MSD is a tradename of Merck & Co., Inc., with headquarters in Whitehouse Station, N.J., U.S.A.

SAFETY DATA SHEET

This SDS was created in accordance with Regulation EC 1907/2006 and all amendments. MSD Animal Health urges each user or recipient of this SDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT IDENTIFIER

SDS NAME: **28% w/v CBPI spot-on solution for dogs / cats**

SYNONYM(S): 28% w/v CBPI spot-on solution for dogs / cats

SDS Number: SP002465

REACH REGISTRATION NUMBER Not available

RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

IDENTIFIED USE(S): Veterinary Product

USE(S) ADVISED AGAINST: Anti-ectoparasiticide

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

EU SUPPLIER/MANUFACTURER: MSD Animal Health
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

INFORMATION: +31 (0) 485-587600 (MSD Animal Health - Boxmeer, Netherlands)

MERCK SDS HELPLINE: +1 (908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SDS EMAIL: mercksds@merck.com

EMERGENCY TELEPHONE NUMBER

EMERGENCY NUMBER(S): +1 (908) 423-6000 (24/7/365) English Only

+31 (0) 485-587777 (MSD Animal Health - Boxmeer, Netherlands)

SECTION 2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to EC Directive 1272/2008:
Flam. Liq. 2 (H225), Repr. 1B (H360D), Acute Tox. 4 (H332), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410)

Classification according to EC Directives 67/548/EEC (substances) or 1999/45/EC (mixtures):
F;R11 Xn;R20 Repr.Cat.2;R61 N;R50/53

COLOR: Yellow
FORM: Liquid
ODOR: Odor unknown

LABEL ELEMENTS

SIGNAL WORD: DANGER

HAZARD STATEMENT(S):
Highly flammable liquid and vapor
Harmful if inhaled
May damage the unborn child
Very toxic to aquatic life with long lasting effects

PRECAUTIONARY STATEMENT(S):
Obtain special instructions before use. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Wear protective gloves/protective clothing/eye protection/face protection. Wash hands thoroughly after handling. IF exposed or concerned: Get medical attention/advice. Avoid release to the environment. Collect spillage. Store locked up.

OTHER HAZARDS

Health-Related Hazards:

May cause effects to:
central nervous system
cardiovascular system
liver
fetus

LISTED CARCINOGENS

INGREDIENT	REACH - Carcinogens	REACH - Mutagens	REACH - Toxic to Reproduction
Dimethylacetamide			1B

Environmental-Related Hazards:

This substance has not been fully tested to meet the criteria for listing as a PBT or a vPvB.

Other Hazards:

No other information known.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

SUBSTANCE

CHEMICAL FAMILY: Isoxazoline derivative in formulation

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	EC NUMBER	REACH REGISTRATION NUMBER	EU CLASSIFICATION	GHS CLASSIFICATION	PERCENT	REASON FOR LISTING
Fluralaner (CBPI)	864731-61-3	Not available	Not available	N;R50	Aquatic Acute 1 (H400)	28	Active Pharmaceutical Ingredient
Diethyltoluamide (DEET)	134-62-3	205-149-7	Not available	Xn; R22 Xi; R36/38 R52-53	Acute Tox. 4 (H302) Eye Irrit. 2 (H319) Skin Irrit. 2 (H315) Aquatic Chronic 3 (H412)	13.2	Classified Active Ingredient
Dimethylacetamide	127-19-5	204-826-4	x	Xn; R20/21 Repr.Cat.2; R61	Acute Tox. 4 (H312) Acute Tox. 4 (H332) Repr. 1B (H360D)	30 - 40	Classified
Acetone	67-64-1	200-662-2	x	F; R11 Xi; R36 R66 R67	Eye Irrit. 2 (H319) STOT SE 3 (H336) Flam. Liq. 2 (H225)	10 - 20	Classified Community workplace exposure limit

Fields in the above table that do not contain data indicate that the substance(s) have not been listed or classified according to EU criteria.

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.

See section 16 for definitions of risk phrases and GHS classifications.

SECTION 4. FIRST AID MEASURES

FIRST AID MEASURES

INHALATION: Remove to fresh air. Administer artificial respiration if breathing has ceased. IMMEDIATELY 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: Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

FIRST AID RESPONDER PROTECTION: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves with appropriate personal protective equipment. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. DO NOT use mouth-to-mouth method if victim ingested or inhaled the substance.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The toxicological properties of this material have not been fully characterized in humans and 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.

Fluralaner, the active ingredient in this product, is also known as CBPI.

Based on animal studies, 28% w/v CBPI spot-on solution for dogs / cats is not expected to be harmful by ingestion or by contact with skin. It is also not expected to be irritating to eyes or skin, or sensitizing to skin.

Fluralaner produced reversible metabolic liver effects in oral and dermal animal studies including increased liver enzyme activity in blood plasma with decreased lipid and protein concentration, increased organ weight, and increased hepatocellular fatty change.

DEET is a common insect repellent which is applied directly to the skin. DEET may cause stinging and slight to moderate eye and mucous membrane irritation. DEET may cause contact dermatitis or excerbation of pre-existing skin disease in sensitive individuals. DEET is efficiently absorbed from the skin or gut. If large amounts of DEET are inhaled, ingested, or applied dermally (especially areas of skin that are occluded), the potential for severe toxicity exists. However, compared to the widespread use of the product, there are relatively few cases of toxicity. Reported acute or chronic effects from overexposure to DEET were restlessness, drowsiness, irritability, weakness, headaches, incoordination, slurred speech, confusion, insomnia, tremor, flexing or extending of extremities, decreases in blood pressure, decreased heartbeat, skin effects (rashes, bullous eruptions and necrosis), pyschosis, seizures, prolonged disability, coma, or anaphylactic reaction. Death has been reported when large amounts of DEET were ingested.

Dimethylacetamide can be absorbed through the skin; however, it has a relatively low order of toxicity following acute exposure by the usual routes (oral, inhalation, or dermal). High concentrations may produce liver necrosis and damage. Repeated exposure and workplace overexposures have been shown to produce signs of liver toxicity. Central nervous system effects such as depression, tiredness, confusion and disorientation, hallucinations, delusions and visual disorders have been observed in patients receiving oral treatments as a solvent in anticancer chemotherapeutic treatments.

Acetone is an irritant to the eyes and mucous membranes. Prolonged or repeated skin contact may produce drying or cracking. Acetone is a CNS depressant at high concentrations or from prolonged or repeated exposure. Effects may include sleepiness or sluggishness, weakness, headaches, dizziness, nausea, vomiting, loss of appetite, or lassitude. Other effects that may be seen are respiratory depression, increased sugar levels, ketonemia (ketone bodies in the plasma), ketonuria (enhanced excretion of ketone bodies in the urine), acidosis, heartburn, bronchitis, gastritis, or coma.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

NOTE TO PHYSICIAN: In cases of overexposure treat supportively and symtomatically.

SECTION 5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO_2), extinguishing powder or water spray.

UNSUITABLE EXTINGUISHING MEDIA:
Do not use solid stream of water.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

SPECIAL FIRE HAZARDS:
Heavier than air vapors can flow along surfaces to distant ignition sources and flash back. Gas may travel to an ignition source causing flashback.

THERMAL DECOMPOSITION PRODUCTS:
Carbon oxides (CO_x).

ADVICE FOR FIREFIGHTERS

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

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

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

ENVIRONMENTAL PRECAUTIONS:

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

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

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

PRECAUTIONS FOR SAFE HANDLING

HANDLING:
Avoid contact with skin, eyes, and mucosa. Avoid breathing mists and vapor. 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.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY IMCOMPATIBILITIES

STORAGE:
Keep away from heat, sparks, open flames, and direct sunlight. Store in a cool, dry, well ventilated area.

SPECIFIC END USE(S)
Refer to Section 1 for identified use(s).

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

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

CONTROL PARAMETERS

EXPOSURE LIMIT VALUES:

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)
Dimethylacetamide	127-19-5	10 ppm	S*	
Acetone	67-64-1	500 ppm	750 ppm	

INGREDIENT	CAS NUMBER	EU	Austria	Belgium	Denmark	France
Dimethylacetamide	127-19-5	S* STEL 20 ppm STEL 72 mg/m^3 TWA 10 ppm TWA 36 mg/m^3	STEL 20 ppm STEL 72 mg/m^3 S* MAK 10 ppm MAK 36 mg/m^3	STEL 20 ppm STEL 72 mg/m^3 S* TWA 10 ppm TWA 36 mg/m^3	TWA 10 ppm TWA 35 mg/m^3 S*	VME 2 ppm VME 7.2 mg/m^3 VLCT 10 ppm VLCT 36 mg/m^3 S*
Acetone	67-64-1	TWA 500 ppm TWA 1210 mg/m^3	STEL 2000 ppm STEL 4800 mg/m^3 MAK 500 ppm MAK 1200 mg/m^3	STEL 1000 ppm STEL 2420 mg/m^3 TWA 500 ppm TWA 1210 mg/m^3	TWA 250 ppm TWA 600 mg/m^3	VME 500 ppm VME 1210 mg/m^3 VLCT 1000 ppm VLCT 2420 mg/m^3

INGREDIENT	CAS NUMBER	Germany	Ireland	Italy	Netherlands
Dimethylacetamide	127-19-5	MAK 10 ppm MAK 36 mg/m^3 S* Peak 20 ppm Peak 72 mg/m^3	STEL 20 ppm STEL 72 mg/m^3 S* TWA 10 ppm TWA 36 mg/m^3	STEL 20 ppm STEL 72 mg/m^3 S* TWA 10 ppm TWA 36 mg/m^3	STEL 72 mg/m^3 S* TWA 36 mg/m^3
Acetone	67-64-1	MAK 500 ppm MAK 1200 mg/m^3 Peak 1000 ppm Peak 2400 mg/m^3	TWA 500 ppm TWA 1210 mg/m^3	TWA 500 ppm TWA 1210 mg/m^3	STEL 2420 mg/m^3 TWA 1210 mg/m^3

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Dimethylacetamide	127-19-5	STEL 20 ppm STEL 52.5 mg/m^3 S* TWA 10 ppm TWA 35 mg/m^3	S* TWA 10 ppm	VLA-ED 10 ppm VLA-ED 36 mg/m^3 VLA-EC 20 ppm VLA-EC 72 mg/m^3 S*	STEL 20 ppm STEL 70 mg/m^3 S* MAK 10 ppm MAK 35 mg/m^3	STEL 20 ppm STEL 72 mg/m^3 S* TWA 10 ppm TWA 36 mg/m^3
Acetone	67-64-1	STEL 156.25 ppm STEL 368.75 mg/m^3 TWA 125 ppm TWA 295 mg/m^3	STEL 750 ppm TWA 500 ppm	VLA-ED 500 ppm VLA-ED 1210 mg/m^3	STEL 1000 ppm STEL 2400 mg/m^3 MAK 500 ppm MAK 1200 mg/m^3	STEL 1500 ppm STEL 3620 mg/m^3 TWA 500 ppm TWA 1210 mg/m^3

INGREDIENT	Greece	Poland	Hungary	Croatia	Turkey
Dimethylacetamide	STEL 20 ppm STEL 72 mg/m^3 S* TWA 10 ppm TWA 36 mg/m^3	NDSCh 70 mg/m^3 S* NDS 35 mg/m^3	STEL 72 mg/m^3 S* TWA 36 mg/m^3	TWA 10 ppm TWA 36 mg/m^3 STEL 20 ppm STEL 72 mg/m^3	STEL 20 ppm STEL 72 mg/m^3 TWA 10 ppm TWA 36 mg/m^3
Acetone	STEL 3560 mg/m^3 TWA 1780 mg/m^3	NDSCh 1800 mg/m^3 NDS 600 mg/m^3	STEL 2420 mg/m^3 TWA 1210 mg/m^3	TWA 750 ppm TWA 1780 mg/m^3	TWA 500 ppm TWA 1210 mg/m^3

S* - Skin Notation

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):

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.

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.

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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FORM: Liquid
COLOR: Yellow
ODOR: Odor unknown
ODOR THRESHOLD: Not determined
pH: Not determined
BOILING POINT / RANGE: 103 deg C (217.4 deg F)

MELTING POINT / RANGE:	Not determined
DECOMPOSITION TEMPERATURE:	Not determined
VAPOR PRESSURE:	67 hPA @ 20 deg C 1013 hPa at 101 deg C
VAPOR DENSITY:	Not determined
SPECIFIC GRAVITY:	Not determined
SOLUBILITY:	
Water:	< 0.001 mg/L (Fluralaner)
Acetone:	300 - 400 mg/L (Fluralaner)
DMSO:	> 700 mg/L (Fluralaner)
Ethanol:	25 - 50 mg/L (Fluralaner)
Other:	Isopropanol: 10 - 20 mg/L (Fluralaner)
PARTITION COEFFICIENT (log Pow):	5.5 (Fluralaner)
VISCOSITY:	Not determined
EVAPORATION RATE:	Not determined
FLAMMABILITY DATA:	
Flash Point:	2 deg C (35.6 deg F)
Flammability (solid, gas):	Not determined
Classification:	Flammable (US OSHA Criteria) Highly Flammable (EU Criteria)
UEL:	Not determined
LEL:	2.7% vol
Autoignition Temperature:	355 deg C (671 deg F)
ADDITIONAL INFORMATION:	Density:1.059

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under conditions specified in Section 7 of this SDS. No hazardous reactions known.

CONDITIONS AND MATERIALS TO AVOID:
Keep away from heat, sparks, open flame, and direct sunlight.

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.

LIKELY ROUTES OF EXPOSURE:
Skin, eye, inhalation, and ingestion.

ACUTE TOXICITY DATA

INHALATION:
Deet: LC50: 5.95 mg/L

Dimethylacetamide: Inhalation LC50 (1hr): 2745 ppm (rat)

Acetone: Inhalation LC50: 16-76 mg/L (rat); 44 mg/L (mouse)
Common adverse effects in animals exposed to high concentrations (>20 mg/L) of acetone for various time periods include eye and nose irritation, inccordination, loss of righting and corneal reflex, respiratory failure, or narcosis.

ORAL:
28% w/v CBPI spot-on solution for dogs / cats: Oral LD50: >2000 mg/kg (rat).
In an acute oral toxicity study in rats, six female RccHan:WIST (SPF) rats were treated with 28% w/v CBPI spot-on solution for dogs / cats (2000 mg/kg) via a single oral gavage. During 15 days observation, there were no mortalities or abnormalities noted. There were no effects on body weights or body weight changes.

Fluralaner: Oral LD50: >2000 mg/kg (rat)

Clinical signs of toxicity noted in animals treated with DEET at 50 to 500 mg/kg included piloerection, increased vocalization and decreased activity. At lethal doses, animals showed signs of lacrimation, depression, prostration, tremors, asphyxial convulsions or respiratory failure usually preceding cardiac failure.

Dimethylacetamide: Oral LD50: 2250-10,000 (rat); 2600-4900 mg/kg (mouse)
Elevation of blood sugar occurred in rats after a single oral dose (1 ml/kg) of dimethylacetamide.

Acetone: Oral LD50: 5800 mg/kg (rat)

EYE:
28% w/v CBPI spot-on solution for dogs / cats is considered to be not irritating to rabbit eyes. Administration of 0.1 mL into the eyes of rabbits resulted in slight to moderate, early-onset and transient ocular changes. These effects were reversible and no longer evident at 72 hours (two animals) and 7 days (one animal) after treatment. No abnormal findings were observed in the cornea or iris, and no ocular discharge was observed in any animals at any of the examinations. No corrosion, staining of the eyes, or clinical signs were observed.

Fluralaner was not irritating to rabbit eyes.

Dimethylacetamide produced mild, reversible corneal injury in the eyes of rabbits, mice, and dogs.

Acetone was moderately irritating to rabbit eyes when dosed at 20 mg for 24 hours in a Standard Draize Test

SKIN:
28% w/v CBPI spot-on solution for dogs / cats: Dermal LD50: >2000 mg/kg (rat)
28% w/v CBPI spot-on solution for dogs / cats: Rabbits treated with semi-occlusive topical application of 0.5 mL showed mild, barely perceptible signs of skin irritation immediately and 1 hour after exposure. In all cases, the mild irritation was reversible and no longer evident at the 28-, 48-, and 72-hour readings. 28% w/v CBPI spot-on solution for dogs / cats is considered to be not irritating to rabbit skin.

Fluralaner Dermal LD50: >2000 mg/kg (Rat).
Fluralaner was not irritating to rabbit skin.

DEET caused minimal to moderate transient dermal irritation in animals, which cleared by day 7.

Dimethylacetamide: Dermal LD50: 2200-5000 mg/kg (rabbit), 7500 mg/kg (rat); <940 mg/kg (guinea pig)
Guinea pigs treated dermally at doses as high as 1000 mg/kg showed severe skin irritation along with lethality. In rabbits, only mild irritation was observed 24 hours after dermal application.

Acetone: Dermal LD50: >7400 mg/kg (male guinea pigs)
Acetone was not irritating to the skin of guinea pigs.

Acetone: Dermal LD50: 20000mg/kg (rabbit)
Acetone was mildly irritating to the skin of rabbits when dosed at 500 mg for 24 hours in a Standard Draize Test.

ASPIRATION:
No data available.

DERMAL AND RESPIRATORY SENSITIZATION:
28% w/v CBPI spot-on solution for dogs / cats was not sensitizing to guinea pig skin in a skin sensitization - maximization test (Magnusson and Kligman test).

Fluralaner was not sensitizing to guinea pig skin.

Dimethylacetamide was not a skin sensitizer in guinea pigs.

Acetone was negative in the mouse ear sensitization assay.

ADDITIONAL INFORMATION:
Glycofurol: Intraperitoneal LD50: 3500 mg/kg (rat)

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
In a 90 day study of Fluralaner in rats, the NOAEL was established orally at the highest dose of 400 mg/kg/body weight/day. In a 90 day study in rats, the NOAEL was established dermally at the highest dose of 500 mg/kg/body weight/day The liver is the main elimination organ of Fluralaner and a sensitive target for effects as reflected by increased liver enzyme activity in blood plasma with decreased lipid and protein concentration, increased organ weight and increased hepatocellular fatty change as the main functional endpoints in rats. In the absence of any indicator of liver injury (Kupffer cell proliferation, necrosis, apoptosis, fibrosis, other degenerative changes, etc.) these changes are considered to represent reversible metabolic effects and hence are of non-adverse character.

Subchronic (56 to 90 days) to chronic (2-year) oral studies with DEET were conducted in animals. Effects noted at dosages ranging from 8.4 to 10,000 mg/kg/day included decreases in food consumption and weight, salivation, tremors, elevated liver and kidney weights and cholesterol, and death (high dose groups only). Microscopic findings were observed in the kidneys, testis, epidiymides, and uterus. NOELs ranged from 61 to 100 mg/kg/day across species.

Dimethylacetamide was tested in multiple oral, dermal, and inhalation repeat-dose studies in dogs, rats, cats, rabbits, and/or mice. Rats were given dimethylacetamide, either in the diet or in drinking water, at dosages ranging from 80 to 1000 mg/kg/day for periods ranging from nine days to two years. Reduction in body weight and liver effects including increased liver weights or liver damage were obsereved at dosages of 100 mg/kg/day and greater. A NOEL was not determined in these studies. Dermal application of 2000 mg/kg/day for four consecutive days produced liver necrosis and death in rabbits. In dogs, dermal application of 95 and 299 mg/kg/day for 6 months produced a slight reticulation in the cytoplasm of the hepatocytes and some thickening and infiltration in the skin of the liver. These findings were more pronounced at 299 mg/kg/day. Dermal application of either 945 or 3780 mg/kg/day in the same study was discontinued after 6 weeks due to toxicity including depression, weakness, and weight loss, along with a moderate skin reaction. NOELs were not determined for the two dermal studies in rabbits or dogs. The most common effect seen in repeat-dose inhalation studies ranging from 5 days to 6 months in rats, dogs, cats, and mice was liver damage at dosages of 30 ppm or greater. Mortality was also observed in rats, mice, and cats at dosages of 475 ppm or greater. Other effects observed included testicular changes, atrophy or damage in rats and mice at dosages of 288 or greater. [Inhalation NOELs: 64.4 ppm (dogs), 10 ppm (rats), 100 ppm (mice), and <475 ppm (cats)]

Chronic inhalation to high concentrations (> 20 mg/L) of acetone in rats is well tolerated. No effects were observed in an 8-week study. The only effect observed in a 2-week study after a single exposure was ataxia; however, tolerance developed and ataxia was not observed on subsequent days. In oral gavage and drinking water studies in mice and rats, acetone was generally well tolerated. At high dose levels (6942-8560 mg/kg), emaciated appearance from decreased weight gain was observed in rats in a 14-day drinking water study. Histopathological effects observed at high dosages (> 500 mg/kg) included changes in hematological parameters, serum activity of enzymes, cholesterol levels, serum glucose levels, liver, kidney, spleen, or testicular weights (absolute or organ-to-body weights), and/or hepatocellular hypertrophy.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
In prenatal development toxicity studies of Fluralaner in rats (embryogenisis pilot and pivotal) the final NOEL was 100 mg/kg/body weight/day in maternal and fetal organisms. No teratogenicity at up to the limit dose of 1000 mg/kg/body weight/day, and no effects on embryo or fetus below maternal toxic dose levels were recorded.

DEET caused no effects on reproduction or development in animals administered oral doses up to 1,000 mg/kg/day. Maternal toxicity was observed at the higher dosages and was consisted with that seen in acute, subchronic and chronic studies. The reproductive and developmental NOEL was 250 mg/kg/day.

Dimethylacetamide was given to rats and rabbits either orally, dermally or by inhalation. Dimethylacetamide caused fetal death or growth retardation in rats at an inhalation dose level of 282 ppm, but not 100 ppm. There was not an increase in birth defects seen in this study, even at doses toxic to the dam. In an inhalation study in rabbits, exposure to dimethylacetamide vapors between 57 and 570 ppm caused fetotoxicity, but there was no clear teratogenic effects. Dermal treatment with 200 mg/kg from gestation days 8 to 16 produced neither embryotoxicity or developmental effects in rabbits, and dermal doses up to 500 mg/kg showed no reproductive effects in rats when treated through the production of two litters. Oral administration of 290 mg/kg to rabbits increased maternal toxicity and produced a marginal increase in fetal resorptions. Five fetuses from three litters were malformed. Doses of 470 mg/kg caused mortality in a proportion of the female rabbits and caused total resorption in the survivors. Administration of a high dose of dimethylacetamide (1400 mg/kg) to pregnant rats resulted in 60% resorptions and in the stunting of surviving offspring. In spite of this incidence of embryotoxicity, no increase in malformations was seen in this or a similar study. At high inhalation doses (2000 to 2500 ppm) in rats and (300 to 480 ppm) in mice, dimethylacetamide was associated with reversible testicular toxicity. However, the solvent has been studied as a cryoprotectant for sperm in animal husbandry without apparent adverse effects.

Acetone was not teratogenic in mice and rats exposed to doses up to 15.7 mg/L (6,600 ppm) and 26.2 mg/L (11,000 ppm), respectively, by inhalation. Resorptions and decreased fetal weights were observed in the highest dosage groups. High doses of acetone in male rats caused minimal decreases in testicular weight along with depressed sperm motility, increased epididymal weight, and an increased incidence of abnormal sperm.

MUTAGENICITY / GENOTOXICITY:
Fluralaner was negative in a bacterial reverse mutation (Ames) study, a mouse lymphoma in vitro study, a chromosome aberration in vitro study, and a mouse erythrocyte micronucleus in vivo study.

DEET was negative in a bacterial mutagenicity study (Ames), a chromosome aberration study, a dominant lethal test, and in an unscheduled DNA synthesis assay. DEET was negative in a mouse lymphoma assay without metabolic activation but positive with metabolic activation.

Dimethylacetamide was negative in an Ames assay, in an unscheduled DNA synthesis assay, in cytogenetics assays in human lymphocytes and rat bone marrow, and in dominant lethal assays in rats and mice. It was positive in a sister chromatid exchange assay.

Acetone was negative in bacterial mutagenicity studies (Ames), mouse lymphoma assay, micronucleus assay in Chinese hamster bone marrow, and in sister chromatid exchange assays and chromosome aberration assays in Chinese hamster ovary cells and human lymphocytes.

CARCINOGENICITY:
There was no evidence of carcinogenicity in mice or rats treated with DEET at dosages up to 1000 mg/kg/day for 78 weeks and 2 years, respectively.

Dimethylacetamide was not carcinogenic in rats when administered in the drinking water or by oral gavage for up to two years at dose levels ranging from 0.1 to 1000 mg/kg/day.

Acetone was not carcinogenic in various dermal carcinogenicity studies in mice.

Classification according to EC Directive 1272/2008:
Flam. Liq. 2 (H225). Repr. 1B (H360D). Acute Tox. 4 (H332). Aquatic Acute 1 (H400). Aquatic Chronic 1 (H410).

Classification criteria have not been met for the following endpoints due to lack of data, inconclusive data, technical impossibility to obtain the data, or data which are conclusive although insufficient for classification (available information to support classification criteria is given in Section 4 or Section 11 of this data sheet):
Respiratory sensitization. Mutagenicity. Carcinogenicity. Specific target organ toxicity (STOT) - Single Exposure. Specific target organ toxicity (STOT) - Repeated Exposure. Aspiration hazard. Dermal toxicity. Eye damage or irritation. Oral toxicity. Skin sensitization. Skin corrosion or irritation.

See Section 4 for human health symptoms and effects.

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

Fluralaner:
96-hr LC50 (Common carp): 2 mg/l
48-hr EC50 (Daphnia magna): 0.0001 - 0.01 mg/l
72-hr EC50 (P. subcapitata): >10 mg/l

Deet: 96-hr LC50 (rainbow trout): 75 mg/L
Deet: 48-hr EC50 (daphnid): 75 mg/L
Deet: Avian Oral LD50 (quail): 1375 mg/kg

Dimethylacetamide: 96-hr LC50 (fathead minnow): 1500 mg/L

Acetone: 48-hr LC50 (daphnid): >12000 mg/L
Acetone: 96-hr LC50 (bluegill): 8300 mg/L
Acetone: 96-hr LC50 (fathead minnow): 6210-9100 mg/L
Acetone: 96-hr LC50 (daphnia magna): 100 mg/L
Acetone: 96-hr EC50 (green algae): 7.2 g/L
Acetone: 22 days LOEC (Fish, Onchorhynchus mykiss): 0.78 g/L
Acetone: 21 days NOEC (daphnia magna): 0.78 mg/L
Acetone: LOEC (green algae): 530 mg/L

PERSISTENCE AND DEGRADABILITY

Biodegradation Results:

Glycofurol is easily biodegradable. Acetone: Readily biodegradable. Degradability 91% in 28 days.

BIOACCUMULATIVE POTENTIAL

Partition Coefficient (log Pow) Results:

5.5 (Fluralaner)

MOBILITY IN SOIL

Soil Adsorption/Desorption Results:

No data available.

PBT and vPvB ASSESSMENT

This substance has not been assessed.

OTHER ADVERSE EFFECTS

ENVIRONMENTAL FATE AND EFFECTS: No data available.

OTHER INGREDIENT ENVIRONMENTAL DATA: Fluralaner: Bioconcentration Factor (BCF): 27

SECTION 13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS

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

Consult current regulatory guidelines for the appropriate transportation classification and labeling of this material. Refer to site-specific procedures and requirements for additional guidance.

IATA/ICAO CLASSIFICATION:

Proper Shipping Name:	Acetone solution
Hazard Class:	3
UN Number:	UN 1090
Packing Group:	II

ADR CLASSIFICATION:

Proper Shipping Name:	Acetone solution
Hazard Class:	3
UN Number:	UN 1090
Packing Group:	II
Classification Code:	F1

IMDG/IMO CLASSIFICATION:

Proper Shipping Name:	Acetone solution
Hazard Class:	3
UN Number:	UN 1090
Packing Group:	II

SECTION 15. REGULATORY INFORMATION

SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Germany, Water Endangering Classes (WGK)

INGREDIENT	Annex 1	Annex 2 - Water Hazard Classes	Annex 3
Fluralaner (CBPI)	Not listed.	Not listed.	Not listed.
Diethyltoluamide (DEET)	Not listed.	Not listed.	4679
Dimethylacetamide	Not listed.	1289	Not listed.
Acetone	Not listed.	6	WGK 1

Ozone Depleting Substance(s)

INGREDIENT	Listing
Fluralaner (CBPI)	Not listed.
Diethyltoluamide (DEET)	Not listed.
Dimethylacetamide	Not listed.
Acetone	Not listed.

Persistent Organic Pollutants

INGREDIENT	Listing
Fluralaner (CBPI)	Not listed.
Diethyltoluamide (DEET)	Not listed.
Dimethylacetamide	Not listed.
Acetone	Not listed.

EU Import and Export Restrictions

INGREDIENT	Requires PIC Notification	Requires Export Notification	Export Ban
Fluralaner (CBPI)	Not listed.	Not listed.	Not listed.
Diethyltoluamide (DEET)	Not listed.	Not listed.	Not listed.
Dimethylacetamide	Not listed.	Not listed.	Not listed.
Acetone	Not listed.	Not listed.	Not listed.

SEVESO II EU Directive

INGREDIENT	Listing
Fluralaner (CBPI)	Not listed.
Diethyltoluamide (DEET)	Not listed.
Dimethylacetamide	Not listed.
Acetone	Not listed.

REACH

INGREDIENT	Subject to Authorization	Candidate List for Authorization	Potential Substances of High Concern	Restrictions
Fluralaner (CBPI)	Not listed.	Not listed.	Not listed.	Not listed.
Diethyltoluamide (DEET)	Not listed.	Not listed.	Not listed.	Not listed.
Dimethylacetamide	Not listed.	Not listed.	Not listed.	x
Acetone	Not listed.	Not listed.	Not listed.	Not listed.

CHEMICAL SAFETY ASSESSMENT

A Chemical Safety Assessment has not been done.

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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SECTIONS CHANGED (EU SUBFORMAT): 1, 2, 4, 11
SIGNIFICANT CHANGES (EU SUBFORMAT): [M]SDS Name Change, Hazard classification, Toxicology data

DEFINITIONS (referred to under Sections 2 and 3):

CLP Classifications:	• Flam. Liq. 2 (H225) • Repr. 1B (H360D) • Acute Tox. 4 (H332) • Aquatic Acute 1 (H400) • Aquatic Chronic 1 (H410) • Acute Tox. 4 (H312) - Harmful in contact with skin. • Skin Irrit. 2 (H315) - Causes skin irritation. • Eye Irrit. 2 (H319) - Causes seroius eye irritation. • STOT Single 3 (H336) - May cause drowsiness and dizziness. • Aquatic Chronic 3 (H412) - Harmful to aquatic life with long lasting effects.	• Highly flammable liquid and vapor • Harmful if inhaled • May damage the unborn child • Very toxic to aquatic life with long lasting effects
Risk Phrases:	• R11 - Highly flammable. • R20 - Harmful by inhalation. • R22 - Harmful if swallowed. • R36 - Irritating to eyes. • R50 - Very toxic to aquatic organisms. • R61 - May cause harm to the unborn child. • R66 - Repeated exposure may cause skin dryness or cracking. • R67 - Vapours may cause drowsiness and dizziness. • R20/21 - Harmful by inhalation and in contact with skin. • R36/38 - Irritating to eyes and skin. • R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. • R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	

GLOSSARY:
IARC - International Agency for Research on Cancer, IARC Group 1 or 2A.
NTP - National Toxicology Program
ACGIH - American Conference of Governmental Industrial Hygienists
ADR - International Carriage of Dangerous Goods by Road
API - Active Pharmaceutical Ingredient
CAS - Chemical Abstract Service
CLP - Classification, Labeling and Packaging
DOT - Department of Transportation
EC - European Council
ETAC - Estimated Target Airborne Concentration
GHS - Globally Harmonized System
HEPA - High Efficiency Particulate Arresting
HHC - Health Hazard Category
HPA - Hypothalamic Pituitary Adrenal
IATA - International Air Transport Association
IMO - International Maritime Organization
IP - Intraperitoneal Injection
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%
LOEL - Lowest Observed Effect Level
NEL - No Effect Level
NOAEL - No Adverse Effect Level
NOEL - No Observe Effect Level
OEG - Occupational Exposure Guideline
PBT - Persistent BioaccumulativeToxic
PG - Packing Group
PIC - Prior Informed Consent
PPE - Personal Protective Equipment
REACH - Registration, Evaluation, Authorization and Restriction of Chemical Substances
RPE - Respiratory Protective Equipment
SCBA - Self Contained Breathing Apparatus
STOT - Specific Target Organ Toxicity
TSCA - Toxic Substances Control Act
TWA - Time Weighted Average
UN - United Nations
vPvB - Very Persistent andVery Bioaccumulative
WGK - Water Hazard Class (Germany)