SAFETY DATA SHEETS

This SDS packet was issued with item:

078071138

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078074260

MSD Animal Health
Breakspear Road South
Harefield, Uxbridge
Middlesex, England UB9 6LS

SAFETY DATA SHEET

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 SUBSTANCE AND CONTACT INFORMATION

SDS NAME: **Flunixin Meglumine Paste**

SYNONYM(S): Banamine Paste
Finadyne Paste

SDS Number: SP000350

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

MSD Security Control Center (908) 820-6921 (24 Hours)

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

INFORMATION: (0 11 44) 1895 62 6000 (MSD Animal Health- Harefield)

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

SDS EMAIL: spmsds@spcorp.com

SECTION 2. HAZARDS IDENTIFICATION

EU CLASSIFICATION(S): Xn;R22 Xi;R36 R52 R53 Xn;R48/22

EMERGENCY OVERVIEW

White to off-white
Paste
Odor unknown
May be severely irritating to the eyes.
Harmful if swallowed.
Prolonged exposure may cause serious health effects.
Harmful to aquatic organisms.
May cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS:

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

Flunixin meglumine is a potent non-narcotic, non-steroidal agent with pain killing, anti-inflammatory, and fever-reducing activity. Based on animal studies, flunixin meglumine may cause severe eye irritation or irreversible ocular effects. It may also cause irritation of the skin, mucous membranes, respiratory tract, and gastrointestinal tract. Repeated dermal contact to high concentrations may cause severe skin irritation. Prolonged inhalation may produce serious lung effects. Repeated ingestion or inhalation of high doses may cause internal bleeding, predominantly of the gastrointestinal tract. Inhalation hazard of Flunixin Meglumine is not expected due to the physical form of the paste.

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.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by IARC or EU Directive 90/394 (Annex I) 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	EC NUMBER	EU CLASSIFICATION	PERCENT
Flunixin Meglumine	42461-84-7	255-836-0	T+;R26 T;R25 T;R48/25 Xi;R41 Xi;R37 N;R51-53	8.3
Propylene Glycol	57-55-6	200-338-0		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. Refer to the package insert or product label for handling guidance for the consumer.

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

SECTION 4. 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. Get IMMEDIATE medical attention.

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: Flunixin meglumine is a potent Non-Steroidal Anti-inflammatory Drug (NSAID), and overexposure may cause gastrointestinal irritation and bleeding, kidney and central nervous system effects.

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.

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 harmful 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

PRECAUTIONS FOR SAFE HANDLING

HANDLING:
Ensure adequate ventilation. Handle in essentially closed systems, or in a laboratory fume hood. Cover containers during material transfer or transportation.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY IMCOMPATIBILITIES

STORAGE:
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

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

OCCUPATIONAL EXPOSURE GUIDELINE (OEG):
An Occupational Exposure Guideline (OEG) of 18 mcg/m^3 (8-hr TWA) has been established for flunixin. Consult your site safety and industrial hygiene professional(s) for additional guidance.

EXPOSURE CONTROLS
For laboratories and small-scale operations, essentially no open handling. Open handling of small quantities may be performed if there is no potential for dust or aerosol generation. For larger quantities or materials that may become airborne, materials should be handled in a properly functioning chemical fume hood, ventilated enclosure or controlled by local exhaust ventilation.

For manufacturing and large-scale operations, essentially no open handling. Open handling is limited to small quantities in appropriately ventilated, enclosed environments. For larger quantities or materials that may become airborne, enclosed processes and the use of containment technology are preferred. Recirculation of general ventilation or local exhaust ventilation is not permitted unless appropriate scrubbing or filtration of incoming recirculated air is controlled.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	In laboratories and small-scale operations, appropriate respiratory protection is required in situations where exposure (e.g. spills, process upsets, or non-routine maintenance) may exceed any available recommended exposure limit. Consult your site safety staff for additional guidance. In manufacturing and large-scale operations, powered air purifying respirators (PAPRs) or positive-pressure air supplied respirators with full-face coverage are required. Consult your site safety staff 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 is required if there is potential for contact with this material. 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	Germany	Ireland	Italy	Netherlands
Propylene Glycol	57-55-6		TWA 150 ppm TWA 470 mg/m^3 TWA 10 mg/m^3		

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Propylene Glycol	57-55-6	STEL 37.5 ppm STEL 118.5 mg/m^3 TWA 25 ppm TWA 79 mg/m^3				STEL 450 ppm STEL 1422 mg/m^3 STEL 30 mg/m^3 TWA 150 ppm TWA 474 mg/m^3 TWA 10 mg/m^3

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: Paste
COLOR: White to off-white
ODOR: Odor unknown
SOLUBILITY:
Water: Not determined

See Section 5 for flammability/explosivity information.

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:
Open flames and high temperatures.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon oxides (COx).

SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. The information presented below pertains to the following individual ingredients, and not to the mixture. The information presented for the active ingredient in this formulation, flunixin meglumine, is either for flunixin (free acid) or the meglumine salt. The toxicity is considered equivalent, except for differences in mutagenicity, based on studies conducted using both forms of the drug.

ACUTE TOXICITY DATA

INHALATION:
Flunixin Meglumine: Inhalation LC50 (4hr): <0.52 mg/L (rat)
Mortality occurred in all rats (10/10) between days 3 and 6 following a single 4-hour exposure to an average analytical concentration of 0.52 mg/L (maximum attainable exposure). Signs exhibited following exposure included lacrimation, nasal discharge, dried red material around facial area, and yellow anogenital staining. Significant weight loss was noted following exposure in all animals.

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

SKIN:
Flunixin meglumine: Slightly irritating
Flunixin meglumine produced mild, transient dermal irritation in rabbits. Dose-related skin irritation effects were observed in rabbits during a 21-day repeat skin application study (see below under Subchronic to Chronic Toxicity).

Propylene glycol: Dermal LD50: 20.8 g/kg (rabbit)
Propylene glycol was irritating in a human patch test. Propylene glycol was not irritating to the skin of rabbits, guinea pigs and swine.

EYE:
Flunixin Meglumine: Severely irritating
All six animals exhibited severe conjunctival irritation including redness, swelling, discharge, and necrosis, as well as corneal opacity, ulceration and iridial damage. Severe ocular irritation was irreversible in most animals.

Propylene glycol was slightly irritating to the eyes of rabbits.

ORAL:
Flunixin Meglumine: Oral LD50: 53 to 157 mg/kg (rat), 176 to 249 mg/kg (male mouse, female estimated)
Flunixin (free acid): Oral LD50: 468.3 mg/kg (guinea pig)
Common effects observed in acute oral studies across species include gastrointestinal effects (perforation/ulceration and hemorrhage), hypoactivity, pallor, spleen enlargement, congestion of kidneys, lungs, or gastrointestinal tract, and respiratory distress. Necropsy of animals that died from flunixin meglumine revealed abnormalities of the brain, epididymides, abdominal cavity, thymus, liver, mesenteric lymph nodes, esophagus, mesentery, pancreas, and lungs. No signs of toxicity were observed following acute oral administration of 100 & 200 mg/kg to rhesus monkeys. However, 1 of 3 monkeys died following administration of 300 mg/kg. That monkey showed lethargy, prostration, and salivation prior to death, and signs of hyperemic mucosa in gastrointestinal tract and lungs at necropsy. Flunixin administered orally to mice at a dose of 300 mg/kg (100x the projected clinical dose) caused slight tremors and ataxia which resolved within 24 hours. Effects from acute oral and IV treatment of horses with 1.1 mg/kg flunixin were limited to sporadic incidence of fecal occult blood.

Propylene glycol: Oral LD50: 21 to 33.7 g/kg (rat), 10 to 20 g/kg (dog)
Propylene glycol caused dyspnea, cramps, loss of equilibrium, depression, analgesia, and death after prolonged moribund state in mice at doses ranging from 23.9 to 31.8 g/kg. In rabbits, 1 to 1.5 g/kg propylene glycol reduced intraocular pressure by raising the osmotic pressure of blood.

DERMAL AND RESPIRATORY SENSITIZATION:
Flunixin Meglumine was found not to be sensitizing in guinea pigs when tested by intradermal induction at 1% and topically at 100%.

Propylene glycol did not cause sensitization in a human patch test.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Repeat oral dosing studies have been performed with flunixin across multiple species. The most common adverse effect seen in these studies is gastrointestinal irritation/ulceration and bleeding as indicated by blood in the stools. Other common adverse effects observed across species from oral, IV or IM routes of exposure include nephrotoxicity, emesis, anorexia, and bleeding. Blood cell count changes, blood coagulation effects, and immune organ effects were observed secondary to gastrointestinal erosion and bleeding. Liver, nervous system and behavioral effects were also noted in mice. In addition to ulceration and bleeding, significant mortality was observed in rats at 8 and 16 mg/kg dosed for six weeks. [6-week oral toxicity NOAEL: 2 mg/kg (rats); 90-day oral toxicity NOAEL: 5 mg/kg (monkeys), 3.0 mg/kg (rats); one year oral toxicity NOEL: 1 mg flunixin/kg (rats)]

In several 21-day repeat skin application studies in rabbits using up to 80 mg/kg flunixin meglumine or the free acid in spray or cream formulations, no conclusive treatment-related toxicity could be established. The incidence and severity of dermal irritation increased in a dose-related manner with severe irritation seen at 80 mg/kg/day.

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:
Reproductive and teratology studies in rats, mice and rabbits were performed with flunixin. Although significant maternal toxicity, including mortality, was reported, these studies indicate that flunixin does not affect offspring development, male or female fertility, or mating behavior. A slight increase in the length of gestation and difficult labor with an increase in stillbirths were observed. No evidence of any drug-related teratogenic effects were observed. Maternal toxicity observed in these studies was consistent with those findings in acute and repeated dose oral toxicity studies with the addition of pale eyes, ears and extremities. [Reproductive or developmental NOELs ranged from 2-21 mg/kg in studies with multiple species. Maternal toxicity NOELs ranged from 3-9 mg/kg in these studies].

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:
Flunixin meglumine was negative in the Ames and mouse micronucleus assays. It was positive in mouse lymphoma L5178Y cells, both in the absence and presence of S-9 metabolic activation and in the chromosomal abberation assay in CHO cells in vitro both in the absence and presence of S-9 metabolic activation. It has been reported to alter cellular DNA and caused primary DNA damage in E. coli. Flunixin free acid yielded the same results as flunixin meglumine. However, it was inconclusive in the bacterial repair assay in E.coli whereas flunixin meglumine was strongly positive. The meglumine moiety (N-methyl-D glucamine) was negative in all studies performed except the micronucleus study in which it was positive in one study and negative in a second.

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

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity. Flunixin meglumine had no carcinogenic effects or increase in tumor incidence relative to controls in either a 104-week study in rats administered 2, 4 and 8 mg flunixin meglumine/kg/day in the diet, or in mice administered 0.6, 2.0 and 6.0 mg flunixin meglumine/kg/day in the diet for 97 weeks. Significant toxicity observed in rats and mice included decreased body weights, increased mortality (high dose groups) and dose-related increases in gastrointestinal lesions in all treated groups. Compound-related lesions observed at necropsy included dose-related gastrointestinal ulcers, ulcer perforation with secondary peritonitis and adhesion formation, and large or edematous lymph nodes. Dose-related nonproliferative lesions were present in the gastrointestinal tract and mesenteric lymph node. Necrosis and ulceration of the mucosa, transmural necrosis, mucosal and mural inflammation, lymphoid hyperplasia, peritonitis and abscess formation were present. Inflammatory lesions and necrosis secondary to the peritonitis were present in other abdominal organs. Splenomegaly (enlarged spleens) were observed at necropsy in mice and were significant in the high dose group only. [Rat NOEL for tumor formation = 8 mg flunixin meglumine/kg/day and the LOEL = 2 mg flunixin meglumine/kg/day based on GI lesions. Mouse NOEL for tumor formation = 6.0 mg flunixin meglumine/kg/day; Toxicity NOEL = 0.6 mg flunixin meglumine/kg/day].

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

Flunixin meglumine: 96-hr LC50 (trout): 9.2 mg/L
Flunixin meglumine: 96-hr LC50 (bluegill): 46 mg/L
Flunixin meglumine: 48-hr EC50 (Daphnia): 25 mg/L
Flunixin meglumine: 72 hr IC50 (Algae): 36-120 mg/L

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

ENVIRONMENTAL DATA

OTHER INGREDIENT ENVIRONMENTAL DATA: Propylene glycol is expected to be readily biodegradable.

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 ECG or OEG.

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

SPECIAL ENVIRONMENTAL HANDLING PROCEDURES:
Do not allow product to reach ground water, water courses, sewage or drainage systems.

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:

Indication of Danger: Xn - Harmful.
N - Dangerous For The Environment.

Risk Phrases:
R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R52 - Harmful to aquatic organisms.
R53 - May cause long-term adverse effects in the aquatic environment.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Safety Phrases:
S46 - If swallowed, seek medical advice immediately and show this container or label.
S29 - Do not empty into drains.
S 1/2 - Keep locked-up and out of the reach of children.

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

MSDS CREATION DATE: 01-Jan-1993
SUPERSEDES DATE: 07-May-2010

SECTIONS CHANGED (EU SUBFORMAT):	2,3,11,15
SIGNIFICANT CHANGES (EU SUBFORMAT):	Hazard classification, Risk and safety phrases, OEB

SAFETY DATA SHEET

Flunixin Paste Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/15/2017
3.1	10/11/2017	656915-00006	Date of first issue: 05/02/2016

SECTION 1. IDENTIFICATION

Product name : Flunixin Paste Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Acute toxicity (Oral) : Category 4

Serious eye damage : Category 1

Specific target organ systemic toxicity - repeated exposure : Category 1 (Gastrointestinal tract, Kidney, Blood)

GHS label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.
H318 Causes serious eye damage.
H372 Causes damage to organs (Gastrointestinal tract, Kidney, Blood) through prolonged or repeated exposure.

Precautionary Statements :

Prevention:

P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P314 Get medical advice/ attention if you feel unwell.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Starch, oxidized	65996-62-5	>= 20 - < 30
Propylene glycol	57-55-6	>= 10 - < 20
1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	>= 5 - < 10

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Get medical attention if symptoms occur.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention immediately.

If swallowed : If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed	:	Harmful if swallowed. Causes serious eye damage. Causes damage to organs through prolonged or repeated exposure.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Fluorine compounds Nitrogen oxides (NOx)
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Local or national regulations may apply to releases and

disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propylene glycol	57-55-6	TWA	10 mg/m³	US WEEL
1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7	TWA	40 µg/m3 (OEB 3)	Merck
		Wipe limit	400 µg/100 cm²	Merck

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face

containment devices).
Minimize open handling.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : paste

Color : white to off-white

Odor	:	No information available.
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	Not classified as a flammability hazard
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity	:	Acute toxicity estimate: 638.55 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Remarks: Inhalation is not regarded as possible exposure path.

Ingredients:

Propylene glycol:

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rabbit): > 159 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Acute oral toxicity	:	LD50 (Rat): 53 - 157 mg/kg LD50 (Mouse): 176 - 249 mg/kg LD50 (Guinea pig): 488.3 mg/kg LD50 (Monkey): 300 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): < 0.52 mg/l

Exposure time: 4 h
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 59.4 - 185.3 mg/kg
Application Route: Intraperitoneal

LD50 (Mouse): 164 - 363 mg/kg
Application Route: Intraperitoneal

Skin corrosion/irritation

Not classified based on available information.

Ingredients:

Propylene glycol:

Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species: Rabbit
Result: Mild skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Ingredients:

Propylene glycol:

Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species: Rabbit
Result: Irreversible effects on the eye

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Ingredients:

Propylene glycol:

Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Assessment: Does not cause skin sensitization.
Result: negative

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Propylene glycol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: in vitro test Test system: mouse lymphoma cells Result: positive Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: positive Test Type: in vitro test Test system: Escherichia coli Result: positive
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative
Germ cell mutagenicity - Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

Ingredients:

Propylene glycol:

Species: Rat

Application Route: Ingestion
Exposure time: 2 Years
Result: negative

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species: Rat
Application Route: oral (feed)
Exposure time: 104 w
LOAEL: 2 mg/kg body weight
Result: negative
Target Organs: Gastrointestinal tract
Remarks: Significant toxicity observed in testing

Species: Mouse
Application Route: oral (feed)
Exposure time: 97 w
NOAEL: 0.6 mg/kg body weight
Result: negative
Target Organs: Gastrointestinal tract
Remarks: Significant toxicity observed in testing

IARC	No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA	No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.
NTP	No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Ingredients:

Propylene glycol:

Effects on fertility	:	Test Type: Three-generation reproduction toxicity study Species: Mouse Application Route: Ingestion Result: negative
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Mouse Application Route: Ingestion Result: negative

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity Parent: LOAEL: 1 - 1.5 mg/kg body weight

Symptoms: No fetal abnormalities.
Result: No effects on fertility and early embryonic development were detected.

Effects on fetal development : Test Type: Development
Species: Rat
Application Route: Oral
General Toxicity Maternal: LOAEL: 2 mg/kg body weight
Embryo-fetal toxicity.: NOAEL: 2 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
General Toxicity Maternal: LOAEL: 3 mg/kg body weight
Embryo-fetal toxicity.: NOAEL: 3 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

STOT-single exposure

Not classified based on available information.

Ingredients:

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Assessment: May cause respiratory irritation.

STOT-repeated exposure

Causes damage to organs (Gastrointestinal tract, Kidney, Blood) through prolonged or repeated exposure.

Ingredients:

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Target Organs: Gastrointestinal tract, Kidney, Blood
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Ingredients:

Propylene glycol:

Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 y

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Species: Rat
NOAEL: 2 mg/kg
LOAEL: < 4 mg/kg
Application Route: Oral

Exposure time: 6 w
Target Organs: Gastrointestinal tract

Species: Rat
NOAEL: 1 mg/kg
Application Route: Oral
Exposure time: 1 y
Target Organs: Gastrointestinal tract, Kidney

Species: Monkey
NOAEL: 15 mg/kg
Application Route: Oral
Exposure time: 90 d
Target Organs: Gastrointestinal tract, Blood

Species: Rabbit
LOAEL: 80 mg/kg
Application Route: Dermal
Exposure time: 21 d
Symptoms: Severe irritation

Species: Dog
LOAEL: 11 mg/kg
Application Route: Oral
Exposure time: 9 d
Target Organs: Gastrointestinal tract
Symptoms: Vomiting

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Ingredients:

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Inhalation	:	Symptoms: respiratory tract irritation
Skin contact	:	Symptoms: Skin irritation
Eye contact	:	Symptoms: Severe irritation
Ingestion	:	Symptoms: Gastrointestinal disturbance, bleeding, hypertension, Kidney disorders

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingredients:

Propylene glycol:

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l Exposure time: 48 h
Toxicity to algae	:	ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 20,000 mg/l Exposure time: 18 h

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 28 mg/l Exposure time: 96 h Method: FDA 4.11 LC50 (Oncorhynchus mykiss (rainbow trout)): 5.5 mg/l Exposure time: 96 h Method: FDA 4.11
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 15 mg/l Exposure time: 48 h Method: FDA 4.08
Toxicity to algae	:	NOEC (Microcystis aeruginosa (blue-green algae)): 97 mg/l Exposure time: 13 d Method: FDA 4.01 NOEC (Selenastrum capricornutum (green algae)): 96 mg/l Exposure time: 12 d

Persistence and degradability

Ingredients:

Propylene glycol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Stability in water	:	Hydrolysis: 0 %(28 d)

Bioaccumulative potential

Ingredients:

Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Partition coefficient: n-octanol/water : log Pow: 1.34

Mobility in soil

Ingredients:

1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate:

Distribution among environmental compartments : log Koc: 1.92

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Acute toxicity (any route of exposure)
Serious eye damage or eye irritation
Specific target organ toxicity (single or repeated exposure)

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Water	7732-18-5
Starch, oxidized	65996-62-5
Propylene glycol	57-55-6
1-Deoxy-1-(methylamino)-D-glucitol 2-[2-methyl-3-(perfluoromethyl)anilino]nicotinate	42461-84-7

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

California Permissible Exposure Limits for Chemical Contaminants

Starch, oxidized	65996-62-5

The ingredients of this product are reported in the following inventories:

AICS : not determined

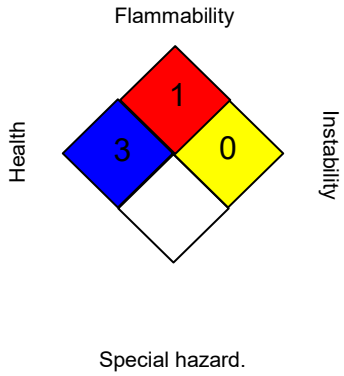
DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

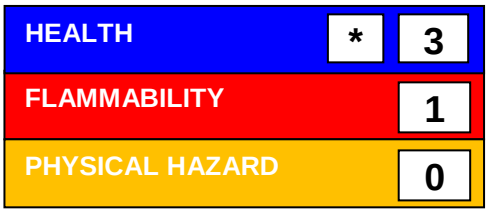
Further information

NFPA:



Special hazard.

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

US WEEL	:	USA. Workplace Environmental Exposure Levels (WEEL)
US WEEL / TWA	:	8-hr TWA

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance

Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/
Revision Date	:	10/11/2017

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8