

SAFETY DATA SHEETS

This SDS packet was issued with item:

078073740

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078081632



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:	Exspot For Dogs (with Dowanol)
SYNONYM(S):	Exspot II Defend Exspot Dog-Net Spot On Exspot Proticall Insecticide for Dogs Pulvex Spot Exil Tick Off (Holland)
MSDS NUMBER:	SP000048
EMERGENCY NUMBER(S):	(908) 423-6000 (24/7/365) English Only Transportation Emergencies - CHEMTREC: (800) 424-9300 (Inside Continental USA) (703) 527-3887 (Outside Continental USA) 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
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
Dark amber
Strong chemical odor
Flammable.
Harmful if swallowed.
May be harmful if absorbed through skin.
May be harmful by inhalation.
Irritating to eyes.
May be irritating to respiratory system.
May cause effects to:
central nervous system
Very toxic to aquatic organisms.

POTENTIAL HEALTH EFFECTS:

This product contains permethrin, a synthetic Type I pyrethroid ester. Occupational exposure to permethrin has induced temporary skin and facial sensations (feelings of numbness and tingling). Workers exposed to permethrin have also reported irritative symptoms, such as itching and burning of the skin, itching and irritation of the eyes, and irritation of the upper respiratory tract as well as increased nasal secretions. Anaphylactic reactions including bronchospasm and shock may occur in very sensitive individuals. Ingestion of large amounts may cause central nervous system effects resulting in seizures, coma, and respiratory arrest.

Ingestion of pyrethroid esters has caused stomach pain, nausea and vomiting, headache, dizziness, numbness and tingling, anorexia, fatigue, tremors, and intermittent convulsions.

Propylene glycol methyl ether (PGME) is a major constituent in Dowanol PM. PGME is transiently painful to the eyes and can be absorbed through the skin in toxic amounts after repeated high-dose exposure. The vapors of PGME are essentially intolerable to humans at acutely toxic concentrations. Concentrations that might cause effects from repeated exposures are very disagreeable (irritating to the eyes and mucous membranes and nauseating to some persons).

LISTED CARCINOGENS

Permethrin technical is classified by IARC as a Group 3 carcinogen (unclassifiable as to carcinogenicity in humans). Fields in the above table that do not contain data indicate that the materials have not been classified as human or animal carcinogens.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

CHEMICAL FAMILY: Pyrethroid insecticide

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
Permethrin Technical	52645-53-1	65
Dowanol PM: (Propylene Glycol Methyl Ether)	107-98-2	30-40

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. Refer to the package insert or product label for handling guidance for the consumer.

MSDS NAME: Exspot For Dogs (with Dowanol)

MSDS NUMBER: SP000048

Latest Revision Date: 23-Sep-2011

Page 2 of 7

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, IMMEDIATELY flush exposed skin thoroughly with plenty of water. While wearing protective gloves, remove any contaminated clothing, including shoes and continue to wash skin thoroughly with soap and water for at least 15 minutes. Get IMMEDIATE medical attention. Treat symptomatically.
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 unless under the direction of a qualified medical professional or Poison Control Center. IMMEDIATELY consult a physician. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth and drink a glass of water.
NOTE TO PHYSICIAN:	Exspot For Dogs is intended for the treatment and control of fleas and ticks in dogs. It contains permethrin, a synthetic Type I pyrethroid ester.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point:	37.8 to 40 deg C (100 to 104 deg F)
Classification:	Combustible (US OSHA Criteria) Flammable (EU Criteria) Combustible (Canada WHMIS Criteria)
UEL:	6.1 Vol %
LEL:	2.3 Vol %
Autoignition Temperature:	270 deg C (518 deg F)

SPECIAL FIRE FIGHTING PROCEDURES:

Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:

Alcohol foam, dry chemical, or carbon dioxide. Water may be ineffective.

UNSUITABLE EXTINGUISHING MEDIA:

Water.

THERMAL DECOMPOSITION PRODUCTS:

Hydrogen chloride (HCl). Carbon monoxide (CO). Carbon dioxide (CO₂).

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.

ENVIRONMENTAL PRECAUTIONS:

This product is very toxic to aquatic organisms. Do not allow product to reach ground water, water course, sewage or drainage systems.

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

SECTION 7. HANDLING AND STORAGE

HANDLING:

Avoid skin and eye contact. 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 in a cool, dry, well ventilated area.

SPECIAL PRECAUTIONS:

Keep away from ignition sources.

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.

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:	<p>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.</p> <p>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.</p>

EXPOSURE LIMIT VALUES

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Dowanol PM: (Propylene Glycol Methyl Ether)	107-98-2	100 ppm	

INGREDIENT	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Dowanol PM: (Propylene Glycol Methyl Ether)	107-98-2	150 ppm			

Fields in the above table(s) that do not contain data indicate that exposure limits are not available for those endpoints.

MSDS NAME: Exspot For Dogs (with Dowanol)

MSDS NUMBER: SP000048

Latest Revision Date: 23-Sep-2011

Page 4 of 7

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Liquid
COLOR: Dark amber
ODOR: Strong chemical odor
BOILING POINT / RANGE: 120 deg C
VAPOR PRESSURE: 12 hPa @ 20 deg C
SPECIFIC GRAVITY: 1.09
SOLUBILITY:
Water: Not miscible

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:

Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:

Oxidizers. Keep away from heat, sparks, open flame, and direct sunlight.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:

Hydrogen chloride (HCl). Chlorine. Carbon monoxide (CO). Carbon dioxide (CO₂).

SECTION 11. TOXICOLOGICAL INFORMATION

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

ACUTE TOXICITY DATA

INHALATION:

Exspot (with Dowanol): No mortality occurred in rats exposed to 2.19 mg/L for 4 hours. Clinical effects noted during the study included crusting around the nose, hypersensitivity, piloerection, and polyuria. Effects resolved by Day 7 of the study.

Permethrin: LC50 (4hr): 2.3 mg/L (rat)

SKIN:

Slightly irritating.

Exspot (with Dowanol): Very slight erythema was observed in 1/6 rabbits at the 1-hour observation and in 3/6 rabbits at the 24-hour observation. Effects resolved with 48 hours. The primary irritation index (PII) was 0.2.

Permethrin: LD50: >2000 mg/kg (rabbit)

Propylene glycol methyl ether: LD50: 13,500 mg/kg (rabbit)

EYE:

Slightly irritating.

Exspot (with Dowanol): Slight to moderate conjunctival irritation (redness, swelling, or chemosis) was observed in rabbits (6/6 rabbits with unwashed eyes and in 3/3 rabbits with washed eyes) at the 1-hour observation. All effects resolved within 72 hours.

ORAL:

Exspot (with Dowanol): Oral LD50 (rat): 1500-2500 mg/kg (1874 mg/kg estimate)

Oral gavage doses of 1500, 2500, and 5050 mg/kg were administered to male and female rats (5 rats/sex), and at 750 mg/kg to female rats only (5 rats). Mortality was observed in the 1500 (4/10 rats), 2500 (6/10 rats), and in the 5050 (10/10 rats) mg/kg dose groups. No mortality occurred in the low dose group (750 mg/kg). Clinical effects noted in these dose groups included crust around the nose and eyes, stained muzzle, diarrhea, body tremors, polyuria, piloerection, decreased activity, nasal discharge, respiratory noises (gurgles), or sensitivity to touch and sound. In addition, ocular discharge, salivation, and convulsions were noted in the animals that died during the study. Abnormalities found at necropsy in rats that died included discoloration of the contents in the gastrointestinal tract, liver, lungs, and spleen, and an empty gastrointestinal tract. No abnormalities were found in animals that survived to the end of the study.

DERMAL AND RESPIRATORY SENSITIZATION:

Exspot (with Dowanol): Not sensitizing to guinea pigs in a dermal sensitization test.

REPEAT DOSE TOXICITY DATA

MSDS NAME: Exspot For Dogs (with Dowanol)

MSDS NUMBER: SP000048

Latest Revision Date: 23-Sep-2011

Page 5 of 7

SUBCHRONIC / CHRONIC TOXICITY:

In sub-chronic studies ranging from 14 days to 26 weeks, rats and mice were treated with oral dosages of permethrin up to 10,000 mg/kg. Dose-dependent effects such as an increase in liver/body weight ratio, hypertrophy of the liver, and clinical signs of poisoning such as tremor were observed. The no-observed effects-level (NOEL) in rats ranged from 20 mg/kg diet (in studies lasting 90 days or 6 months) to 1500 mg/kg diet (in a 6-month study). Chronic studies ranging from 1 to 2 years were conducted in rats, mice and dogs. Dosages varied with species ranging from 1 mg/kg/day to 375 mg/kg/day of permethrin. Target organs of toxicity were the liver (increased liver weight and hepatocellular swelling), lung (increased weight), and testes (decreased weight). Depression and increased mortality were observed in mice at 75 mg/kg/day and above. Additional signs and symptoms of toxicity in the rat include hyperexcitation, sparring behavior, aggressiveness, enhanced startle response, whole body tremor and prostration.

Rats exposed to propylene glycol methyl ether at concentrations as high as 3000 ppm, 6hr/day, for 9 days exhibited reversible central nervous system depression. No other effects were observed. No evidence of adverse effects were observed in rats and monkeys exposed to 800 ppm for 132 daily exposures over a period of 186 days.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

In a three-generation reproductive study with permethrin, rats were administered doses ranging from 25 to 125 mg/kg/day. Systemic effects observed in the offspring were seen in the liver (hepatocyte hypertrophy and eosinophilia) and eye (infantile glaucoma). Body tremors were observed in the parents and offspring at 125 mg/kg/day. No teratogenic effects, maternal toxicity or fetotoxicity were observed in rats and rabbits administered 200 and 400 mg/kg/day, respectively, of permethrin.

Pregnant rats and rabbits exposed by inhalation to propylene glycol methyl ether at concentrations up to 3000 ppm did not exhibit teratogenic or embryotoxic effects. Slight fetotoxicity in the form of delayed sternebral ossification was observed in the offspring of rats exposed at 3000 ppm; a dose that was also maternally toxic. In a continuous breeding study, no change in reproductive parameters was observed in mice treated orally with 3333 mg/kg.

MUTAGENICITY / GENOTOXICITY:

Permethrin was negative in a bacterial mutagenicity study (Ames) and in a mammalian mutagenicity study (mouse lymphoma).

Propylene glycol methyl ether was negative in a variety of assays.

CARCINOGENICITY:

This material or product has not been evaluated for carcinogenicity.

Six carcinogenicity assays, three each in mice and rats, were conducted with permethrin. No tumorigenicity was seen in rat studies. However, species specific increases in pulmonary adenomas, a common benign tumor of mice with a high spontaneous background incidence, were seen in the three mouse studies. In one of these studies, there was an increased incidence of pulmonary alveolar cell carcinomas and benign liver adenomas when permethrin was administered in the diet at 5,000 ppm.

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA**INGREDIENT ECOTOXICITY**

Permethrin:96-hr LC50 (rainbow trout): 0.1 to 314 ug/L
Permethrin: 96-hr LC50 (brook trout): 2.3 to 5.2 ug/L
Permethrin: 96-hr LC50 (channel catfish): 1.1 ug/L
Permethrin: 48-hr EC50 (daphnid): 0.2 to 22 ug/L

ENVIRONMENTAL DATA**OTHER INGREDIENT ENVIRONMENTAL DATA:**

Permethrin is readily biodegradable.

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.

SPECIAL ENVIRONMENTAL HANDLING PROCEDURES:

This product contains materials that are harmful to the environment. Do not allow product to reach ground water, water courses, sewage or drainage systems.

SECTION 14. TRANSPORT INFORMATION

Refer to site-specific procedures and requirements for additional guidance.

MSDS NAME: Exspot For Dogs (with Dowanol)

MSDS NUMBER: SP000048

Latest Revision Date: 23-Sep-2011

Page 6 of 7

DOT CLASSIFICATION: Not regulated in containers less than or equal to 119 gallons (450 L).

IATA/ICAO CLASSIFICATION:

Proper Shipping Name: Flammable liquids, n.o.s. (propylene glycol methyl ether)
Hazard Class: 3
UN Number: UN 1993
Packing Group: III

ADR CLASSIFICATION:

Proper Shipping Name: Flammable liquids, n.o.s. (propylene glycol methyl ether)
Hazard Class: 3
UN Number: UN 1993
Packing Group: III
Classification Code: F1

IMDG/IMO CLASSIFICATION:

Proper Shipping Name: Flammable liquids, n.o.s. (propylene glycol methyl ether)
Hazard Class: 3
UN Number: UN 1993
Packing Group: III

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

INGREDIENT	TSCA
Dowanol PM: (Propylene Glycol Methyl Ether)	X

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK
Permethrin Technical			3422		X
Dowanol PM: (Propylene Glycol Methyl Ether)		X	1613		X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Dowanol PM: (Propylene Glycol Methyl Ether)	X	X		X

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations.

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).

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:

02-Sep-1999

SUPERSEDES DATE:

21-Mar-2008

**SECTIONS CHANGED (US SUBFORMAT):
SIGNIFICANT CHANGES (US SUBFORMAT):**

1, 16
Phone Number(s), OEB

MSDS NAME: Exspot For Dogs (with Dowanol)

MSDS NUMBER: SP000048

Latest Revision Date: 23-Sep-2011

Page 7 of 7

Schirmer Tear Test Strips (EX000044)

This product is exempt from [Material] Safety Data Sheet requirements.

The following regional exemptions apply:

United States:

According to the OSHA Hazard Communication Standard [29 CFR § 1910.1200 (b) (6) (vii)], an MSDS is not required for any drug when it is in the solid, final form (*e.g.* tablets or pills).

European Union:

According to the European Union Commission Directive 2001/58/EC of 27 July 2001, as it relates to Directive 1999/45/EC [Article 1.5.a], an SDS is not required for medicinal products in the finished state, intended for the final user.

Canada:

According to the WHMIS Hazardous Product Act [Part II Controlled Products 12.b], an MSDS is not required for any drug within the meaning of the *Food and Drugs Act*.

If you have additional MSDS requests, please call the Schering-Plough MSDS Help Line at 800-770-8878 (U.S. and Canada) or 908-473-3371 (worldwide) or Schering-Plough marketed products may be also obtained at www.schering-ploughmsds.com. Email MSDS requests to spmsds@spcorp.com.

For inquiries for any of the following; call the designated numbers below:

- Adverse Event
- Product Complaint
- Product Quality Complaint

Designated points of contact in the United States are as follows:

Prescription Pharmaceutical (Rx)	Animal Health (AH) Products	Consumer Health Care Products
Phone: 800-526-4099 Fax: 973-921-7006	Companion Animal/Aquaculture Phone: 800-224-5318 Livestock – Phone: 800-211-3573 Poultry – Phone: 800-219-9286	Phone: 800-842-4090 Fax: 901-320-2292

Thank you for your cooperation.

Sincerely,
Global Safety & Environmental Affairs
Schering-Plough Corporation