



## SAFETY DATA SHEET

122000013012

**Bactine Original First Aid Liquid**

Version 1.0

Revision Date 05/29/2015

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**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****Product information****Product Name:** Bactine Original First Aid Liquid

SDS Number: 122000013012

**Use** : Medicinal products**Company**

BAYER HEALTHCARE LLC

Consumer Care

100 Bayer Boulevard PO Box 915

Whippany, NJ 07981-0915

USA

(800) 743-5423

**In case of emergency:** (800) 331-4536

Chemtec: (800) 424-9300

BAYER INFORMATION PHONE:(800) 331-4536 OR (800) 743-5423

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**2. HAZARDS IDENTIFICATION****Emergency Overview****Colour:** clear, cloudy, colourless **Form:** liquid **Odour:** characteristic.

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**GHS Classification:**

Not a dangerous substance / mixture according to GHS.

**GHS Label element:**This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

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**3. COMPOSITION/INFORMATION ON INGREDIENTS**

| Weight percent | Components              | CAS-No. |
|----------------|-------------------------|---------|
| 2.49%          | Lidocaine Hydrochloride | 73-78-9 |

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**Label Ingredients:** Benzakonium Chloride; Lidocaine hydrochloride; Edetate Disodium; Nonoxynol 9; 1,2-Propanediol; Water;

**Other Ingredients**

| <b>Weight percent</b> | <b>Components</b> | <b>CAS-No.</b> |
|-----------------------|-------------------|----------------|
| 5 - 10%               | Propane-1,2-diol  | 57-55-6        |

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**4. FIRST AID MEASURES**

**General advice:** Take off all contaminated clothing immediately.

**If inhaled:** Remove to fresh air. Call a physician immediately.

**In case of skin contact:** If skin reactions occur, contact a physician.

**In case of eye contact:** In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

**If swallowed:** If swallowed, seek medical advice immediately and show this container or label.

**Contact Number:** Use the Bayer Emergency Number in Section 1

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**5. FIREFIGHTING MEASURES**

**Suitable extinguishing media:** Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**Unsuitable extinguishing media:** High volume water jet

**Specific hazards during firefighting:** Fire may cause evolution of: Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)

**Special protective equipment for firefighters:** In the event of fire, wear self-contained breathing apparatus.

**Further information:** Prevent fire extinguishing water from contaminating surface water or the ground water system.

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**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions:** Use personal protective equipment.

**Methods for cleaning up:** Cover spilled product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labeled, closable containers.

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**Additional advice:** No special precautions required.

**Further Accidental Release Notes** No special precautions required.

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## 7. HANDLING AND STORAGE

**Handling:**

Keep this and all drugs out of the reach of children. Avoid contact with eyes. Store in a dry place away from excessive heat. Reseal containers immediately after use. Use normal precautions for storage of a drug.

Keep away from open flames, hot surfaces and sources of ignition.

**Storage:**

Storage temperature: 59 - 77 °F (15 - 25 °C)

Do not use after expiration date.

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Propane-1,2-diol (57-55-6)**

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides  
Time Weighted Average (TWA): 10 mg/m<sup>3</sup> (Aerosol.)

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US. AIHA Workplace Environmental Exposure Level (WEEL) Guides  
Time Weighted Average (TWA): 10 mg/m<sup>3</sup> (Aerosol.)

**Respiratory protection:**

Recommended Filter type: Organic vapor with prefilter

None required for consumer use of this product.

**Hand protection:**

Chemically resistant gloves.

None required for consumer use of this product.

**Eye protection:**

Safety glasses

None required for consumer use of this product.

**Hygiene measures:**

Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!

**Other protective measures:**

Wear suitable protective equipment.

Please consult label for end-user requirements.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

|                              |  |
|------------------------------|--|
| Form:                        | liquid                                 |
| Colour:                      | clear, cloudy, colourless              |
| Odour:                       | characteristic                         |
| Odour Threshold:             | No applicable information is available |
| Melting point:               | No applicable information is available |
| Boiling point/boiling range: | No applicable information is available |
| Density:                     | No applicable information is available |
| Bulk density:                | No applicable information is available |
| Vapour pressure:             | No applicable information is available |
| Viscosity, dynamic:          | No applicable information is available |
| Viscosity, kinematic:        | No applicable information is available |
| Flow time:                   | No applicable information is available |
| Surface tension:             | No applicable information is available |
| Miscibility with water:      | No applicable information is available |
| Water solubility:            | completely soluble                     |
| pH:                          | 6 - 6.8                                |
| Relative density:            | No applicable information is available |
| Partition coefficient:       | No applicable information is available |
| Solubility(ies):             | No applicable information is available |
| Flash point:                 | No applicable information is available |
| Flammability (solid, gas):   | No applicable information is available |
| Ignition temperature:        | No applicable information is available |
| Explosion limits:            | No applicable information is available |

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## 10. STABILITY AND REACTIVITY

**Conditions to avoid:** No data available

**Materials to avoid:** Oxidizing agents

**Hazardous reactions:** None known.

**Thermal decomposition:**

No data available

**Hazardous decomposition products:**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

**Oxidizing properties:**

No statements available.

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**Impact sensitivity:**

No data available

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**11. TOXICOLOGICAL INFORMATION**

**Other information on toxicity:**

No data is available on the product itself.

**Acute oral toxicity:**

Acute toxicity estimate (ATE) > 2,000 mg/kg

The substance or mixture has no acute oral toxicity

Method: Calculation method

Calculated for GHS Classification and Labelling.

**Acute inhalation toxicity:**

Propane-1,2-diol

LC50 Rabbit: > 317 mg/l, 2 h

The substance or mixture has no acute inhalation toxicity

**Acute dermal toxicity:**

Propane-1,2-diol

LD50 Rabbit: > 5,000 mg/kg

The substance or mixture has no acute dermal toxicity

**Acute toxicity (other routes of administration):**

Lidocaine Hydrochloride

TDL0 intravenous human: 7.1 mg/kg

LD50 intraperitoneal Rat: 122 mg/kg

LD50 subcutaneous Rat: 570 mg/kg

LD50 intravenous Rat: 21 mg/kg

LDL0 intravenous Dog: 65.7 mg/kg

LD50 intravenous Rabbit: 25.6 mg/kg

LD50 intravenous Mouse: 22 mg/kg

LD50 intraperitoneal Mouse: 119 mg/kg

LD50 intramuscular Mouse: 260 mg/kg

**Skin irritation:**

Propane-1,2-diol

Rabbit

Result: No skin irritation

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Lidocaine Hydrochloride

Rabbit

Result: Moderate skin irritation

Method: Draize Test

According to the classification criteria of the European Union, the product is not considered as being a skin irritant.

**Eye irritation:**

Propane-1,2-diol

Rabbit

Result: No eye irritation

Lidocaine Hydrochloride

Rabbit

Result: Moderate eye irritation

Method: Draize Test

No eye irritation

**Sensitisation:**

Propane-1,2-diol

Human experience

Result: Does not cause skin sensitisation.

guinea pig

Result: Does not cause skin sensitisation.

Method: OECD 406

**Subacute, subchronic and prolonged toxicity:**

Propane-1,2-diol

NOEL 50,000 mg/kg, Rat Oral, Exposure time 24 month

NOEL 1 mg/l, Rat Inhalation, Exposure time 3 month

Number of exposures: once daily

**Genotoxicity in vitro:**

Propane-1,2-diol

Ames test Bacteria

Dose: yes

Result: negative

Method: OECD 471

Mammalian cells

Result: negative

Method: OECD 476

Lidocaine Hydrochloride

Ames test Salmonella typhimurium

Result: negative

Hamster ovary-cells

Result: negative

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**Genotoxicity in vivo:**

Propane-1,2-diol

Result: negative  
Method: OECD 478

**Carcinogenicity:**

Propane-1,2-diol

Rat:

Exposure time: 2 a  
Number of exposures: once daily  
Result: negative

**Reproductive toxicity:**

Propane-1,2-diol

Application Route: Oral

Rat, female: Test period: 18 d

NOAEL: 1600 mg/kg

Result: Animal testing did not show any effects on fertility.

**Teratogenicity:**

Propane-1,2-diol

Rat, male: Number of exposures: once daily

Test period: 15 d

NOAEL: 1600 mg/l

Result: No indication of teratogenic effects.

Lidocaine Hydrochloride

Application Route: subcutaneous

Rat: NOAEL: 30 mg/kg 72 mg/kg/day

Result: Did not show teratogenic effects in animal experiments.

Application Route: intraperitoneal

Rat: NOAEL: 56 mg/kg/day

Result: Did not show teratogenic effects in animal experiments.

**Pharmaceutic effects:**

Analgesic Antiseptic

**Carcinogenicity:**

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

**STOT - single exposure:**

No data available

**STOT - repeated exposure:**

No data available

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**12. ECOLOGICAL INFORMATION**

**General advice:**

Do not allow to enter surface waters or groundwater. No data is available on the product itself.

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**Toxicity to fish:**

Propane-1,2-diol

Acute Fish toxicity: LC50 40,613 mg/l

Test species: Pimephales promelas (fathead minnow) Duration of test: 96 h

**Toxicity to daphnia and other aquatic invertebrates:**

Propane-1,2-diol

LC50 18,340 mg/l

Test species: Ceriodaphnia dubia (water flea) Duration of test: 48 h

**Toxicity to algae:**

Propane-1,2-diol

IC50 19,100 mg/l

tested on: Pseudokirchneriella subcapitata (green algae)

**Toxicity to bacteria:**

Propane-1,2-diol

NOEC 20,000 mg/l

tested on: Pseudomonas putida

Duration of test: 18 h

**Biodegradability:**

Propane-1,2-diol

87 - 92 %, 28 d rapidly biodegradable

Method: OECD 301 C

**Bioaccumulation:**

Propane-1,2-diol

Bioconcentration factor (BCF)

0.09

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**13. DISPOSAL CONSIDERATIONS**

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

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**14. TRANSPORT INFORMATION****Land transport (CFR)****non-regulated****US Sea transport (IMDG)****non-regulated**

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**US Air transport (ICAO / IATA cargo aircraft only)**  
non-regulated

**US Air transport (ICAO / IATA passenger and cargo aircraft)**  
non-regulated

**International IATA**                      **non-regulated**  
IMDG    non-regulated

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**15. REGULATORY INFORMATION**

**US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A) Components**

None

**US. EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required Components**

None

**US. EPA CERCLA Hazardous Substances (40 CFR 302) Components**

None

**Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists**

| <b>Weight percent</b> | <b>Components</b> | <b>CAS-No.</b> |
|-----------------------|-------------------|----------------|
| 5 - 10%               | Propane-1,2-diol  | 57-55-6        |

**California Prop. 65**

**To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.**

**OSHA Hazcom Standard Rating**                      Not subject to OSHA

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**16. OTHER INFORMATION**

**Further information**

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.