according to Regulation (EG) no. 1907/2006



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Coming in force: 01.12.2012 replaces version: 6

## Fugaten®-Spray

## 1. Product and Company Identification

#### 1.1 Product information

Trade name: Fugaten®-Spray

# 1.2 Relevant identified applications of the mixture and applications which should be avoided

## Applications of the product

Disinfectant for surfaces, objects and medical devices

For professional use

#### Applications, which should be avoided

Do not apply on materials sensitive to alcohol (for ex. acrylic glass, varnished and stained surfaces).

## 1.3 Particulars about the supplier, who provides the Safety Data Sheet

**Informing department:** Scientific-Technical Department Berlin

E-Mail: kontakt@lysoform.de Telefon: 030/77992-216

Manufacturer / Supplier:

Germany Switzerland

Lysoform Dr. Hans Rosemann GmbH Schweizerische Gesellschaft für Antisepsie AG

Kaiser-Wilhelm-Straße 133 Postfach 444

D-12247 Berlin 5201 Brugg / Windisch Telefon: 030/77992-0 Telefon: 056 / 4416981 Telefax: 030/77992-219 Telefax: 056 / 4424114

www.lysoform.de

1.4 Emergency Overview:

Germany Switzerland

Giftnotruf München Toxikol. Abteilung, Schweizer Toxikologisches Informationszentrum

Klinikum rechts der Isar Freiestrasse 16 Ismaninger Str. 22, 81675 München 8032 Zürich

Telefon: 0049 89 19240 Telefon: 0041 44 2515151 Telefax: 0049 89 4140-2467 Telefax: 0041 44 2528833

#### 2. Hazard Identification

#### 2.1 Classification of the substance or mixture

#### According to Directive 1999/45/EG:

R 11; R 36 (Expert reports, see Section 11)

#### 2.2 Labelling:

## According to Directive 1999/45/EG:

### **Danger Symbols:**



F



Χi

#### **Hazard Warnings:**

R 11 Highly flammable

R 36 Irritating to the eyes (Expert's report: see Paragraph 11)

#### Safety Recommendations:

S 2S 7Keep out of the reach of children:Keep containers tightly closed.

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S 16	Keep away from sources of ignition – No smoking.
S 23	Do not breathe spray
S 26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S 35	This material and its container must be disposed of in a safe way.

#### Hazard determining components for labelling

Ethanol, denatured

#### 2.3 Other hazards

The product does not meet the criteria for the classification as PBT and/or vPvB.

## 3. Composition / Information on the Ingredients

#### 3.1 Substances

This product is a mixture of several substances.

#### 3.2 Product

#### Active substances and hazard-determining components:

#### **Ethanol**

EC-No.: 200-578-6 CAS-No.: 64-17-5 REACH-Registration No.: 01-2119457610-43 Proportion: 65 - 75 %

Classification according to Directive 67/548/EC:

F; R11

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

Flammable liquid category 2; H225 Eye irritation cat. 2; H319

## **Substances with prescribed EU-limit values**

Name of substance: Butanon

EC-No.: 201-159-0 CAS-No.: 78-93-3 REACH-Registration No.: 02-2119752535-35

Proportion:< 1 %

Classification according to Directive 67/548/EC:

F; Xi; R 11; R 36; R 66-67

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

Flammable liquid category 2; H225

Eye irritation cat. 2; H319

Specific Target Organ -Toxicity after a unique exposition (STOT SE) category 3; H336

EUH066

(For the wording of the listed risk phrases refer to Section16)

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## Fugaten®-Spray

#### 4. First Aid Measures

### 4.1 Description of the First Aid Measures

#### General information:

Seek medical advice immediately and show safety data sheet, package or label.

#### After inhalation:

Plenty of fresh air.

#### After skin contact:

Remove immediately all clothing which is soiled or wet with the product.

Rinse out with plenty of water and seek medical advice if skin irritation does not subside.

#### After eye contact:

Rinse out with plenty of running water with the eyelid held wide open for several minutes.

#### After swallowing:

Do not induce vomiting. Rinse mouth with water and then drink plenty of water.

#### 4.2 Most important symptoms and effects appearing immediately or later

**Acute:** Irritation of the mucous membranes

**Delayed:** After oral resorption a possible effect on the central nervous system such as for ex.

dizziness or sleepiness may occur. Also redness of the face / skin can occur due to

the expansion of the facial blood vessels.

### 4.3 Medical first aid or special treatments

Seek medical advice immediately, show safety data sheet, packaging or label.

#### 5. Firefighting Measures

## 5.1 Extinguishing media

## Suitable extinguishing media:

Water jet, carbon dioxide, extinguishing powder, alcohol-resistant foam.

## 5.2 Specific hazards coming from the components or the mixture

While burning some dangerous fumes / gases might be released:

Carbon monoxide, carbon dioxide and potentially explosive vapour/air mixtures.

#### 5.3 Further information for fire fighting

Wear an atmosphere independent breathing apparatus in the danger area. Use water jets for protection of persons and to cool down containers within the danger zone.

#### 6. Accidental Release Measures

# 6.1 Personal precautions, protective equipment and procedures to be used in case of emergency situations

Provide for enough ventilation. Remove all sources of ignition – Do not smoke.

### 6.2 Environmental precautions

Do not allow into sewer system or groundwater.

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#### 6.3 Methods and materials for retention and cleaning

Soak up with absorbent materials for ex. cloths, fleece and with liquid-binding materials (sand, universal binder, saw dust). Discard big amounts of liquid with a pump.

#### 6.4 Reference to other Data

Safe Handling (Section 7), Personal Protection (Section 8) and Elimination (Section 13)

## 7. Handling and Storage

#### 7.1 Protection for a safe handling

#### Safe handling:

Do not inhale aerosols, do not spray overhead and keep an adequate distance to the sprayed surface/object. Ensure adequate ventilation at workplace. Do not use on alcohol sensitive materials (for ex. on acrylic glass, varnished and stained surfaces).

The surfaces should be completely wetted with the product (max. 50 ml/m²). Allow hot surfaces to cool down before disinfection. Before using electrical appliances wait for the surfaces to be dry after treatment with alcohol based disinfectants.

#### General hygienic measures at workplace:

Wash hands before breaks and at the end of the working day. Keep away from foodstuffs. Take off soiled, wet clothing immediately. Avoid contact with the eyes.

#### 7.2 Requirements for a safe storage taking into consideration product incompatibilities

#### Requirements for storage areas and containers

Keep in a cool but frost-free and dry area in the original containers.

#### Advice on protection against fire and explosion

Can form explosive gas-air-mixtures. Ensure good ventilation of area, including close to the ground. Vapours are heavier than the air. Keep away all sources of ignition – do not smoke, take measures against electrostatic charging.

#### Other information concerning storage

Protect from sunlight.

### Information on storage incompatibilities

According to TRGS 510: Keep away from food and beverages.

Storage class: 3 Flammable liquid (TRGS 510)

#### 7.3 Specific end use(s)

No special terminal utilization known with special handling or storage.

# 8. Occupational Exposure Limits and Monitoring Personal Protection

#### 8.1 Parameters to be monitored

### Components with limit values that require monitoring at workplace

Components	CAS-Nr.	Value	Reference
Ethanol	64-17-5	AGW: 960 mg/m <sup>3</sup> , 500 ml/m <sup>3</sup>	TRGS 900
		Top limit-exceedance factor: 2(II)	
		Other indications: DFG, Y	
Butanon	78-93-3	AGW: 600 mg/m <sup>3</sup> , 200 ml/m <sup>3</sup>	TRGS 900
		Top limit-exceedance factor: 1(I) (AWG);	
		Other indications: DFG, H, Y	

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EU (2000/39/EC): Short-time exposure (<15min) 900 mg/m³, 30	00 ppm
BGW: 5 mg/l (urine, b)	TRGS 903

#### If the product is used correctly, the AGW & BGW of Butanon are far from being reached.

**AGW** = workplace limit, **BGW** = biological limit, **DFG** = Senate Committee of the DFG for the testing of the health-hazardous chemicals = (MAK-Commission), **EU** = limit value in the air of the European Union, **H** = skin resorption, **Y** = if AGW & BGW are not exceeded, there is no risk of mutagenity/teratogenity.

#### **DNEL (Derived No Effect Level) - Values:**

#### **Ethanol**

Worker:

Long-term-Exposure - systemic effect, dermal: 343 mg/kg

Worker:

Long-term-Exposure - systemic effect, inhalation: 950 mg/m<sup>3</sup>

Worker:

Short-term-Exposure - local effect, inhalation: 1900 mg/m<sup>3</sup>

#### PNEC (Predicted No Effect Concentration) - Values:

#### **Ethanol**

fresh water: 0,96 mg/l ground: 0,63 mg/kg

sea water: 0,79 mg/kg sewage treatment plant: 580 mg/l sediment (fresh water): 3,6 mg/kg periodical release: 2,75 mg/l

## 8.2 Limitation and Monitoring of the Exposure

#### Individual protective measures - personal protective equipment:

## General protection - and hygienic measures

Keep away from foodstuffs, beverages and animal feed.

Avoid contact with the eyes.

#### Respiratory protection

Not necessary by adequate ventilation. Do not inhale aerosols, do not spray overhead and keep an adequate distance to the sprayed surface/object. Exposure by inhalation is harmless if the amount in unventilated rooms does not exceed 1.5 ml/m³. By adequate ventilation or when people stay in the rooms only for a short time, a lot more product can be used. For more information see TRGS 402 and 900. In exceptional cases a respirator with Filter A (EN 14387) can be used.

#### Hand protection

Wear impervious gloves.

Wearing waterproof gloves for more than four hours on end daily can be seen as burdensome and should not be a permanent measure.

#### Penetration time of the glove material

The durability of gloves depends on a lot of particulars (material, layer thickness, manufacturer, temperature, stress time and duration) and is not predictable. Each user must test the resistance of the gloves for his particular assignment. The break-through time according to EN 374 must be specified by the manufacturer and allows for comparison of the gloves. See more detailed information in the German regulation: TRGS 401.

#### Recommendations

Gloves made of butyl rubber.

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## Fugaten®-Spray

Short-time exposure: Ordinary domestic gloves might offer adequate protection.

#### Skin protection

Protective clothing at workplace

To prevent occupational skin irritations it is recommended to proceed as follows independently from the actual contact to disinfectants:

- Apply a skin cream penetrating the skin rapidly whenever possible.
- Apply a nourishing cream on skin after washing the hands at the end of the working period or before breaks.

#### Protection of eyes and face

No eye or face protection necessary.

## 9. Physical and chemical Properties

## 9.1 General information on the physical and chemical properties

If no details are available on the product the relevant data can be given for the components as follows: "Component: Details".

Form

consistency: liquidcolour: colourlessOdour: characteristic

Odour threshold: ethanol: 19 – 93 mg/m³ (0.001 – 0.0048 Vol.%)

pH at 20 °C: approximately 9.3

Melting point: ethanol: -114.5 ℃ (OECD 102)

Boiling point and boiling range: ethanol: 78 ℃

Flash point: 19.5 °C (DIN 51755, in closed skillet)

Evaporation velocity: Not determined

Flammability: the product is not auto-igniting Explosion limits in the air: ethanol 2.5 – 15 % (Vol.%) Vapour pressure: ethanol: 59 hPa at 20 °C

Vapour density, relative (air =1): ethanol: 1.59
Density at 20 °C: 0.86 g/cm³
Water solubility: completely soluble

Partition coefficient:

n-Octanol/water: not applicable for a mixture

Autoignition temperature: ethanol: 425 ℃

Decomposition temperature: not applicable, no decomposition known viscosity: not determined, product is not viscous

Explosive properties: the product as a liquid represents no explosion hazard

Oxidizing properties: not determined, no oxidizing property known

#### 9.2 Other data

No other physical-chemical data were recorded.

### 10. Stability and Reactivity

#### 10.1 Reactivity

No reactivity when used according to the intended purpose.

#### 10.2 Chemical stability

Stable under recommended storage conditions and when used according to the to the intended purpose.

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## Fugaten®-Spray

## 10.3 Possibility of hazardous reactions

No danger if used according to the intended purpose.

#### 10.4 Conditions to be avoided

See Section 7.

## 10.5 Incompatible materials

None known

#### 10.6 Dangerous decomposition products

No decomposition when used according to the intended purpose.

#### 11. Toxicological Data

#### 11.1 Information about toxicological properties

The active substance has been extensively tested with regard to its toxicological profile. When used correctly the dermal and the inhalation exposures are harmless. As far as the product is concerned no other result can be expected. For this reason it was not tested in all toxicological categories. The data available on the dangerous substances has also to be taken into consideration.

#### 11.1.1 Product:

#### **Acute toxicity**

LD/LC50 values

Oral: non-toxic (14.7 ml/kg - rat)

Skin irritation / corrosion

No data available.

Serious damage/irritation to eyes

OECD 405 rabbits:"moderately irritant" (recommandation R 36),

Sensitization of the respiratory tract / skin

No data available

Germ cell mutagenicity

No data available

Carcinogenic effects

No data available

Reproductive toxicity

No data available

Target organ effects – Toxicity after a single exposure

No data available

Target organ effects - Toxicity after repeated exposure

No data available

**Aspiration hazard** 

No data available

Symptoms and effects (delayed and chronic) with description of the exposure route - also: Information about toxicokinetics, metabolism and distribution

No data available

#### 11.1.2 For the following substances:

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#### **Ethanol**

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### Symptoms:

Dyspnea, drowsiness, loss of consciousness, blood pressure fall, vomiting, cough, headache, drunkenness, sleepiness, irritation of the mucous membranes, dizziness, nausea.

### Experience in human beings:

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Consuming excessive amounts of alcohol during pregnancy can cause alcohol syndrome in foetus (reduced weight at birth, physical and mental disorders).

Toxicity/ Effect	End- point	Value	Unit	Organism	Test method	Comment
Acute toxicity, oral	Pomi			rabbit	OECD 404 (Acute Dermal Irritation/Corrosion)	not irritating
Serious irritation/ damage to the eyes				rabbit	OECD 405 (Acute Eye Irritation/Corrosion)	slightly irritating
Sensitiza- tion of the respiratory tract and skin				mouse	OECD 429 (Skin Sensitisation - Local Lymph Node Assay)	not sensitizing
Germ cell mutagenicity				Salmonella Typhimurium	OECD 471 (Bacterial Reverse Mutation Test)	negative
Germ cell mutagenicity					OECD 475 (Mammalian Bone Marrow Chromosome Aberration Test)	negative
Germ cell mutagenicity				mouse	OECD 476 (In Vitro Mammalian Cell Gene Mutation Test)	negative
Germ cell mutagenicity					OECD 473 (In Vitro Mammalian Chromosome Aberration Test)	negative
Germ cell mutagenicity					OECD 471 (Bacterial Reverse Mutation Test)	negative
Specific target organ- toxicity - repeated exposure (STOT-RE)	NOAEL	1730	mg/kg /d	rat	OECD 408 (Repeated Dose 90- Day Oral Toxicity Study in Rodents)	females
Specific target organ- toxicity - repeated exposure (STOT-RE)	NOAL	>20	mg/l	rat	OECD 403 (Acute Inhalation Toxicity)	males
Aspiration hazard				humans		No indication of such an effect.
Teratoge- nicity						negative

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#### **Butanon**

In the concentration specified for this mixture, the toxicological meaning of butanon (LD 50 >2600 mg/kg in rats) is negligible.

#### 12. Environmental Data

Some of the effects of the products were not tested. The data about the dangerous components have to be taken into consideration.

Butanon is biodegradable and the minute amount of this substance contained in the product is negligible.

### 12.1 Toxicity

#### **Ethanol**

Toxicity, Fish:

LC<sub>50</sub> in 96 h: 13000 mg/l (Oncorhynchus mykiss) OECD 203 (Fish, Acute Toxicity Test)

Toxicity, Daphnia:

LC<sub>50</sub> in 48 h: 12340 mg/l (Daphnia magna)

#### 12.2 Persistence and biological degradability

**Ethanol** 

97% OECD 301 B (Ready Biodegradability - Co2 Evolution Test)

#### 12.3 Bioaccumulation potential

Ethanol

BCF: 3.2 mg/l Log Pow: -0.32

#### 12.4 Mobility in the soil

**Ethanol** 

No data available

#### 12.5 Result of the PBT- and vPvB-Assessments

The product contains no chemicals which can be classified as PBT- or vPvB-substances.

## 12.6 Other adverse effects

The water pollution hazard class 2 (according to VwVwS) was allocated to this product.

### 13. Disposal Considerations

## 13.1 Handling method for the elimination of the product

#### Handling of the product

May be disposed of according to the local regulation, for ex. in an appropriate waste disposal site or incineration plant. Do not dispose of it into the public sewage system.

#### Handling of the used packaging

Emptied packages can be discarded into the adequate recycling (for ex. yellow) containers.

## Waste code according to the ordinance on waste materials catalogues (AVV)

07 06 04 other organic solvents, washing liquids and mother liquors 15 01 02 Packages made of plastic materials

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#### Relevant EU- and other Regulations

TRGS 201 (Labelling of the Chemical Wastes), KrW-/AbfG (Cycle and Waste Management Act)

## 14. Transport

#### 14.1 UN-Number

1170

#### 14.2 UN proper shipping name

All types of transport:

ETHANOL (ETHYL ALCOHOL), solution

#### 14.3 Transport hazard classes

Road: ADR/RID and GGVS/GGVE Class: 3 Flammable liquid materials

Tunnel restriction code: D / E

Sea: IMDG/GGV Sea-Class: 3

EMS-number: F-E, S-D

Air: ICAO-TI / IATA-DGR-class: 3

#### 14.4 Packing Group

Ш

#### 14.5 Environmental risk

### Characterisation of the environmental hazardous substances

ADR/RID / IMDG-Code / ICAO-TI / IATA-DGR: ☐ yes / ☒ no

IMDG-Code: Marine Pollutant: ☐ yes / ☒ no

### 14.6 Special precautions for the user (forwarding agent)

None

# 14.7 Bulk transport according to Annex II of the MARPOL-Agreement 73/78 and according to the IBC-Code

No bulk transport

### 15. Regulatory Information

#### 15.1 Safety, health and environmental regulations / Legislation specific to the product

### **EC Regulations:**

1907/2006 REACh / 1272/2008 CLP GHS / 1999/45/EG Dangerous mixtures (until June 2015) / 98/24/EG Hazards due to exposure to dangerous chemical substances at workplace / 648/2004 Detergents regulation

#### **German Regulation:**

Chemicals act ChemG / German ordinance on hazardous substances GefStoffV / TRGS and Announcements / Regulation for industrial safety BetrSichV / Young persons protection of employment Act / Law on maternity protection / Professional association's and trade inspectorate's guidelines

#### Other regulations, restriction and prohibition ordinances:

Medical device class IIa CE 0482 according to the German law on medical devices Biocide: Baua Reg.-No. N-12738, N-12739, N-12741

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#### 15.2 Chemical safety assessement

No chemical safety assessment was carried out for this products.

#### 16. Other Information

#### Modifications compared to the previous version

Completely revised edition - New format according to the legal ordinance (EU) Nr. 453/2010 Important modifications to be taken into account: See Sections 7 and 8.

### Bibliographical references and data sources

TRGS 510 / TRGS 525 / TRGS 900 / TRGS 903 / Safety Data Sheet of the components

Methods according to Article 9 of the legal ordinance (EG) No. 1272/2008 for the evaluation of the information for the classification of the chemical substances:

The classification was carried out according to 1999/45/EG

Wording of the hazard statement, and of the relevant risk phrases (R-phrases) in accordance with Section 3:

#### **According to Directive 67/548/EWG:**

#### **R-Phrases:**

- 11 Highly flammable.
- 36 Irritating to eyes.
- Repeated exposure may cause skin dryness or cracking.
- Vapours may cause drowsiness and dizziness.

#### According to legal ordinance (EG) No. 1272/2008 (CLP / GHS):

#### **Hazard warnings:**

H319	Causes serious eye irritations.
H225	Highly flammable liquid and vapours.
H336	May cause drowsiness or dizziness.

EUH066 Repeated exposure may cause skin dryness or cracking.

The information contained in this safety data sheet is based on the present state of our knowledge and experience and describes the product with regard to the security requirements for a safe use of this product. This data is definitely not a description of the product itself (product specification). A description of the product or its suitability for a particular application cannot be derived from the data given in the safety data sheet. We will be glad to give you advice on the question whether a product is suitable for a specific use and under which conditions.

Possible trade mark rights as well as existing laws and regulations are to be followed by recipient of our products at his own responsibility.

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