



## SAFETY DATA SHEET

NAME OF PRODUCT: COMFORTCAINE® Topical Anesthetic

FILE NO.: SDS02

SDS DATE: 06/19/2014

### SECTION 1: IDENTIFICATION

**PRODUCT NAME:** COMFORTCAINE Topical Anesthetic  
**PRODUCT CODES:** 16602, 16603, 16604, 16605, 16606, 16607  
**IDENTIFIED USES:** Dentistry  
**USES ADVISED AGAINST:** Non-dental use  
**MANUFACTURER:** Harry J. Bosworth Company  
**ADDRESS:** 7227 North Hamlin Avenue, Skokie, Illinois 60076-3999, USA  
**TELEPHONE:** 847-679-3400  
**FAX:** 847-679-2080  
**EMAIL:** hjbinfo@bosworth.com  
**EMERGENCY PHONE:** 800-535-5053 (US and Canada)  
352-323-3500 (International)

### SECTION 2: HAZARDS IDENTIFICATION

**CLASSIFICATION:** Acute aquatic toxicity (Category 3)  
Chronic aquatic toxicity (Category 3)  
**LABELING:** FDA regulated drug - exempt from Regulation (US) 29 CFR 1910.1200.  
**PICTOGRAM:** None  
**SIGNAL WORD:** None  
**HAZARD STATEMENTS:** H412 Harmful to aquatic life with long lasting effects.  
**PRECAUTIONARY STATEMENTS:** P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P234 Keep only in original container.  
P235+P410 Keep cool. Protect from sunlight.  
P261 Avoid breathing dust/fume/gas/mist/vapors/spray.  
P264 Wash thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
P301+P330 IF SWALLOWED: Rinse mouth.  
P302+P352 IF ON SKIN: Wash with plenty of soap and water.  
P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308+P313 IF exposed or concerned: Get medical advice/attention.  
P332+P313 If skin irritation occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.  
P391 Collect spillage.  
P402 Store in a dry place.  
P403+P233 Store in a well-ventilated place. Keep container tightly closed.  
P501 Dispose of contents/container to an approved waste disposal plant.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

| COMPONENT  | CAS NO. | %WT   | OSHA PEL - TWA | ACGIH TLV - TWA | CLASSIFICATION                           |
|------------|---------|-------|----------------|-----------------|------------------------------------------|
| Benzocaine | 94-09-7 | 18-22 | N/E            | N/E             | Aquatic Acute 2; Aquatic Chronic 2; H411 |

For full text of H-statements mentioned in this section, see section 16.

### SECTION 4: FIRST-AID MEASURES

**INHALATION:** Move person into fresh air. If not breathing, give artificial respiration. If symptoms persist, get medical attention.  
**SKIN:** Wash off with soap and plenty of water. Get medical attention if irritation develops and persists.  
**EYE:** Rinse thoroughly with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.  
**INGESTION:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.



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### SECTION 5: FIRE-FIGHTING MEASURES

**SUITABLE EXTINGUISHING MEDIA:** Water spray, alcohol-resistant foam, dry chemical or carbon dioxide.  
**HAZARDOUS DECOMPOSITION PRODUCTS:** Oxides of carbon and nitrogen.  
**SPECIAL HAZARDS:** Product decomposes with heat. In fire, do not stream extinguishing media; action may intensify fire.  
**ADVICE FOR FIREFIGHTERS:** Wear self contained breathing apparatus for firefighting if necessary.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

**PERSONAL PRECAUTIONS:** Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.  
**ENVIRONMENTAL PRECAUTIONS:** Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.  
**CONTAINMENT AND CLEANUP:** Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Place in suitable, closed container for disposal according to official regulations.

### SECTION 7: HANDLING AND STORAGE

**PRECAUTIONS FOR SAFE HANDLING:** Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals. Avoid contact with the eyes and skin. Avoid inhalation of vapor or mist. Keep away from foodstuffs, beverages and animal feed.  
**CONDITIONS FOR SAFE STORAGE:** Store only in the original package. Keep container tightly sealed in a dry and well-ventilated place. Protect from heat and direct sunlight. Store away from food and beverages.

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**ENGINEERING CONTROLS:** Handle in accordance with good industrial hygiene and safety practice. Use with adequate general or local exhaust ventilation to maintain exposure levels below the occupational exposure limits. Local exhaust ventilation is preferred since it prevents contamination dispersion into the work area by controlling it at its source. Provide eyewash and safety shower if contact or splash hazard exists. Wash hands before breaks and at the end of work.  
**EYE/FACE PROTECTION:** Safety glasses.  
**SKIN PROTECTION:** Glove material impermeable and resistant to the product.  
**BODY PROTECTION:** Protective work clothing.  
**RESPIRATORY PROTECTION:** NIOSH (US) or CEN (EU) approved respirators and components.  
**ENVIRONMENTAL EXPOSURE:** Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

**APPEARANCE/COLOR:** Colored gel  
**ODOR:** Piña colada, cherry, strawberry, banana, grape or peppermint  
**BOILING POINT:** > 590°F (> 310°C)  
**FLASH POINT:** > 300°F (> 149°C)  
**RELATIVE DENSITY (H<sub>2</sub>O=1.0):** 1.1 g/cm<sup>3</sup>  
**WATER SOLUBILITY:** Soluble

### SECTION 10: STABILITY AND REACTIVITY

**CHEMICAL STABILITY:** Stable under recommended storage conditions.  
**HAZARDOUS REACTIONS:** Will not occur.  
**CONDITIONS TO AVOID:** Heat.  
**INCOMPATIBLE MATERIALS:** Strong oxidizing agents.  
**HAZARDOUS DECOMPOSITION PRODUCTS:** Oxides of carbon and nitrogen.

### SECTION 11: TOXICOLOGICAL INFORMATION

**POTENTIAL HEALTH EFFECTS:** **EYES:** May cause eye irritation with redness, tearing and stinging. May cause mild anesthetizing effect.  
**SKIN:** May cause skin irritation with redness, swelling and itching. May cause mild anesthetizing effect.



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### CARCINOGENICITY:

**INGESTION:** May cause mucous membrane and gastrointestinal irritation with nausea, vomiting and diarrhea. May cause anesthetizing effect.

**INHALATION:** No health effects expected. Vapors generated at high temperature may result in respiratory track irritation.

**OSHA:** No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or possible carcinogen by OSHA.

**ACGIH:** No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

**NTP:** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**IARC:** No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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## SECTION 12: ECOLOGICAL INFORMATION

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### ADVERSE EFFECTS:

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Harmful to aquatic life with long lasting effects. Avoid release to the environment.

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## SECTION 13: DISPOSAL CONSIDERATIONS

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### PRODUCT:

Offer surplus and non-recyclable solutions to a licensed disposal company. Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Disposal must be made according to official regulations.

### CONTAMINATED PACKAGING:

Dispose of as unused product.

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## SECTION 14: TRANSPORT INFORMATION

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|                       |     |
|-----------------------|-----|
| UN NUMBER:            | N/A |
| PROPER SHIPPING NAME: | N/A |
| HAZARD CLASS:         | N/A |
| PACKING GROUP:        | N/A |
| LABEL STATEMENT:      | N/A |

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## SECTION 15: REGULATORY INFORMATION

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### US FEDERAL REGULATIONS

TSCA  
CERCLA

This product is an FDA regulated drug and not subject to TSCA regulations.

This product is an FDA regulated drug and not subject to reporting requirements. There may be specific reporting requirements at the local, regional, or state level.

SARA 313 TOXIC CHEMICALS

The following components are subject to reporting levels established by SARA Title III, Section 313 (40 CFR 372): *None*.

SARA 311/312 HAZARDS

This product is an FDA regulated drug and not subject to reporting requirements.

### US STATE REGULATIONS

CALIFORNIA PROPOSITION 65:

This product may contain a chemical known to the State of California to cause cancer and/or reproductive toxicity.

### INTERNATIONAL REGULATIONS

CANADIAN ENVIRONMENTAL  
PROTECTION ACT:  
EUROPEAN INVENTORY OF EXISTING  
COMMERCIAL CHEMICAL SUBSTANCES  
(EINECS):

This product is a drug and not subject to chemical notification requirements.

This product is a drug and not subject to chemical notification requirements.

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## SECTION 16: OTHER INFORMATION

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### FULL TEXT OF H STATEMENTS REFERRED TO UNDER SECTION 3



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|                 |                                                  |
|-----------------|--------------------------------------------------|
| Aquatic Acute   | Acute aquatic toxicity                           |
| Aquatic Chronic | Chronic aquatic toxicity                         |
| H411            | Toxic to aquatic life with long lasting effects. |

### NFPA RATING

|                   |   |
|-------------------|---|
| Health Hazard     | 0 |
| Fire Hazard       | 0 |
| Reactivity Hazard | 0 |

**PREPARATION INFORMATION:** This SDS was prepared in accordance with the requirements of the OSHA Hazard Communication Standard (29 CFR 1910.1200) and is to be used only for this product.

**DISCLAIMER:** To the best of our knowledge, the information contained herein is accurate. However, The Harry J. Bosworth Company does not assume any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown health hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.