MACRODUCT® Supply Kit or Pilogel Discs

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 1 Identification

1.1. Product identifier

Product form : Mixture
Product name : MACRODUCT® Supply Kit or Pilogel Discs
Product code : SS-023, SS-032, SS-032-ND

1.2. Other means of identification

No additional information available

1.3. Recommended use of the chemical and restrictions on use

Use of the substance/mixture : Sweat induction for diagnosis of cystic fibrosis
Recommended use : Professional use only

1.4. Supplier's details

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370 West 1700 South
Logan, UT, Cache, 84321
USA
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qara_ebs@elitechgroup.com - www.elitechgroup.com

1.5. Emergency phone 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 Identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. Label elements

GHS US labeling

No labeling applicable

2.3. Hazards associated with known or reasonably anticipated uses

No additional information available

2.4. Hazards not otherwise classified

Other hazards which do not result in classification : None under normal conditions.

2.5. Unknown acute toxicity

No additional information available

SECTION 3 Composition/information on ingredients

3.1. Substances

Not applicable

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 hazard classes and H-statements : see section 16

SECTION 4 First aid measures

4.1. Description of necessary first-aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow affected person to breathe fresh air. Allow the victim to rest.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash skin with plenty of water.

First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists. Rinse eyes with water as a precaution.

First-aid measures after ingestion : Immediately call a poison center or doctor/physician. Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER or doctor/physician if you feel unwell.

Personal protection for first-aid responders. : First aid workers will be equipped with suitable personal protective equipment.

4.2. Most important symptoms/effects, acute and delayed

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

Symptoms/effects after inhalation : None under normal conditions.

Symptoms/effects after skin contact : None under normal conditions.

Symptoms/effects after eye contact : None under normal conditions.

Symptoms/effects after ingestion : May be harmful if swallowed.

4.3. Indication of immediate medical attention and special treatment needed, if necessary

Other medical advice or treatment : Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Specific hazards arising from the chemical

Fire hazard : No fire hazard.

Explosion hazard : No direct explosion hazard.

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Special protective equipment and precautions for fire-fighters

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. Do not enter fire area without proper protective equipment, including respiratory protection.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. 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

General measures : Notify authorities if product enters sewers or public waters. Absorb spillage to prevent material-damage.

For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.

Emergency procedures : Ventilate spillage area. Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Ventilate area. Evacuate unnecessary personnel.

Environmental precautions : Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.2. Methods and materials for containment and cleaning up

For containment : Using a clean shovel, put the material in a dry container and cover without compressing it.

Methods for cleaning up : Mechanically recover the product. Take up mechanically (sweeping, shoveling) and collect in suitable container for disposal. On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

Other information : Dispose of materials or solid residues at an authorized site.

See Heading 8,Exposure controls and personal protection,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. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor.

Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Always wash hands after handling the product.

Additional hazards when processed : Not expected to present a significant hazard under anticipated conditions of normal use.

7.2. Conditions for safe storage, including incompatibilities

Technical measures : Keep in a cool, well-ventilated place away from heat.

Storage conditions : Store in a well-ventilated place. Keep cool. Store in original container. Keep container closed when not in use.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Heat sources. Sources of ignition. Direct sunlight.

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Packaging materials : Store always product in container of same material as original container.

SECTION 8 Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures, such as personal protective equipment

Personal protective equipment:

Avoid all unnecessary exposure.

Materials for protective clothing:
Wear protective clothing

Hand protection:				
Wear protective gloves				
Type	**Material**	**Permeation**	**Thickness (mm)**	**Penetration**
Disposable gloves	Latex, Nitrile rubber (NBR)	3 (> 60 minutes)	0.1 - 0.15	

Eye protection:
Chemical goggles or safety glasses

Skin and body protection:
Wear suitable protective clothing

Respiratory protection:
Respiratory protection not required in normal conditions. In case of inadequate ventilation wear respiratory protection.

Personal protective equipment symbol(s):



Other information:

Do not eat, drink or smoke during use.

SECTION 9 Physical and chemical properties

9.1. Basic physical and chemical properties

Physical state : Solid

Color : Clear amber

Odor : Characteristic

Odor threshold : No data available

pH : No data available

Melting point : No data available

Freezing point : Not applicable

Boiling point	:	No data available
Flash point	:	Not applicable
Flammability (solid, gas)	:	Non flammable.
Vapor pressure	:	No data available
Relative vapor density at 20°C	:	No data available
Relative density	:	No data available
Solubility	:	Water: No data available
Partition coefficient n-octanol/water (Log Pow)	:	No data available
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	No data available
Viscosity, kinematic	:	Not applicable
Explosion limits	:	Not applicable
Particle characteristics	:	No data available

9.2. Data relevant with regard to physical hazard classes (supplemental)

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.

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

Heat. Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	:	Not classified
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified

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

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Pilocarpine nitrate (148-72-1)	
ATE US (dust, mist)	0.05 mg/l/4h

Skin corrosion/irritation : Not classified

Pilocarpine nitrate (148-72-1)	
pH	3.5 – 4.5

Serious eye damage/irritation : Not classified

Pilocarpine nitrate (148-72-1)	
pH	3.5 – 4.5

Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

MACRODUCT® Supply Kit or Pilogel Discs	
Viscosity, kinematic	Not applicable

Potential Adverse human health effects and symptoms : Harmful if swallowed.
Symptoms/effects after inhalation : None under normal conditions.
Symptoms/effects after skin contact : None under normal conditions.
Symptoms/effects after eye contact : None under normal conditions.
Symptoms/effects after ingestion : May be harmful if swallowed.

SECTION 12 Ecological information

12.1. Ecotoxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short–term (acute) : Not classified
Hazardous to the aquatic environment, long–term (chronic) : Not classified

12.2. Persistence and degradability

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

Pilocarpine nitrate (148-72-1)	
Persistence and degradability	Rapidly degradable

12.3. Bioaccumulative potential

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

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Ozone : Not classified
Fluorinated greenhouse gases : No

Other information : Avoid release to the environment.

SECTION 13 Disposal considerations

Regional waste regulation : Disposal must be done according to official regulations.
Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations : Disposal must be done according to official regulations.
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. Disposal must be done according to official regulations.
Additional information : Do not re-use empty containers.
Ecological waste information : Avoid release to the environment.

SECTION 14 Transport information

In accordance with DOT / TDG / IMDG / IATA

14.1. UN number

Not regulated for transport

14.2. UN Proper Shipping Name

Proper Shipping Name (DOT) : Not regulated
Proper Shipping Name (TDG) : Not regulated
Proper Shipping Name (IMDG) : Not regulated
Proper Shipping Name (IATA) : Not regulated

14.3. Transport hazard class(es)

DOT
Transport hazard class(es) (DOT) : Not regulated

TDG
Transport hazard class(es) (TDG) : Not regulated

IMDG
Transport hazard class(es) (IMDG) : Not regulated

IATA
Transport hazard class(es) (IATA) : Not regulated

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14.4. Packing group

Packing group (DOT) : Not regulated
Packing group (TDG) : Not regulated
Packing group (IMDG) : Not regulated
Packing group (IATA) : Not regulated

14.5. Environmental hazards

Other information : No supplementary information available.

14.6. Transport in bulk

Not applicable

14.7. Special precautions for user

DOT
Not regulated

TDG
Not regulated

IMDG
Not regulated

IATA
Not regulated

SECTION 15 Regulatory information

15.1. Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:		
Pilocarpine nitrate	CAS-No. 148-72-1	< 1%

15.2. International regulations

CANADA

Pilocarpine nitrate (148-72-1)
Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. State regulations

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

SECTION 16 Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
Other information : None.

Full text of hazard classes and H-statements	
H300	Fatal if swallowed
H330	Fatal if inhaled

Safety Data Sheet (SDS), USA

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: updating to latest format and company header logo.

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