



# **Material Safety Data Sheet**

#### Section 1 –Product and Company Identification

# Moni-Trol ® H • Liquid Chemistry Control

Catalog Number  $\begin{array}{lll} & \text{M5155-1 Moni-Trol}^{\$} \bullet \text{ H, Level 1 (6 x 5 mL)} \\ & \text{M5155-2 Moni-Trol}^{\$} \bullet \text{ H, Level 2 (6 x 5 mL)} \\ & \text{M5155-3 Moni-Trol}^{\$} \bullet \text{ H, Level 3 (6 x 5 mL)} \\ & \text{M5155-SP Moni-Trol}^{\$} \bullet \text{ H, sample pack (3 x 5 mL)} \\ & \text{M5158-1 Moni-Trol}^{\$} \bullet \text{ H, Level 1 (10 x 15 mL)} \\ & \text{M5158-2 Moni-Trol}^{\$} \bullet \text{ H, Level 2 (10 x 15 mL)} \\ \end{array}$ 

M5158-2 Moni-Trol® • H, Level 2 (10 x 15 mL)
M5158-3 Moni-Trol® • H, Level 3 (10 x 15 mL)
M5158-SP Moni-Trol® • H, sample pack (3 x 15 mL)

Description Clinical Diagnostic Control Kits

Synonyms

M5155-1 Moni-Trol® • H, Level 1 Liquid Assayed Chemistry Control

M5155-2 Moni-Trol® • H, Level 2 Liquid Assayed Chemistry Control

M5155-3 Moni-Trol® • H, Level 3 Liquid Assayed Chemistry Control

M5155-3 Moni-Trol® • H, Level 3 Liquid Assayed Chemistry Control M5155-SP Moni-Trol® • H, sample pack Liquid Assayed Chemistry Control M5158-1 Moni-Trol® • H, Level 1 Liquid Unassayed Chemistry Control M5158-2 Moni-Trol® • H, Level 2 Liquid Unassayed Chemistry Control M5158-3 Moni-Trol® • H, Level 3 Liquid Unassayed Chemistry Control

M5158-SP Moni-Trol® • H, sample pack Liquid Unassayed Chemistry Control

Company Identification

Office Address

City, State, Zip Code

Company Phone Number

Emergency Phone Number

CHEMTREC Phone Number, US

Company CHEMTREC Phone Number, US

CHEMTREC Phone Number, Europe

Microgenics Corporation

46360 Fremont Blvd.

Fremont, CA 94538

(510) 979-5000

(810) 424-9300

(800) 424-9300

(202) 483-7616

#### Section 2 – Hazard Identification

Caution! This material contains substance of human and bovine origin. Even though tests are negative for infectious diseases, this product should be handled as a potentially infectious biological material. By normal use the product is not regarded as hazardous to health. The product is not classified as flammable or harmful to the environment; may cause eyes, skin, digestive track, and respiratory track irritation. The toxicological properties of this material have not been fully investigated. This product is not classified as dangerous in accordance with Directive 1999/45/EC or 67/548/EEC

# Section 3 – Composition/Information on Ingredients

CAS#	Component Name	Content	EINECS/ELINCS
66-81-9	Cycloheximide	0.01- 0.08%	200-636-0
64-17-5	Ethyl alcohol	0.01- 0.08%	200-578-6
50-06-6	Phenobarbital	0.01- 0.08%	200-007-0
298-46-4	Carbamazepine	0.01-0.08%	206-062-7
630-93-3	Phenytoin	0.01-0.08%	211-148-2
99-66-1	Valproic acid	0.01-0.08%	202-777-3
1405-41-0	Gentamicin	0.01-0.08%	215-778-9
7732-18-5	Water	59.1-64.7%	231-791-2
N/A	Human Serum	35-40%	N/A
N/A	BSA	0.2-0.3%	N/A

Component comments Have no OSHA, Canadian, or EU hazardous ingredients above applicable threshold. The

product contains protein materials, salts and stabilizer

 Specialty Diagnostics
 Microgenics Corporation
 Fremont, CA USA
 510-979-5000
 www.thermo.com/Diagnostics

 46360 Fremont Blvd
 94538
 510-979-5002 fax
 Toll Free: 800-232-3342

Doc: 92770-MMSDS-4 Page 1 of 14 Revision Date: 11/30/09





#### **Section 4 – First Aid Measures**

Eyes In case of contact immediately remove any contact lenses, hold the eyelids apart and flush eyes

with plenty of water for at least 15 minutes. Consult physician if symptoms should occur

Skin In case of contact remove contaminated clothing immediately, wash area with soap and flush with

plenty of water. Get medical attention if irritation develops and persists

Ingestion If swallowed, do not induce vomiting unless directed to do so by medical personnel. Drink plenty of

water. Get medical attention

Inhalation If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give

oxygen. Consult physician

Notes to Physician Treat symptomatically

#### **Section 5 – Fire Fighting Measures**

Flammable properties

Methods for clean-up

Personal protective equipment Combustion products may be health hazardous. In case of evacuation use OSHA/NIOSH

(or equivalent) approved protection mask. See section 8 Liquid product is not combustible; solid product may burn

Extinguishing Media All common fire extinguishing agents may be used

Protection of Firefighters Minimum protection for all firefighters should include a self-containing breathing apparatus

(SCBA) an full fire-fighting turn out gear. Upon decomposition this product may emit

carbon dioxide, carbon monoxide and/or low molecular weight hydrocarbons

NFPA Rating (estimated) Health: 1; Flammability: 0; Instability: 0 HMIS Rating (estimated) Health: 1; Flammability: 0; Instability: 0

#### Section 6 – Accidental Release Measures

Personal precautions Use proper personal protective equipment as indicated in Section 8. Keep unnecessary personnel

away

Environmental precautions Product is not water pollutant. Keep out of drains, sewers, ditches and open waterways.

Methods for containment If without risk prevent further spread of spilled material or leaking containers. Where possible dike

the spilled material. Absorb spill with inert material e.g. vermiculite, sand or diatomaceous earth Clean up spills immediately, observing precautions in the Exposure Controls/Personal Protection,

Section 8. Place in suitable container and provide ventilation. Wash area with a 5% chlorine

bleach solution or equivalent, then rinse with water

Other information For reporting requirements refer to Section 15

# Section 7 – Handling and Storage

Handling Keep container tightly closed. Wash thoroughly after handling. Avoid contact with eyes, skin, and

clothing. Avoid ingestion and inhalation. Use with adequate ventilation. Material produced in compliance to USDA and/or CPMP/BWP/1230/98 (or amendment as applicable) (Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products). This is a CPMP/BWP/1230/98 Category IV material: It does not contain, nor is it derived from Specified Risk Materials as defined in Commission decision 97/534/EC (or successive amendments). This material is prepared from a human source base. Donors have been tested by FDA approved methods and found negative for antibodies to HIV-1 and HIV-2, non-reactive for HBsAg, and non-reactive for HCV. Handle as potentially infectious material. This material should be handled at the biosafety level 2 (BSL2) as required by OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030.7) and consistent with the U.S. Department of Health and Human Services, the U.S. Public Health Service, Centers for Disease Control (CDC), and National Institute of Health (NIH) guidelines "Biosafety in Microbiological and Biomedical

Laboratories" (May 1988, HHS Publication No. (NIH) 88-8395)

Storage Store in a tightly closed container. For shelf life, store between 2° to 8°C

#### Section 8 – Exposure Controls/ Personal Protection

#### **Occupational Exposure Limits**

Chemical Name - Cycloheximide

	OSHA PEL					CGIH TL	<b>V</b>	All	IA	NIOSH REL			
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not
listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed

Specialty Diagnostics Microgenics Corporation Fremont, CA USA 510-979-5000 www.thermo.com/Diagnostics 46360 Fremont Blvd 94538 510-979-5002 fax Toll Free: 800-232-3342

Doc: 92770-MMSDS-4 Page 2 of 14 Revision Date: 11/30/09



Part of Thermo Fisher Scientific

Section 8 – Exposure Controls/ Personal Protection- contin	nued
--	------

	(	OSHA PE	EL		AC	GIH TL	٧		AIHA	NIOSH REL			
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not	1000	Not	1000	1000	Not	1000	1000	Not	180 ppm	Not	1000	Not	3300
listed	ppm	listed	ppm	ppm	listed	ppm	ppm	listed	(detectable);	listed	ppm	listed	ppm
	1900		1900	1900					100 ppm		1900		
	mg/m3		mg/m3	mg/m3					(recognizable)		mg/m3		

Chemical Name -Phenobarbital

		OSHA PE	EL		A	CGIH TL	٧	All	łΑ		NIOSH	IREL	
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not
listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed

Chemical Name - Carbamazepine

		OSHA PE	L		Α	CGIH TL	/	All	ΗA		NIOSH	l REL	
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not
listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed

Chemical Name - Phenytoin

		OSHA PE	L		A	CGIH TL	/	All	ΗA		NIOSH	l REL	
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not
listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed

Chemical Name - Valproic acid

		OSHA PE	L		A	CGIH TL	V	All	ΑF		NIOSE	l REL	
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not
listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed

Chemical Name - Gentamicin

		OSHA PE	L		Α	CGIH TL	/	All	łΑ		NIOSH	l REL	
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not
listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed

Chemical Name - Water

		OSHA PE	L		A	CGIH TL	<b>V</b>	All	IA	NIOSH REL				
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH	
Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	
listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	

Chemical Name - Human serum

		OSHA PE	EL		A	CGIH TL	<b>V</b>	All	łΑ		NIOSH	I REL	
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not
listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed

Chemical Name - BSA

		<u>osha pe</u>	L		A	CGIH TL	/	All	-AF		NIOSE	l REL	
Ceiling	3				Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not	Not
listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed	listed

Exposure Guidelines This pr

This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

**Engineering Controls** 

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations below the permissible exposure limits. Ventilation fans and other electrical service must be non-sparking and have an explosion-proof design

Specialty Diagnostics Microgenics Corporation 46360 Fremont Blvd Page 3 of 14 Fremont, CA USA 510-979-5000 www.thermo.com/Diagnostics 510-979-5002 fax Toll Free: 800-232-3342 Revision Date: 11/30/09





# Section 8 - Exposure Controls/ Personal Protection- continued

**Personal Protective Equipment** 

Eye/Face protection Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye

and face protection regulations in 29 CFR 1910.133 or European Standard EN166

Skin protection Wear appropriate protective gloves to prevent skin exposure. No skin irritation expected A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 Respiratory protection

requirements or European Standard EN 149 must be followed whenever workplace conditions

warrant a respirator's use

General Hygiene Considerations

Wear appropriate protective clothing to prevent skin exposure

# Section 9 – Physical and Chemical Properties

Appearance Clear Flash point No information Odor and odor threshold No information Flammable properties No information Physical State Liquid Solubility in water Miscible PH Density/specific Gravity 5-8 No information Vapor density Evaporation rate No information No information Octanol/Water partition coefficient (Kow) No information Boiling point No information Vapor pressure Auto-ignition temperature No information No information Melting Point/Freezing Point **Decomposition Temperature** No information No information

# Section 10 - Stability and Reactivity

Chemical Stability Stable at room temperature in closed containers under normal storage and handling

conditions

Conditions to Avoid Excess heat Incompatible Materials None reported

Hazardous Decomposition Products None

Possibility of hazardous reactions Has not been reported

# **Section 11 – Toxicological Information**

Acute dose effect (LD50/LC50)

CAS#66-81-9 Draize test, rabbit, skin: 1 pph/24H Moderate

Intraperitoneal, rat: LD50 = 3700 ug/kg Oral, rat: LD50 = 2 mg/kg Oral, mouse: LD50 = 133 mg/kg Intravenous, rat: LD50 = 2 mg/kg Intraperitoneal, mouse: LD50 = 100 mg/kg Intravenous, mouse: LD50 = 150 mg/kg Subcutaneous, mouse: LD50 = 160 mg/kg Oral, monkey: LD50 = 60 mg/kg Oral, guinea pig: LD50 = 60 mg/kg

Oral, dog: LD50 = 1 mg/kg

Intraperitoneal, cat: LD50 = 4 mg/kg Subcutaneous, guinea pig: LD50 = 60 mg/kg

Draize test, rabbit, eye: 500 mg Severe CAS# 64-17-5 Draize test, rabbit, eye: 500 mg/24H Mild

Draize test, rabbit, skin: 20 mg/24H Moderate Oral, rabbit: LD50 = 6300 mg/kg

Inhalation, mouse: LC50 = 39 gm/m3/4H Intravenous, mouse: LD50 = 1973 mg/kg Intraperitoneal, mouse: LC50 = 528 mg/kg Subcutaneous, mouse: LD50 = 8285 mg/kg

Inhalation, rat: LC50 = 20000 ppm/10H Oral, mouse: LD50 = 3450 mg/kg Oral, rat: LD50 = 7060 mg/kg Intraperitoneal, rat: LD50 = 3600 ug/kg Intravenous, rat: LD50 = 1440 mg/kg Intraarterial, rat: LD50 = 11 mg/kg Oral, rat: LD50 = 162 mg/kg Intraarterial, rat: LD50 = 151 mg/kg

CAS# 50-06-6

Subcutaneous, rat: LD50 = 200 mg/kg Intravenous, rat: LD50 = 209 mg/kg Rectal, rat: LD50 = 284 mg/kg Oral, mouse: LD50 = 137 mg/kg

Intraperitoneal, mouse: LD50 = 116 mg/kg

Subcutaneous, mouse: LD50 = 228 mg/kg Intravenous, mouse: LD50 = 218 mg/kg Intramuscular, mouse: LD50 = 175 mg/kg Oral, rabbit: LD50 = 185 mg/kg Intravenous, rabbit: LD50 = 187 mg/kg Oral, rabbit: LD50 = 2680 mg/kg

CAS# 298-46-4 Oral, mouse: LD50 = 529 mg/kg

Oral, rat: LD50 = 1957 mg/kg

Oral, mouse: LD50 = >11269 mg/kg CAS# 630-93-3 Oral, rat: LD50 = >5 gm/kgOral, mouse: LD50 = 1098 mg/kg Oral, rat: LD50 = 670 mg/kg. CAS# 99-66-1 CAS# 1405-41-0 Oral, mouse: LD50 = >11269 mg/kg Oral, rat: LD50 = >5 gm/kgCAS# 7732-18-5 Oral, rat: LD50 =998.21 mg/cm<sup>3</sup>@20<sup>0</sup>C

Repeated dose effect (NOAEL, LOEL)

Specialty Diagnostics Fremont, CA USA 510-979-5000 www.thermo.com/Diagnostics Microgenics Corporation 46360 Fremont Blvd 94538 510-979-5002 fax Toll Free: 800-232-3342

Doc: 92770-MMSDS-4 Page 4 of 14 Revision Date: 11/30/09





Section 11 – Toxicological Information - continued

CAS#66-81-9 Intraperitoneal, hamster: LDLo = 40 mg/kg Subcutaneous, chicken: LDLo = 2 mg/kg

CAS# 64-17-5 Oral, dog: LDLo = 5500 mg/kg Intraperitoneal, dog: LDLo = 3 gm/kg

Subcutaneous, dog: LDLo = 6 gm/kg Intravenous, dog: LDLo = 1600 mg/kg

CAS# 50-06-6 Oral, woman: LDLo = 25272 ug/kg/13D-l Oral, man: LDLo = 6485 ug/kg/2W-l Intraperitoneal, rabbit: LDLo = 150 mg/kg Subcutaneous, rabbit: LDLo = 150 mg/kg

Oral, cat; LDLo = 125 mg/kg Subcutaneous cat; LDLo = 125 mg/kg

Irritation prolonged exposure may cause irritation

Corrosivity No information found

Sensitization (inhalation, dermal, ocular) prolonged exposure may cause dermal irritation

Genotoxicity Genotoxic properties are not known

Teratogenicity Teratogenic properties are not known

Reproductive system effect

CAS# 66-81-9 Intraperitoneal, rat: TDLo = 250 ug/kg female 10 day(s) after conception

Parenteral, rat: TDLo = 750 ug/kg female 18 day(s) after conception Intraperitoneal, mouse: TDLo = 30 mg/kg female 10 day(s) after conception Subcutaneous, mouse: TDLo = 5 mg/kg female 11 day(s) after conception Parenteral, rabbit: TDLo = 5 ug/kg female 1 day(s) after conception Intraperitoneal, hamster:: TDLo = 60 mg/kg female 1 day(s) pre-mating

CAS# 64-17-5 Oral, woman: TDLo = 41 gm/kg female 41 week(s) after conception

Intravenous, woman: TDLo = 8 gm/kg female 32 week(s) after conception Intrauterine, woman: TDLo =200 mg/kg female 5 day(s) pre-mating

Oral, rat: TDLo = 322 gm/kg male 35 day(s) pre-mating

Oral, rat: TDLo = 132 gm/kg female 1-22 day(s) after conception

Inhalation, rat: TDLo = 20000 ppm/7H female 1-22 day(s) after conception Intraperitoneal, rat: TDLo = 15 gm/kg female 8-13 day(s) after conception Intravenous, rat: TDLo = 3 gm/kg female 6-7 day(s) after conception

Intracerebral, rat: TDLo = 5 mg/kg female 1 day(s) pre-mating

CAS# 50-06-6 Oral, woman: TDLo = 151 mg/kg female 27-39 week(s) after conception

Oral, rat: TDLo = 880 mg/kg female 7-17 day(s) after conception Intraperitoneal, rat: TDLo = 1 gm/kg female 1-20 day(s) after conception

Subcutaneous, rat: TDLo = 320 mg/kg multigenerations

Subcutaneous, rat: TDLo = 750 mg/kg female 1 day(s) pre-mating

Intramuscular, rat: TDLo = 200 mg/kg female 18-20 day(s) after conception

Carcinogenicity (IARC, NTP, OSHA (NIOSH & ACGIH)) or CA Prop 65

None of the components present in this material at concentrations equal to or greater than 0.1% are listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA, or CA Prop 65

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA

CAS# 66-81-9 Not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA, or CA Prop 65. NIOSH: Group I pesticide

CAS# 64-17-5 ACGIH: A4 -Not Classifiable as a Human Carcinogen

CAS# 50-06-6 ACGIH: Not listed California: carcinogen; initial date 1/1/90 NIOSH: Not listed NTP: Not listed OSHA: Possible Select carcinogen IARC: Group 2B carcinogen

CAS# 298-46-4: Not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA

CAS# 630-93-3 IARC - Group 2B (Possibly Carcinogenic to Humans)

CAS# 99-66-1: Not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA

CAS# 1405-41-0: Not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA,

CAS# 7732-18-5: Not listed as a carcinogen by ACGIH, IARC, NIOSH, NTP, OSHA, or CA Prop 65

Neurotoxicity Neurotoxic properties are not known

 Specialty Diagnostics
 Microgenics Corporation 46360 Fremont Blvd
 Fremont, CA USA 510-979-5000 510-979-5000 fax
 510-979-5000 fax
 www.thermo.com/Diagnostics 510-979-5002 fax

 Doc: 92770-MMSDS-4
 Page 5 of 14
 Revision Date: 11/30/09





# Section 11 - Toxicological Information - continued

Mutagenicity

CAS# 66-81-9 DNA repair, Escherichia coli = 50 ug/disc

Cytogenetic analysis, Drosophila melanogaster Cells: 100 mg/L

CAS# 64-17-5 DNA repair, Escherichia coli = 5 mg/well

Cytogenetic analysis, Parenteral = 500 mmol/L

CAS# 50-06-6 DNA inhibition, rat Liver = 1500 umol/L

Cytogenetic analysis, Human Lymphocyte = 10 mg/L

Target organ effect Ingestion of significant amount may cause nausea and vomiting

Epidemiology No information found

NOES Hazard Codes (NOHS, NOES) **RTECS** CAS# 66-81-9 84338 MA4375000 CAS# 64-17-5 31500 KQ6300000 CAS# 50-06-6 84369 CQ6825000 CAS# 298-46-4 X4467 HN8225000 CAS# 630-93-3 X4463 MU1400000 CAS# 99-66-1 X8970 YV7875000 CAS# 1405-41-0 X3126 LY2625000 CAS# 7732-18-5 M1000 ZC0110000

#### Section 12- Ecological Information

Ecotoxicity Not regarded as dangerous for the environment LC/EC/IC50 > 100 mg/l

Persistence/Degradability

No information found
Bioaccumulation/Accumulation

Mobility in Environmental media

No information found
Soluble in water

Environmental Not classified as harmful to the environment

Other Adverse Effects No information found

# Section 13 - Disposal Considerations

Waste from Residue/Unused

Products

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. Consult US EPA guidelines for the classification and determination (RCRA 40CFR Parts 261). Chemical waste generators must determine whether discarded chemical is classified as hazardous waste. Ensure complete and accurate classification

Contaminated packaging Clean container with water

RCRA P Series Wastes
RCRA U Series Wastes
EWC waste code

None of the components are on this list

Microgenics Corporation

Other Information According to the European Waste Catalogue, Waste Codes are not product

specific, but application specific. Waste codes should be assigned by the user

510-979-5000

www.thermo.com/Diagnostics

based on the a application for which the product was used

# Section 14 – Transport Information

Not regulated as hazardous material under US DOT, TDG, UNECE, ADR, ADN, IATA, ICAO, RID, IMDG/IMO, OTIF, Mexico

# Section 15 - Regulatory Information

#### **US Federal**

CAA -HAPs, CAA - Class 1, Class 2 Ozone Depletors, OSHA, OSHA - Highly Hazardous, SDWA, USDA, 21 CFR-IVD – No information found

CAS# 66-81-9
TSCA | SARA | SARA | CERCLA | RCRA | TSCA | TSCA | FIFRA | CWC | SARA | EPICRA | CAA- | FDA | DEA

Specialty Diagnostics

8(b)	302	313		261.33	8(d)	12(b)			311/312		SNAP		
no	yes	no	yes	no	no	no	no	no	yes	no	no	no	yes
CAS# (	64-17-5												
TSCA	SARA	SARA	CERCLA	RCRA	TSCA	TSCA	FIFRA	CWC	SARA	EPICRA	CAA-S	SNAP	FDA
8(b)	302	313		261.33	8(d)	12(b)			311/312				
no	no	no	no	no	no	no	yes	no	no	no	n	0	yes

Fremont, CA USA

46360 Fremont Blvd 94538 510-979-5002 fax Toll Free: 800-232-3342

Doc: 92770-MMSDS-4 Page 6 of 14 Revision Date: 11/30/09



Part of Thermo Fisher Scientific

Section	on 15	– Re	egula	itory	Infor	mat	ion -	con	itinu	ed										
CAS#	50-06	5-6																		
TSCA	S	SARA		SARA	١	CER	CLA	RCF	RA	-	ΓSC,	A	TS	CA	FIFRA	CWC	S	ARA		EPICRA
8(b)	3	302		313				261.	.33	8	3(d)		12	(b)			3	11/312		
no		yes		nc	)	n	0		no		n	10	n	0	no	no		yes		no
CAA-SI	NAP F	-DA		DEA																
no	.00 10	no		ye	S															
CAS# 2	_		CAE	٠,	OED/	οι Λ	DOE	٠.	TSC	٠,	-	SCA	FIFRA	CW	C   SA	D.4	-	EPICRA	C A A	FDA
8(b)	302	RA 2	313		CER	JLA	RCR 261.		8(d)			30A 12(b)	FIFKA	CVV	-	KA  /312	-	PICKA	CAA- SNAP	FDA
no		no .		0	no	<u> </u>	201.		n o(u)		<u>'</u>	no	no	no	31	no	-	no	no	no
CAS# 6					110	<u>,                                     </u>						110	110	110		110		110	110	110
TSCA 8(b)	SAF 302	RA	SARA 313	4	CERCL		RCRA 261.33		SCA		SCA 2(b)	FIFR	A CW	-	ARA 11/312	EP	ICR/	A CAA- SNAF		OSHA
ves	n		no		no	-	no		no		no	no	no	_	no		าด	no	no	ves
CAS# 9	9-66-1	<u> </u>								<u> </u>			1					1		, ,
TSCA	SA	RA	SAF	RA	CER	CLA	RCR	RA	TSC	A	Т	SCA	FIFRA	CW	C SA	RA	E	EPICRA	CAA-	FDA
8(b)	302	2	313				261.	33	8(d)		1	12(b)			311	/312			SNAP	
no		no	n	0	no	)	n	0	n	0		no	no	no		no		no	no	no
CAS# 1		_													. 1			T		
TSCA		RA	SAF		CER	CLA	RCR		TSC	Α			FIFRA	CWC			E	PICRA	CAA-	FDA
8(b)	302		313				261.		8(d)			2(b)			311	/312			SNAP	
no		no	n	0	nc	)	n	0	n	0		no	no	no		no		no	no	yes
CAS#7			101	055	201.4			<b>TOO</b>		T00		FIEDA	T 0144	<del></del>	101	LEDI	20.4	1 0 1 1	0114.5	
TSCA	302		ARA 13	CEI	RCLA	_	RA 1.33	TSC		TSC/		FIFRA	CW	-	ARA 11/312	EPI	JKA	CAA-	SNAP	FDA
8(b) ves	no	3	no		no	+ -	1.33	8(d) no		12(b) no		ves	no	_	no	n	^	.,	es	no
		), CED									4 TD							Ih EDCE		110

CAS# 66-81-9: CERCLA/SARA Section 302, 100 lb lower threshold TPQ; 10000 lb upper threshold TPQ, 100 lb EPCRA RQ CAS# 50-06-6: U.S. - DEA (Drug Enforcement Administration) - Schedule IV Controlled Substances Product as a whole is not subject to ITAR and EAR regulations

#### **US State**

# State Right to Know

CAS# 66-81-9 can be found on the following state Right-to-Know lists – Delaware, Massachusetts, Michigan, New Jersey, New York, Ohio, Pennsylvania, Texas

CAS# 64-17-5 – Connecticut, Hawaii, Idaho, Indiana, Massachusetts, Michigan, Minnesota, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Vermont, Washington

CAS# 50-06-6 can be found on the following state Right-to-Know lists – Alabama, Arizona, Colorado, Connecticut, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Massachusetts, Michigan, Minnesota, Mississippi, New Mexico, Ohio, Oregon, Pennsylvania, West Virginia, Wisconsin, Wyoming – Schedule IV Controlled Substances CAS# 630-93-3 can be found on the following state Right-to-Know lists California, Kentucky, Michigan, New York, Pennsylvania, Wisconsin

CAS# 99-66-1 can be found on the following state Right-to-Know lists California, Massachusetts

#### California

CAS# 66-81-9 is on the list of U.S. - California - 22 CCR - Presumed Extremely Hazardous Wastes, U.S. - California - 8 CCR Section 339 - Director's List of Hazardous Substances, U.S. - California - Air Toxics Hot Spots Act - Appendix A-I Substances - Quantified Emissions, U.S. - California - Air Toxics Hot Spots Act - Emissions Inventory Criteria & Guidelines - Appendix A-I Substances - ADOA, U.S. - California - Regulated Substances for Accidental Release Prevention

CAS# 50-06-6 8 CCR Section 339 - Director's List of Hazardous Substances, Air Toxics Hot Spots Act - Emissions Inventory Criteria & Guidelines - Appendix A-III Substances, Schedule IV Controlled Substances, No Significant Risk Levels (NSRL)

CAS# 630-93-3 8 CCR Section 339 - Director's List of Hazardous Substances, Air Toxics Hot Spots Act - Appendix A-I Substances - Quantified Emissions, Air Toxics Hot Spots Act - Emissions Inventory Criteria & Guidelines - Appendix A-I Substances - ADOA

CAS# 99-66-1 Air Toxics Hot Spots Act - Emissions Inventory Criteria & Guidelines - Appendix A-III ubstances

 Specialty Diagnostics
 Microgenics Corporation 46360 Fremont Blvd
 Fremont, CA USA 510-979-5000 510-979-5000 fax
 www.thermo.com/Diagnostics 510-979-5002 fax

 Doc: 92770-MMSDS-4
 Page 7 of 14
 Revision Date: 11/30/09





# Section 15 - Regulatory Information - continued

# California Prop 65

WARNING: This product contains Cycloheximide, a chemical known to the state of California to cause birth defects or other reproductive harm January 1, 1989, Title 8 CCR, Title 22 CCR, ATHS, Regulated Substances for Accidental Release Prevention - 100 lb TQ (in powdered form and with a particle size of less than 100 microns or if handled in solution or in molten form or the substance has an NFPA rating for reactivity of 2, 3 or 4); 10000 lb TQ (otherwise) WARNING: This product contains Ethyl Alcohol is Known To The State of California To Cause developmental toxicity, initial date 10/1/87 (when in alcoholic beverages), Title 8 CCR, Title 22 CCR

WARNING: This product contains Phenobarbital, a chemical known to the State of California to cause cancer January 1, 1990, California 8 CCR Section 339 - Director's List of Hazardous Substances, California - Air Toxics Hot Spots Act - Emissions Inventory Criteria & Guidelines - Appendix A-III, California - No Significant Risk Levels (NSRL), 2 µg/day, California - Schedule IV Controlled Substances

WARNING: This product contains Carbamazepine a chemical known to the State of California to cause birth defects or other reproductive harm January 29, 1999

WARNING: This product contains Diphenylhydantoin (Phenytoin), sodium salt a chemical known to the State of California to cause January 1, 1988

WARNING: This product contains Valproate (Valproic acid) a chemical known to the State of California to cause birth defects or other reproductive harm July 1, 1987

WARNING: This product contains Gentamicin, sulfate (salt) (listed as Aminoglycosides), a chemical known to the state of California to cause developmental reproductive toxicity

# Africa/ Asia-Pacific/Europe Non-EU /EU Member Countries/Latin America and Caribbean/ Middle East/Government Inventory Lists

CAS# 66-81-9

AICS	New Zealand-	Russia	ENCS	Switzerland	Belgium	PICCS	Malaysia	Singapore	France	Germany	EINECS
	GHS									VwVws	
yes	yes	no	yes	no	no	yes	yes	no	no	yes	200-636-0
India	Africa	Australia	Czech	Indonesia	Japan	China	New	Thailand	Austria	Check	Luxembourg
			Republic		(ENCS)		Zealand				
yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Malta	Netherlands	UK	Philippi	KE CL	Bermuda	Latvia	Estonia	Lithuania	Hungary	EC	Italy
			nes						,		,
yes	yes	yes	yes	yes	yes	no	yes	no	yes	no	yes

CAS# 64-17-5

AICS	New Zealand	Russia	ENCS	Switzerland	Belgium	PICCS	Malaysia	Singapore	France	Germany VwVws	Latvia	Lithuania	EC	EINECS
yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	no	200-578-6
Korea	South	Tan	Vietn	New	Hong	Taiw	India	Netherlan	Egypt	Japan	China	Australi	Polan	Indone
	Africa	zani	am	Zealand	Kong	an		ds		(ENCS		a	d	sia
		а								)				
yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	Yes	yes	yes	yes	yes
Croati	Island	Nor	Turke	Australia	Bulgaria	Che	Denm	Estonia	Finlan	Greece	Hun	Roman	Slove	Spain
a		way	У			ck	ark		d		gary	ia	nia	
yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Swed	UK	Thail	Slov	Portugal	Argentin	Ber	Brazil	Chile	Colo	Mexico	Isra	Venezu	Peru	Nicara
en		and	ak		a	mud			mbia		el	ela		gua
						а								
yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes

CAS# 50-06-6

CI IOII	20 00 0										
AICS	New	Russia	ENCS	Switzerland	Belgium	PICCS	Malaysia	Singapore	France	Germany	EINECS
	Zealand-									VwVws	
	GHS										
yes	yes	yes	yes	yes	no	yes	no	yes	no	no	200-007-
	-	-									0
Egypt	South	Australia	Cambodia	China	India	Japan	Korea	Philippines	Taiwar	Thailand	Bermuda
	Africa										
yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes
Latvia	Iceland	Lithuania	Denmark	EC		•			•		
no	ves	no	ves	no	Ĭ						

Specialty Diagnostics

Doc: 92770-MMSDS-4

Microgenics Corporation 46360 Fremont Blvd Fremont, CA USA 94538

510-979-5000 510-979-5002 fax www.thermo.com/Diagnostics
Toll Free: 800-232-3342
Revision Date: 11/30/09





# Section 15 – Regulatory Information - continued

	-46-4	

AICS	New	Russia	ENCS	Switzerland	Belgium	PICCS	Malaysia	Singapore	France	<b>EINECS</b>
	Zealand- GHS									
yes	yes	no	yes	no	no	yes	yes	yes	no	206- 062- 7
Australia	Japan	China	KECL	Bermuda	Germany VwVws	Latvia	Lithuania	EC		
yes	yes	yes	yes	Yes	yes	no	no	no		

#### CAS# 630-93-3

C1 10 11											
AICS	New	Russia	ENCS	Switzerland	Belgium	PICCS	Malaysia	Singapore	France	Germany	<b>EINECS</b>
	Zealand-				_					VwVws	
	GHS										
yes	yes	no	no	no	no	no	no	no	no	no	211-
											148-2
Japan	Denmark	KECL	HPV-	Bermuda	Latvia	Lithuania	EC				
			LPV								
yes	yes	yes	yes	yes	no	no	no				

# CAS# 99-66-1

AICS	New	Russia	ENCS	Switzerland	Belgium	PICCS	Malaysia	Singapore	France	Germany	EINECS
	Zealand- GHS						,			VwVws	
yes	yes	no	yes	no	no	yes	yes	yes	no	no	202- 777-3
Australia	KECL	Bermuda	Latvia	Lithuania	EC						
yes	yes	yes	no	no	no						

# CAS# 1405-41-0

OI TOT	1400 41 (	,									
AICS	New	Russia	ENCS	Switzerland	Belgium	PICCS	Malaysia	Singapore	France	Germany	<b>EINECS</b>
	Zealand-									VwVws	
	GHS										
yes	yes	no	yes	no	no	yes	no	no	no	no	215-
											778-9
Japan	Thailand	China	KECL	Latvia	Lithuania	EC					
yes	yes	yes	yes	no	no	no					

# CAS#7732-18-5

AICS	New Zealand	China	ENCS	Korea	PICCS	Malaysia	Denmark	EC	EINECS
yes	yes	yes	yes	yes	yes	yes	yes	yes	231-791-2

# **Advisory Agencies**

# CAS# 66-81-9

OECD	OSPAR	Australia Group	ICCA	IPCS	CICAD	WHO	UNEP	WGK	SIN
no	no	no	no	no	no	no	no	no	yes

# CAS# 64-17-5

OECD	OSPAR	Australia Group	ICCA	PCS	CICAD	WHO	UNEP	WGK
yes	yes	no	no	no	no	yes	no	no
CAS# 1	50-06-6							

no	no	no	no	no	no	yes	no	no	yes
OECD	OSPAR	Australia Group	ICCA	IPCS	CICAD	WHO	UNEP	WGK	IARC

# CAS# 298-46-4

OECD	OSPAR	Australia Group	ICCA	IPCS	CICAD	WHO	UNEP	WGK
yes	no	no	no	no	no	yes	no	no

#### CAS# 630-93-3

OECD	OSPAR	Australia Group	ICCA	IPCS	CICAD	WHO	UNEP	WGK
no	no	no	no	no	no	yes	no	no

www.thermo.com/Diagnostics Specialty Diagnostics Fremont, CA USA Microgenics Corporation 510-979-5000 46360 Fremont Blvd 94538 Toll Free: 800-232-3342 510-979-5002 fax Doc: 92770-MMSDS-4 Revision Date: 11/30/09

Page 9 of 14





www.thermo.com/Diagnostics

# Section 15 - Regulatory Information - continued

#### CAS# 99-66-1

OECD	OSPAR	Australia Group	ICCA	IPCS	CICAD	WHO	UNEP	WGK
no	no	no	no	no	no	yes	no	no

#### CAS# 1405-41-0

·		•						
OECD	OSPAR	Australia Group	ICCA	IPCS	CICAD	WHO	UNEP	WGK
no	no	no	no	no	no	yes	no	no

CAS# 7732-18-5

	OECD	OSPAR	Australia Group	ICCA	IPCS	CICAD	WHO	UNEP	WGK
I	yes	no	no	no	no	no	yes	no	no

#### **Exposure Limits**

CAS# 64-17-5

OEL-Alberta: 1000 ppm TWA; 1880 mg/m3 TWA

OEL-Argentina: 1000 ppm TWA

OEL-Australia: TWA 1000 ppm (1900 mg/m3) JAN 1993

OEL-Austria: 1000 ppm MAK; 1900 mg/m3 MAK, 2000 ppm STEL (3 X 60 min); 3800 mg/m3 STEL (3 X 60 min)

OEL-Belgium: TWA 1000 ppm (1880 mg/m3) JAN 1993, 1000 ppm TWA; 1907 mg/m3 TWA

OEL-Brazil: 780 ppm TWA; 1480 mg/m3 TWA OEL-British Columbia: 1000 ppm TWA OEL-Bulgaria: 1000 mg/m3 TWA

OEL-California: 1000 ppm PEL; 1900 mg/m3 PEL OEL-Chile: 800 ppm TWA; 1500 mg/m3 TWA

OEL-Colombia: 1000 ppm TWA

OEL-Croatia: 1000 ppm MAC; 1900 mg/m3 MAC, 2000 ppm Ceiling; 3800 mg/m3 Ceiling, 1000 ppm TWA; 1900 mg/m3 TWA

OEL-Czech Republic: 3000 mg/m3 Ceiling, 1000 mg/m3 TWA

OEL-Denmark: TWA 1000 ppm (1900 mg/m3) JAN 1993, 1000 ppm TWA; 1900 mg/m3 TWA

OEL-Egypt: TWA 1000 ppm; TWA 1880 mg/m3

OEL-Estonia: 1000 ppm STEL; 1900 mg/m3 STEL, 500 ppm TWA; 1000 mg/m3 TWA OEL-Finland: TWA 1000 ppm (1900 mg/m3); STEL 1250 ppm (2400 mg/m3) JAN 1993

OEL-France: TWA 1000 ppm (1900 mg/m3); STEL 5000 ppm JAN 1993

OEL-Germany: TWA 1000 ppm (1900 mg/m3) JAN 1993 OEL-Greece: 1000 ppm TWA; 1900 mg/m3 TWA OEL-Hawaii: 1000 ppm TWA; 1900 mg/m3 TWA OEL-Honk Kong: 1000 ppm TWA; 1880 mg/m3 TWA

OEL-Hungary: TWA 1000 mg/m3;STEL 3000 mg/m3 JAN 1993

OEL-Idaho: 1000 ppm TWA; 1900 mg/m3 TWA OEL-India: 1000 ppm TWA; 1900 mg/m3 TWA OEL-Indiana: 1000 ppm TWA; 1900 mg/m3 TWA OEL-Indonesia: 1000 ppm NAB; 1880 mg/m3 NAB OEL-Ireland: 1000 ppm TWA; 1900 mg/m3 TWA

OEL-Israel: 1000 ppm TWA

OEL-Korea: 1000 ppm TWA; 1900 mg/m3 TWA

OEL-Latvia: 1000 mg/m3 TWA

OEL-Lithuania: 1000 ppm NRV; 1900 mg/m3 NRV, 1000 ppm TPRV; 1900 mg/m3 TPRV, 500 ppm IPRV; 1000 mg/m3 IPRV

OEL-Malasia: 1000 ppm TWA; 1880 mg/m3 TWA

OEL-Manitoba: 1000 ppm TWA

OEL-Mexico: 1000 ppm TWA; 1900 mg/m3 TWA OEL-Michigan: 1000 ppm TWA; 1900 mg/m3 TWA OEL-Minnesota: 1000 ppm TWA; 1900 mg/m3 TWA OEL-New Brunswick: 1000 ppm TWA; 1880 mg/m3 TWA

OEL-New Foundland: 1000 ppm TWA

OEL-New York: 1000 ppm TWA; 1900 mg/m3 TWA OEL-New Zealand: 1000 ppm TWA; 1880 mg/m3 TWA

OEL-Nicaragua: 1000 ppm TWA

Specialty Diagnostics

OEL-North Carolina: 1000 ppm TWA: 1900 mg/m3 TWA

OEL-Northwest Territories: 1250 ppm STEL; 2355 mg/m3 STEL, 1000 ppm TWA; 1884 mg/m3 TWA

Microgenics Corporation

OEL-Norway: 625 ppm STEL; 1187.5 mg/m3 STEL, 500 ppm TWA; 950 mg/m3 TWA

46360 Fremont Blvd 94538 510-979-5002 fax Toll Free: 800-232-3342 Doc: 92770-MMSDS-4 Page 10 of 14 Revision Date: 11/30/09

Fremont, CA USA

510-979-5000





# Section 15 - Regulatory Information - continued

OEL-Nova Scotia: 1000 ppm TWA

OEL-Nunavut: 1250 ppm STEL; 2355 mg/m3 STEL, 1000 ppm TWA; 1884 mg/m3 TWA

OEL-Ontario: 1000 ppm TWAEV; 1900 mg/m3 TWAEV OEL-Oregon: 1000 ppm TWA; 1990 mg/m3 TWA OEL-Peru: 1000 ppm TWA; 1884 mg/m3 TWA

OEL-Philippines: TWA 1000 ppm (1900 mg/m3) JAN 1993

OEL-Poland: TWA 1000 mg/m3 JAN 1993

OEL-Portugal: 1000 ppm TWA

OEL-Prince Edward Island: 1000 ppm TWA

OEL-Quebec: 1000 ppm TWAEV; 1880 mg/m3 TWAEV

OEL-Romania: 5000 ppm STEL; 9500 mg/m3 STEL, 1000 ppm TWA; 1900 mg/m3 TWA

OEL-Russia: STEL 1000 mg/m3 JAN 1993, 2000 mg/m3 STEL (vapor), 2000 mg/m3 STEL (vapor)

OEL-Saskatchewan: 1250 ppm STEL, 1000 ppm TWA OEL-Singapore: 1000 ppm PEL; 1880 mg/m3 PEL

OEL-Slovak Republic: 1920 mg/m3 Ceiling, 500 ppm TWA; 960 mg/m3 TWA

OEL-Slovenia: 4000 ppm STEL: 7600 mg/m3 STEL, 1000 ppm TWA: 1900 mg/m3 TWA

OEL-South Africa: 1000 ppm TWA: 1900 mg/m3 TWA

OEL-Spain: 1000 ppm VLA-ED; 1910 mg/m3 VLA-ED, 1000 ppm TLV-TWA

OEL-Sweden: TWA 1000 ppm (1900 mg/m3) JAN 1993, 1000 ppm STV; 1900 mg/m3 STV, 500 ppm LLV; 1000 mg/m3 LLV OEL-Switzerland: TWA 1000 ppm (1900 mg/m3) JAN 1993, 500 ppm MAK; 960 mg/m3 MAK, 1000 ppm STEL; 1920 mg/m3 STEL

OEL-Taiwan: 1000 ppm TWA; 1880 mg/m3 TWA OEL-Tennessee: 1000 ppm TWA; 1900 mg/m3 TWA

OEL-Texas: 1000 ppb ESL; 1880 µg/m3 ESL - Long Term, 10000 ppb ESL; 18800 µg/m3 ESL - Short Term

OEL-Thailand: TWA 1000 ppm (1900 mg/m3) JAN 1993 OEL-Netherlands: TWA 1000 ppm (1900 mg/m3) JAN 1993 OEL-Turkey: TWA 1000 ppm (1900 mg/m3) JAN 1993

OEL-United Kingdom: TWA 1000 ppm (1900 mg/m3) JAN 1993, 3000 ppm STEL; 5760 mg/m3 STEL, 1000 ppm TWA; 1920 mg/m3 TWA

OEL-Venezuela: 1000 ppm TWA

OEL-Vermont: 1000 ppm TWA; 1900 mg/m3 TWA OEL-Vietnam: 3000 mg/m3 STEL, 1000 mg/m3 TWA OEL-Washington: 1250 ppm STEL, 1000 ppm TWA

OEL-Yukon: 1000 ppm STEL; 1900 mg/m3 STEL, 1000 ppm TWA; 1900 mg/m3 TWA

CAS# 66-81-9

OEL-DELAWARE: DRQ 100 lb

OEL-MASSACHUSETTS: RC - 0.1 mg/L; RQ 10 mg/kg

OEL-MICHIGAN: TRQ 1 lb

OEL-NEW JERSEY: TPQ SN 0574 100 lb

OEL-OHIO: TQ 100 lb (liquid or solution); 500 lb (solid)

OEL-NEW YORK: RQ 1 lb (air, acutely hazardous substance); 1 lb (land/water, acutely hazardous substance)

Microgenics Corporation

OEL-TEXAS: TPQ 100 lb; RQ 100 lb lower threshold; 10000 lb upper threshold

CAS# 630-93-3

OEL-CALIFORNIA: ADOA (POM) 100 lbs/yr

OEL-KENTUCKY: Significant Level 0.00000051 lbs/hr

OEL-MICHIGAN: TRQ 10 lb

OEL-NEW YORK: RQ 1 lb (air), 1 lb (land/water)

OEL-WISCONSIN: TQ 10 lb/yr Emissions From Stack Heights 25 Feet to Less Than 40 Feet; 23.8 lb/yr Emissions From Stack Heights 40 Feet to Less Than 75 Feet; 83.9 lb/yr Emissions From Stack Heights 75 Feet or Greater; 2.43 lb/yr Emissions From Stack Heights Less Than 25 Feet

#### **European Union Directives**

Seveso II Directive (96/82/EC), 67/548/EEC, 2006/15/EC, 98/24/EC, 304/2003, 76/769/EEC, 273/2004, 1277/2005, 2037/2000/EC, Directive 96/59/EC, Directive 79/117/EEC and Directive 91/414/EEC, 2000/479/EC (EPER), 2002/95/EC (RoHS), 2002/96/EC -WEEE, 2006/11/EC, Directive 98/83/EC - No information found

#### CAS# 66-81-9

Specialty Diagnostics

793/93/EEC	1907/2006	EU - CLP 1272/2008)	(67/548/EEC)	76/768/EEC	EU - Marketing and Use
	– REACH	- Annex VI - Table 3.1	- Annex I		Directive (76/769/EEC)
yes	yes	yes	deleted	yes	yes

46360 Fremont Blvd 94538 510-979-5002 fax Toll Free: 800-232-3342 Doc: 92770-MMSDS-4 Revision Date: 11/30/09

Page 11 of 14

Fremont, CA USA

510-979-5000

www.thermo.com/Diagnostics





# Section 15 - Regulatory Information - continued

CVCH	C 1 1	7 5
CAS#	04-1	7-5

793/93/EEC	1907/2006 - REACH	67/548/EEC
yes	yes	yes

CAS# 50-06-6

793/93/EEC	1907/2006 - REACH
yes	yes

CAS# 298-46-4

793/93/EEC	1907/2006 - REACH	HPV-LPV Chemicals
yes	yes	yes

CAS# 630-93-3

793/93/EEC	1907/2006 - REACH
no	yes

CAS# 99-66-1

793/93/EEC	1907/2006 - REACH	HPV-LPV Chemicals
no	yes	yes

CAS# 1405-41-0

793/93/EEC	1907/2006 - REACH
no	yes

CAS#7732-18-5

793/93/EEC	1907/2006 – REACH
yes	yes

1999/45/EC - European Labeling in Accordance with EC Directives,

Hazard Symbols: Not available Risk Phrases: Not available

Safety Phrases: S 24/25 Avoid contact with skin and eyes

#### **United Nations List**

CAS# 50-06-6 INCB - Schedule IV Substances UN, UN/FAO, UNEP - No information found

#### Canada Federal/Provincial Government

CAS# 66-81-9 - Saskatchewan - Dangerous Goods - Acute Hazardous Substances

CAS# 64-17-5 Alberta, British Columbia, Manitoba A4 - Not Classifiable as a Human Carcinogen , New Brunswick Not Classifiable as a Human Carcinogen, Newfoundland, Northwest Territories, Nova Scotia A4 - Not Classifiable as a Human Carcinogen, Nunavut, Ontario - Air Pollution - Local Air Quality - Guidelines Ethanol 19000 µg/m3 30 minute Guideline (odour); 19000 µg/m3 1 hour Guideline (odour, TBU), Ontario - Ambient Air Quality Criteria (AAQCs) Ethanol 19000 µg/m3 1 hour average (odour, TBU), Prince Edward Island, Quebec, Saskatchewan - Dangerous Goods - Industrial Hazardous Substances Ethyl alcohol Present, Yukon (see section 8 for OEL values) CAS# 50-06-6 - Controlled Drugs - Schedule IV

#### CAS# 66-81-9- listed in the Canadian Provincial Government of Saskatchewan

DWQ

CEPA	NPRI	DSL	NDSL	CEPA	DWQ	Council of Ministers of	Controlled Drugs	WHMIS
						the Environment	and Substances	
no	no	no	no	no	no	no	no	no

#### CAS# 64-17-5 CEPA NPRI

DSL

NDSL

CEPA

yes	no	yes	no	no	no	no	no	yes
CAS#	50-06-6							
CEPA	NPRI DSL NDSL CEPA DWQ		DWQ	Council of Ministers of the	Controlled Drugs and	WHMIS		
						Environment	Substances	
no	no	yes	no	no	no	no	Yes, Schedule IV	no

Council of Ministers of the

Environment

Controlled Drugs and

Substances

WHMIS

Specialty Diagnostics www.thermo.com/Diagnostics Microgenics Corporation Fremont, CA USA 510-979-5000 46360 Fremont Blvd 94538 510-979-5002 fax Toll Free: 800-232-3342 Revision Date: 11/30/09

Doc: 92770-MMSDS-4 Page 12 of 14



Part of Thermo Fisher Scientific

# Section 15 - Regulatory Information - continued

	CAS# 298-46-4 Substances	Regulated Under	· F&DA That Wer	e In Commerce Be	tween 1/1/84 and 12/31/86
--	--------------------------	-----------------	-----------------	------------------	---------------------------

no no yes no no no no no no	CEPA	NPRI	DSL	NDSL	CEPA	DWQ	Council of Ministers of the Environment	Controlled Drugs and Substances	WHMIS
	no	no	yes	no	no	no	no	no	no

CAS# 630-93-3

I	CEPA	NPRI	DSL	NDSL	CEPA	DWQ	Council of Ministers of	Controlled Drugs	WHMIS
l							the Environment	and Substances	
I	no	no	no	yes	no	no	no	no	no

CAS# 99-66-1 Substances Regulated Under F&DA That Were In Commerce Between 1/1/84 and 12/31/86

CEPA	NPRI	DSL	NDSL	CEPA	DWQ	Council of Ministers of the Environment	Controlled Drugs and Substances	WHMIS
no	no	yes	no	no	no	no	no	no

CAS# 1405-41-0 Substances Regulated Under F&DA That Were In Commerce Between 1/1/84 and 12/31/86

CEPA	NPRI	DSL	NDSL	CEPA	DWQ	Council of Ministers of the Environment	Controlled Drugs and Substances	WHMIS			
no no yes no no no no no											
CAS#7722 19 5											

the Environment and Substances		U/\0#1	732-10	J-J						
	ſ	CEPA	NPRI	DSL	NDSL	CEPA	DWQ			WHMIS
	r	no	no	ves	no	no	no	no	no	no

#### WHMIS:

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all the information required by the CPR

#### Other

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the US OSHA Hazard Communication Standard, European Communities Safety Data Sheets Directive, Canadian Controlled Products Regulations, UK Chemical Hazard Information and Packaging Regulations, and UN Globally Harmonized System of Classification and Labeling of Chemicals

#### Section 16 – Other Information

Color information has been updated

Revision: 4

Date prepared: 11/30/09

# **Acronym keys**

Specialty Diagnostics

**1277/2005** – Narcotics

**1907/2006** – **REACH -** Registration, Evaluation and Authorization of Chemicals

2000/479/EC (EPER) - European Pollutant Emission Register 2002/95/EC (RoHS) - Hazardous Substances Restricted or Prohibited in Electrical Equipment

2002/96/EC (WEEE) - Waste Electrical and Electronic Equipment

2006/11/EC - Water Pollution Directive

2006/15/EC, 98/24/EC - Occupational Exposure Directives 2037/2000/EC - Ozone Depleting Substances Regulation 21 CFR-IVD –Code of Federal Regulations, In-vitro Diagnostics

273/2004 - Export Requirements and Drug Precursors

304/2003 - Export and Import Restrictions

67/548/EEC Dangerous Substances Directive

**76/769/EEC** - Marketing Restrictions Directive **793/93/EEC** - Existing Substance Regulation

ACGIH – American Conference of Governmental

Industrial Hygienists

ADN - European Agreement Concerning the International
Carriage of Dangerous Goods by Inland Waterways

ADR - The European Agreement concerning the International

Microgenics Corporation

Carriage of Dangerous Goods by Road

AICS (Australia Inventory of Chemical Substances)

AIHA - American Industrial Hygiene Association

ATHS - Air Toxics Hot Spots Act

Australia Group – Export Control List - European Commission for Chemical Weapons Precursors

CAA - Clean Air Act of 1990

**CCR -** California Code of Regulations

CEPA - Canadian Environmental Protection Act, 1999,

**CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act of 1980

CICADs - International Chemical Safety Documents

CWA - Clean Water Act

510-979-5000

**CWC -** Chemical Weapons Convention

**DEA -** Drug Enforcement Administration

**Department of Homeland Security - Chemical** Facility Anti-Terrorism Standards

Directive 79/117/EEC and Directive 91/414/EEC - Plant Protection Products

**Directive 96/59/EC -** Disposal of Polychlorinated Biphenyls and Polychlorinated Terphenyls

Directive 98/83/EC - Water Quality - Water Intended for Human

www.thermo.com/Diagnostics

46360 Fremont Blvd 94538 510-979-5002 fax Toll Free: 800-232-3342 Doc: 92770-MMSDS-4 Page 13 of 14 Revision Date: 11/30/09

Fremont, CA USA



Part of Thermo Fisher Scientific

Consumption

DSL - Domestic Substances List

**DWQ - Drinking Water Quality** 

**EAR** – Export Administration Regulations

ENCS - Japan Existing and New Chemical Substances

EPICRA - Emergency Planning and Community Right-to-

**FDA** – Food and Drug Administration

FIFRA - Federal Insecticide, Fungicide and Rodenticide Act

HAPs - Hazardous Air Pollutants (CAA)

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

ICAO - International Civil Aviation Organization

ICCA - International Council of Chemical Associations

IMDG - International Maritime Dangerous Goods Code

**IMO-** International Maritime Organization

INCB - International Narcotics Control Board

IPCS - International Program on Chemical Safety

ITAR - International Traffic in Arms Regulations

KECL - Korea - Existing and Evaluated Chemical Substances

NDSL - Non-Domestic Substances List

NIOSH - national institute for occupational safety and health

NPRI - National Pollutant Release Inventory

NTP - National Toxicology Program

OECD - The Organisation for Economic Co-Operation and Development

**OEL** - Occupational Exposure Level

OSHA - occupational safety and health

OSPAR - Oslo/Paris Convention of September 22, 1992 - List

of Chemicals for Priority Action

OTIF- Intergovernmental Organization for International Carriage by Rail

PICCS (Philippines Inventory of Chemicals and Chemical Substances)

Specialty Diagnostics

POP - Persistent Organic Pollutants

RCRA - Resource Conservation & Recovery Act

REL - recommended exposure limits

RID - The Intergovernmental Organization for International Carriage by Rail

SARA - Superfund Amendments and Reauthorization Act of 1986

SCAQMD – Toxic Air Contaminants List Schedule I, IV - Controlled Substances

SDWA (Safe Drinking Water Act)

Seveso II Directive (96/82/EC) - Qualifying Quantities for Safety Report Requirements

SNUR - Significant New Use Rule (TSCA)

State Department (Munitions List Category XIV - Toxicological, Biological, Chemical Agents)

STEL - short term exposure limit

TDG - Transport Canada

Substances

Transportation of Dangerous Goods Act, 2001

Title 22 - Health and Safety Code, Hazardous Waste Codes Title 8 - Industrial Relations, Director's List of Hazardous

TLV - threshold Limit Values

TSCA - Toxic Substance Control Act

TWA - Time Weighted Average

**UN** - Convention on Marking Plastic Explosives

UN/FAO - Chemicals Subject to Prior Informed Consent (PIC)

UNECE - United Nations Économic Commission for Europe

**UNEP** United Nations Environment Program

**US DOT** – United States Department of Transportation

**USDA** – United States Department of Agriculture

WEEL - Workplace Environmental Exposure Level

WGK - Wassergefährdungsklasse or WHC - Water Hazard Class

WHMIS - Classifications of Substances

WHO - World Health Organization

This MSDS is intended for review and guidance in the receipt, storage, handling, use and disposal of product purchased from Thermo Fisher Scientific, and for no other purpose. Use this product only as directed and in accordance with applicable instructions and warnings provided with the product. Please consult your institution's policies regarding use of this product. If you have obtained this MSDS other than in connection with the supply of this product from Thermo Fisher Scientific, this MSDS should be consulted for general information only, and should not be relied upon for any purpose. As with the use of all hazardous materials, you should in all instances follow the guidance of the MSDS provided or available with the specific product purchased.

End of MSDS

Fremont, CA USA

510-979-5000

www.thermo.com/Diagnostics

Microgenics Corporation