Amitraz Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
6.0	28.09.2024	9373329-00009	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 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
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.
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) 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.
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
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.
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
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 % Skin Sens. 1A; H317 >= 0.2 %	2.55
Sodium bis(2-ethylhexyl)sulfosuccinate	577-11-7 209-406-4	Skin Irrit. 2; H315 Eye Dam. 1; H318	1
Substances with a workplace exposure limit :			
Calcium carbonate	471-34-1 207-439-9		>= 10 - <= 20

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.

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 (NOx)
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.
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 : 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 re-

leased 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.

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 of any kind

10 mg/m3
Value type (Form of exposure): TWA (Inhalable)
Basis: GB EH40

4 mg/m3
Value type (Form of exposure): TWA (Respirable fraction)
Basis: GB EH40

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
amitraz (ISO)	33089-61-1	TWA	10 µg/m3 (OEB 3)	Internal
		Wipe limit	1250 µg/100 cm²	Internal
Calcium carbonate	471-34-1	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40

Occupational exposure limits of decomposition products

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Formaldehyde	50-00-0	TWA	2 ppm 2.5 mg/m3	GB EH40
	Further information: Capable of causing cancer and/or heritable genetic damage.			
		STEL	2 ppm 2.5 mg/m3	GB EH40
	Further information: Capable of causing cancer and/or heritable genetic damage.			
		TWA	0.3 ppm 0.37 mg/m3	2004/37/EC
	Further information: Dermal sensitisation, Carcinogens or mutagens			
		STEL	0.6 ppm 0.74 mg/m3	2004/37/EC
	Further information: Dermal sensitisation, Carcinogens or mutagens			

Derived No Effect Level (DNEL)

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)

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.)

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 BS 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. Equipment should conform to BS 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

Appearance	:	powder
Colour	:	white
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, han-

dling or other means.

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	:	insoluble
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)	:	No data available
Molecular weight	:	Not applicable
Particle size	:	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

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: 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

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

Calcium carbonate:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 420 Assessment: The substance or mixture has no acute oral toxicity
Acute inhalation toxicity	:	LC50 (Rat): > 3 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: The substance or mixture has no acute inhalation toxicity
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

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

Calcium carbonate:

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

Serious eye damage/eye irritation

Causes serious eye damage.

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

Calcium carbonate:

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:

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

Calcium carbonate:

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

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

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
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

Calcium carbonate:

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

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

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

Calcium carbonate:

Effects on fertility	:	Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test Species: Rat Application Route: Ingestion Method: OECD Test Guideline 422 Result: negative
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414 Result: negative

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.

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

Calcium carbonate:

Species	:	Rat
NOAEL	:	> 1,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	28 Days
Method	:	OECD Test Guideline 422

Aspiration toxicity

Not classified based on available information.

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
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

Calcium carbonate:

Toxicity to fish	:	LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EL50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	NOELR (Pseudokirchneriella subcapitata (green algae)): 50 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction

		Method: OECD Test Guideline 201
Toxicity to microorganisms	:	NOEC : 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 EC50 : > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

12.2 Persistence and degradability

Components:

Paraformaldehyde:

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

Sodium bis(2-ethylhexyl)sulfosuccinate:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 91.2 % Exposure time: 28 d

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 Other adverse effects

Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

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 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

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

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)	:	Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	amitraz (ISO)

Control of Major Accident Hazards Regulations 2015 (COMAH)

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 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.

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 or mutagens at work

GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
2004/37/EC / STEL	:	Short term exposure limit
2004/37/EC / TWA	:	Long term exposure limit
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL	:	Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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:		**Classification procedure:**
Acute Tox. 4	H302	Calculation method
Eye Dam. 1	H318	Calculation method
Skin Sens. 1	H317	Calculation method
Muta. 2	H341	Calculation method
Carc. 1B	H350	Calculation method

STOT RE 2	H373	Calculation method
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.

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