

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	27.11.2023	10660103-00005	Date of first issue: 09.04.2022

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

1.1 Product identifier

Trade name : Amitraz (50%) Solid Formulation
Other means of identification : COOPERS AMITIK CATTLE DIP AND SPRAY (41044)

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

Use of the Sub-
stance/Mixture : Veterinary product
Recommended restrictions : Not applicable
on use

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 : EHSDATASTEWARD@msd.com
responsible for the SDS

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.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Germ cell mutagenicity, Category 2	H341: Suspected of causing genetic defects.
Carcinogenicity, Category 1B	H350: May cause cancer.
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.

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements :

- H302 Harmful if swallowed.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.
- H341 Suspected of causing genetic defects.
- H350 May cause cancer.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

- P201 Obtain special instructions before use.
- P260 Do not breathe dust.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

- P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
- P391 Collect spillage.

Hazardous components which must be listed on the label:

amitraz (ISO)
Nonylphenol, ethoxylated
Paraformaldehyde

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.

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

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

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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	>= 50 - < 70
Nonylphenol, ethoxylated	9016-45-9	Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 10	>= 1 - < 2.5
Paraformaldehyde	30525-89-4	Acute Tox. 4; H302 Acute Tox. 4; H332 Skin Irrit. 2; H315 Eye Dam. 1; H318 Skin Sens. 1A; H317 Muta. 2; H341 Carc. 1B; H350 STOT SE 3; H335 specific concentration limit Skin Sens. 1A; H317 >= 0.2 % Acute toxicity estimate	>= 1 - < 3

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	27.11.2023	10660103-00005	Date of first issue: 09.04.2022

		Acute oral toxicity: 592 mg/kg	
--	--	-----------------------------------	--

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 immediately.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : Harmful if swallowed.
May cause an allergic skin reaction.
Causes serious eye damage.
Suspected of causing genetic defects.
May cause cancer.
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.

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	27.11.2023	10660103-00005	Date of first issue: 09.04.2022

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Sulphur oxides
Metal 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.

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.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	27.11.2023	10660103-00005	Date of first issue: 09.04.2022

tainer for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to 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 | : | Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Keep away from water.
Protect from moisture.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
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. 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 |

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

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. 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

dusts non-specific 4 mg/m³
Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)
Basis: IE OEL

10 mg/m³
Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)
Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
amitraz (ISO)	33089-61-1	TWA	10 µg/m ³ (OEB 3)	Internal
		Wipe limit	1250 µg/100 cm ²	Internal

Occupational exposure limits of decomposition products

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Formaldehyde	50-00-0	TWA	0.3 ppm 0.37 mg/m ³	2004/37/EC
		Further information: Dermal sensitisation, Carcinogens or mutagens		
		STEL	0.6 ppm 0.74 mg/m ³	2004/37/EC
		Further information: Dermal sensitisation, Carcinogens or mutagens		
		OELV - 8 hrs (TWA)	0.3 ppm 0.37 mg/m ³	IE OEL
		Further information: Chemical agents which following exposure may cause sensitisation of the respiratory tract and lead to asthma, rhinitis or extrinsic		

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

	allergic alveolitis, Carc 1B - Substances presumed to have carcinogenic potential for humans		
	OELV - 15 min (STEL)	0.6 ppm 0.738 mg/m3	IE OEL
	Further information: Chemical agents which following exposure may cause sensitisation of the respiratory tract and lead to asthma, rhinitis or extrinsic allergic alveolitis, Carc 1B - Substances presumed to have carcinogenic potential for humans		

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Calcium carbonate	Workers	Inhalation	Long-term systemic effects	6.36 mg/m3
	Consumers	Ingestion	Acute systemic effects	6.1 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1.06 mg/m3
	Consumers	Ingestion	Long-term systemic effects	6.1 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Calcium carbonate	Sewage treatment plant	100 mg/l

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.
Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

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

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

Filter type : sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 14387
: Combined particulates and inorganic gas/vapour type (B-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : white
grey

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

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 : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity
Viscosity, kinematic : Not applicable

Solubility(ies)
Water solubility : No data available

Partition coefficient: n- : Not applicable

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	27.11.2023	10660103-00005	Date of first issue: 09.04.2022

octanol/water

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics
Particle size : No data available

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : Not applicable

Molecular weight : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.
Hazardous decomposition products will be formed upon contact with water or humid air.

10.4 Conditions to avoid

Conditions to avoid : Exposure to moisture
Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents
Water

10.6 Hazardous decomposition products

Contact with water or humid air : Formaldehyde

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

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: 946.17 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

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

Nonylphenol, ethoxylated:

Acute oral toxicity : LD50 (Rat): 500 - 2,000 mg/kg

Paraformaldehyde:

Acute oral toxicity : LD50 (Rat, male): 592 mg/kg

Acute inhalation toxicity : LC50 (Rat): 1.07 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 10,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

Components:

amitraz (ISO):

Species : Rabbit
Result : No skin irritation

Nonylphenol, ethoxylated:

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

Paraformaldehyde:

Species : Rabbit
Result : Skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

amitraz (ISO):

Species : Rabbit
Result : No eye irritation

Nonylphenol, ethoxylated:

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

Paraformaldehyde:

Species : Rabbit
Result : Irreversible effects on the eye

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

amitraz (ISO):

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

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

Nonylphenol, ethoxylated:

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

Paraformaldehyde:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Result : positive
Remarks : Based on data from similar materials

Assessment : Probability or evidence of high skin sensitisation rate in humans

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:

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

Nonylphenol, ethoxylated:

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

Paraformaldehyde:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: positive
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Result: positive
Remarks: Based on data from similar materials

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

Test Type: in vitro micronucleus test
Result: positive
Remarks: Based on data from similar materials

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: positive
Remarks: Based on data from similar materials

Test Type: In vitro sister chromatid exchange assay in mammalian cells
Result: positive
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: inhalation (vapour)
Result: positive
Remarks: Based on data from similar materials

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

Germ cell mutagenicity- Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity

May cause cancer.

Components:

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

Paraformaldehyde:

Species : Rat
Application Route : Ingestion

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

Exposure time : 105 weeks
Result : negative

Species : Rat
Application Route : Inhalation
Exposure time : 28 Months
Result : positive
Remarks : Based on data from similar materials

Carcinogenicity - Assessment : Sufficient evidence of carcinogenicity in animal experiments

Reproductive toxicity

Not classified based on available information.

Components:

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
Result: Effects on foetal development

STOT - single exposure

Not classified based on available information.

Components:

Paraformaldehyde:

Assessment : May cause respiratory irritation.

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.

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

Repeated dose toxicity

Components:

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

Paraformaldehyde:

Species : Rat, male
NOAEL : 15 mg/kg
Application Route : Ingestion
Exposure time : 105 Weeks
Remarks : Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

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

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

SECTION 12: Ecological information

12.1 Toxicity

Components:

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)
- 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

Nonylphenol, 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 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

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

- 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
- Paraformaldehyde:**
- Toxicity to fish : LC50 : > 1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia pulex* (Water flea)): > 1 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials
- Toxicity to algae/aquatic plants : ErC50 (*Desmodesmus subspicatus* (green algae)): > 1 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
- Toxicity to microorganisms : EC50 : > 10 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials
- Toxicity to fish (Chronic toxicity) : NOEC: > 1 mg/l
Exposure time: 28 d
Species: *Oryzias latipes* (Orange-red killifish)
Remarks: Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 1 mg/l
Exposure time: 21 d
Species: *Daphnia magna* (Water flea)
Method: OECD Test Guideline 211
Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

Nonylphenol, ethoxylated:

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

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

Paraformaldehyde:

Biodegradability : Result: Readily biodegradable.
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

amitraz (ISO):

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

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

Nonylphenol, ethoxylated:

Partition coefficient: n-octanol/water : log Pow: 4.48

Paraformaldehyde:

Partition coefficient: n-octanol/water : log Pow: -1.40
Remarks: Calculation

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:

Nonylphenol, ethoxylated:

Assessment : The substance is considered to have endocrine disrupting

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	27.11.2023	10660103-00005	Date of first issue: 09.04.2022

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 or ID number

- ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

- ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(amitraz (ISO), Nonylphenol, ethoxylated)
- ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(amitraz (ISO), Nonylphenol, ethoxylated)
- RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(amitraz (ISO), Nonylphenol, ethoxylated)
- IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(amitraz (ISO), Nonylphenol, ethoxylated)
- IATA : Environmentally hazardous substance, solid, n.o.s.
(amitraz (ISO), Nonylphenol, ethoxylated)

14.3 Transport hazard class(es)

Class	Subsidiary risks
-------	------------------

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	27.11.2023	10660103-00005	Date of first issue: 09.04.2022

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

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

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

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

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.

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

Nonylphenol, 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) : Nonylphenol, 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)
Nonylphenol, ethoxylated
- REACH - List of substances subject to authorisation : Nonylphenol, ethoxylated

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	27.11.2023	10660103-00005	Date of first issue: 09.04.2022

(Annex XIV)

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

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 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.
H315 : Causes skin irritation.
H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
H332 : Harmful if inhaled.
H335 : May cause respiratory irritation.
H341 : Suspected of causing genetic defects.
H350 : May cause cancer.
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.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Carc. : Carcinogenicity
Eye Dam. : Serious eye damage
Muta. : Germ cell mutagenicity
Skin Irrit. : Skin irritation

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version 2.2 Revision Date: 27.11.2023 SDS Number: 10660103-00005 Date of last issue: 30.09.2023
Date of first issue: 09.04.2022

Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
2004/37/EC : Europe. Directive 2004/37/EC on the protection of workers
from the risks related to exposure to carcinogens or mutagens
at work
IE OEL : List of Chemical Agents and Carcinogens with Occupational
Exposure Limit Values - Code of Practice, Schedule 1 and 2
2004/37/EC / STEL : Short term exposure limit
2004/37/EC / TWA : Long term exposure limit
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference peri-
od)

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 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/>

SAFETY DATA SHEET

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



Amitraz (50%) Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
2.2	27.11.2023	10660103-00005	Date of first issue: 09.04.2022

Classification of the mixture:

Acute Tox. 4	H302
Eye Dam. 1	H318
Skin Sens. 1	H317
Muta. 2	H341
Carc. 1B	H350
STOT RE 2	H373
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
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