

Safety data sheet according to regulation (EC) No. 1907/2006

Trade name: AZACTIVA Creation Date: 01.03.2023

Version: 1.0

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identifier AZACTIVA

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

Insecticide and Acaricide

1.3 Details of the supplier of the safety data sheet

Distributing company in EU

Trifolio-M GmbH

Dr.-Hans-Wilhelmi-Weg 1

35633 Lahnau

Germany

Telefon: 0049-6441-20977-0

Telefax: 0049-6441-20977-50

1.4 Emergency telephone number:

Deutsche Vergiftungszentrale Mainz

Phone: +49 6131-19240

* 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EU) No. 1272/2008:

Aquatic chronic 3; H412

2.2 Label elements

Labelling according to Regulation (EU) No. 1272/2008:

Hazard Statements:

H412 Harmful to aquatic life with long lasting effects.

EUH208-0147 Contains Azadirachtin- may cause an allergic reaction.

EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary Statements:

P102 Keep out of reach of children.

P103 Read carefully and follow all instructions.

P501 Dispose of contents/container in accordance with local/ national-regulations.

Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties.

* 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance

Not applicable

3.2 Mixture

Composition/Information on hazardous ingredients

AZACTIVA technical (Margosa, ext., Azadirachtin; lead substance: Azadirachtin A)

Concentration: 2.3 - 4%

Classification according to Regulation (EC) No. 1272/2008:

Skin Sens. cat. 1; H317; GHS07

Aquatic chronic 1; H410; GHS09

Further information and wording of the H-Phrases can be found in section 16.

*** 4. FIRST AID MEASURES**

4.1 Description of first aid measures:

Remove contaminated clothes. Remove the exposed individual from source of risk. Consult a physician. Show this safety data sheet to the physician in attendance.

If inhaled:

Move person into fresh air. Consult a physician in case of complaints.

In case of skin contact:

Wash off with soap and plenty of warm water. Consult a physician in case of complaints.

In case of eye contact:

Remove contact lenses. Rinse thoroughly with plenty of water for at least 15 min. Consult a physician in case of complaints.

If swallowed:

Do not induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician in case of complaints.

4.2 Most important symptoms and effects, both acute and delayed

AZACTIVA contains Azadirachtin (Margosa ext.). This may cause reversible skin sensitisation or allergic reactions.

4.3 Indication of any immediate medical attention and special treatment needed

If person is unconscious: Call an ambulance.

*** 5. FIREFIGHTING MEASURES**

5.1 Extinguishing media

Suitable extinguishing media: Alcohol-resistant foam, dry chemicals, or carbon dioxide.

Unsuitable extinguishing media: Full water jet.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases/vapours is possible in case of fire: Carbon oxides.

5.3 Advice for firefighters

Keep containers cool with water spray. Stop influx of product. Wear self-contained breathing apparatus and eye protection for firefighting in case of exposure to smoke.

*** 6. ACCIDENTAL RELEASE MEASURES**

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Pump off or soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For further information refer to protective measures in sections 7 and 8.

*** 7. HANDLING AND STORAGE**

7.1 Precautions for safe handling

Safe use

Keep out of reach of children.

Avoid leaks, risk of slipping, use collection trays

Advice on general occupational hygiene:

- Avoid contact with skin and eyes.
- Do not eat, drink or smoke.
- Keep away from food, drinks and feeding stuff.
- Wash hands after use.
- Remove contaminated clothing and protective equipment before entering eating areas.

Precautions against fire and explosion

Avoid formation of aerosols. Keep away from source of ignition - for example welding equipment.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Avoid exposure to direct sunlight.

Storage category: 12

7.3 Specific end uses

AZACTIVA is a plant protection product which is used as insecticide and acaricide.

*** 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

8.1 Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2 Exposure controls

Appropriate engineering controls

Technical measures and the design of appropriate work processes go before the use of personal protective equipment; apply adequate ventilation.

Personal protective equipment

Personal protective equipment and sturdy shoes must be selected specifically for the working place, depending on concentration and quantity of hazardous substance handled.

Respiratory protection

Not required

Skin protection

Hand protection

The selected protective gloves must satisfy the specifications auf EU Directive 89/686/EEC and the standard EN 374 derived from it.

Suitable gloves type for full contact:

Nitril rubber - thickness $\geq 0,5$ mm.

Tightness of gloves shall be tested prior to use. Breakthrough time may vary, depending on glove brand and application conditions.

Contact glove manufacturer for information on permeability and breakthrough time.

Eye/Face protection

Tightly fitting safety goggles. Use equipment for eye protection tested and approved under appropriate government standards such as EN 166 (EU).

Environmental exposure controls

See section 6 and 7.

*** 9. PHYSICAL AND CHEMICAL PROPERTIES**

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Colour	Honey-yellow
Odour	Typical Neem odour
Melting point/freezing point	Not available
Boiling point or initial boiling point and boiling range	Not available
Flammability	Not flammable
Lower/upper explosive limit	Not available
Flash point	171°C
Auto-ignition temperature	> 390°C.
Decomposition temperature	Not available
pH-Value	7.00 $\pm$ 0.02 (1% aqueous solution, 18°C)
Kinematic viscosity	281,4 mm ² /s (20°C)
Solubility	Emulsifiable in water
Partition coefficient n-Octanol/Water (log-value)	log Pow (n-Octanol/Water) = 0.99 (Azadirachtin A)
Vapour pressure	3.6 $\times$ 10 ⁻¹³ Pa (estimated for Azadirachtin A)
Density and/or relative density	0.98 g/ml
Relative vapour density	Not available
Particle characteristics	Not applicable

9.2 Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available.

*** 10. Stability and Reactivity**

10.1 Reactivity

The product is not reactive under normal conditions of use, storage and transport.

10.2 Chemical stability

AZACTIVA is chemically stable under normal conditions.

10.3 Possibility of hazardous reactions

If used appropriate no hazardous reactions are expected.

10.4 Conditions to avoid

High temperatures and strong light sources. Keep away from sources of ignition.

10.5 Incompatible materials

Acids and strong oxidizing or reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide and carbon dioxide.

*** 11. TOXICOLOGICAL INFORMATION**

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

Acute toxicity Oral - Rat (OECD 401) Dermal - Rat (OECD 402)	Not classified LD ₅₀ > 5000 mg/kg LD ₅₀ > 2000 mg/kg
Skin corrosion/irritation Skin– Rabbit (OECD 404)	Not classified Non-irritant. For AZACTIVA corrosive properties are not known.
Serious eye damage/irritation Eye – Rabbit (OECD 405)	Not classified Non-irritant (may cause temporary redness and lacrimation)
Respiratory or skin sensitisation Skin – Guinea pig (OECD 406)	Not classified Non-sensitising
Germ cell mutagenicity Mutagenicity tests (OECD 471) Micronucleustest - Mouse (OECD 474)	Not classified Non-mutagenic (AZACTIVA technical) Non-mutagenic (AZACTIVA technical)
Carcinogenicity Oral – Rat, 105 weeks (OECD 451)	Not classified NOAEL = 448 mg/kg bw/day (AZACTIVA technical)
Reproductive toxicity Two generation reproduction study - Rat (OECD 416)	Not classified NOAEL = 50 mg/kg bw/d (AZACTIVA technical)
Specific target organ toxicity - single exposure Rat (OECD 401)	Not classified NOAEL: 5000 mg/kg bw
Specific target organ toxicity - repeated exposure Rat - 90d (OECD 408)	Not classified NOAEL = 32 mg/kg bw (liver) (AZACTIVA technical)
Aspiration hazard	No data available

11.2 Information on other hazards

No additional information available.

11.2.1 Endocrine disrupting properties

No additional information available.

11.2.2 Other information

No additional information available.

* 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Fish Acute toxicity, 96h (OECD 203)	LC ₅₀ = 141 mg/L (<i>Oncorhynchus mykiss</i>)
Crustaceae Acute immobilisation, 48h (OECD 202) Reproduction, 21d (OECD 202)	EC ₅₀ > 800 mg/L (<i>Daphnia magna</i>) NOEC = 3,4 mg/L
Other Invertebrates Chronic toxicity, 28d (OECD 219)	NOEC = 0,573 mg/L (<i>Chironomus riparius</i>) EC ₅₀ = 1,15 mg/L
Algae Growth rate, 72h (OECD 201)	 ErC ₅₀ >2494 mg/L (<i>Scenedesmus subspicatus</i>)
Honey bee Acute, oral (EPPO 170) Acute, contact (EPPO 170) Reproduction (BBA guideline)	LD ₅₀ > 561 µg/bee LD ₅₀ > 2000 µg/bee Not harmful to brood with an application rate of 6 L/ha (<i>Apis mellifera</i>)
Earthworm Acute Toxicity (BBA-guideline) Chronic Toxicity (OECD 222)	EC ₅₀ >1000 mg/kg soil (<i>Eisenia fetida</i>) NOEC > 1000 mg/kg soil (<i>Eisenia fetida</i>)

12.2 Persistence and degradability

AZACTIVA is readily biodegradable (OECD 301 D).

12.3 Bioaccumulation potential

Not bioaccumulative.

Partition coefficient n-Octanol/Water (log Pow) Azadirachtin A < 3.

12.4 Mobility in soil

K_{OC} Azadirachtin A: 75.2 ml/g (geomean).

12.5 Results of PBT and vPvB assessment

The criteria for classification as PBT or vPvB are not met.

12.6 Endocrine disrupting properties

No additional information available.

12.7 Other adverse effects

Harmful to syrphid flies (*Episyrphus balteatus*), ladybird (*Coccinella septempunctata*), green lacewing (*Chrysoperla carnea*), predatory mite (*Amblyseius cucumeris*).

* 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with relevant local regulations. Do not allow larger amounts to be released into the sewage system.

Waste code:

02 01 09 (Agricultural chemical waste).

Cleaned packaging

Empty containers should be recycled after washing out.

* 14. TRANSPORT INFORMATION

14.1 UN-Number

No dangerous goods.

14.2 UN proper shipping name

ADR/RID

No dangerous goods, classification not required.

IMDG-Code / ICAO-TI / IATA-DGR

No dangerous goods, classification not required.

14.3 Transport hazard class(es)

No dangerous goods, classification not required.

14.4 Packaging group

No dangerous goods, classification not required.

14.5 Environmental hazards

ADR/RDI: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

See sections 6, 7 and 8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

AZACTIVA is only delivered in suitable containers in accordance with transport laws.

* 15. REGULATORY INFORMATION

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

EU regulations

Regulation (EC) No 1005/2009 (Substances that deplete the ozone layer):

Not applicable.

Regulation (EC) No 850/2004 (Persistent organic pollutants):

Not applicable.

Regulation (EC) No 649/2012 (export and import of dangerous chemicals):

Not applicable.

Regulation (EC) No 1107/2009 on placing plant protection products on the market

AZACTIVA is an authorised plant protection product.

15.2 Chemical Safety Assessment

Chemical Safety Assessment has not been carried out with AZACTIVA.

* 16. OTHER INFORMATION

Changes compared to prior versions

Not applicable.

Bibliographical references and data sources

Regulations

REACH Regulation (EC) No. 1907/2006, last amended by Regulation (EU) No. 2022/586.

Regulation (EC) No. 1272/2008, last amended by Regulations (EC) 2021/1962.

Wording of hazard statements which are not fully stated in section 2-15

The classification and labeling was carried out in accordance with Regulation (EC) No. 1272/2008.

H317 – skin sensitization category 1; May cause an allergic skin reaction.

H410 – aquatic chronic category 1; very toxic to aquatic life with long lasting effects.

H412 – aquatic chronic category 3, harmful to aquatic life with long lasting effects.

Methods of evaluating information referred to in Article 9 of Regulation (EC) No 1272/2008 was used for the purpose of classification

Environmental hazards: Assessment of test data of the substance/ mixture (*Chironomus riparius*).

Abbreviations

ADR	European A greement concerning the International Carriage of D angerous Goods by R oad
bw	Body weight
CAS	C hemical A bstracts S ervices
EC	E ffective concentration E uropean community
EN	E uropean N orm
IATA-DGR	I nternational A ir T ransport A ssociation- D angerous G oods R egulation
IBC-Code	I nternational Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk.
ICAO-TI	I nternational C ivil A viation O rganization - T echnical I nstructions
IMDG-Code	I nternational M aritime Code for D angerous G oods
K _{OC}	Organic carbon based adsorption coefficient
LC	L ethal concentration
LD	L ethal dose
Log P _{OW}	Common logarithm of the partition coefficient between octanol and water
MARPOL	M aritime P ollution Convention
NOEC	N o O bserved E ffect C oncentration
OECD	O rganisation for E conomic C o-operation and D evelopment
PBT	P ersistent, b ioaccumulative, t oxic
RID	I nternational Rule for Transport of Dangerous Substances by Railway
UN	U nited N ations (Vereinte Nationen)
VOC	V olatile o rganic compounds
vPvB	v ery p ersistent, v ery b ioaccumulative

FURTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall only be used as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Trifolio-M GmbH shall not be held liable for any damage resulting from handling or from contact with the above product.

This safety data sheet is in accordance with Regulation (EC) No. 1907/2006 last amended by Regulation (EC) No. 2022/586.