

MATERIAL SAFETY DATA SHEET

Belladonna and Opium Suppositories

PADDOCK LABORATORIES, INC. 3940 QUEBEC AVENUE NORTH MINNEAPOLIS, MINNESOTA 55427 PHONE: (763)-546-4676	<u>EMERGENCY ASSISTANCE:</u>	
	CHEMTREC	800-424-9300 202-483-7616 PADDOCK TECH. ASST. 800-328-5113

DATE PREPARED: February 19, 1996

By: Matthew Greuel

Revised 12/10/96

SECTION 1 - PRODUCT IDENTIFICATION AND HAZARDOUS COMPONENTS

PRODUCT NAME: Belladonna and Opium Suppositories 16.2 mg / 60 or 30 mg

SYNONYMS: None

MOLECULAR FORMULA: Mixture

MOLECULAR WEIGHT: N/A

CHEMICAL NAME: N/A

CHEMICAL FAMILY: N/A

<u>INGREDIENT (CAS NUMBER)</u>	<u>%</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>
Polyethylene Glycol (25322-68-3)	92	N/A	N/A
Polysorbate 60 (9005-67-8)	<5.0	N/A	N/A
Opium Powder	<5.0	N/A	N/A

Which might contain any or all of the following

- Morphine (57-27-2)
- Opium (8088-60-4)
- Thebaine (115-37-7)
- Codeine (76-57-3)
- Narcotine /Noscapine (128-62-10)
- Parzone (125-28-0)
- Papaverine (58-74-2)
- Hydrocodone (34195-34-1)

Belladonna Extract (none)	<1.0	N/A	N/A
---------------------------	------	-----	-----

Which might contain any or all of the following

- Lactose (63-42-3)
- Atropine (51-55-8)
- Hyoscamine (101-31-5)
- d-Scopolamine (64069-63-2)
- l-Scopolamine (51-34-3)

SECTION 2 - PHYSICAL AND CHEMICAL CHARACTERISTICS

BOILING POINT: N/A

VAPOR PRESSURE: N/A

MELTING POINT: 55-61^o C

VAPOR DENSITY: N/A

SPECIFIC GRAVITY: <1.2 @25^oC
(WATER = 1)

EVAPORATION RATE: N/A
(BUTYL ACETATE = 1)

WATER SOLUBILITY: Soluble

WATER REACTIVE: No

APPEARANCE AND ODOR: Brown to greenish-brown opaque solid with visible particulates, bullet-shaped suppository with a characteristic opium smell

SECTION 3 - FIRE AND EXPLOSION DATA

FLASH POINT (METHOD): N/A

NFPA RATING: N/A

AUTOIGNITION TEMPERATURE: N/A

FLAMMABLE LIMITS: LOWER: N/A UPPER: N/A

EXTINGUISHING MEDIA: Water spray, carbon dioxide, dry chemical, or foam as appropriate for surrounding fire conditions and materials.

SPECIAL FIRE FIGHTING PROCEDURES: Fire fighters should wear self-contained breathing apparatus and full protective clothing.

UNUSUAL FIRE AND EXPLOSION HAZARDS: As with any organic compound, this material may emit toxic carbon monoxide and dioxide fumes when heated to decomposition as well as nitrogen oxides (as under fire conditions).

SECTION 4 - REACTIVITY HAZARD DATA

STABILITY: Stable (X) Unstable ()

INCOMPATIBILITY (MATERIALS TO AVOID): Acids, oxidizing materials.

HAZARDOUS DECOMPOSITION PRODUCTS: As with any organic compound, this material may emit toxic carbon monoxide and dioxide fumes when heated to decomposition as well as nitrogen oxides.

HAZARDOUS POLYMERIZATION: May Occur () Will Not Occur (X)

SECTION 5 - HEALTH HAZARD DATA

TOXICITY: Data for major components of opium powder

Morphine		
LD ₅₀ :	Oral (rat)	335mg/kg
	Oral (mouse)	524mg/kg
Codeine		
LD ₅₀ :	Oral (rat)	427 mg/kg
	Oral (mouse)	250 mg/kg

CARCINOGEN LISTED BY:	NTP	Yes ()	No (X)
	IARC	Yes ()	No (X)
	OSHA	Yes ()	No (X)
	Other	Yes (X)	No ()

SIGNS AND SYMPTOMS OF OVEREXPOSURE:

INHALATION: Narcotic. Use by intended route only.

EYE CONTACT: May cause irritation. May cause narcotic effect (pupil contraction)

SKIN CONTACT: May cause irritation.

INGESTION: Narcotic. Use by intended route only. May cause irritation of the gastrointestinal tract.

CHRONIC EFFECTS OF OVEREXPOSURE: Can lead to habituation and addiction.

MEDICAL CONDITIONS AGGRAVATED BY OVEREXPOSURE: Some individuals may become sensitized from exposure and develop skin rashes, coughs, stuffy nose, asthma, and other allergic complaints.

OTHER PRECAUTIONS TO CONSIDER: Narcotic. May cause addiction. This product, contains polyethylene glycol base which may contain the following: Acetaldehyde (75-07-0), Dioxane (123-91-1), Ethylene Oxide (75-21-8) and Formaldehyde (50-00-00).

EMERGENCY FIRST AID PROCEDURES:

INHALATION: Not likely under normal usage. Remove from exposure. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

EYE CONTACT: Flush with water for at least 15 minutes. If irritation persists or develops seek medical attention.

SKIN CONTACT: Wash thoroughly with soap and water. If irritation persists or develops seek medical attention.

INGESTION: Induce vomiting. Seek medical attention.

SECTION 6 - CONTROL AND PROTECTIVE MEASURES

RESPIRATORY PROTECTION: Not necessary under normal conditions.

PROTECTIVE GLOVES: Latex.

EYE PROTECTION: Safety glasses or goggles. Avoid wearing contact lenses when working with this or any chemical due to the possibility of increased severity of eye damage.

VENTILATION: General or local exhaust recommended.

OTHER PROTECTIVE EQUIPMENT: Appropriate laboratory apparel.

HYGIENIC WORK PRACTICES: Do not eat, drink or smoke near this material. Wash thoroughly after handling and wash contaminated clothing before reuse.

SECTION 7 - HANDLING AND STORAGE PRECAUTIONS

HANDLING PRECAUTIONS: Avoid contact with eyes, skin or clothing and avoid breathing dust. Wash thoroughly after handling and wash any contaminated clothing before reuse.

STORAGE PRECAUTIONS: CONTROLLED SUBSTANCE (Schedule II). Store in a tight container in a cool, dry, well ventilated location.

SECTION 8 - SPILL AND DISPOSAL PROCEDURES

STEPS TO BE TAKEN IN CASE OF SPILL OR DISCHARGE: Wear all protective gear including: NIOSH/MSHA approved respirator, goggles, gloves. Vacuum or sweep up spillage and place in a tight container. Wash and ventilate spill site. Wash thoroughly or shower after handling and wash all clothing and protective gear before reuse.

WASTE DISPOSAL METHOD: Dispose of in accordance with all applicable local, state, federal, and environmental regulations.

SECTION 9 - REGULATORY INFORMATION

STATUS ON SUBSTANCE LISTS: The concentrations shown are maximum or ceiling levels (weight %) to be used for calculation for regulations. Trade secrets are indicated by "TS".

FEDERAL EPA: Comprehensive Environmental Response Compensation, and Liability Act of 1980 (CERCLA) requires notification of the National Response Center of release of quantities of Hazardous Substances equal to or greater than the reportable quantities (RQs) in 40 CFR 302.4.

Components present in this product at a level which could require reporting under the statute are:

CHEMICAL	CAS NUMBER	UPPER BOUND CONCENTRATION %
Ethylene Oxide	75-21-8	0.0005
Dioxane	123-91-1	0.0005

Superfund Amendments and Reauthorization Act of 1986 (SARA) Title III requires emergency planning based on Threshold Planning Quantities (TPQs) and release reporting based on reportable Quantities (RQs) in 40 CFR 355 (used for SARA 302, 311 and 312).

Components present in this product at a level which could require reporting under the statute are: NONE

Superfund Amendments and Reauthorization Act of 1986 (SARA) Title III requires submission of annual reports of release of toxic chemicals that appear in 40 CFR 372 (for SARA 313). This information must be included in all MSDSs that are copied and distributed for this material.

Components present in this product at a level which could require reporting under the statute are: NONE

TSCA INVENTORY STATUS: The ingredients of this product are on the TSCA inventory.

STATE RIGHT TO KNOW:

California Proposition 65: This product contains trace levels of ACETALDEHYDE, DIOXANE, ETHYLENE OXIDE, and FORMALDEHYDE which the state of California has found to cause cancer, birth defects or other reproductive harm.

Massachusetts 105 CMR 670.000 Right-to-Know, Substance List (MSL) Hazardous Substances and Extraordinarily Hazardous Substances on the MSL must be identified when present in products.

Components present in this product at a level which could require reporting under the statute are:

CHEMICAL	CAS NUMBER	UPPER BOUND CONCENTRATION%
Acetaldehyde	75-07-0	0.0006
Dioxane	123-91-1	0.0005
Ethylene Oxide	75-21-8	0.0005
Formaldehyde	50-00-0	0.0004

Pennsylvania Right-To-Know, Hazardous Substance List Hazardous Substances and Special hazardous Substances on the List must be Identified when present in products. Components present in this product at a level which could require reporting under the statute are: NONE

SECTION 10 - DISCLAIMER

The information contained in this Material Safety Data Sheet has been compiled from reliable sources and is believed to be correct as of the date issued. It is the responsibility of the user to determine the appropriateness and applicability to their situation. Paddock Laboratories, Inc. disclaims any expressed or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental, or consequential damages from use or reliance on the above information.

DEFINITIONS OF ABBREVIATIONS USED:

ACGIH:	American Conference of Governmental Industrial Hygienists
CAS:	Chemical Abstract Service
IARC:	Internal Agency for Research on Cancer
IDLH:	Immediately Dangerous to Life or Health level
LC ₅₀ :	Median Lethal Concentration
LD ₅₀ :	Median Lethal Dose
MSHA:	Mine Safety and Health Administration
N/A:	Not available
NIOSH:	National Institute for Occupational Safety and Health
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Administration
PEL:	Permissible Exposure Limit
STEL:	Short Term Exposure Limit
TLV:	Threshold Limit Value
TWA:	Time Weighted Average