Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Thiamine Hydrochloride Injection

Other means of identification : 200 mg per 2 mL (100 mg/mL), carton of 25 vials NDC 55150-273-25

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics

279 Princeton Highstown Road East Windsor, NJ 08520

1.4. Emergency telephone number

Emergency number : 1-888-238-7880

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Resp. Sens. 1 H334 Skin Sens. 1 H317 Repr. 2 H361

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

GHS US labeling

Hazard pictograms (GHS US)



GHS08

Signal word (GHS US) : Danger

Hazard statements (GHS US) : H317 - May cause an allergic skin reaction

H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled

H361 - Suspected of damaging fertility or the unborn child

Precautionary statements (GHS US) : P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray.

P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P284 - [In case of inadequate ventilation] wear respiratory protection.

P302+P352 - If on skin: Wash with plenty of water.

P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep

comfortable for breathing.

P308+P313 - If exposed or concerned: Get medical advice/attention.

P321 - Specific treatment (see supplemental first aid instruction on this label). P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.

P363 - Wash contaminated clothing before reuse.

P405 - Store locked up.

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

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SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Water	(CAS-No.) 7732-18-5	≤ 99	Not classified
Sodium hydroxide	(CAS-No.) 1310-73-2	≤ 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Thiamine hydrochloride	(CAS-No.) 67-03-8	≤ 1	Not classified
Thioglycerol	(CAS-No.) 96-27-5	0.5	Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317
Chlorobutanol	(CAS-No.) 57-15-8	0.5	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 STOT SE 3, H335

Full text of hazard classes and H-statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : If not breathing, give artificial respiration.

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.

First-aid measures after eye contact : In case of contact with eyes, rinse immediately with plenty of water. Seek immediate medical

attention.

First-aid measures after ingestion : Wash mouth with water. Do not induce vomiting unless directed by medical personnel. Seek

immediate medical attention.

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

Symptoms/effects after inhalation : May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

Symptoms/effects after skin contact : May cause an allergic skin reaction.

Symptoms/effects after eye contact : May cause eye irritation.

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

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.

Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

6.2. Environmental precautions

Prevent entry to sewers and public waters.

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6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.

Methods for cleaning up : Recycle product or dispose safely.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store at 20° to 25°C (68° to 77°F)

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Water (7732-18-5)

Not applicable			
Sodium hydroxide (1310	Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH OEL Ceiling	2 mg/m³	
OSHA	OSHA PEL (TWA) [1]	2 mg/m³	
IDLH	IDLH	10 mg/m³	
NIOSH	NIOSH REL (Ceiling)	2 mg/m³	

Thiamine hydrochloride (67-03-8)

Not applicable

Thioglycerol (96-27-5)

Not applicable

Chlorobutanol (57-15-8)

Not applicable

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.

Hand protection : Use suitable protective gloves to minimize skin contact.

Eye protection : Wear safety glasses or goggles. Skin and body protection : Wear suitable working clothes.

Respiratory protection : Wear NIOSH approved respirator if workplace exposure limits may be exceeded.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear.
Color : Colorless
Odor : Odorless
Odor threshold : No data av

Odor threshold : No data available pH : No data available Melting point : No data available Freezing point : No data available Boiling point : No data available Flash point : No data available Relative evaporation rate (butyl acetate=1) : No data available Flammability (solid, gas) : No data available

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Vapor pressure : No data available Relative vapor density at 20 °C : No data available No data available Relative density Solubility : completely soluble. Partition coefficient n-octanol/water (Log Pow) : No data available Auto-ignition temperature : No data available Decomposition temperature : No data available : No data available Viscosity, kinematic : No data available Viscosity, dynamic **Explosion limits** : No data available Explosive properties : No data available Oxidizing properties : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Do not freeze.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Water (7732-18-5)		
LD50 oral rat	> 90 ml/kg	
Sodium hydroxide (1310-73-2)		
LD50 oral rat	140 – 340 mg/kg	
LD50 dermal rabbit	1350 mg/kg	
ATE US (dermal)	1350 mg/kg	
Thioglycerol (96-27-5)		
ATE US (oral)	500 mg/kg body weight	

ATE 00 (oral)	300 mg/kg body weight
ATE US (dermal)	300 mg/kg body weight
Chlorobutanol (57-15-8)	
ATE US (oral)	500 mg/kg body weight

Skin corrosion/irritation : Not classified Serious eye damage/irritation : Not classified

Respiratory or skin sensitization : May cause an allergy or asthma symptoms or breathing difficulties if inhaled. May cause an

allergic skin reaction.

Germ cell mutagenicity : Not classified Carcinogenicity : Not classified

Reproductive toxicity : Suspected of damaging fertility or the unborn child.

STOT-single exposure : Not classified

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STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Sodium hydroxide (1310-73-2)	
LC50 - Fish [1]	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international

regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Water (7732-18-5)

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

Sodium hydroxide (1310-73-2)

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

CERCLA RQ 1000 lb

15.2. US State regulations

Sodium hydroxide (1310-73-2)

- U.S. Massachusetts Right To Know List
- U.S. Minnesota Hazardous Substance List
- U.S. New Jersey Right to Know Hazardous Substance List
- U.S. Pennsylvania RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4

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Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Repr. 2	Reproductive toxicity Category 2
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation
H290	May be corrosive to metals
H302	Harmful if swallowed
H311	Toxic in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child

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.

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