



Auralgan

Preparation Date 20-Aug-2007

Revision Date Not applicable

Revision Number Not applicable

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Auralgan
Common Name Not available
Chemical Name Not applicable
Synonyms Auralgan Solution
Product Use Pharmaceutical product
Classification Not available

Supplier Wyeth
P.O. Box 8299
Philadelphia, PA 19101 USA.
Telephone: 1-610-688-4400

Emergency Telephone Number Chemtrec USA, Puerto Rico, Canada 1-800-424-9300
Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical Liquid **Physical State** Liquid **Odor** Not available

Potential Physical Hazards None known.

Potential Health Effects

Eyes May cause eye irritation.
Skin May cause skin irritation.
Inhalation May cause irritation of respiratory tract.
Ingestion The most common effects may include nausea, vomiting, dizziness, dilated pupils, blueish skin color, kidney damage, convulsions, allergic reactions and coma.

Please see Patient Package Insert for further information.

Therapeutic Target Organ(s) Not available

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects There is no known ecological information for this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Antipyrine	60-80-0	4 - 4.5%

Common Name	CAS-No	Composition
Benzocaine	94-09-7	1 - 1.15%
Glycerine	56-81-5	94 - 95%
Oxyquinoline Sulfate	134-31-6	< 1%

4. FIRST AID MEASURES

Eye Contact	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
Skin Contact	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
Inhalation	Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.
Ingestion	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties	Not flammable.
Extinguishing Media	
Suitable Extinguishing Media	Use water spray, foam, dry chemical or carbon dioxide.
Unsuitable Extinguishing Media	Do NOT use water jet.
Fire Fighting	Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.
Hazardous Combustion Products	Carbon oxides, nitrogen oxides.
Protective Equipment and Precautions for Firefighters	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Refer to protective measures listed in Sections 7 and 8.
Environmental Precautions	Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.
Methods for Containment	Not available
Methods for Cleaning up	Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling	For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
Storage	No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name Glycerine Benzocaine Antipyrine	Exposure Guideline 10 mcg/m ³ (ACGIH) 500 mcg/m ³ None assigned
Engineering Controls	Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.
Personal Protective Equipment	
Eye/face Protection	Provide eye protection based on risk assessment.
Skin Protection	Wear nitrile or latex gloves. Wear protective garment.
Respiratory Protection	Base respirator selection on a risk assessment.
General Hygiene Considerations	When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
Other	Limit access to only personnel trained in the safe handling of this material Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Pharmaceutical Liquid	Physical State	Liquid
Color	Clear	Odor	Not available
Odor Threshold	Not available		
Molecular Formula	Not applicable	Molecular Weight	Not applicable
pH	Not applicable		
Specific Gravity	Not applicable	Water Solubility	Not applicable
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Pressure	Not applicable
Boiling Point	Not applicable	Autoignition Temperature	Not applicable
Flash Point	Not applicable	Method	None
Melting Point	Not applicable		
Flammability Limits in Air	Upper Not applicable	Lower	Not applicable
Explosion Limits	Upper Not applicable	Lower	Not applicable

10. STABILITY AND REACTIVITY

Chemical Stability	Stable at room temperature.
Conditions to Avoid	No data available
Materials to Avoid	No materials to be especially mentioned.
Hazardous Decomposition Products	None under normal use.
Possibility of Hazardous Reactions	None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Antipyrine

LD50 Oral	1705 mg/kg rats, 1310 mg/kg mice
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Benzocaine

LD50 Oral	3042 mg/kg rats
Acute Dermal Irritation	Mild irritation effect in guinea pigs.
Primary Eye Irritation	Not available
Sensitization	Not available

Glycerine

LD50 Oral	12.6 gm/kg rats, 4090 mg/kg mice
Acute Dermal Irritation	Mild irritation effect in rabbits.
Primary Eye Irritation	Irritating to rabbit eyes.
Sensitization	Not available

Multiple Dose Toxicity

Antipyrine

No Toxicologic Effect Dose/Species/Study Length:	No data available
---	-------------------

Benzocaine

No Toxicologic Effect Dose/Species/Study Length:	No data available
---	-------------------

Glycerine

No Toxicologic Effect Dose/Species/Study Length:	In a 180-day study in rats, 5% in drinking water caused calcification in the renal tubules. A further drinking water study in rats resulted in increased urinary levels of oxalic acid.
---	---

Maximum Tolerated Dose (MTD), Oral

Antipyrine

Carcinogenicity	No data available
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of <i>in vitro</i> and <i>in vivo</i> assays.
Reproductive Toxicity	In a two-generation study in rats a slight decrease in body weight gain was observed in parents and F ₂ generation. No effects on fertility were observed in F ₁ generation.
Developmental Toxicity	Developmental toxicity studies in rats have been conducted in rats and rabbits. In rats, after maternal toxic doses Fetotoxicity was evident including decreased body weight, food consumption and motility, blood around nose and mouth, increased embryo/fetal mortality and anomalies of scapula and ribs. In rabbits, although maternally toxic doses showed a decreased body weight in dams and increased embryotoxicity, no compound-related anomalies in fetuses were observed.
Benzocaine	
Carcinogenicity	No data available
Genetic Toxicity	No data available
Reproductive Toxicity	No data available
Developmental Toxicity	No data available
Glycerine	
Carcinogenicity	No data available
Genetic Toxicity	Non-mutagenic in Ames test; non-clastogenic in chromosomal aberrations assay.
Reproductive Toxicity	Studies in rats were found to have no effect on fertility.
Developmental Toxicity	No teratogenic effects were observed in mice, rats and rabbits given large oral doses of >1 g/kg/day during pregnancy. In a further study, increased rates of embryonic and fetal death were seen when rats were dosed IV at 4 mg/kg; this was not seen in rabbit or mice studies.
Antipyrine	
Target Organ(s) of Toxicity	No data available
Benzocaine	
Target Organ(s) of Toxicity	No data available
Glycerine	
Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information	Not available
Ecotoxicity	Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT) Not regulated

Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated
Transport of Dangerous Goods by Rail (RID)	Not regulated
Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

This product does not contain any HAPs.

State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

Canada

Not classified

WHMIS Hazard Class

Non-controlled

European Union

In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References	See Patient Package Insert for more information.
Revision Summary	Not applicable

Disclaimer:

The information, data, recommendations, and suggestions appearing in this material safety data sheet (MSDS) and/or in materials regarding our active pharmaceutical ingredients (APIs) or products are based upon tests and data believed to be reliable as of the date of publication. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS MADE WITH REGARD TO THE INFORMATION PROVIDED IN THE MSDS, REGARDING THE API, OR THE PRODUCT TO WHICH THE INFORMATION PERTAINS. Accordingly, Wyeth will not be responsible for any damages resulting from use of, or reliance upon, this information as conditions of use are beyond our control. Users are responsible for assuring the safety of their workers and safe operating conditions, and for determining whether the API or product is suitable for their particular purposes. Users shall assume all risks of their use, handling, and disposal of the API and/or product in accordance with all appropriate and applicable regulations. This information relates only to the API or product designated herein, and does not relate to its use in combination with any other API, material, product, or process. No permission is granted for the use of any API or product in a manner that might infringe on existing patents.

End of MSDS