

Material Safety Data Sheet

Section 1 –Product and Company Identification

MSDS Name	DRI® Oxycodone Assay for SYNCHRON® Systems
Catalog Number	10012653
Description	Drugs of Abuse Diagnostic Kit, Reagents
Synonyms	Oxycodone Reagents
Company Identification	Microgenics Corporation
Office Address	46360 Fremont Blvd.
City, State, Zip Code	Fremont, CA 94538
Company Phone Number	(510) 979-5000
Emergency Phone Number	(510) 979-5000
CHEMTREC Phone Number, US	(800) 424-9300
CHEMTREC Phone Number, Europe	(202) 483-7616

Section 2 - Hazard Identification

Caution! This material contains substance of 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
77-86-1	Tris (hydroxymethyl) aminomethane	1.0-2.0%	201-064-4
7647-14-5	Sodium Chloride	0.8-0.9%	231-598-3
N/A	Bovine Serum Albumin	0.1-0.2%	N/A
7732-18-5	Water	balance	231-791-2
Component comments	have no OSHA, Canadian, or EU hazardous ingredients above applicable threshold. The product contains proteins, antibodies, enzymes, sugars, salts, stabilizer, and water		

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

Personal protective equipment	Combustion products may be health hazardous. In case of evacuation use OSHA/NIOSH (or equivalent) approved protection mask. See section 8
Flammable properties	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
Methods for clean-up	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).
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 - Tris (hydroxymethyl) aminomethane

OSHA PEL					ACGIH TLV			AIHA		NIOSH REL			
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Chemical Name - Sodium Chloride

OSHA PEL					ACGIH TLV			AIHA		NIOSH REL			
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Chemical Name - Bovine Serum Albumin

OSHA PEL					ACGIH TLV			AIHA		NIOSH REL			
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Chemical Name - water

OSHA PEL					ACGIH TLV			AIHA		NIOSH REL			
Ceiling	TWA	STEL	Final	Vacated	Ceiling	TWA	STEL	WEEL	OEL	Ceiling	TWA	STEL	IDLH
Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Exposure Guidelines

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

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
Respiratory protection	A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 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	5-8	Density/specific Gravity	No information
Vapor density	No information	Evaporation rate	No information
Boiling point	No information	Octanol/Water partition coefficient (K _{ow})	No information
Vapor pressure	No information	Auto-ignition temperature	No information
Melting Point/Freezing Point	No information	Decomposition Temperature	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# 77-86-1	Oral, rat: LD50 =5900 mg/kg Intravenous, rat: LD50=1800 mg/kg Oral, rabbit: LD50=1000 mg/kg
CAS#7647-14-5	Oral, mouse: LD50=1210 mg/kg Intravenous, mouse: LD50=1210 mg/kg
CAS#7647-14-5	Oral, rat: LD50 =3000 mg/kg Inhalation, rat: LD50>42 gm/m3/1H Subcutaneous, rat: LD50=3500 mg/kg Skin, rabbit: LD50>10000mg/kg
CAS#7647-14-5	Oral, mouse: LD50=4000 mg/kg Intraperitoneal, mouse: LD50=2602 mg/kg Subcutaneous, mouse: LD50=3000mg/kg
CAS#7732-18-5	Oral, rat: LD50 =998.21 mg/cm ³ @20°C
Repeated dose effect (NOAEL, LOEL)	No information found
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	Effects on fertility or fetus development are not known
Carcinogenicity (IARC, NTP, OSHA (NIOSH & ACGIH))	Carcinogenic properties are not known
Neurotoxicity	Neurotoxic properties are not known
Mutagenicity	Mutagenic properties are not known
Target organ effect	Ingestion of significant amount may cause nausea and vomiting
Epidemiology	No information found
NOES Hazard Codes (NOHS, NOES)	
CAS# 77-86-1	NOHS – 81165 NOES - 81165
CAS# 7647-14-5	NOHS – 68880 NOES – E0256
CAS#7732-18-5	NOHS – M1000 NOES – M1000
RTECS	
CAS# 77-86-1	TY2900000
CAS# 7647-14-5	VZ4725000
CAS#7732-18-5	ZC0110000

Section 12– Ecological Information

Ecotoxicity	Not regarded as dangerous for the environment LC/EC/IC50 > 100 mg/l
Persistence/Degradability	<i>No information found</i>
Bioaccumulation/Accumulation	<i>No information found</i>
Mobility in Environmental media	Soluble in water
Environmental	not classified as harmful to the environment
Other Adverse Effects	<i>No information found</i>

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	None of the components are on this list
RCRA U Series Wastes	None of the components are on this list
EWC waste code	18 01 05 discard as chemicals and medicines
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 based on the a application for which the product was used

Section 14 – Transport Information

Not regulated 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, OSHA - Specifically Regulated Chemicals, SDWA, DEA, USDA, 21 CFR-IVD – *No information found*

CAS# 77-86-1

TSCA 8(b)	SARA 302	SARA 313	CERCLA	RCRA 261.33	TSCA 8(d)	TSCA 12(b)	FIFRA	CWC	SARA 311/312	EPICRA	CAA-SNAP	FDA
yes	no	no	no	no	no	no	yes	no	yes	no	no	no

CAS# 7647-14-5

TSCA 8(b)	SARA 302	SARA 313	CERCLA	RCRA 261.33	TSCA 8(d)	TSCA 12(b)	FIFRA	CWC	SARA 311/312	EPICRA	CAA-SNAP	FDA
yes	no	no	no	no	no	no	yes	no	yes	no	no	yes

CAS#7732-18-5

TSCA 8(b)	SARA 302	SARA 313	CERCLA	RCRA 261.33	TSCA 8(d)	TSCA 12(b)	FIFRA	CWC	SARA 311/312	EPICRA	CAA-SNAP	FDA
yes	no	no	no	no	no	no	yes	no	no	no	yes	no

Not subject to ITAR and EAR regulations

US State

State Right to Know

CAS# 77-86-1 – Texas, ESL = 100µg/m³

CAS# 7647-14-5 – Texas, ESL = 50µg/m³

Schedule I, IV - ***No information found***

California

Prop 65, Title 8 CCR, Title 22 CCR, ATHS, Occupational Exposure Limits, Ozone Depleting Compounds, Precursor Chemicals, SCAQMD, California No Significant Risk Level - ***No information found***

None of the chemicals are on Prop 65 lists

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

CAS# 77-86-1

AICS	New Zealand-GHS	China	ENCS	Korea	New Zealand	PICCS	Bermuda	EC	EINECS
yes	6.1E,6.3A,6.4A	yes	2-318	KE-01403	yes	yes	yes	yes	201-064-4

CAS# 7647-14-5

AICS	New Zealand-GHS	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	yes	231-598-3

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# 77-86-1

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

CAS# 7647-14-5

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

CAS#7732-18-5

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

Exposure Limits - **No information found**

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# 7647-14-5

793/93/EEC	1907/2006 – REACH
yes	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

UN, INCB, UN/FAO, UNEP - **No information found**

Canada Federal/Provincial Government

CAS# 77-86-1

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	D2B

CAS# 7647-14-5

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#7732-18-5

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

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

No information found

Section 16 – Other Information

Color information has been updated

Revision: 1

Date prepared: 11/13/2008

Acronym keys

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 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

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 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-Know Act

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)

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
Transportation of Dangerous Goods Act, 2001
Title 22 - Health and Safety Code, Hazardous Waste Codes
Title 8 - Industrial Relations, Director's List of Hazardous Substances

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 Economic 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

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