



# SAFETY DATA SHEET

## 1. Identification

**Product identifier**

**DIGIBIND**

**Other means of identification**

**Synonyms**

DIGOXIN IMMUNE FAB (OVINE) \* DIGIBIND INJECTION 38 MG \* NDC NO 0173-0230-44 \*  
OVINE DIGOXIN ANTIBODY FAB FRAGMENTS, FORMULATED PRODUCT

**Recommended use**

Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Recommended restrictions**

No other uses are advised.

**Manufacturer/Importer/Supplier/Distributor information**

**Manufacturer**

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249

Email Address: [msds@gsk.com](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)

EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES:  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

**Classified hazards**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Label elements**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Hazard(s) not otherwise classified (HNOC)**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

**Mixtures**

Chemical name	Common name and synonyms	CAS number	%
OVINE DIGOXIN ANTIBODY FAB FRAGMENTS		Unassigned	< 30
SODIUM CHLORIDE	COMMON SALT ROCK SALT SODIUM MONOCHLORIDE SALT SEA SALT TABLE SALT SALT, WHITE CRYSTALS, SOLAR	7647-14-5	< 20
Other components below reportable levels			< 55

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

## 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	Not assigned.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Alcohol resistant foam. Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	Assume that this product is capable of sustaining combustion.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	No special control measures required for the normal handling of this product. Use personal protective equipment as required. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	
<b>GSK</b>	Not established
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure guidelines</b>	
<b>Appropriate engineering controls</b>	General ventilation normally adequate.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	Not normally needed. If contact is likely, safety glasses with side shields are recommended.

<b>Skin protection</b>	
<b>Hand protection</b>	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
<b>Other</b>	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Vial. Powder. (Lyophilized). and Vial. Diluent
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.

**Hazardous decomposition products** None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** Under normal conditions of intended use, this material is not expected to be an inhalation hazard.  
**Skin contact** Health injuries are not known or expected under normal use.  
**Eye contact** Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.  
**Ingestion** Health injuries are not known or expected under normal use.

**Symptoms related to the physical, chemical and toxicological characteristics** Not assigned.

### Information on toxicological effects

**Acute toxicity** Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Rat	3000 mg/kg

\* Estimates for product may be based on additional component data not shown.

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.  
**Serious eye damage/eye irritation** Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.

### Respiratory or skin sensitization

**Respiratory sensitization** No studies have been conducted.  
**Skin sensitization** This product is not expected to cause skin sensitization.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Carcinogenicity** Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to carcinogenicity to humans.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

**Reproductive toxicity** Contains no ingredient listed as toxic to reproduction  
**Specific target organ toxicity - single exposure** Not assigned.  
**Specific target organ toxicity - repeated exposure** Not assigned.  
**Aspiration hazard** Not established.  
**Chronic effects** Prolonged inhalation may be harmful.  
**Further information** Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

## 12. Ecological information

**Ecotoxicity** Not expected to be harmful to aquatic organisms.

Components	Species	Test Results
SODIUM CHLORIDE (CAS 7647-14-5)		
<b>Aquatic</b>		
<i>Acute</i>		
Algae	EC50 Algae ( <i>Nitscheria linearis</i> )	2430 mg/l, 5 days
Crustacea	EC50 Water flea ( <i>Daphnia magna</i> )	3310 mg/l, 48 hours Static test
Fish	EC50 Bluegill sunfish (Juvenile <i>Lepomis macrochirus</i> )	1295 mg/l, 96 hours Static test

Components	Species	Test Results
	Fathead minnow (Juvenile Pimephales promelas)	6390 mg/l, 96 hours Static test
	Goldfish (Adult Carassius auratus)	7000 mg/l, 96 hours
	Mosquito fish (Adult Gambusia affinis)	17550 mg/l, 96 hours Static test

\* Estimates for product may be based on additional component data not shown.

<b>Persistence and degradability</b>	Not available.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	Not available.
<b>Mobility in general</b>	Not available.
<b>Other adverse effects</b>	Not available.

### 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

### 14. Transport information

#### DOT

Not regulated as a dangerous good.

Not available.

#### 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

##### 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)

<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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##### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** 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**

**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**  
Not listed.

**US. Massachusetts RTK - Substance List**  
Not regulated.

**US. New Jersey Worker and Community Right-to-Know Act**  
Not listed.

**US. Pennsylvania Worker and Community Right-to-Know Law**  
Not listed.

**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**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	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** 09-25-2015

**Revision date** 09-25-2015

**Version #** 09

**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. HMIS® is a registered trade and service mark of the NPCA.

**HMIS® ratings** Health: 1  
Flammability: 1  
Physical hazard: 0

**NFPA ratings**

Health: 1  
Flammability: 1  
Instability: 0

**References**

GSK Hazard Determination

**Disclaimer**

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**Revision Information**

Product and Company Identification: Product and Company Identification  
Composition / Information on Ingredients: Undisclosed Ingredient Statement  
Physical & Chemical Properties: Multiple Properties  
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection  
Regulatory Information: United States  
GHS: Classification