

SAFETY DATA SHEET

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



Amitraz Solid Formulation

Version
11.0

Revision Date:
17.06.2025

SDS Number:
1734742-00020

Date of last issue: 14.04.2025
Date of first issue: 06.06.2017

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

1.1 Product identifier

Trade name : Amitraz Solid Formulation

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

Use of the Substance/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.
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.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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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)

Paraformaldehyde

Sodium bis(2-ethylhexyl)sulfosuccinate

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown acute oral toxicity: 10 %

The following percentage of the mixture consists of ingredient(s) with unknown acute dermal toxicity: 10 %

The following percentage of the mixture consists of ingredient(s) with unknown acute inhalation toxicity: 10 %

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 10 %

2.3 Other hazards

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

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

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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.

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

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
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 concentra- tion limit Skin Sens. 1A; H317 >= 0,2 % Acute toxicity esti- mate	>= 1 - < 3

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		Acute oral toxicity: 592 mg/kg	
Sodium bis(2-ethylhexyl)sulfosuccinate	577-11-7 209-406-4	Skin Irrit. 2; H315 Eye Dam. 1; H318	>= 1 - < 3

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.

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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 : 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
Silicon oxides
Metal oxides
Nitrogen oxides (NO_x)
Sulphur oxides

5.3 Advice for firefighters

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

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

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.

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6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container 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.

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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

Dust 5 mg/m³
Value type (Form of exposure): TWA (respirable dust)
Basis: FOR-2011-12-06-1358

10 mg/m³
Value type (Form of exposure): TWA (total dust)
Basis: FOR-2011-12-06-1358

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	FOR-2011-12-06-1358
	Further information: Substances considered to be carcinogenic, Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin			
		STEL	0,6 ppm 0,74 mg/m ³	FOR-2011-12-06-1358
	Further information: Substances considered to be carcinogenic, Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin			
		TWA	0,3 ppm 0,37 mg/m ³	2004/37/EC
	Further information: Dermal sensitisation, Carcinogens or mutagens			

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	STEL	0,6 ppm 0,74 mg/m3	2004/37/EC
Further information: Dermal sensitisation, Carcinogens or mutagens			

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Aluminium silicate	Workers	Inhalation	Long-term systemic effects	3 mg/m3
	Workers	Inhalation	Acute systemic effects	3 mg/m3
	Workers	Inhalation	Long-term local effects	3 mg/m3
	Workers	Inhalation	Acute local effects	3 mg/m3
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
Sodium bis(2-ethylhexyl)sulfosuccinate	Workers	Inhalation	Long-term systemic effects	1416,82 mg/m3
	Workers	Skin contact	Long-term systemic effects	200,89 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	419,25 mg/m3
	Consumers	Skin contact	Long-term systemic effects	120,54 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	13,39 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Aluminium silicate	Fresh water	4,1 mg/l
	Freshwater - intermittent	25 mg/l
	Marine water	0,082 mg/l
Calcium carbonate	Sewage treatment plant	100 mg/l
Sodium bis(2-ethylhexyl)sulfosuccinate	Fresh water	0,18 mg/l
	Intermittent use/release	0,152 mg/l
	Marine water	0,018 mg/l
	Sewage treatment plant	12,2 mg/l
	Fresh water sediment	17,789 mg/kg dry weight (d.w.)
	Marine sediment	1,779 mg/kg dry weight (d.w.)
	Soil	1,04 mg/kg dry weight (d.w.)

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8.2 Exposure controls

Engineering measures

Processing may form hazardous compounds (see section 10).

Minimize workplace exposure concentrations.

Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

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

Personal protective equipment

Eye/face protection	: Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield Equipment should conform to NS EN 166
Hand protection	
Material	: Chemical-resistant gloves
Remarks	: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Skin and body protection	: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to NS EN 14387
Filter type	: 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
Odour	: No data available
Odour Threshold	: No data available
Melting point/freezing point	: No data available

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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 : No data available

Solubility(ies)

Water solubility : insoluble

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 : No data available

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

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Molecular weight : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : 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

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: 958,7 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

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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

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

Sodium bis(2-ethylhexyl)sulfosuccinate:

Acute oral toxicity	:	LD50 (Rat): 3.080 mg/kg
Acute dermal toxicity	:	LD50 (Rabbit): > 5.000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

amitraz (ISO):

Species	:	Rabbit
Result	:	No skin irritation

Paraformaldehyde:

Species	:	Rabbit
Result	:	Skin irritation

Sodium bis(2-ethylhexyl)sulfosuccinate:

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

Serious eye damage/eye irritation

Causes serious eye damage.

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Components:

amitraz (ISO):

Species	:	Rabbit
Result	:	No eye irritation

Paraformaldehyde:

Species	:	Rabbit
Result	:	Irreversible effects on the eye

Sodium bis(2-ethylhexyl)sulfosuccinate:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
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

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

Sodium bis(2-ethylhexyl)sulfosuccinate:

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Species	:	Humans
Result	:	negative

Germ cell mutagenicity

Suspected of causing genetic defects.

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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

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

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

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

Sodium bis(2-ethylhexyl)sulfosuccinate:

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: equivocal

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

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
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

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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

Sodium bis(2-ethylhexyl)sulfosuccinate:

Effects on fertility	: Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative

STOT - single exposure

Not classified based on available information.

Components:

Paraformaldehyde:

Assessment	: May cause respiratory irritation.
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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.

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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

Sodium bis(2-ethylhexyl)sulfosuccinate:

Species	:	Rat
NOAEL	:	750 mg/kg
Application Route	:	Ingestion
Exposure time	:	90 Days

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

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.
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Experience with human exposure

Components:

amitraz (ISO):

|| Ingestion : Target Organs: Central nervous system

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

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

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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

Sodium bis(2-ethylhexyl)sulfosuccinate:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): 49 mg/l Exposure time: 96 h Method: Directive 67/548/EEC, Annex V, C.1.
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 6,6 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): 82,5 mg/l Exposure time: 72 h EC10 (Desmodesmus subspicatus (green algae)): 22 mg/l Exposure time: 72 h
Toxicity to microorganisms	:	EC50 (Pseudomonas putida): 164 mg/l Exposure time: 16 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	EC10: 9 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

12.2 Persistence and degradability

Components:

Paraformaldehyde:

Biodegradability	:	Result: Readily biodegradable. Remarks: Based on data from similar materials
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Sodium bis(2-ethylhexyl)sulfosuccinate:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 91,2 % Exposure time: 28 d
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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

Paraformaldehyde:

Partition coefficient: n-octanol/water

: log Pow: -1,40
Remarks: Calculation

Sodium bis(2-ethylhexyl)sulfosuccinate:

Partition coefficient: n-octanol/water

: log Pow: 1,998
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

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

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

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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))
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (amitraz (ISO))
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (amitraz (ISO))
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (amitraz (ISO))
IATA	:	Environmentally hazardous substance, solid, 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

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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

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

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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.

Number on list 77: Paraformaldehyde

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

: Not applicable

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

: Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer

: Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)

: Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

: amitraz (ISO)

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:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect

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pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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
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, mutagens or reprotoxic substances at work - Annex III
FOR-2011-12-06-1358	: Norway. Occupational Exposure limits
2004/37/EC / STEL	: Short term exposure limit
2004/37/EC / TWA	: Long term exposure limit

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FOR-2011-12-06-1358 / : Long term exposure limit

TWA

FOR-2011-12-06-1358 / : Short term exposure limit

STEL

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; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

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

Classification procedure:

Calculation method

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Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

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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.

NO / EN