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SAFETY DATA SHEET

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

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

PRODUCT IDENTIFIER

SDS NAME: Pasteurella Multocida Vaccine

SYNONYM(S): Avichol
Orachol
PM-Onevax-C
PM-Onevax
M-Ninevax-C
M-Ninevax

SDS Number: SP000404

REACH REGISTRATION NUMBER Not available

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

IDENTIFIED USE(S): Veterinary Product, Animal Vaccine

USE(S) ADVISED AGAINST: None known.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

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Wim de Körverstraat 35
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Netherlands

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

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SECTION 2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to EC Directive 1272/2008:

Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC Directive 1272/2008.

Classification according to EC Directives 67/548/EEC (substances) or 1999/45/EC (mixtures):

Based on available data, this preparation does not meet the criteria to be classified as hazardous according to EC Directive 1999/45/EC.

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COLOR: Brown-White
FORM: Powder
ODOR: Odorless

LABEL ELEMENTS

Based on available data, this mixture does not meet the criteria to be classified as hazardous in accordance with Directive 1272/2008.

OTHER HAZARDS

Health-Related Hazards:

LISTED CARCINOGENS

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

Environmental-Related Hazards:

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

Other 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.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

SUBSTANCE

CLASS: Avirulent live bacteria

CHARACTERISTIC: Live

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.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	EC NUMBER	REACH REGISTRATION NUMBER	EU CLASSIFICATION	GHS CLASSIFICATION	PERCENT	REASON FOR LISTING
Pasteurella multocida (Modified Live)		Not available	Not available			Varies	
Sucrose	57-50-1	200-334-9	Not available	Not Classified	Not Classified	40 - 50	Community workplace exposure limit
Bovine Calf Serum		Not available	Not available			10 - 20	
NLG Stabilizer	Mixture	Not available	Not available			30 - 40	

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

ADDITIONAL INFORMATION:

This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient.

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

SECTION 4. FIRST AID MEASURES

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.

FIRST AID RESPONDER PROTECTION:

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

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material.

Pasteurella multocida, the live bacteria contained in this vaccine, is not considered to be pathogenic for the normal immunocompetent human even if inhaled, ingested, or applied to the eyes or skin. If the vaccine is accidentally injected, the bacteria will multiply at the site of injection causing an abscess or systemic infection. In immunoincompetent humans, the bacteria should be considered to be pathogenic if inhaled, ingested, applied to the eyes or injected.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

NOTE TO PHYSICIAN:

This product is a vaccine. Accidental injection may cause local swelling, irritation or necrosis at the injection site.

Penicillin treatment may be necessary upon exposure to eyes, skin, inhalation or ingestion. No medical conditions are aggravated by exposure, but immunoincompetence will potentiate the problem.

SECTION 5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

SUITABLE EXTINGUISHING MEDIA:

Carbon dioxide (CO₂), extinguishing powder or water spray.

UNSUITABLE EXTINGUISHING MEDIA:

None known.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

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 HAZARDS:

None known.

ADVICE FOR FIREFIGHTERS**SPECIAL FIRE FIGHTING PROCEDURES:**

Wear full protective clothing and self-contained breathing apparatus (SCBA).

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES**PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES****PERSONAL PRECAUTIONS:**

Avoid generation of dust during clean-up. Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP**SPILL RESPONSE / CLEANUP:**

All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE**PRECAUTIONS FOR SAFE HANDLING****HANDLING:**

Avoid dust generation. Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES**STORAGE:**

Refrigerate.

SPECIFIC END USE(S)

Refer to Section 1 for identified use(s).

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

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION**CONTROL PARAMETERS****EXPOSURE LIMIT VALUES:**

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)
Sucrose	57-50-1	10 mg/m ³		

INGREDIENT	CAS NUMBER	EU	Austria	Belgium	Denmark	France
Sucrose	57-50-1			TWA 10 mg/m ³		VME 10 mg/m ³

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INGREDIENT	CAS NUMBER	Germany	Ireland	Italy	Netherlands
Sucrose	57-50-1		STEL 20 mg/m ³ TWA 10 mg/m ³		

INGREDIENT	CAS NUMBER	Norway	Portugal	Spain	Switzerland	UK:
Sucrose	57-50-1		TWA 10 mg/m ³	VLA-ED 10 mg/m ³		STEL 20 mg/m ³ TWA 10 mg/m ³

INGREDIENT	Greece	Poland	Hungary	Croatia	Turkey
Sucrose				TWA 10 mg/m ³ STEL 20 mg/m ³	

EXPOSURE CONTROLS

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Body Protection:	In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.
	In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Powder
COLOR:	Brown-White
ODOR:	Odorless
ODOR THRESHOLD:	Not determined
pH:	Not determined
BOILING POINT / RANGE:	Not determined
MELTING POINT / RANGE:	Not determined
DECOMPOSITION TEMPERATURE:	Not determined
VAPOR PRESSURE:	Not determined
VAPOR DENSITY:	Not determined
SPECIFIC GRAVITY:	Not determined
SOLUBILITY:	
Water:	Not determined
PARTITION COEFFICIENT (log Pow):	Not determined
VISCOSITY:	Not determined
EVAPORATION RATE:	Not determined
FLAMMABILITY DATA:	
Flash Point:	Not determined (liquids) or not applicable (solids).
Flammability (solid, gas):	Not determined

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UEL: Not determined
LEL: Not determined
Autoignition Temperature: Not determined

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:

Oxidizers. Strong acids and bases. Open flames and high temperatures.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:

Carbon monoxide (CO). Carbon dioxide (CO₂).

SECTION 11. TOXICOLOGICAL INFORMATION

LIKELY ROUTES OF EXPOSURE:

Skin, eye, inhalation, and ingestion.

ACUTE TOXICITY DATA

This product has not been tested for acute toxicity.

INHALATION:

No data available.

SKIN:

No data available.

EYE:

No data available.

ORAL:

No data available.

ASPIRATION:

No data available.

DERMAL AND RESPIRATORY SENSITIZATION:

No data available.

REPEAT DOSE TOXICITY DATA

These products have not been tested for repeat dose toxicity.

SUBCHRONIC / CHRONIC TOXICITY:

No data available.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:

No data available.

MUTAGENICITY / GENOTOXICITY:

No data available.

CARCINOGENICITY:

This material or product has not been evaluated for carcinogenicity.

Classification according to EC Directive 1272/2008:

Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC Directive 1272/2008..

See Section 4 for human health symptoms and effects.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

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

PERSISTENCE AND DEGRADABILITY

Biodegradation Results: No data available.

BIOACCUMULATIVE POTENTIAL

Partition Coefficient (log Pow) Results: No data available.

MOBILITY IN SOIL

Soil Adsorption/Desorption Results: No data available.

PBT and vPvB ASSESSMENT

This substance has not been assessed.

OTHER ADVERSE EFFECTS

ENVIRONMENTAL FATE AND EFFECTS: No data available.

SECTION 13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS

MATERIAL WASTE:

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:

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

SECTION 14. TRANSPORT INFORMATION

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

SECTION 15. REGULATORY INFORMATION

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

Germany, Water Endangering Classes (WGK)

INGREDIENT	Annex 1	Annex 2 - Water Hazard Classes	Annex 3
Pasteurella multocida (Modified Live)	Not listed.	Not listed.	Not listed.
Sucrose	Not listed.	Not listed.	Not listed.
Bovine Calf Serum	Not listed.	Not listed.	Not listed.
NLG Stabilizer	Not listed.	Not listed.	Not listed.

Ozone Depleting Substance(s)

INGREDIENT	Listing
Pasteurella multocida (Modified Live)	Not listed.
Sucrose	Not listed.
Bovine Calf Serum	Not listed.
NLG Stabilizer	Not listed.

Persistent Organic Pollutants

INGREDIENT	Listing
Pasteurella multocida (Modified Live)	Not listed.
Sucrose	Not listed.

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Bovine Calf Serum	Not listed.
NLG Stabilizer	Not listed.

EU Import and Export Restrictions

INGREDIENT	Requires PIC Notification	Requires Export Notification	Export Ban
Pasteurella multocida (Modified Live)	Not listed.	Not listed.	Not listed.
Sucrose	Not listed.	Not listed.	Not listed.
Bovine Calf Serum	Not listed.	Not listed.	Not listed.
NLG Stabilizer	Not listed.	Not listed.	Not listed.

SEVESO II EU Directive

INGREDIENT	Listing
Pasteurella multocida (Modified Live)	Not listed.
Sucrose	Not listed.
Bovine Calf Serum	Not listed.
NLG Stabilizer	Not listed.

REACH

INGREDIENT	Subject to Authorization	Candidate List for Authorization	Potential Substances of High Concern	Restrictions
Pasteurella multocida (Modified Live)	Not listed.	Not listed.	Not listed.	Not listed.
Sucrose	Not listed.	Not listed.	Not listed.	Not listed.
Bovine Calf Serum	Not listed.	Not listed.	Not listed.	Not listed.
NLG Stabilizer	Not listed.	Not listed.	Not listed.	Not listed.

CHEMICAL SAFETY ASSESSMENT

A Chemical Safety Assessment has not been done.

SECTION 16. OTHER INFORMATION

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

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SDS CREATION DATE:

28-Oct-2011

SIGNIFICANT CHANGES (EU SUBFORMAT):

New regional format

DEFINITIONS (referred to under Sections 2 and 3):

CLP Classifications:	<ul style="list-style-type: none"> Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC Directive 1272/2008.
Risk Phrases:	

GLOSSARY:

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