

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : MACRODUCT Advanced Supply Kit or Pilogel Discs
Product code : SS-268, SS-268-ND

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

Use of the substance/mixture : Sweat Induction for Diagnosis of Cystic Fibrosis

1.3. Details of the supplier of the safety data sheet

ELITechGroup Inc.
370 West 1700 South
Logan, UT 84321 - USA
T +1 (435) 752-6011 - F +1 (435) 752-4127
qara_ebs@elitechgroup.com - www.elitechgroup.com

1.4. Emergency telephone number

Emergency number : Contact your distributor or poison control center in your country.
InfoTrac Emergency Response: Calls within the USA, phone: 1-800-535-5053. Calls outside the USA, phone: +1 352-323-3500 (call collect)
Customer ID: #90104 (NOTE: this number is required when a customer calls into either phone number above).

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Acute Tox. 4 (Oral) H302 - Harmful if swallowed
Full text of H statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US) :



GHS07

Signal word (GHS US) :

Warning

Hazard statements (GHS US) :

H302 - Harmful if swallowed

Precautionary statements (GHS US) :

P102 - Keep out of reach of children.
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product.
P301+P312 - If swallowed: Call a POISON CENTER, a doctor if you feel unwell.
P330 - Rinse mouth.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

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3.2. Mixtures

Name	Product identifier	%	GHS US classification
Pilocarpine nitrate	(CAS-No.) 148-72-1	< 1	Acute Tox. 2 (Oral), H300 Acute Tox. 2 (Inhalation), H330

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Call a poison center/doctor/physician if you feel unwell.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Wash skin with plenty of water.
First-aid measures after eye contact : Rinse eyes with water as a precaution.
First-aid measures after ingestion : Rinse mouth. Call a poison center/doctor/physician if you feel unwell.

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

- Symptoms/effects after ingestion : Swallowing a small quantity of this material will result in serious health hazard.

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. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures : Ventilate area.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

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 : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep cool.
Incompatible products : Strong bases. Strong acids.
Incompatible materials : Sources of ignition. Direct sunlight.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

- Appropriate engineering controls : Ensure good ventilation of the work station.
- Personal protective equipment : Avoid all unnecessary exposure.
- Hand protection : Wear protective gloves. The glove material has to be impermeable and resistant to the product/the substance/the preparation. Use equipment tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Materials including natural rubber latex or nitrile with a material thickness of 4-6 mm are suggested for general use, however the selection of suitable gloves does not only depend on the material, but also on other marks of quality. Quality may vary from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance and penetration time/breakthrough time of the glove material cannot be calculated/observed in advance and therefore has to be checked prior to the application.
- Eye protection : Safety glasses.
- Skin and body protection : Wear suitable protective clothing.
- Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.
- Environmental exposure controls : Avoid release to the environment.
- Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state : Solid
- Color : Semi-clear; amber
- Odor : Characteristic
- Odor threshold : No data available
- pH : No data available
- Melting point : Not applicable
- Freezing point : Not applicable
- Boiling point : No data available
- Flash point : Not applicable
- Relative evaporation rate (butyl acetate=1) : No data available
- Flammability (solid, gas) : No data available
- Explosion limits : Not applicable
- Explosive properties : No data available
- Oxidizing properties : No data available
- Vapor pressure : No data available
- Relative density : No data available
- Relative vapor density at 20 °C : No data available
- Solubility : No data available
- Partition coefficient n-octanol/water (Log Pow) : No data available
- Auto-ignition temperature : Not applicable
- Decomposition temperature : No data available
- Viscosity : No data available
- Viscosity, kinematic : Not applicable
- Viscosity, dynamic : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

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10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

MACRODUCT Advanced Supply Kit or Pilogel Discs	
ATE US (oral)	500 mg/kg body weight
Pilocarpine nitrate (148-72-1)	
LD50 oral rat	911 mg/kg
ATE US (oral)	5 mg/kg body weight
ATE US (gases)	100 ppmV/4h
ATE US (vapors)	0.5 mg/l/4h
ATE US (dust, mist)	0.05 mg/l/4h

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified

Based on available data, the classification criteria are not met

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity – single exposure : Not classified

Specific target organ toxicity – repeated exposure : Not classified

Aspiration hazard : Not classified

Potential Adverse human health effects and symptoms : Harmful if swallowed.

Symptoms/effects after ingestion : Swallowing a small quantity of this material will result in serious health hazard.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

12.2. Persistence and degradability

MACRODUCT Advanced Supply Kit or Pilogel Discs	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

MACRODUCT Advanced Supply Kit or Pilogel Discs	
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Other information : Avoid release to the environment.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
- Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
- Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT
Not regulated for transport

Transportation of Dangerous Goods

No additional information available

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Pilocarpine nitrate (148-72-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

No additional information available

SECTION 16: Other information

- Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
- Abbreviations and acronyms : European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways. European Agreement concerning the International Carriage of Dangerous Goods by Road. Acute Toxicity Estimate. Biological limit value. Chemical Abstract Service number. Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008. Derived Minimal Effect level. Derived-No Effect Level. Median effective concentration. European Community number. European Standard. International Air Transport Association. International Maritime Dangerous Goods. Median lethal concentration. Median lethal dose. Lowest Observed Adverse Effect Level. No-Observed Adverse Effect Concentration. No-Observed Adverse Effect Level. No-Observed Effect Concentration. Occupational Exposure Limit. Persistent Bioaccumulative Toxic. Predicted No-Effect Concentration. Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006. Regulations concerning the International Carriage of Dangerous Goods by Rail. Safety Data Sheet. Very Persistent and Very Bioaccumulative. Water Hazard Class.
- Other information : None.

Full text of H-phrases:

H300	Fatal if swallowed
H302	Harmful if swallowed
H330	Fatal if inhaled

SDS US Custom - EBS

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.

Reason For Change: Updated information in latest GHS format to meet compliance.