

SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006

AUTODERM EXTRA (DRUG)

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

1.1 Product identifier

Product name : AUTODERM EXTRA (DRUG)

Product code : 104434E

Use of the

Substance/Mixture

: Skin antiseptic

Substance type: : Mixture

For professional users only.

Product dilution information : No dilution information provided.

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

Identified uses : Drug

Recommended restrictions

on use

: Reserved for industrial and professional use.

1.3 Details of the supplier of the safety data sheet

Company : Ecolab Deutschland GmbH

Ecolab-Allee 1

40789 Monheim am Rhein, Germany +49 (0)2173 599 0

OfficeService.DEDUS@ecolab.com

1.4 Emergency telephone number

Emergency telephone

number

: +32-(0)3-575-5555 Trans-european, German speaking, 24/7

or +49 32 212249407 German speaking, 24/7

Poison Information Centre

telephone number

: +49 (0)551 38318854

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Section: 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 2 H225

Although the product is not classified as health hazard, we recommend you to take the safety

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advice given below into account.

According to the current legislation creation of Safety Data Sheets is not mandatory for medicinal products or cosmetics

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms

Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapour.

Precautionary Statements : Prevention:

P210 Keep away from heat, hot surfaces, sparks,

open flames and other ignition sources. No

smoking.

2.3 Other hazards

None known.

Section: 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous components

Chemical Name	CAS-No. EC-No. REACH No.	Classification REGULATION (EC) No 1272/2008	Concentration : [%]
Drug mixture		Not Classified;	>= 50 - <= 100

Section: 4. FIRST AID MEASURES

4.1 Description of first aid measures

In case of eye contact : Rinse with plenty of water.

In case of skin contact : Rinse with plenty of water.

If swallowed : Rinse mouth. Get medical attention if symptoms occur.

If inhaled : Get medical attention if symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 for more detailed information on health effects and symptoms.

4.3 Indication of immediate medical attention and special treatment needed

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Treatment : Treat symptomatically.

Section: 5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

: High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during

firefighting

: Fire Hazard

Keep away from heat and sources of ignition. Flash back possible over considerable distance.

Beware of vapours accumulating to form explosive concentrations.

Vapours can accumulate in low areas.

Hazardous combustion

products

: Depending on combustion properties, decomposition products

may include following materials:

Carbon oxides

5.3 Advice for firefighters

for firefighters

Special protective equipment : Use personal protective equipment.

Further information : Use water spray to cool unopened containers. Fire residues and

> contaminated fire extinguishing water must be disposed of in accordance with local regulations. In the event of fire and/or

explosion do not breathe fumes.

Section: 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency

personnel

: Remove all sources of ignition. Refer to protective measures listed

in sections 7 and 8.

Advice for emergency

responders

If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable

materials.

6.2 Environmental precautions

: Do not allow contact with soil, surface or ground water. Environmental precautions

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up Eliminate all ignition sources if safe to do so. Stop leak if safe to

> do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Flush away traces with water. For large spills, dike spilled material or otherwise contain

material to ensure runoff does not reach a waterway.

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6.4 Reference to other sections

See Section 1 for emergency contact information.

For personal protection see section 8.

See Section 13 for additional waste treatment information.

Section: 7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling : Use only with adequate ventilation. Keep away from fire, sparks

and heated surfaces. Take necessary action to avoid static electricity discharge (which might cause ignition of organic vapours). Wash hands thoroughly after handling. Open drum carefully as content may be under pressure. In case of mechanical malfunction, or if in contact with unknown dilution of product, wear

full Personal Protective Equipment (PPE).

Hygiene measures : Handle in accordance with good industrial hygiene and safety

practice. Remove and wash contaminated clothing before re-use.

Wash face, hands and any exposed skin thoroughly after

handling.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

: Keep away from heat and sources of ignition. Keep in a cool, well-ventilated place. Keep away from oxidizing agents. Keep out of reach of children. Keep container tightly closed. Store in suitable

labeled containers.

Storage temperature : 0 °C to 25 °C

7.3 Specific end uses

Specific use(s) : Drug

Section: 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values.

. Cad Haar Madrana

DNEL Alaskal

Isopropyi Alcohol	End Use: Workers Exposure routes: Dermal Potential health effects: Long-term systemic effects 888 mg/kg
	End Use: Workers Exposure routes: Inhalation Potential health effects: Long-term systemic effects Value: 500 mg/m3
	End Use: Consumers Exposure routes: Dermal Potential health effects: Long-term systemic effects 319 mg/kg

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End Use: Consumers
Exposure routes: Inhalation

Potential health effects: Long-term systemic effects

Value: 89 mg/m3

End Use: Consumers Exposure routes: Ingestion

Potential health effects: Long-term systemic effects

26 mg/kg

PNEC

| Sopropyl Alcohol | : Fresh water | Value: 140.9 mg/l

Marine water Value: 140.9 mg/l

Intermittent use/release Value: 140.9 mg/l

Fresh water Value: 552 mg/kg

Marine sediment Value: 552 mg/kg

Soil

Value: 28 mg/kg

Sewage treatment plant Value: 2251 mg/l

Oral

Value: 160 mg/kg

8.2 Exposure controls

Appropriate engineering controls

Engineering measures : Effective exhaust ventilation system. Maintain air concentrations

below occupational exposure standards.

Individual protection measures

Hygiene measures : Handle in accordance with good industrial hygiene and safety

practice. Remove and wash contaminated clothing before re-use.

Wash face, hands and any exposed skin thoroughly after

handling.

Eye/face protection (EN 166) : No special protective equipment required.

Hand protection (EN 374) : No special protective equipment required.

Skin and body protection

(EN 14605)

: No special protective equipment required.

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Respiratory protection (EN

143, 14387)

: None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified

respiratory protection equipment meeting EU

requirements(89/656/EEC, (EU) 2016/425), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods

or procedures of work organization.

Environmental exposure controls

General advice : Consider the provision of containment around storage vessels.

Section: 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour colourless Odour alcohol-like pΗ : 6.5, 100 %

Particle characteristics

Assessment : not applicable Particle size : not applicable Particle Size Distribution : not applicable **Dustiness** not applicable Specific surface area not applicable Surface charge/Zeta not applicable

potential

Shape : not applicable Crystallinity not applicable Surface treatment : not applicable

/Coatings

Flash point : 21 °C closed cup

Odour Threshold : Not applicable and/or not determined for the mixture Melting point/freezing point : Not applicable and/or not determined for the mixture Boiling point, initial boiling : Not applicable and/or not determined for the mixture

point and boiling range

: Not applicable and/or not determined for the mixture

Evaporation rate **Flammability** : Not applicable and/or not determined for the mixture Upper explosion limit : Not applicable and/or not determined for the mixture Lower explosion limit : Not applicable and/or not determined for the mixture Vapour pressure Not applicable and/or not determined for the mixture : Not applicable and/or not determined for the mixture Relative vapour density

Density and / or relative

density

: 0.87

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Water solubility : soluble

Solubility in other solvents : Not applicable and/or not determined for the mixture Partition coefficient: n- : Not applicable and/or not determined for the mixture

octanol/water (log value)

Auto-ignition temperature : Not applicable and/or not determined for the mixture

Thermal decomposition : Not applicable and/or not determined for the mixture

Viscosity, kinematic : Not applicable and/or not determined for the mixture

Explosive properties : Not applicable and/or not determined for the mixture

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

9.2 Other information

Not applicable and/or not determined for the mixture

Section: 10. STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Heat, flames and sparks.

10.5 Incompatible materials

None known.

10.6 Hazardous decomposition products

Depending on combustion properties, decomposition products may include following materials: Carbon oxides

Section: 11. TOXICOLOGICAL INFORMATION

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

Information on likely routes of : Inhalation, Eye contact, Skin contact

exposure

Product

Acute oral toxicity : There is no data available for this product.

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Acute inhalation toxicity : There is no data available for this product.

Acute dermal toxicity : There is no data available for this product.

Skin corrosion/irritation : There is no data available for this product.

Serious eye damage/eye

irritation

: There is no data available for this product.

Respiratory or skin

sensitization

: There is no data available for this product.

Carcinogenicity : There is no data available for this product.

Reproductive effects : There is no data available for this product.

Germ cell mutagenicity : There is no data available for this product.

Teratogenicity : There is no data available for this product.

STOT - single exposure : There is no data available for this product.

STOT - repeated exposure : There is no data available for this product.

Aspiration toxicity : There is no data available for this product.

Potential Health Effects

Eyes : Health injuries are not known or expected under normal use.

Skin : Health injuries are not known or expected under normal use.

Ingestion : Health injuries are not known or expected under normal use.

Inhalation : Health injuries are not known or expected under normal use.

Chronic Exposure : Health injuries are not known or expected under normal use.

Experience with human exposure

Eye contact : No symptoms known or expected.

Skin contact : No symptoms known or expected.

Ingestion : No symptoms known or expected.

Inhalation : No symptoms known or expected.

11.2 Information on other hazards

Further information : no data available

Section: 12. ECOLOGICAL INFORMATION

12.1 Toxicity

Environmental Effects : This product has no known ecotoxicological effects.

Product

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Toxicity to fish : no data available

Toxicity to daphnia and other : no data available

aquatic invertebrates

Toxicity to algae : no data available

12.2 Persistence and degradability

Product

no data available

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

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

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

12.7 Other adverse effects

no data available

Section: 13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

13.1 Waste treatment methods

Product : Where possible recycling is preferred to disposal or incineration. If

recycling is not practicable, dispose of contents/container in accordance with local regulations Dispose of wastes in an

approved waste disposal facility.

Contaminated packaging : Dispose of as unused product. Empty containers should be taken

to an approved waste handling site for recycling or disposal. Do not re-use empty containers. Dispose of in accordance with local,

state, and federal regulations.

Guidance for Waste Code

selection

: Organic wastes containing dangerous substances. If this product is used in any further processes, the final user must redefine and assign the most appropriate European Waste Catalogue Code. It

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is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable European (EU Directive 2008/98/EC) and local regulations.

Section: 14. TRANSPORT INFORMATION

The shipper/consignor/sender is responsible to ensure that the packaging, labeling, and markings are in compliance with the selected mode of transport.

Land transport (ADR/ADN/RID)

14.1 UN number or ID : 1993

number

14.2 UN proper shipping : FLAMMABLE LIQUID, N.O.S.

name

(Ethanol, Isopropanol)

14.3 Transport hazard : 3

class(es)

14.4 Packing group : II 14.5 Environmental hazards : No 14.6 Special precautions for : None

user

Air transport (IATA)

14.1 UN number or ID : 1993

number

14.2 UN proper shipping : Flammable liquid, n.o.s.

name

(Ethanol, Isopropanol)

14.3 Transport hazard : 3

class(es)

14.4 Packing group : 11 14.5 Environmental hazards : No 14.6 Special precautions for : None

user

Sea transport (IMDG/IMO)

14.1 UN number or ID : 1993

number

14.2 UN proper shipping : FLAMMABLE LIQUID, N.O.S.

name

(Ethanol, Isopropanol)

14.3 Transport hazard : 3

class(es)

14.4 Packing group : 11 14.5 Environmental hazards : No 14.6 Special precautions for : None

user

14.7 Maritime transport in

: Not applicable. bulk according to IMO

instruments

Section: 15. REGULATORY INFORMATION

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

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Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of majoraccident hazards involving dangerous substances.

FLAMMABLE LIQUIDS P5c Lower tier: 5,000 t

Upper tier : 50,000 t

Candidate List of Substances : Not applicable. of Very High Concern for

Authorisation

National Regulations

Take note of Dir 94/33/EC on the protection of young people at work.

Hazard class for water : WGK 1

Classification according to AwSV, Annex 1

German storage class : 3

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out on the product.

Section: 16. OTHER INFORMATION

Procedure used to derive the classification according to REGULATION (EC) No 1272/2008

Classification	Justification
Flammable liquids 2, H225	Based on product data or assessment

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways: ADR - European 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; NZloC - 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,

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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

Prepared by : Regulatory Affairs

Numbers quoted in the MSDS are given in the format: 1,000,000 = 1 million and 1,000 = 1 thousand. 0.1 = 1 tenth and 0.001 = 1 thousandth

REVISED INFORMATION: Significant changes to regulatory or health information for this revision is indicated by a bar in the left-hand margin of the SDS.

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Annex: Exposure Scenarios

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