-Factor (Chronic aquatic toxicity) : 10
- amitraz (ISO):**
- Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.45 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.035 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 0.04 mg/l
Exposure time: 91 h
- M-Factor (Acute aquatic toxicity) : 10
- Toxicity to fish (Chronic toxicity) : NOEC: 0.00148 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.0011 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity) : 10

Bis(2,6-diisopropylphenyl)carbodiimide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.1 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

NOEC (Desmodesmus subspicatus (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

12.2 Persistence and degradability

Components:

Hydrocarbons, C10, aromatics, <1% naphthalene:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 49.56 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

4-Nonylphenol, branched, ethoxylated:

Biodegradability : Result: Not readily biodegradable.
Remarks: Based on data from similar materials

Bis(2,6-diisopropylphenyl)carbodiimide:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 3 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

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12.3 Bioaccumulative potential

Components:

4-Nonylphenol, branched, ethoxylated:

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

amitraz (ISO):

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 1,333

Partition coefficient: n-octanol/water : log Pow: 5.5

Bis(2,6-diisopropylphenyl)carbodiimide:

Bioaccumulation : Bioconcentration factor (BCF): > 500

Partition coefficient: n-octanol/water : log Pow: > 6.2

12.4 Mobility in soil

Components:

amitraz (ISO):

Distribution among environmental compartments : log Koc: 3.3

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 : This substance/mixture contains components considered to have endocrine disrupting properties for environment, according to REACH Article 57(f), Commission Regulation (EU) 2018/605 or Commission Delegated Regulation (EU) 2017/2100.

Components:

4-Nonylphenol, branched, ethoxylated:

Assessment : The substance is considered to have endocrine disrupting properties according to REACH Article 57(f) for the environment.

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

14.2 UN proper shipping name

- | | | |
|------|---|--|
| ADN | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(amitraz (ISO)) |
| ADR | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(amitraz (ISO)) |
| RID | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(amitraz (ISO)) |
| IMDG | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(amitraz (ISO)) |
| IATA | : | Environmentally hazardous substance, liquid, n.o.s.
(amitraz (ISO)) |

14.3 Transport hazard class(es)

- | | Class | Subsidiary risks |
|-----|-------|------------------|
| ADN | : | 9 |
| ADR | : | 9 |

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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 : (-)

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

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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.

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. 4-Nonylphenol, branched, ethoxylated (Number on list 46b, 46a.) 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).	:	4-Nonylphenol, branched, ethoxylated
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	:	amitraz (ISO) 4-Nonylphenol, branched, ethoxylated
REACH - List of substances subject to authorisation (Annex XIV)	:	4-Nonylphenol, branched, ethoxylated

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

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t
34	Petroleum products: (a) gasolines and naphthas, (b) kerosenes (including jet fuels), (c) gas oils (including diesel fuels, home heating oils and gas oil blending streams),(d) heavy fuel oils (e) alternative fuels serving the same purposes and with similar properties as regards flammability and environmental hazards as the products referred to in points (a) to (d)	2,500 t	25,000 t

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

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.

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

H302 : Harmful if swallowed.
H304 : May be fatal if swallowed and enters airways.
H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H336 : May cause drowsiness or dizziness.
H360F : May damage fertility.

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- H372 : Causes damage to organs through prolonged or repeated exposure.
- 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.
- H411 : Toxic to aquatic life with long lasting effects.
- H413 : May cause long lasting harmful effects to aquatic life.
- EUH066 : Repeated exposure may cause skin dryness or cracking.

Full text of other abbreviations

- Acute Tox. : Acute toxicity
- Aquatic Acute : Short-term (acute) aquatic hazard
- Aquatic Chronic : Long-term (chronic) aquatic hazard
- Asp. Tox. : Aspiration hazard
- Eye Irrit. : Eye irritation
- Repr. : Reproductive toxicity
- Skin Sens. : Skin sensitisation
- STOT RE : Specific target organ toxicity - repeated exposure
- STOT SE : Specific target organ toxicity - single 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; 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; TECl -

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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:

Acute Tox. 4	H302
Eye Irrit. 2	H319
Skin Sens. 1	H317
Repr. 1B	H360F
STOT SE 3	H336
STOT RE 2	H373
Asp. Tox. 1	H304
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Calculation method
Based on product data or assessment
Calculation method
Calculation method

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IE / EN