

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



Amitraz (12.5%) Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 9373378-00007 Date of last issue: 04.04.2023
Date of first issue: 27.08.2021

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

- 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.

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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) |
|---|---|--|--------------------------|
| Hydrocarbons, C10, aromatics, <1% naphthalene | 64742-94-5 | STOT SE 3; H336 Asp. Tox. 1; H304 Aquatic Chronic 2; H411 | >= 50 - < 70 |
| 4-Nonylphenol, branched, ethoxylated | 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 | >= 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 nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10 | >= 10 - < 20 |
| Bis(2,6-diisopropylphenyl)carbodiimide | 2162-74-5 218-487-5 | Acute Tox. 4; H302 Repr. 1B; H360F STOT RE 1; H372 (Kidney, Heart, Gastrointestinal tract, Lymph nodes) Aquatic Chronic 4; H413 | >= 1 - < 2.5 |

Alternative CAS Numbers for some regions

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

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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.
- 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.

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.

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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.
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.
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 contain-

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ment 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 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 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 |

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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 |
|---------------|------------|-------------------------------|------------------------------|----------|
| 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):

| 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 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/m ³ |
| | Workers | Skin contact | Long-term systemic effects | 12.5 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 32 mg/m ³ |
| | 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):

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|-------|
|----------------|---------------------------|-------|

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| | | |
|--|--------------------------|-------------------------------|
| 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.
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 BS 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

Appearance : liquid
Colour : yellow
Odour : characteristic, aromatic, hydrocarbon-like
Odour Threshold : No data available

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| | | |
|--|---|--|
| pH | : | No data available |
| Melting point/freezing point | : | Not applicable |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | 106 °C |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | 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 |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| 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) | : | Not applicable |
| Molecular weight | : | No data available |
| Particle size | : | Not applicable |

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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 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

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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

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

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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
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

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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

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
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

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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
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 develop- : Test Type: Embryo-foetal development

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ment
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 develop- : Test Type: Embryo-foetal development
ment 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
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 develop- : Test Type: Reproduction/Developmental toxicity screening
ment test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 421
Result: equivocal

Reproductive toxicity - As- : Clear evidence of adverse effects on sexual function and fertili-
sessment ty, based on animal experiments.

STOT - single exposure

May cause drowsiness or dizziness.

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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.

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

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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.

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.

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 : EL50 (Pseudokirchneriella subcapitata (green algae)): > 1 - 3

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plants 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:

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 : EC50 (Ceriodaphnia dubia (water flea)): > 0.1 - 1 mg/l
aquatic invertebrates Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic : ErC50 (Selenastrum capricornutum (green algae)): > 1 - 10
plants 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 tox- : 1
icity)

Toxicity to fish (Chronic tox- : NOEC: > 0.1 - 1 mg/l
icity) Exposure time: 100 d
Species: Oryzias latipes (Japanese medaka)
Remarks: Based on data from similar materials

Toxicity to daphnia and other : NOEC: > 0.001 - 0.01 mg/l
aquatic invertebrates (Chron- Exposure time: 28 d
ic toxicity) Species: Mysidopsis bahia (opossum shrimp)
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic : 10
toxicity)

amitraz (ISO):

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.45 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0.035 mg/l
aquatic invertebrates Exposure time: 48 h

Toxicity to algae/aquatic : NOEC (Pseudokirchneriella subcapitata (green algae)): 0.04
plants mg/l
Exposure time: 91 h

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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)

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

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Bis(2,6-diisopropylphenyl)carbodiimide:

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

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 environ-
mental 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.

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Components:

4-Nonylphenol, branched, ethoxylated:

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

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

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))

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IATA : Environmentally hazardous substance, liquid, n.o.s.
(amitraz (ISO))

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 : (-)

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

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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.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

- | | | |
|---|---|---|
| UK REACH List of restrictions (Annex 17) | : | Conditions of restriction for the following entries should be considered: Number on list 3 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. |
| UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation | : | 4-Nonylphenol, branched, ethoxylated |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) | : | Not applicable |
| Regulation (EC) No 1005/2009 on substances that de- | : | Not applicable |

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plete the ozone layer

UK REACH List of substances subject to authorisation (Annex XIV) : 4-Nonylphenol, branched, ethoxylated

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : amitraz (ISO)
4-Nonylphenol, branched, ethoxylated

Control of Major Accident Hazards Regulations 2015 (COMAH)

| | | 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 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.

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.

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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. |
| 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. |

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 |

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 substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European

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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 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 |

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.

GB / EN