

## Zilactin®-B Long Lasting Mouth Sore Gel

**APPLIED LABORATORIES, INC.**

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 03/21/2016

Version: 1.0

## SECTION 1: Identification

## 1.1. Identification

Product form	: Mixture
Product name	: Zilactin®-B Long Lasting Mouth Sore Gel
Product code	: B5503 (0.25oz.), B3303 (0.4g), B7332 (6g)
Other means of identification	: NDC Number: 50486-550-32 UPC Number: 3-50486-55032-3, 6-24558-87332-1

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

Use of the substance/mixture : Personal Heath Care

### 1.3. Details of the supplier of the safety data sheet

Applied Laboratories, Inc.  
3240 N. Indianapolis Road  
Columbus, IN 47201  
Phone: 812.372.2607  
Fax: 812.372.1033

## 1.4. Emergency telephone number

Emergency number : 800.252.4739

## SECTION 2: Hazard(s) identification

## 2.1. Classification

<b>Classification (GHS-US)</b>	
Flammable liquids Category 2	H225
Serious eye damage/eye irritation Category 2A	H319
Reproductive toxicity Category 2	H361

Full text of U1 statements - see section 4G

## 3.3 Label elements

## GHS-US labeling

## **Hazard pictograms (CHS 11S)**



#### Signal word (GHS-11S)

- : Danger
- : H225 - Highly flammable liquid and vapor
- : H319 - Causes serious eye irritation
- : H361 - Suspected of damaging fertility or the unborn child

### Procedural statements (QHS-HS)

H361 - Suspected of damaging fertility or the unborn child

- : P201 - Obtain special instructions before use
- P202 - Do not handle until all safety precautions have been read and understood
- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P233 - Keep container tightly closed
- P240 - Ground/bond container and receiving equipment
- P241 - Use explosion-proof electrical/ventilating/lighting equipment
- P242 - Use only non-sparking tools
- P243 - Take precautionary measures against static discharge
- P264 - Wash hands and other exposed areas thoroughly after handling
- P280 - Wear eye protection
- P303 + P361 + P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
- 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
- P337+P313 - If eye irritation persists: Get medical advice/attention
- P370+P378 - In case of fire: Use foam, dry powder, carbon dioxide, water spray to extinguish
- P403+P235 - Store in a well-ventilated place. Keep cool

# Zilactin®-B Long Lasting Mouth Sore Gel

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

### 2.3. Other hazards

No additional information available

### 2.4. Unknown acute toxicity (GHS US)

Not applicable

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Ethyl alcohol	(CAS No) 64-17-5	62	Flam. Liq. 2, H225
Salicylic acid	(CAS No) 69-72-7	2.5	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318
Boric acid	(CAS No) 11113-50-1	1	Repr. 2, H361

Full text of H-phrases: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general

: Never give anything by mouth to an unconscious person. If exposed or concerned: Get medical advice/attention.

First-aid measures after inhalation

: Allow victim to breathe fresh air. Allow the victim to rest.

First-aid measures after skin contact

: Rinse skin with water/shower. Remove/Take off immediately all contaminated clothing.

First-aid measures after eye contact

: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion

: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries

: Suspected of damaging fertility or the unborn child.

Symptoms/injuries after eye contact

: Causes serious eye irritation.

### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media

: Foam. Dry powder. Carbon dioxide. Water spray.

Unsuitable extinguishing media

: Do not use a heavy water stream.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard

: Highly flammable liquid and vapor.

Explosion hazard

: May form flammable/explosive vapor-air mixture.

### 5.3. Advice for firefighters

Firefighting instructions

: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting

: Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures

: Remove ignition sources. Use special care to avoid static electric charges. No smoking.

#### 6.1.1. For non-emergency personnel

Emergency procedures

: Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

Protective equipment

: Equip cleanup crew with proper protection.

Emergency procedures

: Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

# Zilactin®-B Long Lasting Mouth Sore Gel

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

### 6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Additional hazards when processed : Handle empty containers with care because residual vapors are flammable.  
Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor. No smoking. Use only non-sparking tools. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.  
Hygiene measures : Wash hands and other exposed areas thoroughly after handling.

### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Proper grounding procedures to avoid static electricity should be followed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting equipment.  
Storage conditions : Keep only in the original container in a cool, well ventilated place. Keep in fireproof place. Keep container tightly closed.  
Incompatible products : None known.  
Incompatible materials : Sources of ignition. Direct sunlight. Heat sources.  
Storage temperature : 15 - 30 °C

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Boric acid (11113-50-1)

Not applicable

#### Salicylic acid (69-72-7)

Not applicable

#### Ethyl alcohol (64-17-5)

ACGIH	ACGIH STEL (ppm)	1000 ppm
OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	1900 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) (ppm)	1000 ppm
IDLH	US IDLH (ppm)	3300 ppm (10% LEL)
NIOSH	NIOSH REL (TWA) (mg/m <sup>3</sup> )	1900 mg/m <sup>3</sup>
NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm

### 8.2. Exposure controls

Personal protective equipment : Avoid all unnecessary exposure.  
Hand protection : Not typically required.  
Eye protection : Chemical goggles or safety glasses.  
Respiratory protection : Not typically required under normal conditions of use.  
Other information : Follow good hygienic work practices.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Gel  
Color : Amber  
Odor : Mild alcohol  
Odor threshold : No data available  
pH : No data available

# Zilactin®-B Long Lasting Mouth Sore Gel

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Melting point	: No data available
Freezing point	: No data available
Boiling point	: 80 °C
Flash point	: 15.6 °C
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Vapor pressure	: No data available
Relative density	: 0.9 - 0.94
Relative vapor density at 20 °C	: No data available
Solubility	: No data available
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available

### 10.2. Chemical stability

Stable under normal conditions of storage and use.

### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures. Open flame.

### 10.5. Incompatible materials

No known incompatibilities.

### 10.6. Hazardous decomposition products

Carbon monoxide. Carbon dioxide. May release flammable gases.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Not classified

Salicylic acid (69-72-7)	
LD50 oral rat	891 mg/kg
LC50 inhalation rat (mg/l)	> 900 mg/m <sup>3</sup> (Exposure time: 1 h)
ATE US (oral)	891.000 mg/kg body weight

Ethyl alcohol (64-17-5)	
LC50 inhalation rat (mg/l)	124.7 mg/l/4h
ATE US (vapors)	124.700 mg/l/4h
ATE US (dust, mist)	124.700 mg/l/4h

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitization : Not classified

# Zilactin®-B Long Lasting Mouth Sore Gel

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential Adverse human health effects and symptoms	: No additional information available.
Symptoms/injuries after eye contact	: Causes serious eye irritation.

## SECTION 12: Ecological information

### 12.1. Toxicity

Salicylic acid (69-72-7)	
EC50 Daphnia 1	870 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
Ethyl alcohol (64-17-5)	
LC50 fish 1	12.0 - 16.0 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	9268 - 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 2	2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

### 12.2. Persistence and degradability

Zilactin®-B Long Lasting Mouth Sore Gel	
Persistence and degradability	Not established.
Ethyl alcohol (64-17-5)	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

Zilactin®-B Long Lasting Mouth Sore Gel	
Bioaccumulative potential	Not established.
Salicylic acid (69-72-7)	
BCF fish 1	>= 1000
Log Pow	0 - 2.26 (at 37 °C)
Ethyl alcohol (64-17-5)	
Log Pow	-0.32
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

Other information : Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations	: Dispose in a safe manner in accordance with local, state and federal regulations.
Additional information	: Handle empty containers with care because residual vapors are flammable.
Ecology - waste materials	: Avoid release to the environment.

# Zilactin®-B Long Lasting Mouth Sore Gel

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Consumer Commodity, ORM-D

#### TDG

No additional information available

#### Transport by sea

No additional information available

#### Air transport

No additional information available

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

Zilactin®-B Long Lasting Mouth Sore Gel	
SARA Section 311/312 Hazard Classes	Delayed (chronic) health hazard Fire hazard Immediate (acute) health hazard

#### 15.2. International regulations

##### CANADA

###### Boric acid (11113-50-1)

Listed on the Canadian DSL (Domestic Substances List)

###### Salicylic acid (69-72-7)

Listed on the Canadian DSL (Domestic Substances List)

###### Ethyl alcohol (64-17-5)

Listed on the Canadian DSL (Domestic Substances List)

##### EU-Regulations

###### Boric acid (11113-50-1)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

###### Salicylic acid (69-72-7)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

###### Ethyl alcohol (64-17-5)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

##### National regulations

###### Boric acid (11113-50-1)

Listed on the AICS (Australian Inventory of Chemical Substances)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on the Korean ECL (Existing Chemicals List)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on Turkish inventory of chemical

###### Salicylic acid (69-72-7)

Listed on the AICS (Australian Inventory of Chemical Substances)

Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)

Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory

Listed on the Korean ECL (Existing Chemicals List)

Listed on NZIoC (New Zealand Inventory of Chemicals)

Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Listed on the Canadian IDL (Ingredient Disclosure List)

Listed on INSQ (Mexican national Inventory of Chemical Substances)

Listed on Turkish inventory of chemical

# Zilactin®-B Long Lasting Mouth Sore Gel

## Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

### Ethyl alcohol (64-17-5)

Listed on IARC (International Agency for Research on Cancer)  
Listed on the AICS (Australian Inventory of Chemical Substances)  
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)  
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory  
Listed on the Korean ECL (Existing Chemicals List)  
Listed on NZIoC (New Zealand Inventory of Chemicals)  
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)  
Listed on the Canadian IDL (Ingredient Disclosure List)

### 15.3. US State regulations

Ethyl alcohol (64-17-5)				
U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significance risk level (NSRL)
Yes	Yes	No	No	

## SECTION 16: Other information

Other information : None.

Full text of H-phrases:

H225	Highly flammable liquid and vapor
H302	Harmful if swallowed
H318	Causes serious eye damage
H319	Causes serious eye irritation
H361	Suspected of damaging fertility or the unborn child

SDS US (GHS HazCom 2012)

*The information herein is accurate to the best knowledge of Applied Laboratories, Inc. at the time of publication. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The user should determine how to use this information following federal, state, and local guidelines. No warranty, express or implied, is made for the fitness for use of this product in the user's operation.*