



SAFETY DATA SHEET

PRO-Mcomplete™

Section 1. Identification

GHS product identifier : PRO-Mcomplete™

Other means of identification : Not available.

Trade name : PRO-Mcomplete™

PRO-Mcomplete™ Test Cassette
 PRO-Mcomplete™ Extraction Buffer
 Sterile Swab

Code

PL.950-1, PL.950-5,
 PL.950-10
 PL.951
 PL.952
 520CS01

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

Identified uses : PRO-Mcomplete™ is a simple and rapid qualitative immunochromatographic test for *in vitro* detection of IGFBP-1 (Insulin-like Growth Factor-Binding Protein-1) and AFP (Alpha-FetoProtein) from amniotic fluid in a vaginal swab sample. It is a point-of-care test intended to aid in the detection of the rupture of fetal membranes in pregnant women reporting signs and/or symptoms of possible membrane rupture.

Supplier's details : Pro-Lab Diagnostics
 20 Mural Street, Unit 4
 Richmond Hill, ON
 Canada L4B 1K3
 Tel: +1-905-731-0300
 Fax: +1-905-731-0206
 www.pro-lab.com

Emergency telephone number (with hours of operation) : 905-731-0300 –Monday to Friday 8:00 am to 4:30 pm Eastern Standard Time.
 416-230-0692 –Outside the above hours.

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : **PL.951** No signal word.
520CS01 No signal word.
PL.952 No signal word.

Hazard statements : **PL.951** No known significant effects or critical hazards.
520CS01 No known significant effects or critical hazards.
PL.952 No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Section 2. Hazards identification

- Storage** : Not applicable.
- Disposal** : Not applicable.
- Hazards not otherwise classified** : None known.

Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture
- Other means of identification** : Not available.

United States

Ingredient name	%	CAS number
PRO·Mcomplete™ Extraction Buffer Sodium Azide	<0.25	26628-22-8

The exact percentage (concentration) in the composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.

Canada

Ingredient name	% (w/w)	CAS number
PRO·Mcomplete™ Extraction Buffer Sodium Azide	0.01 - 0.1	26628-22-8

The exact percentage (concentration) in the composition has been withheld as a trade secret in accordance with the amended HPR as of April 2018.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- Skin contact** : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Section 4. First aid measures

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : No specific data.

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Section 6. Accidental release measures

- Spill** : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store between the following temperatures: 2 to 30°C (35.6 to 86°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
PRO-Mcomplete™ Extraction Buffer Sodium Azide	ACGIH TLV (United States, 3/2017). C: 0.29 mg/m ³ , (as Sodium azide) C: 0.11 ppm, (as Hydrazoic acid vapor) NIOSH REL (United States, 10/2016). Absorbed through skin. CEIL: 0.1 ppm, (as HN3) CEIL: 0.3 mg/m ³ , (NAN3)

Canada

Occupational exposure limits

None.

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Section 8. Exposure controls/personal protection

- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

- Physical state** : **PL.951** Solid. [Test strip in a plastic cassette packaged in a aluminum foil pouch with a desiccant.]
520CS01 Solid. [Single swab wrapped inside a peel-sleeve.]
PL.952 Liquid.
- Color** : **PL.951** Not available.
520CS01 Not available.
PL.952 Colorless.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : **PL.951** Not available.
520CS01 Not available.
PL.952 Not available.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- Vapor density** : Not available.
- Relative density** : Not available.
- Solubility** : Not available.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- Viscosity** : Not available.

Section 9. Physical and chemical properties

Flow time (ISO 2431) : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
PRO-Mcomplete™ Extraction Buffer				
Sodium Azide	LD50 Dermal	Rabbit	20 mg/kg	-
	LD50 Dermal	Rat	50 mg/kg	-
	LD50 Oral	Rat	27 mg/kg	-

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Section 11. Toxicological information

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

- Potential immediate effects** : No known significant effects or critical hazards.
Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

- General** : No known significant effects or critical hazards.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Teratogenicity : No known significant effects or critical hazards.
Developmental effects : No known significant effects or critical hazards.
Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

There is no data available.

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
PRO-Mcomplete™ Extraction Buffer Sodium Azide	Acute EC50 0.348 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata	96 hours
	Acute EC50 6.4 mg/L Fresh water	Crustaceans - Simocephalus serrulatus - Larvae	48 hours
	Acute EC50 4.2 mg/L Fresh water	Daphnia - Daphnia pulex - Larvae	48 hours
	Acute LC50 0.68 mg/L Fresh water	Fish - Lepomis macrochirus	96 hours
	Chronic NOEC 5600 µg/L Marine water	Algae - Macrocyctis pyrifera	96 hours

Persistence and degradability

Section 12. Ecological information

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	TDG Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-
Transport hazard class(es)	-	-	-	-
Packing group	-	-	-	-
Environmental hazards	No.	No.	No.	No.

AERG : Not applicable

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

U.S. Federal regulations : **United States inventory (TSCA 8b)**: Not determined.

Clean Air Act Section 112 : Not listed

(b) Hazardous Air Pollutants (HAPs)

Clean Air Act Section 602 : Not listed

Class I Substances

Clean Air Act Section 602 : Not listed

Class II Substances

DEA List I Chemicals : Not listed

(Precursor Chemicals)

DEA List II Chemicals : Not listed

(Essential Chemicals)

SARA 302/304

Composition/information on ingredients

Name	EHS	SARA 302 TPQ		SARA 304 RQ	
		(lbs)	(gallons)	(lbs)	(gallons)
PRO·Mcomplete™ Extraction Buffer Sodium Azide	Yes.	500	-	1000	-

SARA 304 RQ : 12000000 lbs / 5448000 kg

SARA 311/312

Classification : Not applicable.

SARA 313

There is no data available.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

Canadian lists

Canada inventory (DSL NDSL) : Not determined.

Canadian NPRI : None of the components are listed.

CEPA Toxic substances : None of the components are listed.

Section 16. Other information

Procedure used to derive the classification

Classification	Justification
Not classified.	

History

Date of issue mm/dd/yyyy : 09/30/2018

Date of previous issue : Not applicable

Version : 1



Section 16. Other information

Prepared by	: KMK Regulatory Services Inc.
Key to abbreviations	: ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals IATA = International Air Transport Association IBC = Intermediate Bulk Container IMDG = International Maritime Dangerous Goods LogPow = logarithm of the octanol/water partition coefficient MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution) UN = United Nations

Notice to reader

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