

PRODUCT DATA SHEET T-cell GAD65

Product Name: Diamyd® T-cell GAD65

Description: Recombinant human Glutamic Acid Decarboxylase (EC 4.1.1.15, 65kDa isoform, rhGAD65) generated by infection of *Spodoptera frugiperda* cells with baculoviral vector construct, purified in a multi-step process, formulated in RPMI medium with Human Serum Albumin.

Article number: #10-4508029-01

Quantity: 1mg/vial

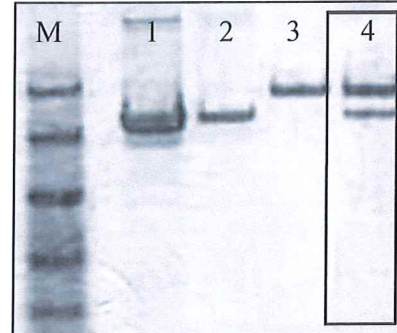
Concentration: 1mg/ml

Composition: RPMI medium with 1mg/ml clinical grade Human Serum Albumin

- Quality Assurance:**
1. >95% purity confirmed by SDS-PAGE and/or HPLC
 2. Identity of protein confirmed by Western Blot analysis with anti-rhGAD65 antibody
 3. Identity of protein confirmed by analysis of enzymatic activity
 4. Immune cell stimulatory effect confirmed by *in vitro* assays.

Shipping Conditions: Shipped on dry ice

Storage Conditions: Store at <-60°C



Coomassie stained SDS-PAGE gel of rhGAD65, BSA (same size as HSA) and T-cell GAD65 run under reduced conditions. (1) rhGAD65 1µl (2) rhGAD65 0.1µl (3) BSA (4) T-cell GAD65

THIS CERTIFICATE IS A DECLARATION OF ANALYSIS AT THE TIME OF MANUFACTURE

The validity of the information contained in this Product Sheet, including Material Safety information, is verified by:

Sign: 
Name: Anton Lindqvist
Title: Chief Scientific Officer

This product is to be used for research purposes only

Please note that our GAD-products is sold for research and non-commercial purposes only under exclusive licenses from several universities in the USA.

Our GAD-based products are not approved for use in humans by any Regulatory authority in any country.

MATERIAL SAFETY DATA SHEET (MSDS)

The enclosed information has been compiled from reliable sources, knowledge and experience, but does not claim, or purport to claim, to be all-inclusive, and shall be used only as a guide. Diamyd shall not be held liable for any damages resulting from the use of this product since it is the user's responsibility to determine whether this product is suitable for their particular purposes. The user assumes all risk of use, contact with this material, handling, and disposal.

Date of or revision: December 5, 2017

IDENTIFICATION OF SUBSTANCE AND COMPANY:

Product Name: recombinant 65 kDa isoform of human Glutamic Acid
Decarboxylase (rhGAD65)

Supplier: Diamyd Medical AB, Kungsgatan 29, SE-111 56 Stockholm, Sweden

Telephone: +46(0)8-661 00 26 (only during office hours)
Fax: +46(0)8-661 63 68
Email: info@diamyd.com
finance@diamyd.com

COMPOSITION/INFORMATION ON INGREDIENTS:

Name: rhGAD65 (T-cell GAD65)
CAS Registry Number: not available
E.C. Number: EC 4.1.1.15
Molecular Weight: ca. 65 kDa

This rhGAD65 is manufactured by cDNA expression in a baculovirus/insect cell system. Though there have not yet been any indications toxicity, the chemical, physical and toxicological properties of this protein has not yet been fully investigated. Exercise care to prevent contact or exposure.

Hazards identified with this product are those derived from the named product compound (as described in this MSDS) and those associated with the its buffer components (RPMI and Humans Serum Albumin).

HAZARDS IDENTIFICATION:

No hazards relating to the protein have been identified in *in vitro*, *in vivo* or clinical studies.

No classification has been assigned

Caution: Avoid contact and inhalation.

MATERIAL SAFETY DATA SHEET (MSDS)

FIRST AID MEASURES:

If swallowed, wash out mouth with water, if the person is conscious. Consult a physician.
In case of skin contact, wash immediately with soap and copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes and wash before re-wearing. Consult a physician.
In case of eye contact, flush immediately with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating eyelids with fingers. Consult a physician.
In case of inhalation, remove to fresh air and monitor breathing. If breathing becomes difficult, consult a physician.

FIRE AND EXPLOSION HAZARD DATA:

Flash Point: No information available
Extinguishing Media: Use media appropriate to the surrounding fire.
Special Fire-Fighting Procedures: None required for this material; dress appropriately for surrounding fire.
Unusual Fire and Explosion Hazards: None known.

ACCIDENTAL RELEASE MEASURES:

Wear protective clothing and equipment (at least a lab coat, chemical safety goggles and laboratory gloves). Avoid raising dust. Blot spilled liquid and dispose as an organic waste in accordance with local restrictions. Ventilate area and wash spill site with water after material pickup is complete.

HANDLING AND STORAGE:

Store at according to conditions recommended for reagent stability. Avoid contact with material. Avoid repeated or prolonged exposure to material. Refer also to the next section.

EXPOSURE CONTROLS/PERSONAL PROTECTION:

Protective equipment: Wear suitable protective clothing, such as a lab coat, chemical resistant gloves and chemical safety goggles.
Respiratory protection and ventilation: Handle in a laboratory with adequate ventilation. Avoid breathing dust.

PHYSICAL AND CHEMICAL PROPERTIES:

Appearance: Frozen until thawed, then liquid (aqueous solution).

STABILITY AND REACTIVITY:

Stability: Stable.
Hazardous combustion or decomposition products: Nature of combustion products and decomposition products are not known.
Hazardous polymerization: Will not occur.

MATERIAL SAFETY DATA SHEET (MSDS)

TOXICOLOGICAL INFORMATION:

May be harmful if inhaled, ingested or absorbed through the skin. May cause irritation. Prolonged or repeated exposure may result in allergic or autoimmune reactions in certain sensitive individuals.

The toxicological properties of this material have not been fully established.

ECOLOGICAL INFORMATION:

No information available.

DISPOSAL CONSIDERATIONS:

Country, federal state and local regulations concerning disposal are different and subject to frequent change. For this reason, we recommend that you contact local authorities for information on the disposal of this product and observe any applicable regulations. Alternatively, arrange for disposal by a licensed disposal company. Due to the biological nature of this material, we recommend that disposal include a biological inactivation method (e.g., autoclaving, incineration, etc.), even though the biohazardous properties of this product do not make such a step mandatory.

TRANSPORT INFORMATION:

Must be transported below -60°C. Dry ice shipment is recommended.

REGULATORY INFORMATION:

Caution: This material has not yet been fully tested. Based on general health and good laboratory practice considerations, the observation of the following risk and safety phrases are recommended:

Risk Phrases:

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

Safety Phrases:

S24/25: Avoid contact with skin and eyes.

S36/37/38: Wear suitable protective clothing, gloves and eye/face protection.

OTHER INFORMATION:

Wash thoroughly after handling.

Material should be handled only by qualified, experienced professionals.