SAFETY DATA SHEETS

This SDS packet was issued with item:

078798221

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

078798239

Schering-Plough Animal Health Corporation
556 Morris Avenue
Summit, NJ 07901

MATERIAL SAFETY DATA SHEET

Schering-Plough urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: **Swine Influenza Vaccines**

SYNONYM(S):
Swine Influenza Vaccines
MAXIVAC M+
Swine Influenza Vaccine, H1N1, Killed Virus- Mycoplasma Hyopneumoniae Bacterin
MAXIVAC Platinum
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus- Mycoplasma Hyopneumoniae Bacterin
MAXIVAC Excell
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus
MAXIVAC Excell 3
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus
MAXIVAC Excell 5.0
Swine Influenza Vaccine, H1N1 and H3N2, Killed Virus
MAXIVAC H1N1
MAXIVAC H3N2

MSDS NUMBER: SP000022

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

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

SCHERING-PLOUGH MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

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SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Cloudy, Viscous solution
Pink to white color
Odor unknown
May be irritating to eyes, skin or respiratory tract.
May be an aspiration hazard if ingested (mineral oil).
May cause allergic reactions in susceptible individuals (preservatives).

POTENTIAL HEALTH EFFECTS:

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s). Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) are presented.

This product is a vaccine for use in animals. This vaccine is not pathogenic to humans or animals. Local irritation to the eyes, skin, or respiratory tract may occur following direct contact or inhalation of the product. Accidental injection may cause local swelling, irritation or necrosis at the injection site. As with any vaccine, exposure may cause hypersensitivity reactions.

Ingestion of mineral oil may cause laxative effect, nausea, dehydration or lipid pneumonia. Long-term dermal exposure to mineral oil may cause dermatitis and oil acne. Ethanol, glycerin, or mineral oil may cause eye, skin, or respiratory tract irritation.

LISTED CARCINOGENS

INGREDIENT	CAS NUMBER	OSHA	IARC	NTP	ACGIH
Ethyl Alcohol	64-17-5		1	K	

Ethanol (ethyl alcohol): IARC (International Agency for Research on Cancer) has classified Alcoholic Beverages as Group 1 (indicating in their evaluation that the agent is carcinogenic to humans). However, occupational handling or manufacturer's specified use of this product is not expected to result in relevant exposures.

ADDITIONAL INFORMATION: The preservatives in the product(s) may cause allergic-type reactions, including anaphylactic shock, in susceptible individuals. Individuals allergic or sensitive to antibiotics similar to those used as preservatives in the formulation(s) may also be sensitive to the product(s).

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Vaccine

CHEMICAL FORMULA: Mixture.

The formulations for these products are proprietary information. These formulations have the same hazardous profile; however, the presence of hazardous ingredients may vary by formulation. 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.

The product(s) may contain preservatives, as listed, in concentrations less than 1%. This formulation may contain some hydrochloric acid and/or sodium hydroxide for pH adjustment.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Inactivated Swine Influenza Virus, H1N1		Varies
Inactivated Swine Influenza Virus, H3N2		Varies
Inactivated Mycoplasma Hyopneumoniae Bacteria		Varies
Mineral Oil	8012-95-1	10-20
Aluminum Hydroxide	21645-51-2	<10
Ethyl Alcohol	64-17-5	<10
Glycerin	56-81-5	<10
Thimerosal (Preservative)	54-64-8	<1
Gentamicin Sulfate (Preservative)	1405-41-0	<1

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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.

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: 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: This product contains mineral oil which may represent an aspiration hazard.

This product is a vaccine. Accidental injection may cause local swelling, irritation or necrosis at the injection site. This preparation contains a preservative or antibiotic or both which may cause allergic reactions in susceptible individuals.

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 (CO_2), 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 in a cool, dry, well ventilated area.

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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)	OSHA PEL (TWA)
Mineral Oil	8012-95-1	5 mg/m^3	5 mg/m^3
Aluminum Hydroxide	21645-51-2	1 mg/m^3	
Ethyl Alcohol	64-17-5	1000 ppm	1000 ppm 1900 mg/m^3
Glycerin	56-81-5	10 mg/m^3	15 mg/m^3 5 mg/m^3
Thimerosal (Preservative)	54-64-8	0.01 mg/m^3	0.01 mg/m^3

INGREDIENT	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Mineral Oil	8012-95-1	10 mg/m^3 STEL (sampled by method that does not collect vapor)			
Thimerosal (Preservative)	54-64-8	S* 0.03			0.04 mg/m^3

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Cloudy, Viscous solution
COLOR:	Pink to white color
ODOR:	Odor unknown
pH:	6.8 - 7.6
SOLUBILITY:	

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Water: Not determined

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
Oxidizers. Strong acids and bases. Open flames and high temperatures.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
Carbon monoxide. Carbon dioxide (CO2).

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(s).

ACUTE TOXICITY DATA

INHALATION:
Glycerin: Inhalation LC50 (1hr): >570 mg/m^3 [>0.57 mg/L] (rat)

Ethanol: Inhalation LC50 (10hr): 20,000ppm
Ethanol caused dose dependent effects following inhalation exposure in rats on the central nervous system including drowsiness, incoordination, narcosis and excitation.

SKIN:
Mineral Oil: Slight irritant

Glycerin: Skin LD50: >10,000 mg/kg (rabbit)
Glycerin was slightly irritating to the skin of rabbits.

Ethanol was mildly to moderately irritating to the skin of rabbits.

EYE:
Mineral Oil: Moderately irritating.

Ethanol (95%) was irritating to the eyes of rabbits.

ORAL:
Glycerin: Oral LD50: 12,600 mg/kg (rat)

Ethanol: Oral LD50: 6.2 to 17.8 g/kg (rat); 5.5 to 6.6 g/kg (dog)

SENSITIZATION:
Ethanol has been shown to be a weak sensitizer in a human patch test. Ethanol was negative in the mouse ear sensitization assay.

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
Animals received mineral oil in the diet at high concentrations. Effects observed included increased liver, kidney, and spleen weights and enlargement of the lymph nodes together with granulomatous lipoid granules.

Rats fed 6 to 10 mg of aluminum (as aluminum hydroxide) daily showed significant impairment of growth by the third and fourth week. Dietary administration of 14,470 ppm for 28 days to rats produced no adverse effects.

Ethanol, at high concentrations, caused kidney and liver effects including necrosis, cirrhosis, hepatitis, fibrosis and fatty liver in repeat dose oral studies in dogs, rats, and non-human primates. Exposure to saturated vapor concentrations caused liver cirrhosis in rabbits.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Pregnant rats or mice given aluminum hydroxide at doses of 192-768 mg/kg/day or 66.5-300 mg/kg/day, respectively, during organogenesis produced no teratogenic effects.

Ethanol caused fetotoxicity and postnatal effects in a reproductive study in rats following exposure of adult males to 20% ethanol in the drinking water. Adult male rats showed significant decreases in testicular weight. Pregnant rats exposed for 7 hours/day to concentrations up to 20,000 ppm ethanol on gestation days 1 to 19 gave birth to pups with no adverse developmental effects.

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MUTAGENICITY / GENOTOXICITY:
Aluminum compounds were negative in standard mutagenic assays.

Glycerin was negative in a bacterial mutagenicity study (Ames). Glycerin was positive in chromosome aberration studies in rat bone marrow and sperm cells; however, it was negative in an occupational cytogenetics chromosome aberration study.

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

CARCINOGENICITY:
This material or product has not been evaluated for carcinogenicity.

There was no evidence of carcinogenicity in animals exposed to mineral oil mist at 100 mg/m^3 or higher for as long as two years.

Rats given 25 to 50% ethanol by oral gavage or in the drinking water for one to two years did not show a significant increase in tumors compared to the control groups. Mice given 43% ethanol in drinking water for three years showed an increase in papillomas of the forestomach, malignant lymphomas and lung adenomas. Ethanol was an effective promoter of liver tumors in rats given a single intraperitoneal dose of diethylnitrosamine followed by treatment of ethanol in the drinking water for 12 to 18 months.

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

Glycerin: 96-hr LC50 (trout): 50-67 mg/L
Glycerin: 96-hr LC50 (goldfish): >5000 mg/L
Glycerin: Toxicity threshold-cell multiplication inhibition test (algae): 2900 mg/L

Ethanol: 96-hr (static) LC50 (rainbow trout): 13 g/L
Ethanol: 96-hr (flow-through) LC50 (fathead minnow): 12.9-15.3 g/L

ENVIRONMENTAL DATA

There are no environmental data available for these products or their components.

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

TSCA LISTING

INGREDIENT	TSCA
Mineral Oil	X
Aluminum Hydroxide	X
Ethyl Alcohol	X
Glycerin	X
Thimerosal (Preservative)	X

U.S. STATE REGULATIONS

INGREDIENT	California Proposition 65	CARTK	NJRTK	CTRTK	MARTK

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Mineral Oil		X			X
Ethyl Alcohol	D	X	sn 0844		X
Glycerin			sn 3319		X
Thimerosal (Preservative)	D	X	sn 2414		X

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Mineral Oil	X	X		X
Ethyl Alcohol	X	X		X
Glycerin	X	X		X
Thimerosal (Preservative)	X	X	X	X

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

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

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DEPARTMENT ISSUING MSDS:
Global Safety and Environmental Affairs
Occupational and Environmental Toxicology
Schering-Plough Corporation
556 Morris Avenue
Summit, NJ 07901 USA

SCHERING-PLOUGH MSDS HELPLINE:
(800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

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01-Apr-2002

SECTIONS CHANGED (US SUBFORMAT):
1
SIGNIFICANT CHANGES (US SUBFORMAT):
Synonyms

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