



MicroGEM International PLC

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Safety Data Sheet

A MicroGEM International PLC Product

SECTION 1: PRODUCT IDENTIFICATION and COMPANY IDENTIFICATION

Product Name	PDQeX <i>prep</i> GEM Universal kits
Generic Name	NA
Synonyms	NA
Product Description	Genomic DNA extraction kit. For research use only
REACH Registration number	A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration.
CAS #	NA – mixture
Date of Revision	May 2019
Company Support	Email: info@microgembio.com

Supplier Details in NZ	ZyGEM NZ Ltd, Subsidiary of MicroGEM International PLC Waikato Innovation Park Ruakura Road, Hamilton. Emergency telephone: +64 0800-764-766 (National Poison Centre)
Supplier Details in USA	ZyGEM US Ltd, Subsidiary of MicroGEM International PLC 705D Dale Avenue, Charlottesville, VA 22903 Emergency telephone: +1-800-222-1222 (National Poison Centre)
Manufacturer Details in China	Guilin LiGEM Biotech Limited Co, Subsidiary of MicroGEM International PLC Floor3, No.32 Canluan Road, Qixing District, Guilin City, China Phone +86 0773-363-6602 Emergency telephone: +86-07715319955 (National Poison Centre)

SECTION 2: HAZARD IDENTIFICATION

Potential Health Effects:

Australia: NOHSC 2011 National Code of Practice: This material is not considered hazardous according to safe work Australia

New Zealand: This substance is hazardous according to the EPA Hazardous Substances (Classification) Notice 2017

EPA Approval No: Reagent Kits Group Standard 2017 -HSR002647

Signal Word: **DANGER**

Pictograms:



Irritant



Chronic

Kit includes four separate clear liquids and one lyophilized powder as follows:

PDQeX <i>prep</i>GEM: HSNO Classification	Hazard Code	Hazard Statement	GHS Category
6.5A	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	Resp. Sens. 1
6.5B	H317	May cause an allergic skin reaction.	Skin Sens. 1

RED+ Buffer: HSNO Classification	Hazard Code	Hazard Statement	GHS Category
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9.3C	H433	Harmful to terrestrial vertebrates.	-
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ORANGE+ Buffer: HSNO Classification	Hazard Code	Hazard Statement	GHS Category
6.3B	H316	Causes mild skin irritation.	Skin Irrit. 3
6.4A	H319	Causes serious eye irritation.	Eye Irrit. 2A
9.3C	H433	Harmful to terrestrial vertebrates.	

Blue Buffer:
Enhancer Buffer:
Non hazardous
Cartridges:
Non hazardous

Histosolv: HSNO Classification	Hazard Code	Hazard Statement	GHS Category
6.5A	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	Resp. Sens. 1
6.5B	H317	May cause an allergic skin reaction.	Skin Sens. 1

CONSOLIDATED PREVENTION AND RESPONSE STATEMENT

Prevention Code	Prevention Statement
P103	Read label before use.
P261	Avoid breathing vapours or dust.
P264	Wash hands thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.
P273	Avoid release to the environment.
P280	Wear protective clothing as detailed in Section 8.
P285	In case of inadequate ventilation wear respiratory protection.

Response code	Response Statement
P363	Wash contaminated clothing before reuse.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P304 + P341	IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.
P305 + P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Storage code	Storage Statement
None allocated	Keep in a tightly closed container. This product can be stored at 4°C. Once opened store at -20°C. Protect material from long-term exposure to light. Short periods of exposure to light are acceptable.

Disposal code	Disposal Statement
P501	

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Product Kit Name	Catalog Codes	Reactions per kit	Total Solution volume per kit (rounded)	Description of kit components
PDQeX <i>prep</i> GEM Universal	XPU0050	50	3 ml	<ul style="list-style-type: none"> •.....<i>prep</i>GEM •.....RED+ Buffer •.....ORANGE+ Buffer •.....BLUE Buffer •.....<i>Histosolv</i> •.....Cartridges: This kit may or may not have cartridges supplied with the shipment
	XPU0100	100	3 ml	
	XPU0500	500	19 ml	
	XPU1000	1000	46 ml	

SECTION 3B: HAZARDOUS COMPONENTS

Kit Component	Contains	CAS #	Weight %
PDQeX <i>prep</i> GEM	EA1 Enzyme – Proteinase Glycerol	Proprietary 56-81-5	0.1-0.2 18-23
<i>Histosolv</i>	Purified lyophilised powder. <i>Histosolv</i> is an hydrolytic enzyme cocktail whose formulation is protected as a trade secret as defined by WIPO (World Intellectual Property Organisation) http://www.wipo.int/sme/en/ip_business/trade_secrets/protection.htm		≤5%
RED+ Buffer	Potassium Chloride	7447-40-7	<5%
ORANGE+ Buffer	Potassium Chloride	7447-40-7	10-15%

SECTION 3C: NON HAZARDOUS COMPONENTS

Kit Component	Contains	CAS #	Weight %
BLUE Buffer	tris(hydroxymethyl)aminomethane; TRIS	77-86-1	<5%
Enhancer Buffer	protected as a trade secret as defined by WIPO (World Intellectual Property Organisation) http://www.wipo.int/sme/en/ip_business/trade_secrets/protection.htm		
Cartridges	The cartridges are considered a manufactured article and therefore exempt from the HSNO Act and its regulations. The cartridges are a single use sample preparation purification column for use in laboratory analysis. The product is made from plastic components and contains a food grade polymer to form a micro-purification column.		

Non-hazardous components may or may not be listed. Carcinogens are listed when present at 0.1% or more; components which are otherwise hazardous according to OSHA are listed when present at 1.0% or more. This is not intended to be complete compositional disclosure. See Section 15 for applicable states right to know and other regulatory information.

Some reagents are Trade Secrets as permitted under USA: 29 CFR 1910.1200, Canadian CPR Sections 12 and 19, European Union Directive 1999/45/EC. All such reagents are highly purified enzymes from non-pathogenic organisms. These reagents are at concentrations of < 1%.

SECTION 4: FIRST AID MEASURES

Inhalation	Remove to fresh air. Not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention
Ingestion	Drink several glasses of water or milk. Never give anything by mouth to an unconscious person. Get medical attention
Skin	Immediately flush skin with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
Eyes	Remove contact lenses immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.
Most important symptoms and effects, both acute and delayed	Ingestion: Not applicable Inhalation: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin: Causes mild skin irritation. May cause an allergic skin reaction. Eye: Causes serious eye irritation

SECTION 5: FIRE FIGHTING MEASURES

Fire	Flash point: Not flammable
Extinguishing Media	Use appropriate media for the surrounding fire
Explosion	Not considered an explosion hazard
Special Precautions	Use appropriate media for the surrounding fire

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full face piece operated in the pressure demand or other positive pressure mode.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8.

Do not allow to enter waterways.

Collect liquid in an appropriate container or absorb with an inert material (e. g., vermiculite, dry sand, earth), and place in a chemical waste container. Wash contaminated area with plenty of water. Dispose as per Section 15.


SECTION 7: HANDLING AND STORAGE


Read label before use. Avoid breathing vapours or dust. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective clothing as detailed in Section 8.

In case of inadequate ventilation wear respiratory protection.

Keep in a tightly closed container. This product can be stored at 4°C. Once opened store at -20°C. Protect material from long-term exposure to light. Short periods of exposure to light are acceptable.

SECTION 8: EXPOSURE CONTROL/ PERSONAL PROTECTION

Exposure Guidelines	WORKPLACE EXPOSURE STANDARDS (provided for guidance only)			
	Substance	TWA ppm mg/m ³		STEL ppm mg/m ³
	Glycerin (mist) [56-81-5]	-	10	- -
	Workplace Exposure Standard – Time Weighted Average (WES-TWA). The time-weighted average exposure standard designed to protect the worker from the effects of long-term exposure. Workplace Exposure Standard – Short-Term Exposure Limit (WES-STEL). The 15-minute average exposure standard. Applies to any 15- Minute period in the working day and is designed to protect the worker against adverse effects of irritation, chronic or irreversible tissue change, or narcosis that may increase the likelihood of accidents. The WES-STEL is not an alternative to the WES-TWA; both the short-term and time-weighted average exposures apply. Workplace Exposure Standards and Biological Exposure Indices NOV 2017 9TH EDITION.			
Skin and body Protection	 <p>Lightweight protective clothing. Wear protective latex gloves and handle in accordance with good laboratory safety practice</p>			

Eye Contact	 <p>Safety glasses with side shields in accordance with good laboratory safety practice</p>
Inhalation	In case of insufficient ventilation wear suitable respiratory equipment.
Engineering Controls	Ensure adequate ventilation.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

	All buffer solutions	Lyophilized Enzymes	Enzyme solution
Appearance	Liquid	Powder	Liquid
Colour	Clear	White	Clear
Odour	Not available	Not available	Not available
Odour Threshold	Not available	Not available	Not available
pH	8.3	Not available	7.0
Boiling Point	> 100°C	Not available	> 100°C
Melting Point	< 0°C	Not available	< 0°C
Freezing Point	Not available	Not available	Not available
Flash Point	Not available	Not available	Not available
Flammability	Not available	Not available	Not available
Upper and Lower Explosive Limits	Not available	Not available	Not available
Vapour Pressure	Not available	Not available	Not available
Vapour Density	Not available	Not available	Not available
Specific Gravity	About 1.0	Not available	About 1.0
Water Solubility	Complete	Complete	Complete
Partition Coefficient:	Not available	Not available	Not available
Auto-ignition Temperature	Not available	Not available	Not available
Decomposition Temperature	Not available	Not available	Not available
Kinematic Viscosity	Not available	Not available	Not available
Particle Characteristics	Not available	Not available	Not available

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability	This product is stable in closed containers at room temperature.
Hazardous Decomposition Products	Carbon oxides (CO, CO ₂), nitrogen oxides (NO, NO ₂ , N ₂ O), hydrogen chloride
Incompatibilities	Strong oxidizers, heat
Conditions to Avoid	Incompatible materials, combustible materials.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute Effects:

Swallowed	Not applicable.
Dermal	Not applicable.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Eye	Causes serious eye irritation.
Skin	Causes mild skin irritation. May cause an allergic skin reaction.

Chronic Effects:

Carcinogenicity	Not applicable
Reproductive Toxicity	Not applicable
Germ Cell Mutagenicity	Not applicable
Aspiration	Not applicable
STOT/SE	Not applicable
STOT/RE	Not applicable

SECTION 12: ECOLOGICAL INFORMATION

New Zealand:		
HSNO Classes:	9.3 C	Harmful to terrestrial vertebrates.
Environmental Fate:	This product is not expected to bioaccumulate. When released into water or air its expected half-life is 1- 10 days.	
Ecotoxicity:	Dilute nature and small volumes of products makes any ecological effect highly unlikely.	

SECTION 13: DISPOSAL CONSIDERATIONS

As a waste, this material in its raw form IS NOT considered a HAZARDOUS WASTE under RCRA (29 CFR 261).

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

SECTION 14: TRANSPORT INFORMATION

New Zealand:	
This product is NOT classified as a Dangerous Good for transport in NZ ; NZS 5433:2012	
Proper Shipping Name:	Not regulated by DOT, TDG, IATA, IMDG
DOT Hazard Class:	N/A
UN Number:	N/A
Packing Group:	N/A
CERCLA Reportable Quantity (RQ):	N/A

Releases exceeding the reportable quantity (RQ) must be reported to the National Response Center (800) 424-8802. This data provided for information only. The description shown may not apply to all shipping situations. Consult 49 CFR, or appropriate regulations to properly classify your shipment for transportation.

SECTION 15: REGULATORY INFORMATION

New Zealand:
This substance is classified hazardous according to the EPA Hazardous Substances (Classification) Notice 2017

EPA Approval Code: Reagent Kits Group Standard 2017 -HSR002647
HSNO Classification: 6.3B, 6.4A, 6.5A/B, 9.3C

HSW (HS) Regulations 2017 and EPA Notices	Trigger Quantity
Certified Handler	Not required
Location Certificate	Not required
Tracking Trigger Quantities	Not required
Signage Trigger Quantities	1000L/kg (9.3C)
Emergency Response Plan	1000L/kg (6.5A)
Secondary Containment	1000L/kg (6.5A)
Restriction of Use	Only use for the intended purpose.

TSCA Chemical Inventory: All of the chemicals in this product are listed on the TSCA Inventory.

TSCA Sec 4 Chemical Test Rule: None of the chemicals in this product are under a Chemical Test Rule.

TSCA Sec 8(d): None of the chemicals in this product are on the Health and Safety Reporting List.

TSCA Sec 12(b) Notices of Export: None of the chemicals in this product are on this list.

TSCA Significant New Use Rule (SNUR): None of the chemicals in this product are on this list.

SARA Sec 302 (EHS) TPQ: None of the chemicals in this product have a TPQ.

SARA Sec 302 (EHS) RQ: None of the chemicals in this product have a RQ.

SARA Sec 311/312: Acute – NO; Chronic – NO; Fire – NO; Release of Pressure – NO; Reactivity – NO

SARA 313 List: No materials in this product are reportable under Section 313 Title III and 40 CFR Part 372.

CERCLA Hazardous Substances and corresponding RQs: N/A

RCRA: None of the chemicals in this product are on this list.

Clean Air Act: Hazardous Air Pollutants? NO **Class 1 Ozone Depletors?** NO **Class 2 Ozone Depletors?** NO

Clean Water Act: Hazardous Substance? NO **Priority Pollutant?** NO **Toxic Pollutant?** NO

Chemical Weapons Convention: None of the chemicals in this product are on this list.

Drug Enforcement Agency (DEA) CDTA: None of the chemicals in this product are on this list.

OSHA: None of the chemicals in this product are considered Highly Hazardous by OSHA.

State Right-to-Know Lists: None of the materials in this product are found on the Right-to-Know lists of California, Florida, New Jersey, Pennsylvania, Massachusetts or Minnesota.

Canada

All materials are listed on Canada's DSL List. One compound is listed on Canada's Ingredient Disclosure List, but below the *de minimus* concentration.

WHMIS: Not WHMIS controlled.

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

European Union

Hazard Symbols:	Xi
Risk Phrases:	R36/38- Irritating to eyes and skin
Safety Phrases:	S1/2 Keep locked up and out of the reach of children S 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S 37/39 Wear suitable gloves and eye/face protection. S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). S46 If swallowed, seek medical advice immediately and show this container or label.
REACH Registration Number:	Not available

SECTION 16: OTHER INFORMATION

Abbreviations and acronyms used:

ACGIH	American Conference of Governmental Industrial Hygienists	NA	not applicable, not available
ANSI	American National Standards Institute	NIOSH	National Institute for Occupational Safety and Health
atm	atmosphere (pressure unit)	ND	not determined
BOD	biological oxygen demand	NFPA	National Fire Prevention Association
CAS	Chemical Abstracts Service	NTP	National Toxicology Program
CC	closed cup	OC	open cup
CDTA	Chemical Drug and Trafficking Act	OSHA	Occupational Safety and Health Administration
COC	Cleveland Open Cup	Part	partition
COD	chemical oxygen demand	PEL	permissible exposure limits
coeff.	coefficient	ppb	parts per billion
CFR	Code of Federal Regulations	PPE	personal protective equipment
CPR	cardio-pulmonary resuscitation	ppm	parts per million
DEA	Drug Enforcement Agency	psi	pounds per square inch
DOT	Department of Transportation	RCRA	Resource Conservation and Recovery Act
FDA	Food and Drug Administration	RQ	Reportable quantity
IARC	Internat'l Agency for Research on Cancer	RTK	Right to Know
IDLH	immediate danger to life and health	SARA	Superfund Amendments and Reauthorization Act
kg	kilogram	STEL	short-term exposure limit
L	liter	TCC	Tagliabue Closed Cup
LC50	median lethal concentration	TPQ	threshold planning quantity
LD50	median lethal dose	TQ	threshold quantity
LEL	lower explosive limit	TSCA	Toxic Substances Control Act
mg	milligram	TWA	time-weighted average
mL	milliliter	WHMIS	Workplace Hazardous Materials Information System

References:

1. EPA Hazardous Substances (Safety Data Sheets) Notice 2017
2. Workplace Exposure Standards and Biological Exposure Indices Nov 2017 edition.
3. Assigning a hazardous substance to a HSNO Approval (Aug 2013).
4. Transport of Dangerous goods on land NZS 5433:2012
5. HSW (Hazardous Substances) Regulations 2017

This document was prepared in accordance with 29 CFR 1910.1200 and ANSI Z400.1-2004.

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