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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 Sub-: Veterinary product

stance/Mixture

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 H373: May cause damage to organs through pro-

longed or repeated exposure.

exposure, Category 2 H400: Very toxic to aquatic life. Short-term (acute) aguatic hazard, Cate-

Long-term (chronic) aquatic hazard, Cat-

egory 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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Hazard pictograms









Signal word Danger

Hazard statements Harmful if swallowed. H302

> May cause an allergic skin reaction. H317 H318 Causes serious eve damage. H341 Suspected of causing genetic defects.

May cause cancer. H350

May cause damage to organs through prolonged H373

or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Prevention: Precautionary statements

> P201 Obtain special instructions before use.

Do not breathe dust. P260

Avoid release to the environment. P273

Wear protective gloves/ protective clothing/ eye P280

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 toxicitv: 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	50
		aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	
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 ———————————————————————————————————	2.55
		Acute toxicity estimate 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

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For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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, 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 prod-

ucts

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 pro-

tective 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 con-

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 deter-

mine 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 as-

sessment

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

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/m3 (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	2004/37/EC	
			0.37 mg/m3		
	Further inform	Further information: Dermal sensitisation, Carcinogens or mutagens			
		STEL	0.6 ppm	2004/37/EC	
			0.74 mg/m3		
	Further inform	Further information: Dermal sensitisation, Carcinogens or mutagens			
		OELV - 8 hrs	0.3 ppm	IE OEL	
		(TWA)	0.37 mg/m3		
	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 po-				

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tential for hum	ans		
	OELV - 15 min	0.6 ppm	IE OEL
	(STEL)	0.738 mg/m3	
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
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- ethylhex- yl)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

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	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 I.S. 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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to I.S. 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

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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, han-

dling 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

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

Evaporation rate : No data available

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, han-

dling or other means.

Can react with strong oxidizing agents.

Hazardous decomposition products will be formed upon con-

tact 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 : Formaldehyde

air

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 958.7 mg/kg

Method: Calculation method

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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

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

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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

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 hu-

mans

Sodium bis(2-ethylhexyl)sulfosuccinate:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact
Species : Humans
Result : negative

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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 syn-

thesis 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 syn-

thesis in mammalian cells (in vitro)

Result: positive

Remarks: Based on data from similar materials

Test Type: In vitro sister chromatid exchange assay in mam-

malian 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)

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Species: Rat

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Germ cell mutagenicity- As-

sessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity 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

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Carcinogenicity - Assess-

ment

: 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 develop-

ment

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 develop-

ment

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.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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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

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 consid-

ered 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.

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



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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

aquatic invertebrates

Toxicity to daphnia and other : 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

Exposure time: 91 h

M-Factor (Acute aquatic tox- :

icity)

Toxicity to fish (Chronic tox-:

icity)

NOEC: 0.00148 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic 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

aquatic invertebrates

Toxicity to daphnia and other : 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

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



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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 tox-

icity)

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 (Chron-

ic 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.

aquatic invertebrates

Toxicity to daphnia and other : 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 : EC10: 9 mg/l

aquatic invertebrates (Chronic toxicity)

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

Sodium bis(2-ethylhexyl)sulfosuccinate:

Biodegradability Result: Readily biodegradable.

Biodegradation: 91.2 % Exposure time: 28 d

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



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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-

: log Pow: -1.40

octanol/water

Remarks: Calculation

Sodium bis(2-ethylhexyl)sulfosuccinate:

Partition coefficient: n- : log Pow: 1.998

octanol/water 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 consid-

ered 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

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



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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 han-

dling 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

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



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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 : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

ger aircraft)

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

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



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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.

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

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.

Not applicable

Not applicable

Not applicable

amitraz (ISO)

: Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

E1

Regulation (EC) on substances that deplete the ozone Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast) Regulation (EU) No 649/2012 of the European Parlia-

ment and the Council concerning the export and import of dangerous chemicals

REACH - List of substances subject to authorisation

(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.

ENVIRONMENTAL HAZARDS

Quantity 1

100 t

Quantity 2

200 t

23 / 26

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



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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
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 : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

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



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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 : Occupational exposure limit value (15-minute reference peri-

(STEL) 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: 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sheet

Sources of key data used to compile the Safety Data

: 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

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



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Carc.	1B	H350	Calculation method	
STOT	ΓRE 2	H373	Calculation method	
Aqua	tic Acute 1	H400	Calculation method	
Aqua	tic Chronic 1	H410	Calculation method	

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IE / EN