SAFETY DATA SHEET

1. Identification

Product identifier **Kavault**

Other means of identification

Item Code AF0375, AF0369, AF0374

Synonyms Avilamycin Premix * Maxus * Kavault * Surmax Premix

Recommended use Veterinary Product

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company Name Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140
US

Phone: 1-877-Elanco1 (1-877-352-6261)

Email: lilly_msds@lilly.com

Emergency Telephone Numbers: Elanco Product Technical Support / Human or Animal Exposure Reporting: 1-888-545-5973
Transportation Emergency Telephone: CHEMTREC: 1-800-424-9300 (Outside U.S. 1-703-527-3887)

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Serious eye damage/eye irritation	Category 2B
Sensitization, respiratory	Category 1

OSHA defined hazards Combustible dust

Label elements

Signal word Danger

Hazard statement

	May form combustible dust concentrations in air.
H320	Causes eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Prevention

P261	Avoid breathing dust.
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P285	In case of inadequate ventilation wear respiratory protection.

Response

P304 + P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Storage	Not available.
Disposal	
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Avilamycin	[(2R,3S,4R,6S)-6-[(2'R,3'S,3aR,4R,4'R,6S,7aR)-6-[(2S,3R,4R,5S,6R)-2-[(2R,3S,4S,5S,6S)-6-[(2R,3aS,3'aR,6'R,7R,7'S,7aR,7'aR)-7'-acetyl-7'-hydroxy-6'-methyl-7-(2-methylpropanoyloxy)spiro[4,6,7,7a-tetrahydro-3aH-[1,3]dioxolo[4,5-d]pyran-2,4'-6,7a-dihydro-3aH-[1,3]dioxolo[4,5-c]pyran]-6-yl]oxy-4-hydroxy-5-methoxy-2-(methoxymethyl)oxan-3-yl]oxy-3-hydroxy-5-methoxy-6-methyloxan-4-yl]oxy-4'-hydroxy-2',4,7a-trimethylspiro[3a,4,6,7-tetrahydro-[1,3]dioxolo[5,4-c]pyran-2,6'-oxane]-3'-yl]oxy-4-hydroxy-2-methyloxan-3-yl]3,5-dichloro-4-hydroxy-2-methoxy-6-methylbenzoate	11051-71-1	20
Excipient: Grain Dust		NA	77 - 80
Anti-dusting oil	MINERAL OIL	8012-95-1	<= 3

Composition comments Excipients may include: Rice hulls. Soybean mill run.
The anti-dusting oil reduces potential exposure under normal handling conditions of use.

4. First-aid measures

Inhalation Remove victim to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Get medical attention immediately.

Skin contact Wash off immediately with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists. Take off contaminated clothing and wash before reuse.

Eye contact Do not rub eyes. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.

Ingestion Give several glasses of water. Never give liquid to an unconscious person. Call a physician or poison control center immediately.

Most important symptoms/effects, acute and delayed Irritating to eyes. Wheezing.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

General information If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemicals. Carbon dioxide (CO2). Apply extinguishing media carefully to avoid creating airborne dust.

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical Dust may form explosive mixture with air. During fire, gases hazardous to health may be formed.
No ignition up to 2.0 oz/cu ft (2 kg/m3)
Minimum Ignition Temperature of Dust Layer: 200 C

Special protective equipment and precautions for firefighters Wear self-contained breathing apparatus and protective clothing. Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Avoid inhalation of dust. Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.

Methods and materials for containment and cleaning up Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist/wet material and remove by mopping or wet wiping. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.

Environmental precautions Avoid discharge into drains, water courses or onto the ground. Prevent spilled material from flowing onto adjacent land or into streams, ponds, or lakes.

7. Handling and storage

Precautions for safe handling Minimize dust generation and accumulation. Wash hands thoroughly after handling. Avoid contact with eyes, skin, and clothing. Wear appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

Occupational exposure limits

ACGIH

Components	Type	Value	Form
Excipient: Grain Dust	TWA	4 mg/m3	(grain dust)

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
Anti-dusting oil (CAS 8012-95-1)	TWA	5 mg/m3	Inhalable fraction.

U.S. - OSHA

Components	Type	Value	Form
Excipient: Grain Dust	TWA	10 mg/m3	(grain dust)

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Anti-dusting oil (CAS 8012-95-1)	PEL	5 mg/m3	Mist.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Anti-dusting oil (CAS 8012-95-1)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.

Lilly (LEG)

Material	Type	Value
Kavault	TWA (8hrs)	4 mg/m3

Components	Type	Value
Avilamycin (CAS 11051-71-1)	TWA (8hrs)	10 mg/m3

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Laboratory fume hood or local exhaust ventilation.

In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection	
Hand protection	Chemical resistant gloves.
Other	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Respiratory protection	In case of insufficient ventilation, wear suitable respiratory equipment. Select appropriate respirator for physical characteristics of material. Select respirator with appropriate protection factor.
Thermal hazards	Not available.
General hygiene considerations	Under normal use and handling conditions, wear goggles to protect eyes and wear impermeable gloves and protective equipment to avoid direct contact with skin. Wash thoroughly with soap and water after handling. When mixing and handling, use protective clothing, impervious gloves, and dust respirator (recommended). Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse with plenty of water.

9. Physical and chemical properties

Appearance	
Physical state	Solid.
Form	Free flowing material which may contain light colored particles.
Color	Brown
Odor	Musty
Odor threshold	No data available.
pH	6 - 8
Melting point/freezing point	No data available.
Initial boiling point and boiling range	No data available.
Flash point	No data available.
Evaporation rate	No data available.
Flammability (solid, gas)	No test data available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	No data available.
Flammability limit - upper (%)	No data available.
Explosive limit - lower (%)	No data available.
Explosive limit - upper (%)	No data available.
Vapor pressure	No data available.
Vapor density	No data available.
Relative density	No data available.
Solubility(ies)	
Solubility (water)	Insoluble
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	No data available.
Other information	
Density	No data available.
Explosive properties	Not explosive
Flammability	No data available.
Molecular weight	No data available.
Oxidizing properties	The substance or mixture is not classified as oxidizing.
Thermal hazards	
Thermal stability	Not applicable.

VOC (Weight %) No data available.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous reactions Hazardous polymerization does not occur.

Conditions to avoid Keep away from heat, sparks and open flame. Contact with incompatible materials. Minimize dust generation and accumulation.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products Fire or excessive heat may produce hazardous decomposition products.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Avilamycin (CAS 11051-71-1)		
Acute		
Dermal		
LD	Rabbit	> 2000 mg/kg (14.9% formulation)
Inhalation		
LC50	Rat	> 770 mg/m3, 4 hours (14.9% formulation)
Oral		
LD	Rat	> 5000 mg/kg (14.9% formulation)

Skin corrosion/irritation (14.9% Avilamycin)
Rabbit: Slight irritation.
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Rabbit: Irritating to eyes. (14.9 % Avilamycin) (cleared within 7 days)

Respiratory or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled. Allergic reactions in a manufacturing setting have been reported. Did not cause sensitization on laboratory animals. (Avilamycin)

Skin sensitization Allergic reactions in a manufacturing setting have been reported. Did not cause sensitization on laboratory animals. (Avilamycin)
Based on available data, the classification criteria are not met.

Germ cell mutagenicity Result in genetic toxicity assays (in vitro and in vivo): Negative (Avilamycin)

Carcinogenicity No effects identified in animal studies. (Avilamycin)

IARC Monographs. Overall Evaluation of Carcinogenicity

Anti-dusting oil (CAS 8012-95-1) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

Reproductive toxicity No effects identified in animal studies. (Avilamycin)

Specific target organ toxicity - single exposure No effects identified in animal studies. (Avilamycin)

Specific target organ toxicity - repeated exposure No target organ toxicity identified through animal studies. (Avilamycin)

Aspiration hazard No aspiration toxicity classification

12. Ecological information

Ecotoxicity

Components		Species	Test Results
Avilamycin (CAS 11051-71-1)			
		Audrain (Silty clay loam)	66.5 ml/g Mean Kd (adsorption)
		Mutcher sandy loam, pesticide free (sandy clay loam)	143 ml/g Mean Kd (adsorption)
		Raymondville (Sandy clay loam)	2.05 ml/g Mean Kd (adsorption)
		Tehama (Loam)	56 ml/g Mean Kd (adsorption)
		Tift (Sand)	3.57 ml/g Mean Kd (adsorption)
Acute			
	LC50	Anas platyrhynchos (Mallard duck)	> 730 ppm, 5 days (Dietary)
		Colinus virginianus (Quail)	> 660 ppm, 5 days (Dietary)
		Earthworm (Eisenia fetida)	> 100 mg/kg, 14 days
		Oncorhynchus mykiss (Rainbow trout)	> 47.8 mg/l, 96 hours
	LD50	Colinus virginianus (Quail)	> 372.5 mg/kg, 5 days
Chronic			
	EC50	Corn (Zea mays)	> 500 mg/kg, 21 days
		Earthworm (Eisenia fetida)	> 1300 mg/kg, 56 days (reproduction)
		Oat (Avena sativa)	> 500 mg/kg, 21 days
		Radish (Raphanus sativus)	> 500 mg/kg, 21 days
		Soybean (Glycine max)	> 500 mg/kg, 21 days
		Sugar beet (Beta vulgaris)	> 500 mg/kg, 21 days
		Tomato (Solanum lycopersicon)	> 500 mg/kg, 21 days
	NOEC	Earthworm (Eisenia fetida)	1300 mg/kg, 56 days (reproduction)
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 138 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	138 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	> 35.4 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Partition coefficient n-octanol / water (log Kow)

Avilamycin	0.681 Shake flask method, (pH 9) 2.55 Shake flask method, (pH 7) 3.97 Shake flask method, (pH 4.5)

Bioconcentration factor (BCF)

Avilamycin	15

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

Ecotoxicological Properties

Drinking Water

Components	Test Results
Avilamycin	6.6 mg/l, (Lilly Aquatic Exposure Guideline)

Chronic Exposure of Aquatic Organisms

Components	Test Results
Avilamycin	2.4 mg/l, (Lilly Aquatic Exposure Guideline)

Acute Exposure of Aquatic Organisms

Components	Test Results
Avilamycin	12 mg/l, (Lilly Aquatic Exposure Guideline)

13. Disposal considerations

Disposal instructions Do not allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations.

Disposal methods

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Anti-dusting oil (CAS 8012-95-1)

US. Massachusetts RTK - Substance List

Anti-dusting oil (CAS 8012-95-1)

US. New Jersey Worker and Community Right-to-Know Act

Anti-dusting oil (CAS 8012-95-1)

US. Pennsylvania Worker and Community Right-to-Know Law

Anti-dusting oil (CAS 8012-95-1)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 05-11-2015

Revision date 02-03-2016

Version # 02

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Lilly Lab Code
Health: 2
Fire: 1
Reactivity: 0

Disclaimer As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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Revision Information
Product and Company Identification: Synonyms
Physical & Chemical Properties: Multiple Properties
GHS: Classification