

Safety Data Sheet

acc. to OSHA HCS

SDS010 Rev 2

USA

PCN 3581 Printing date 11/28/2016

Reviewed on 11/28/2016

1 Identification

- **Product identifier**
- **Trade name:** Iontopak - Iontophoresis Solution Kit - Pilocarpine Nitrate
- **Article number:** CFA200
- **CAS Number:**
148-72-1
- **EC number:**
205-723-7
- **Index number:**
614-017-00-1
- **Application of the substance / the mixture**
Reconstituted solution for use with the Cystic Fibrosis Analyzer (Model CFA).
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Advacned Instruments
2 Technology Way
USA-NORWOOD, MA 02062
USA
info@acompanies.com
+1 (781) 320-9000
- **Information department:** Regulatory Affairs
- **Emergency telephone number:** 1 (877) 740-5015 - Rocky Mountain Poison & Drug Center (24 hour)

2 Hazard(s) identification

- **Classification of the substance or mixture**



Acute Tox. 4 H302 Harmful if swallowed.

- **Label elements**
- **GHS label elements** The substance is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



- **Signal word** Warning
- **Hazard-determining components of labeling:**
pilocarpine nitrate
- **Hazard statements**
Harmful if swallowed.
- **Precautionary statements**
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
Rinse mouth.
Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	1	Health = 1
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**
148-72-1 pilocarpine nitrate
- **Identification number(s)**
- **EC number:** 205-723-7
- **Index number:** 614-017-00-1

4 First-aid measures

- **Description of first aid measures**
- **General information:**
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Immediately call a doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
- **Breathing equipment:** Not required.
- **Protection of hands:**
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** Not required.

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9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Solid
Color:	Not determined.
Odor:	Characteristic
Odor threshold:	Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Product is not flammable.

- **Ignition temperature:**

Decomposition temperature: Not determined.

- **Auto igniting:** Not determined.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Vapor pressure:** Not applicable.

- **Density:** Not determined.

- **Relative density** Not determined.

- **Vapor density** Not applicable.

- **Evaporation rate** Not applicable.

- **Solubility in / Miscibility with**

Water: Insoluble.

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

Dynamic:	Not applicable.
Kinematic:	Not applicable.

- **Solvent content:**

Organic solvents:	0.0 %
VOC content:	0.0 g/l / 0.00 lb/gl

Solids content: 100.0 %

- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.

- **Chemical stability**

- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

- **Possibility of hazardous reactions** No dangerous reactions known.

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- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

148-72-1 pilocarpine nitrate

Oral	LD50	911 mg/kg (rat)
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- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

Substance is not listed.

- **NTP (National Toxicology Program)**

Substance is not listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

Substance is not listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**

- **General notes:**

Water hazard class 3 (Assessment by list): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**

- **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|---------------------------------------|
| • UN proper shipping name | Pilocarpine Nitrate |
| • Packing group | |
| • DOT, IMDG, IATA | 2811 |
| • Environmental hazards: | Not applicable. |
| • Special precautions for user | Warning: Toxic substances |
| • Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| • UN "Model Regulation": | UN 1544 ALKALOIDS, SOLID, N.O.S., 6.1 |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

- **Section 355 (extremely hazardous substances):**

Substance is not listed.

- **Section 313 (Specific toxic chemical listings):**

Substance is not listed.

- **TSCA (Toxic Substances Control Act):**

Substance is listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

Substance is not listed.

- **Chemicals known to cause reproductive toxicity for females:**

Substance is not listed.

- **Chemicals known to cause reproductive toxicity for males:**

Substance is not listed.

- **Chemicals known to cause developmental toxicity:**

Substance is not listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

Substance is not listed.

- **TLV (Threshold Limit Value established by ACGIH)**

Substance is not listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

Substance is not listed.

- **GHS label elements** The substance is classified and labeled according to the Globally Harmonized System (GHS).

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- **Hazard pictograms**



GHS07

- **Signal word** Warning

- **Hazard-determining components of labeling:**

pilocarpine nitrate

- **Hazard statements**

Harmful if swallowed.

- **Precautionary statements**

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

Rinse mouth.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Regulatory Affairs

- **Contact:** Regulatory Affairs

- **Date of preparation / last revision** 11/28/2016 / -

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

DOT: US Department of Transportation

IATA: International Air Transport Association

BEI: Biological Exposure Limit

Acute Tox. 4: Acute toxicity – Category 4

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