Autogenous Vaccine
Safety Data Sheet

Complies with OSHA's Hazard Communication Standard, 29 CFR 1910.1200.
Revision date : March 19, 2015 Supersedes: October 5, 2007

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture

Product name : Autogenous Vaccine

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Inactivated virus fractions in water, mineral oil, emulsifiers and/or aluminum hydroxide

1.3. Details of the supplier of the safety data sheet

Ceva BIOMUNE
8906 Rosehill Rd.
Lenexa, Kansas 66215
(913) 894-0230

1.4. Emergency telephone number

Country	Official advisory body / Company	Address	Emergency number
UNITED STATES	Infotrac	-	1-800-535-5053
INTERNATIONAL	Infotrac	-	1-352-323-3500

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

GHS-US classification

Not classified

2.2. Label elements

GHS-US labelling

No labeling applicable

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

2.4 Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Viral Antigens	Not applicable	Varies	Not applicable
Emulsifiers	Not applicable	Varies	Not a hazardous substance or mixture.
Stabilizer	Not applicable	Varies	Not a hazardous substance or mixture.
Gentamicin, sulfate	(CAS No) 1405-41-0	*	Respiratory sensitization (Category 1), H334 Skin sensitization (Category 1), H317
Amphotericin B	$C_{47}H_{73}NO_{17}$	*	No components need to be disclosed according to the applicable regulations.
Thimersol	(CAS No) 54-64-8	*	Acute toxicity, Oral (Category 2), H300 Acute toxicity, Inhalation (Category 2), H330 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure (Category 2), H373 Acute aquatic toxicity (Category 1), H400 Chronic aquatic toxicity (Category 1), H410
Formaldehyde	(CAS No) 50-00-0	*	Flammable liquids (Category 4), H227 Acute toxicity, Oral (Category 3), H301 Acute toxicity, Inhalation (Category 3), H331 Acute toxicity, Dermal (Category 3), H311 Skin corrosion (Category 1B), H314 Serious eye damage (Category 1), H318 Skin sensitisation (Category 1), H317 Carcinogenicity (Category 2), H351 Specific target organ toxicity - single exposure (Category 1), H370 Acute aquatic toxicity (Category 3), H402

*Chemicals are present in a concentration less than 1% which is below the cut off limit according to §1910.1200

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove to fresh air and provide oxygen if necessary. If any trouble breathing, get immediate medical attention. If irritation or symptoms occur or persist, consult a doctor.

First-aid measures after skin contact : In the event of accidental injection, seek medical attention immediately.

First-aid measures after eye contact : In case of contact, rinse immediately with plenty of water and seek medical attention if irritation develops.

First-aid measures after ingestion : Rinse mouth and drink a glass of water. If irritation or symptoms occur or persist, consult a doctor. May cause gastrointestinal discomfort and have laxative properties if orally ingested.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after skin contact : None to our knowledge.

Symptoms/injuries after eye contact : None to our knowledge.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Foam. Polyvalent powders. Carbon dioxide (CO_2).

Unsuitable extinguishing media : None

5.2. Special hazards arising from the chemicals

Fire hazard : No specific hazardous decomposition products known.

Reactivity : To our knowledge, the product does not present any particular risk, under normal conditions of use.

5.3. Advice for firefighters

Firefighting instructions : None

Protection during firefighting : None

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Avoid accidentail injection or oral ingestion. Wash and disinfect area of contact. See attached accidental injection injuries sheet.

6.1.2. For emergency responders

Protective equipment : Apply the same recommendations as section 6.1.1.

6.2. Environmental precautions

Do not allow product to spread into the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Contain spill. Absorb with inert material such as sand, clay etc. Wash the area with soap and water.

Methods for cleaning up : Wash the area with soap and water.

Other information : Follow good vaccination procedures. Refer to packaging for complete directions.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Follow good vaccination procedures. Refer to packaging for complete directions.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at 2-7°C (35-45°F).

Incompatible materials : Strong acids. Strong bases. Strong oxidizing agents.

Special rules on packaging : Refer to packaging for complete directions.

7.3. Specific end use(s)

No additional information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

The mixture is not classified for Health hazards: use aseptic technique

Hand protection	: Protective gloves are recommended.
Eye protection	: Safety glasses are recommended.
Skin and body protection	: Optional
Respiratory protection	: None required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid or Crystalline powder in cake form if in freeze dried.
Colour	: Gray to off white color or light tan color if in freeze dried form.
Odour	: No perceptible odor.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Not Soluble or very soluble if in freeze dried form
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Not explosive.
Oxidising properties	: Non oxidizing material
Explosive limits	: No data available

9.2. Other information

None

SECTION 10: Stability and reactivity

10.1. Reactivity

To our knowledge, the product does not present any particular risk, under normal conditions of use.

10.2. Chemical stability

None under normal conditions.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

None under normal conditions.

10.5. Incompatible materials

Strong acids. Strong bases. Strong oxidizing agents.

10.6. Hazardous decomposition products

None

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified
(Based on available data, the classification criteria are not met)

Skin corrosion/irritation : Potential health hazard if accidentally injected into a human. Wash and disinfect area of contact. See attached accidental injection injuries sheet.

Serious eye damage/irritation : Not classified
(Based on available data, the classification criteria are not met)

Respiratory or skin sensitisation : Not classified
(Based on available data, the classification criteria are not met)

Germ cell mutagenicity : Not classified
(Based on available data, the classification criteria are not met)

Carcinogenicity : Not classified
(Based on available data, the classification criteria are not met)

Reproductive toxicity : Not classified
(Based on available data, the classification criteria are not met)

Specific target organ toxicity (single exposure) : Not classified
(Based on available data, the classification criteria are not met)

Specific target organ toxicity (repeated exposure) : Not classified
(Based on available data, the classification criteria are not met)

Aspiration hazard : Not classified
(Based on available data, the classification criteria are not met)

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Do not allow the product to be released into the environment.

12.2. Persistence and degradability

Persistence and degradability	Low surviability in the environment.

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Incinerate unused vaccine and vials.

Additional information : None

SECTION 14: Transport information

In accordance with DOT

Not classified as a dangerous good for transport

Additional information

Other information : No supplementary information available.

None

Transport document description : No supplementary information available.

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Not classified as a hazardous or toxic

15.2. International regulations

CANADA

Not classified as a hazardous or toxic

EU-Regulations

Not classified as a hazardous or toxic

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified as a hazardous or toxic

Classification according to Directive 67/548/EEC or 1999/45/EC

Not classified as a hazardous or toxic

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer and/or reproductive toxicity

SECTION 16: Other information

Data sources : SDS of suppliers.

HMIS III Rating

Health	: 0 Minimal Hazard
Flammability	: 0 Minimal Hazard
Physical	: 0 Minimal Hazard
Personal Protection	: B

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

TO: Poultry Company Health Specialists, Vaccinating Crew Personnel, Pullet and Breeder Managers and Company Nurse/Attending Physician

FROM: Biomune Co.

WARNING: COMPLICATIONS MAY RESULT FROM ACCIDENTAL INJECTION INJURIES OF THE HAND WITH OIL CONTAINING VACCINES AND BACTERINS

Oil emulsion vaccines and bacterins, used to immunize poultry, contain a mineral oil carrier which can cause serious complications when injected in a person if it is not immediately removed. The injection of foreign material into the fingers or palm is a potentially serious injury. An accidental injection into the finger of a vaccinating crew person can occur if proper care is not taken while performing the injection of a chicken or turkey. The human can not metabolize the mineral oil in the vaccine. Therefore, the vaccine must be immediately removed to prevent complications.

The best treatment is prevention! These injuries occur more often in persons less experienced in the use of injection equipment. Proper instruction in their use and the serious nature of the injury should be stressed.

PATHOLOGY

After entry of the vaccine into the hand, it can remain in a small area or distribute itself along the tendon sheath and neurovascular bundles away from the injection site. If the vaccine is not removed by a medical expert the same day the injury occurs, within 24 hours there is usually an inflammatory response resulting in significant swelling and increasing pain. Subsequent problems occur with the possible onset of bacterial infection and late formation of oleogranulomas (tumors resulting from chronic inflammation because of the body's response to the mineral oil). If the blood supply of the finger remains intact, the late problems consist of continuing pain and stiffness of the involved part. The inactivated virus or bacteria in the vaccine are not expected to be a problem as there are no living microorganisms present.

RECOMMENDED TREATMENT

If an accident has occurred, time is extremely important - do not delay treatment. It is recommended that the individual be immediately referred to a surgeon experienced in the care of hand injuries. Take along a copy of this information sheet for the surgeon's review.

Such injuries should not be handled in an office setting by someone unfamiliar with the problem.

Although there is some disagreement among hand surgeons about management, the following is an outline of the usual course taken.

1. The incident should be treated as a grease gun injury experienced by mechanics. The mineral oil-containing vaccine must be removed.
2. Xeroradiograms (special soft tissue x-rays) can help to ascertain the extent of distribution of the oil material in the finger or hand.
3. An extensive debridement (opening the affected part and removing as much of the foreign material as possible) should be carried out. The wound is generally left open for several days and closed later.
4. Broad spectrum antibiotics are given in high doses for as long as two weeks depending on the clinical picture.
5. The use of an anti-inflammatory drug, such as Cortisone, should be considered.

Biomune Co.
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Lenexa, Kansas 66215 (913) 894-0230