



MATERIAL SAFETY DATA SHEET

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First Issue: September 28, 2007
Revised: January 4, 2011
Prepared by: Greg Baker

Section 1 Chemical Product and Company Identification

Product Name	Ontak [®]
Active Ingredient, Chemical Name	Denileukin Diftitox
Synonyms	DAB ₃₈₉ IL-2 Injection, IL-2 Fusion Toxin, IL-2 Fusion Protein, Ly335348 Injection
Eisai Material Numbers	NDC62856-603-01, 300129, 300126, E7777
Chemical Family	Recombinant DNA fusion protein
Manufacturer/Supplier	Eisai Inc. Woodcliff Lake, NJ 07677
Telephone Number	877-873-4724
24 Hour Emergency Number	CHEMTREC 800-424-9300 Internationally 703-527-3887
Fax Number	201-746-3207

Section 2 Composition/ Information on Ingredients

Chemical Composition	% Composition	Exposure Limits
Denileukin Diftitox	trace	2 µg/m ³
Citric Acid Monohydrate	< 1	NE
Sodium Hydroxide	< 1	2 mg/m ³
Sodium Edetate	< 1	NE
Polysorbate 20	< 1	NE
Water	99	

CAS #	173146-27-5
NIOSH/RTECS NO.	Not Established for the Formulation

Section 3 Hazards Identification

DAB₃₈₉IL-2 is a recombinant protein consisting of a portion of the diphtheria toxin molecule (fragments A and B) and human Interleukin-2. When dry, protein loses activity and is considered non-hazardous.



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The most commonly reported adverse effects seen in clinical trials were hypersensitivity reaction, loss of visual acuity, and vascular leak syndrome; effects have been delayed in onset and/or persistent

Dose-limiting toxicities were moderate-to-severe nausea, vomiting, fever, chills, and/or persistent asthenia

Potential Exposure Routes of Entry: Accidental injection or ingestion, eye or skin contact.

Section 4 First Aid Measures

The following general precautions should be observed.

Ingestion	Allergic reactions are possible if material is ingested. Observe individual for signs of anaphylaxis; if none within one hour, reaction unlikely
Injection	For accidental injection get medical attention immediately
Inhalation	Symptoms of inhalation are unlikely to occur. Non-volatile.
Eye contact	Immediately flush eyes with water for at least 15 minutes. Obtain medical attention.
Skin contact	Immediately flush skin with water for at least 15 minutes. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes. Get medical attention if irritation develops.

Section 5 Fire Fighting Measures

NFPA Rating	Health: 2 , Flammability: 0 , Reactivity: 0 , Special: None
Flash Point (Closed Cup)	Not Established
Flammable Limits	Upper - NE % Lower - NE %
Autoignition Temperature	Not Established
Extinguishing Media	Use water, dry chemical, or carbon dioxide
Special Fire Fighting Procedures	None Known



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Section 6 Accidental Release Measures

Prevent migration into the environment. Absorb material and place waste in appropriate container. Dispose according to all applicable laws and regulations. Wash area of spill with soap and water.

Section 7 Handling and Storage

Handling Practices:	Observe all precautions contained on product label and package insert. See section 8 for personal protective equipment.
Storage Practices:	Store at, or below – 10 degrees C. It can be stored at room temperature up to 6 hours prior to use.

Section 8 Exposure Controls/Personal Protection

Ventilation	Local exhaust ventilation is required during compounding or when performing operations in a laboratory setting.
Respiratory Protection	None required during normal handling or when engineering controls are sufficient.
Eye/Skin Protection	Wear chemically resistant gloves, and lab coats or other body covering to minimize potential for skin contact. Safety glasses are always required.

Section 9 Physical and Chemical Properties

Boiling Point	Not Established
Vapor Pressure(Mm Hg)	Not Established
Melting Point	Not Established
Specific Gravity	1.000



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Evaporation Rate	Not Established
pH (Aqueous)	6.9 – 7.2
Solubility in Water	100%
% Volatiles By Volume	0 %
Appearance & Color	Clear, colorless solution
Odor	Odorless

Section 10 Stability and Reactivity Data

Stability	Material is Stable under normal conditions of temperature and pressure.
Hazardous Polymerization	Will not occur.
Decomposition Products	None
Incompatible materials	None

Section 11 Toxicological Information

Target Organ Effects:	Liver and kidney effects, reversible cellular necrosis
Sensitization:	Antibody development occurs
Mutagenicity:	No evidence in the Ames test and chromosomal aberration assay.
Carcinogenicity:	No studies to assess the carcinogenic potential of Denileukin Diftitox
Teratogenicity:	No studies to assess the carcinogenic potential of Denileukin Diftitox

Section 12 Ecological Information

No ecological information is available for the product.

Section 13 Disposal Considerations

Burn in a permitted waste incinerator. Observe all Federal, State, and Local Laws.

Section 14 Transportation Data and Additional Information



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DOT: Not regulated for surface transport
ICAO: Not regulated for air transport
IMO: Not regulated for water transport
Shipping Conditions: Frozen, on dry ice

Section 15 Regulatory Information

Data have not yet been transferred to this section.

Components of this product are not listed as carcinogenic by IARC, NCI/NTP, ACGIH, and OSHA.

Section 16 Other Information

In case of emergency, please contact CHEMTREC 800-424-9300, Internationally 703-527-3887

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