Essex Animal Health Friesoythe
A division of Essex Pharma GmbH
Sedelsberger StraBe 2-4
26169 Friesoythe
Germany

SAFETY DATA SHEET

Schering-Plough 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 SUBSTANCE AND CONTACT INFORMATION

SDS NAME: **ORBAX Oral Suspension**

SYNONYM(S): ORBAX Oral Suspension
ORBAX Oral Liquid
Orbifloxacin, SCH 51854

MSDS NUMBER: SP000999

EMERGENCY NUMBER(S): Schering-Plough Security Control Center (908) 820-6921 (24 hours)

(49) (4491) 294-0 (Essex Animal Health Friesoythe)

EU Transportation Emergencies - Carechem24:
+44 (0)208 762 8322 (24 hours/7 days/week)

INFORMATION: (49) (4491) 294-0 (Essex Animal Health Friesoythe)

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

SCHERING-PLOUGH SDS EMAIL: spmsds@spcorp.com

SECTION 2. HAZARDS IDENTIFICATION

This preparation has been classified as dangerous according to EC Directive 1999/45/EC.

EMERGENCY OVERVIEW

Light to medium brown
Liquid Suspension
Odorless
May cause allergic reactions in susceptible individuals.
May cause developmental effects.
May cause effects to:
gastrointestinal tract
central nervous system
fetus

POTENTIAL HEALTH EFFECTS:

Orbifloxacin is a broad-spectrum antibacterial agent from the class of fluoroquinolone carboxylic acid derivatives. The effects of orbifloxacin in animals are characteristic of fluoroquinolone antimicrobial agents where the target organs are the cartilage and gastrointestinal tract. In immature animals, quinolones and fluoroquinolones are known to cause lesions in the cartilage of weight bearing joints and other signs of diseases affecting the joints. In humans, this class of compounds may cause central nervous system disturbances such as dizziness, insomnia and convulsions, gastrointestinal disturbances, rashes, including photosensitive eruptions, elevated liver enzymes, hepatitis, blood in urine, and anaphylactic reactions.

Propylene glycol is considered to be relatively non-toxic. It is a mild irritant to the eyes and has been reported to irritate the skin. It may cause skin sensitization resulting in allergic contact dermatitis in susceptible individuals. Inhalation exposure to saturated and supersaturated atmospheres of propylene glycol for prolonged periods of time produced no adverse effects. Propylene glycol may cause nervous system depression, acidosis, stupor, and seizures after chronic ingestion.

Sodium hydroxide is highly corrosive, it is a severe irritant of the eyes, mucous membraines, and skin.

LISTED CARCINOGENS

Not listed as a carcinogen by IARC or EU Directive 90/394 (Annex I).

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

SUBSTANCE / PREPARATION NAME: 1-Cyclopropyl-5,6,8-trifluoro-1,4-dihydro-7-(cis-3,5-dimethyl-1-piperazinyl)-4-oxoquinoline-3-carboxylic acid

CHEMICAL FAMILY: Fluroquinolone antibiotic

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: C19H20F3N3O3

MOLECULAR WEIGHT: 395.4

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EU NUMBER	EU CLASSIFICATION	PERCENT
Orbifloxacin	113617-63-3		Repr. Cat.3;R63	3
Methacrylic Acid Copolymer	25086-15-1			15
Propylene Glycol	57-55-6	200-338-0		10
Sodium Hydroxide	1310-73-2	215-185-5	C;R35	1
Silica	7631-86-9	418-260-2 231-545-4		1.5
Lactic Acid	50-21-5	200-018-0		1.05

See section 15 for EU hazard classification symbols and risk and safety phrases.

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: 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.

NOTE TO PHYSICIAN: Orbifloxacin is a synthetic broad-spectrum antibacterial agent from the class of fluoroquinolone carboxylic acid derivatives. This class of drugs in humans has been reported to cause central nervous system effects such as convulsions and photosensitivity or anaphylactic reactions.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

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

OTHER EXPLOSION HAZARDS:
Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This hazard may exist where sufficient quantities of finely divided material are (or may become) suspended in air during typical process operations. An assessment of each operation should be conducted and suitable deflagration prevention and protection techniques employed.

The sensitivity of this material to ignition by electrostatic discharges has not been determined. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

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.

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.

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 between 15 and 30 deg C (and deg F). Store out of direct light.

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

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

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

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)
Sodium Hydroxide	1310-73-2			2 mg/m^3

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

INGREDIENT	CAS NUMBER	EU	Austria	Belgium	Denmark	France
Sodium Hydroxide	1310-73-2		STEL = 4 mg/m^3 MAK = 2 mg/m^3		Ceiling = 2 mg/m^3	VME = 2 mg/m^3
Silica	7631-86-9		MAK = 4 mg/m^3			

INGREDIENT	CAS NUMBER	Germany	Ireland	Italy	Netherlands
Propylene Glycol	57-55-6		TWA = 470 mg/m^3 TWA = 10 mg/m^3 TWA = 150 ppm		
Sodium Hydroxide	1310-73-2		STEL = 2 mg/m^3		
Silica	7631-86-9	MAK = 4 mg/m^3	TWA = 2.4 mg/m^3 TWA = 6 mg/m^3		

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Propylene Glycol	57-55-6	STEL = 118.5 mg/m^3 STEL = 37.5 ppm TWA = 79 mg/m^3 TWA = 25 ppm				STEL = 30 mg/m^3 STEL = 1422 mg/m^3 STEL = 450 ppm TWA = 10 mg/m^3 TWA = 474 mg/m^3 TWA = 150 ppm
Sodium Hydroxide	1310-73-2	Ceiling = 2 mg/m^3	Ceiling = 2 mg/m^3	VLA-EC = 2 mg/m^3	STEL = 2 mg/m^3 MAK = 2 mg/m^3	STEL = 2 mg/m^3
Silica	7631-86-9	STEL = 3 mg/m^3 TWA = 1.5 mg/m^3			MAK = 0.3 mg/m^3 MAK = 4 mg/m^3	STEL = 7.2 mg/m^3 STEL = 18 mg/m^3 TWA = 2.4 mg/m^3 TWA = 6 mg/m^3

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Liquid Suspension
COLOR: Light to medium brown
ODOR: Odorless
MOLECULAR WEIGHT: 395.4

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

MELTING POINT / RANGE: 263 deg C

SOLUBILITY:

Water: 0.476 to 0.909 mg/mL

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

CONDITIONS AND MATERIALS TO AVOID:
None known.

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

SECTION 11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY DATA

INHALATION:
Propylene glycol caused no adverse effects in monkeys or rats following exposure to saturated atmospheres for prolonged periods of time.

SKIN:
ORBAX Oral Suspension is rated as nonirritating to the skin, based on the responses observed following dermal application on rabbits.

EYE:
ORBAX Oral Suspension was slightly irritating in the unrinsed eyes and practically nonirritating to the rinsed eyes of the rabbits.

ORAL:
Orbifloxacin was evaluated in the rat, mouse, and dog. No mortalities occured in any of the three species. The only effects observed were ataxia in rats and soft feces and emesis in dogs at doses of 2000 to 3000 mg/kg and 150 to 600 mg/kg, respectively.

Sodium Hydroxide: Oral LD50: 40 mg/kg (ip mouse)

SENSITIZATION:
ORBAX Oral Suspension is not considered to be a dermal sensitizer in guinea pigs.

ADDITIONAL INFORMATION:
Orbifloxacin IV LD50 (rodent): 233 to 283 mg/kg

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Orbifloxacin was studied in rats, dogs, and cats at doses ranging from 7.5 to 360 mg/kg/day in subchronic oral studies ranging from 10 to 90 days. In rats, folicular hyperplasia was observed in the spleen of rats treated with 80 mg/kg/day. Dose-dependent effects including histopathological renal changes, vacuolation of hepatocytes, renal lymphoid infiltrates, testicular degeneration, and nephritis were observed at doses of 250 mg/kg/day or greater. Effects observed in dogs were similar to those identified with fluoroquinolone antimicrobial agents (e.g. articular cartilage and joint changes). Other organs affected included the testes, kidney, liver spleen, bone marrow, and heart. At higher dose levels, 250 mg/kg/day and greater, mortality was observed in dogs preceded by ataxia and convulsions. Decreased body weight and food consumption, emesis, and transient diarrhea were observed in dogs and cats secondary to the antimicrobial effects on intestinal flora. The no observed effect levels (NOELs) were 20 mg/kg/day (rat), 15 mg/kg/day (dog), and 7.5 mg/kg/day (cat).

Propylene glycol caused no adverse effects in monkeys or rats exposed to saturated vapor concentrations for 12 to 18 months. Rats exposed to 25 or 50% (7.7 and 13.2 g/kg/day) propylene glycol in water died within 69 days in a 140 day study. In a separate study, a diet of 30% propylene glycol was not well tolerated in young rats, and dams could not bring their young to weaning; diets containing 40, 50, or 60% propylene glycol were lethal after a few days.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
In a dietary two-generation study in rats with orbifloxacin, no effects on reproductive capabilities, and neonatal viability, growth and development were seen in animals treated with 20 to 50 mg/kg/day. Parental toxicity was indicated in the 150 mg/kg/day group by decreased body weights and/or body weight gains. Prenatal and/or neonatal toxic effects included decreased pup vialbility and litter size, decreased pup weight gain, and increased incidence of pups which were pale, cool to touch and edematous were observed at 150 mg/kg/day. (NOAEL: 50 mg/kg/day)

In developmental toxicity studies, rats and rabbits were treated with orbifloxacin at dosages ranging from 20 to 1000 mg/kg/day. In rabbits, maternal toxicity (decreased body weight and/or body weight gains) was observed at all dose levels (20 to 120 mg/kg/day). Developmental toxicity was apparent at a dose level of 120 mg/kg/day by an increased incidence of structural malformations; however, because it was in the presence of maternal toxicity, orbifloxacin did not result in selective effects on the development of the embryo/fetus. There was no evidence of teratogenicity in rats.

Propylene glycol caused decreased food consumption, retarded growth, smaller litters, changes in breeding patterns, and inhibited weaning in rats that were fed 30% propylene glycol through six generations; however, this may have been due to nutritional insufficiency. Propylene glycol was not teratogenic in rabbits, monkeys or chickens.

MUTAGENICITY / GENOTOXICITY:
Orbifloxacin was positive in a mouse lymphoma assay (high concentrations without activation) and in an in vitro assay in human peripheral blood lymphocytes (concentrations exceeding the solubility in the assay medium). Orbifloxacin was negative in a hepatocyte DNA repair assay in rats and in a mouse micronucleus assay. There was both negative and positive findings in a bacterial mutagenicity assay (Ames).

Propylene glycol was negative in a bacterial mutagenicity study (Ames).

CARCINOGENICITY:
Propylene glycol was not carcinogenic when applied to the skin, or when given orally in mice and rats.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY	Propylene glycol: 96-hr LC50 (sheepshead minnow): 23,800 mg/L Propylene glycol: 48-hr EC50 (daphnid): >43,500 mg/L Propylene glycol: 72-hr EC50 (green algae): >19,000 mg/L
	Lactic acid: 48-hr EC50 (daphnia): 240 mg/L Lactic Acid: 48-hr LC50 (fish): 320 mg/L Lactic acid: EC50 (algae): 3500 mg/L
	Methacrylic Acid is predicted to have low toxicity to aquatic organisms.

ENVIRONMENTAL DATA

PRODUCT / CHEMICAL NAME:	Orbifloxacin
Dissociation Constant Results:	5.95 and 9.01
OTHER INGREDIENT ENVIRONMENTAL DATA:	Propylene glycol is expected to be readily biodegradable.
	Lactic acid 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.

SECTION 14. TRANSPORT INFORMATION

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

SECTION 15. REGULATORY INFORMATION

The following classification is based on available data and is in accordance with European Union criteria.

EUROPEAN UNION REGULATIONS:

Based on available data, this material or product does not require labelling according to the EC directives.

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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