

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

INSTATENS ACTIVE INGREDIENT

1. Identification of the substance/mixture and company

Trade name: InstaTens
I.N.C.I. Water (and) Glycerin (and) Gleditsia Triacanthos Seed Extract
CAS No.: 7732-18-5, 56-81-5, 92128-64-8
EC No.: 231-791-2, 200-289-5, 295-761-0
Supplier company identification: Elemental SRL, Piața Cazărmii no.15, 410188-Oradea, jud.Bihor, Romania
Tel/Fax: +40259-436.755, www.ellemental.com
Emergency: RO: număr național pentru cazuri de urgență: 021 3183606 Institutul de
Sănătate Publică București.
International emergency number: +49 180 2273-112

2. Hazards Identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, the product does not present any particular risk, under normal conditions of use.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

EUH-statements: EUH208 - Contains octanoic acid, monoester with glycerol. May produce an allergic reaction.

2.3 Other hazards

Results of PBT and vPvB assessment

To our knowledge, contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

Other hazards which do not result in classification: Sensitive people may develop an allergic reaction

Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII

octanoic acid, monoester with glycerol (26402-26-6)

Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII

octanoic acid, monoester with glycerol (26402-26-6)

Substance(s) not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605: octanoic acid, monoester with glycerol (26402-26-6)

3. Declaration of ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name Product identifier % Classification according to Regulation (EC) No. 1272/2008 [CLP]

octanoic acid, monoester with glycerol

CAS-No.: 26402-26-6 EC-No.: 247-668-1 0.1 – 0.5%

Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317

Full text of H- and EUH-statements: see section 16

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

INSTATENS ACTIVE INGREDIENT

4. First aid measures

4.1 Description of first aid measures

General information: No special measures required.

After inhalation: Supply fresh air ; consult doctor in case of complaint.

After skin contact: Wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing: Seek immediate medical advice.

Information for doctor: No further relevant information available.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. Fire fighting measures

5.1 Extinguishing media

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

No special measures required.

Protective equipment: No special measures required.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures: Ventilate spillage area. Caution : this product can cause the floor to be slippery.

6.1.1. For non-emergency personnel

Emergency procedures: Avoid contact with skin and eyes. Do not breathe vapours.

6.1.2. For emergency responders

Protective equipment: Do not attempt to take action without suitable protective equipment. Concerning personal protective equipment to use, see section Environmental precautions

Contain the spilled material by bunding. Do not allow product to spread into the environment.

6.3. Methods and material for containment and cleaning up

For containment: Liquid spill: take up in sand, earth, vermiculite.

Methods for cleaning up: Wash contaminated area with large amounts of water.

Other information: Dispose of contaminated materials in accordance with current regulations.

6.4. Reference to other sections

For waste disposal after cleaning, see section 13.

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

INSTATENS ACTIVE INGREDIENT

7. Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling: Ensure good ventilation of the work station. Avoid contact with skin and eyes. Do not breathe vapours. Handle in accordance with good industrial hygiene and safety practice.

Hygiene measures: Do not drink, eat or smoke in the workplace. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Store in original packagings. Store at room temperature, < 25 °C. Ensure suitable ventilation. Keep away from heat, flame sparks and other ignition sources.

7.3. Specific end use(s)

See section 1.2.

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

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses. ISO 16321-1

8.2.2.2. Skin protection

Skin and body protection:

Protective clothing

Hand protection:

Protective gloves. The protective gloves to be used must comply with the specifications of the regulation 2016/425 and the resultant standard ISO 374-1. Breakthrough time: refer to the recommendations of the supplier

8.2.2.3. Respiratory protection

Respiratory protection:

If the ventilation is suitable, it is not essential to wear respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

INSTATENS ACTIVE INGREDIENT

Environmental exposure controls:

Avoid discharge of the product as is into the environment.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state liquid viscous

Colour yellowish

Odour: characteristic

Melting point/freezing point: no available

Boiling point or initial boiling point and boiling range: >100°C

Flammability: No data available.

Lower and upper explosion limit: no data available

Flash point: > 130 °C +/- 5°C

Auto-ignition temperature: no data available

Decomposition temperature: no data available

pH: 4,0-6,0

Kinematic viscosity: no data available

Solubility: Water. soluble

Partition coefficient: n-octanol/water (log value): no data available

Vapour pressure: no data available

Density and/or relative density: no data available

Refractive index: 1.347 - 1.361

Relative vapour density: no data available

Particle characteristics: no data available

9.2. Other information

Information with regard to physical hazard classes: no data available

Other safety characteristics: no data available

10. Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Storage at high temperatures

10.5. Incompatible materials

Concentrated acids, alkalis & oxidising agents.

10.6. Hazardous decomposition products

This product does not decompose under normal conditions. Under fire conditions the product will produce a mixture of irritating fumes & smoke.

11. Toxicological information

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

INSTATENS ACTIVE INGREDIENT

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

Acute toxicity (oral): Not classified (Based on available data, the classification criteria are not met)

Acute toxicity (dermal): Not classified (Based on available data, the classification criteria are not met)

Acute toxicity (inhalation): Not classified (Based on available data, the classification criteria are not met)

LD50 oral rat 8587 mg/kg (IC50 = 136,14 mg/ml; Cytotoxicity Test 3T3 NRU, OECD 129 method, EURL ECVAM DB-ALM Protocol n°139)

Skin corrosion/irritation: Not classified (Based on available data, the classification criteria are not met)

pH: 4 – 6

Additional information: Reconstructed Human Epidermis Test Method (Episkin™ Model), (Pure product), (OECD 439 method): Not irritating (Study IC-CHEM 19.573)

Serious eye damage/irritation: Not classified (Based on available data, the classification criteria are not met)

pH: 4 – 6

Additional information: Eye irritation (NRR test - 50 % diluted product) : negligible cytotoxicity (Report 6.01_S-53349-ID-19/10075)

Respiratory or skin sensitisation: Not classified (Based on available data, the classification criteria are not met)

Additional information: Sens-Is in vitro skin sensitization assay : non sensitizer (Report Nr L03F004a) KeratinoSens™ in vitro skin sensitization assay (OECD 442D method, ECVAM DB-ALM protocol 155 : KeratinoSens™): non sensitizer (Report Nr 6.52-52292-ID-19/10075) h-CLAT assay (OECD 442E method, h-CLAT DB-ALM protocol 158) : may have potentiel to cause skin sensitization (Report DC22205/CL01) Sensitive people may develop an allergic reaction

Germ cell mutagenicity: Not classified (Based on available data, the classification criteria are not met)

Additional information: Ames test (with and without metabolic activation) : negative (OECD 471 method) Test method EU B13/B14

Carcinogenicity: Not classified (Based on available data, the classification criteria are not met)

Reproductive toxicity: Not classified (Based on available data, the classification criteria are not met)

STOT-single exposure: Not classified (Based on available data, the classification criteria are not met)

STOT-repeated exposure: Not classified (Based on available data, the classification criteria are not met)

Aspiration hazard: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information available

11.2.2. Other information

Other information: UV spectrum (10 and 25% in water): low UV absorption between 290-400 nm. Therefore, according to ANSM (Ex AFSSAPS) recommendations, no phototoxic potential could be suspected

12. Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute): Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic): Not classified (Based on available data, the classification criteria are not met)

EC50 Daphnia > 100 mg/l/48 h (Daphnia magna) (OECD 202 method)

ErC50 algae > 100 mg/l/72 h (Pseudokirchneriella subcapitata) (OECD 201 method)

Persistence and degradability Readily biodegradable.

Biodegradation: 75.82 % (28 days) (OECD 301D method)

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

INSTATENS ACTIVE INGREDIENT

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment Component

Substance(s) not meeting the PBT criteria of REACH regulation, in accordance with Annex XIII
octanoic acid, monoester with glycerol (26402-26-6)

Substance(s) not meeting the vPvB criteria of REACH regulation, in accordance with Annex XIII
octanoic acid, monoester with glycerol (26402-26-6)

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

13. Disposal considerations

13.1. Waste treatment methods

Waste treatment methods: Dispose of in accordance with relevant local regulations.

Additional information: Empty the packaging completely prior to disposal. Recycle or dispose of in compliance with current legislation.

14. Transport information

14.1 UN-Number

Not regulated. not subject to transport regulations

ADR Not regulated

IMDG Not regulated

IATA Not regulated

14.2 UN proper shipping name

Not regulated. not subject to transport regulations

ADR Not regulated

IMDG Not regulated

IATA Not regulated

14.3 Transport hazard class(es)

Not regulated. not subject to transport regulations

ADR

Class Not regulated

IMDG

Class Not regulated

IATA

Class Not regulated

14.4 Packing group

Not regulated. not subject to transport regulations

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

INSTATENS ACTIVE INGREDIENT

ADR Not regulated

IMDG Not regulated

IATA Not regulated

14.5 Environmental hazards:

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

Transport/Additional information: Not applicable.

15. Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment Assessment has not been carried out.

16. Additional information

16.1 Full text of H- and EUH-statements:

EUH208 Contains octanoic acid, monoester with glycerol. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

Material safety data sheet

According to EU Regulation 1907/2006 in the current version

INSTATENS ACTIVE INGREDIENT

Eye Irrit. 2 Serious eye damage/eye irritation, Category 2

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Skin Irrit. 2 Skin corrosion/irritation, Category 2

Skin Sens. 1 Skin sensitisation, Category 1

16.2 Abbreviations:

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 Test-ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-tion (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 - Emergen-cy Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration as-sociated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good La-boratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships car-rying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - Interna-tional Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO – International Maritime Organization; INCI: International Nomenclature of Cosmetic Ingredients; 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 popula-tion; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - Interna-tional 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) Ef-fect 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 sub-stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quanti-tative) Structure Activity Relationship; PNEC: Predicted No Effect Concentration; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Re-striction 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; STE: Short-term exposure; STEL: Short Term Exposure limit; STOT: Specific Target Organ Toxicity; 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

Disclaimer:

This material safety data sheet does not constitute a guarantee of the properties of the product and is not a contractual legal report. The information is given in good faith on the basis of our best knowledge of the product at the indicated time. However, we cannot accept responsibility or liability for any consequences arising from its use, no warranty for correctness and completeness is given. We caution the users against the incurred possible risks when the product is used at other ends than the use for which it was initially planned. It is the user's responsibility during handling, storage and product use to consult the main regulatory texts in force regarding workers and environment protection.