Merck Animal Health
One Merck Dr.
Whitehouse Station, NJ 08889

MATERIAL SAFETY DATA SHEET

Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: **BUTALEX Injection**

SYNONYM(S): BUTALEX Injection

MSDS NUMBER: SP001426

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Liquid
Clear, Red
Odor unknown
Irritating to eyes.
May be irritating to skin.
May cause effects to:
blood
May cause birth defects.

POTENTIAL HEALTH EFFECTS:

SECTION 2. HAZARDS IDENTIFICATION

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material. Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) are presented.

N-methyl-2-pyrrolidone (NMP) is a moderate to severe eye irritant in humans. Prolonged occupational exposure to low concentrations has caused chronic eye irritation and headache. Prolonged or repeated skin contact may cause dermatitis with blistering, edema, and erythema. In animal studies, fetotoxicity and teratogenicity was observed.

Based on animal studies, BUTALEX may cause slight skin irritation.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Buparvaquone	88426-33-9	5
N-Methyl-2-Pyrrolidone	872-50-4	50 - 60
Coconut Oil Fractionated	8001-31-8	30 - 40
Sorbitan Monooleate	1338-43-8	10 - 20

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: DO NOT induce vomiting. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth, drink a glass of water and IMMEDIATELY consult a physician.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO2), extinguishing powder or water spray.

SECTION 5. FIRE FIGHTING MEASURES

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:
Store out of direct light. Store up to 37 deg C.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

OCCUPATIONAL EXPOSURE BAND (OEB):
OEB 3: 10-100 mcg/m^3. Materials in an OEB 3 category are considered moderate health hazards. The OEB is a range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

EXPOSURE CONTROLS
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection:

In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES

No exposure limits are available for the active ingredient(s) or any other hazardous ingredient in this formulation.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Liquid
COLOR: Clear, Red
ODOR: Odor unknown
SPECIFIC GRAVITY: 1.00 at 20 deg C
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
Extremes of temperature. Direct light.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the formulated product unless indicated otherwise.

ACUTE TOXICITY DATA

SKIN:
Butalex: Slight irritant

N-methyl-2-pyrrolidone (NMP): Dermal LD50 (rabbit): 8000 mg/kg
NMP was a moderate skin irritant to humans after a 24 hour exposure. It was not irritating after a 8 hour exposure. NMP was not a skin irritant to guinea pigs.

EYE:
Buparvaquone: Slight irritant.

N-methyl-2-pyrrolidone was a moderate to severe eye irritant to humans and rabbits.

ORAL:
Butalex: Low oral toxicity.

N-methyl-2-pyrrolidone: Oral LD50 (rat): 3900-4300 mg/kg

DERMAL AND RESPIRATORY SENSITIZATION:
N-methyl-2-pyrrolidone did not cause skin sensitization in guinea pigs.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Subchronic (6 months) animal studies where Butalex was administered to animals at high doses levels resulted in a transient prolongation of blood clotting time.

Inhalation toxicity of N-methyl-2-pyrrolidone (NMP) was evaluated in male and female rats exposed to 0.1, 0.5, or 1.0 mg/L for four weeks. Mortality was seen in animals in the high-dosage group during the first nine days of exposure. Treatment-related effects noted in the high-dosage group included lethargy, irregular heartbeat, increased neutrophils, decreased lymphocytes, pulmonary edema and congestion, necrosis in hemopoietic cells, and atrophy or necrosis in lymphoid tissue. Surviving animals recovered following a two-week of recovery period.

Mice and rats were fed NMP dosages ranging from 2,000 to 30,000 ppm and 500 to 10,000 ppm for 28 days in rats and mice, respectively. Decreased body weight gains as well as clinical chemical changes, indicating possible alterations in lipid, protein, and carbohydrate metabolism, occurred in male rats dosed with 18,000 ppm and in both sexes dosed with 30,000 ppm. In mice, swelling of the epithelium of the distal parts of the renal tubules was observed at dosages of 7,500 ppm or higher. The NOAELs for these studies were 6,000 ppm for male rats, 18,000 ppm for female rats, and 2,500 ppm for mice. In a reproductive study, rats exposed to 116 ppm of NMP for 100 exposure days had a detectable decrease in response to sound.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
N-methyl-2-pyrrolidone (NMP) was not teratogenic to the offspring of rats exposed to 0.1 or 0.36 mg/L by inhalation from days 6 to 15 of gestation. No adverse reproductive effects were found in male or female rats exposed to airborne concentrations up to 116 ppm (6hr/day x 100 days) in a two-generation reproductive study. NMP was fetotoxic and teratogenic to the offspring of mice and rats following dermal, oral, or intraperitoneal exposure during gestation [NOEL: 1154 mg/kg/day (oral; mice); 237 mg/kg/day (oral and dermal; rats); LOEL: 166 mg/kg/day (IP; mice)]. Maternal toxicity was also observed in these studies.

MUTAGENICITY / GENOTOXICITY:
N-methyl-2-pyrrolidone (NMP) induced aneuploidy in Saccharomyces. NMP was negative in a bacterial (Salmonella) mutagenicity assay, an in vitro mouse micronucleus assay, and in an in vitro chromosomal aberration assay in CHO cells.

CARCINOGENICITY:
N-methyl-2-pyrrolidone was not carcinogenic in rats exposed, by inhalation, to 0.04 to 0.4 mg/L for six hours/day for two years.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

There are no ecototoxicity data available for this product or its components.

ENVIRONMENTAL DATA

There are no environmental data available for this product or its components.

SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

INGREDIENT	TSCA
N-Methyl-2-Pyrrolidone	X
Coconut Oil Fractionated	X
Sorbitan Monooleate	X

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
N-Methyl-2-Pyrrolidone	D		3716		X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
N-Methyl-2-Pyrrolidone	X			

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations. "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

X: Listed on applicable state hazardous substance or right-to-know lists.
D: Developmental hazard

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

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DEPARTMENT ISSUING MSDS:
Global Safety & the Environment
Merck & Co., Inc.
One Merck Drive
Whitehouse Station, NJ 08889

MERCK MSDS HELPLINE:
(800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

MSDS CREATION DATE: 06-Dec-1996

SUPERSEDES DATE: 04-Dec-2009

SIGNIFICANT CHANGES (US SUBFORMAT): New regional format, OEB