SAFETY DATA SHEET

according to 1907/2006/EC, Article 31

PDQ 2 Reagent

Revision 7
Revision date 2015-05-19

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name	PDQ 2 Reagent
Product code	01-03-0065

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

Description	For use with Trinity Biotech PDQ Plus Analyzer hemoglobin A1c assay systems. Follow instructions for use as provided in the system operator manual. No substitutions or other uses are permitted. For in Vitro Diagnostic Use only.

1.3. Details of the supplier of the safety data sheet

Company	Trinity Biotech
Address	IDA Business Park Bray Co. Wicklow Ireland
Web	www.trinitybiotech.com
Telephone	+353 1 276 9800
Fax	+353 1 276 9883
Email	info@trinitybiotech.com
Local Supplier	
Company	Trinity Biotech USA
Address	2823 Girts Rd Jamestown NY 14701 USA
Telephone	+1 800-325-3424
Fax	+1 716-487-1419

1.4. Emergency telephone number

	Contact your local Emergency Health Provider. Ireland-Technical Support Group 00353 -1- 276- 9800 USA-Technical Support Group 1-800-325-3424

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Main hazards	No Significant Hazard

2.2. Label elements

Risk phrases	No Significant Hazard

SECTION 3: Composition/information on ingredients

3.2. Mixtures

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3.2. Mixtures

67/548/EEC / 1999/45/EC

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Water		7732-18-5			90 - 100%		
Ammonia solution	007-001-01-2	1336-21-6	215-647-6		0 - 0.5%	C; R34 N; R50	
Methanol	603-001-00-X	67-56-1	200-659-6		0 - 0.5%	F; R11 T; R23/24/25-39/23/24/25	
PROCLIN 950					0 - 0.5%	C; R34 Xn; R20/22 Xi; R37-43 N; R50	

EC 1272/2008

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc. (%w/w)	Classification	M-factor.
Water		7732-18-5			90 - 100%		
Ammonia solution	007-001-01-2	1336-21-6	215-647-6		0 - 0.5%	Skin Corr. 1B: H314; Aquatic Acute 1: H400;	
Methanol	603-001-00-X	67-56-1	200-659-6		0 - 0.5%	Flam. Liq. 2: H225; Acute Tox. 3: H331; Acute Tox. 3: H311; Acute Tox. 3: H301; STOT SE 1: H370;	
PROCLIN 950					0 - 0.5%	Acute Tox. 4: H302; Skin Corr. 1A: H314; Skin Sens. 1: H317; Acute Tox. 3: H331; STOT SE 3: H335; Aquatic Acute 1: H400;	

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove the affected person from the source of contamination immediately. Seek medical attention if irritation or symptoms persist.
Eye contact	Bathe the eye with running water for 15 minutes. Seek medical attention if irritation or symptoms persist.
Skin contact	Wash off immediately with plenty of soap and water. Seek medical attention if irritation or symptoms persist.
Ingestion	If ingested, induce vomiting, but only under medical supervision. Seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

	Use extinguishing media appropriate to the surrounding fire conditions.

5.2. Special hazards arising from the substance or mixture

	No Significant Hazard.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

	Wear suitable protective clothing, gloves and eye/face protection.

6.3. Methods and material for containment and cleaning up

	Wash with soap and water.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

	Do NOT allow to freeze. Keep containers tightly closed.

7.2. Conditions for safe storage, including any incompatibilities

	Store in original container. Store at temperatures between 2 °C and 28 °C. Do NOT allow to freeze.

SECTION 8: Exposure controls/personal protection

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8.1. Control parameters

8.1.1. Exposure Limit Values

Methanol	WEL 8-hr limit ppm:	200	WEL 8-hr limit mg/m3:	266
	WEL 15 min limit ppm:	250	WEL 15 min limit mg/m3:	333
	WEL 8-hr limit mg/m3 total inhalable dust:	-	WEL 15 min limit mg/m3 total inhalable dust:	-
	WEL 8-hr limit mg/m3 total respirable dust:	-	WEL 15 min limit mg/m3 total respirable dust:	-

8.2. Exposure controls

Eye / face protection	Avoid contact with eyes. Wear eye/face protection.
Skin protection - Handprotection	Wash with soap and water. Wear suitable protective clothing and gloves.
Skin protection - Other	Wear suitable protective clothing.
Respiratory protection	Not normally required. In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid
Colour	Clear
pH	9 - 10
Freezing Point	0 °C
Initial boiling point	78.1 °C
Flash point	78.1 °C
Evaporation rate	5.2
Vapour pressure	17065.26 Pa
Vapour density	1.1
Solubility	Soluble in water

9.2. Other information

Specific gravity	1.1
VOC (Volatile organic compounds)	15 g/l

SECTION 10: Stability and reactivity

10.4. Conditions to avoid

	Avoid contact with: Oxidising agents.

10.5. Incompatible materials

	Oxidising agents.

10.6. Hazardous decomposition products

	None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	Toxic in contact with skin and if swallowed. May cause damage to liver and kidneys. May cause damage to organs eye heart.
Skin corrosion/irritation	May cause irritation to skin.
Serious eye damage/irritation	May cause irritation to eyes.
Respiratory or skin sensitisation	May cause irritation to respiratory system.

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11.1. Information on toxicological effects

Repeated or prolonged exposure	Avoid prolonged or repeated exposure. Harmful if swallowed, in contact with skin or if inhaled. Very toxic if swallowed.

11.1.4. Toxicological Information

Methanol	**Inhalation Rat LC50/4 h:** 128.2 **Dermal Rabbit LD50:** 17100	**Oral Rat LD50:** 1187-2769
PROCLIN 950	**Dermal Rat LD50:** 5000 mg/kg	**Oral Rat LD50:** 1091 mg/kg

SECTION 12: Ecological information

12.2. Persistence and degradability

This product is not known to present any environmental hazards related to persistence in the environment, resistance to biodegradability, or hazardous degradation intermediates. The plastic container consists of polypropylene and may be recycled.

12.3. Bioaccumulative potential

Does not bioaccumulate. If released into the soil, this material is expected to evaporate and degrade. If released into the water, this material is expected to have a half-life of less than 5 days.

12.6. Other adverse effects

This material is expected to be slightly toxic to aquatic life.

Further information

This product does not present an environmental hazard in the terrestrial, atmospheric, or food-chain via accumulation.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal should be made in accordance with local and national regulations. Trinity Biotech analyzer systems discharge no more than 2 mL per minute. Consult local wastewater discharge requirements. Discharge only to public waste water treatment (POTW) systems. The preservative used is toxic to fish and wildlife. Do not discharge to lakes, streams, ponds, or surface watershed. The reagent is biodegradable. Once used with patient blood samples, handle under universal precautions as potentially infectious waste.

SECTION 14: Transport information

14.6. Special precautions for user

Transportation of this product is not regulated. Fragile containers, handle with care. Protect from freezing. Protect from extended storage at elevated temperatures.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

For in Vitro Diagnostic Use only.

SECTION 16: Other information

Other information

	Do not use after expiry date printed on label. The information contained in this MSDS does not purport to be all-inclusive and is provided for general guidance only. The manufacturer is not liable for any damage resulting from mishandling or unprotected contact with the above product.
Revision	This document differs from the previous version in the following areas:. 12 - 12.1. Toxicity.
Text of risk phrases in Section 3	R11 - Highly flammable. R20/22 - Harmful by inhalation and if swallowed. R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed. R34 - Causes burns. R37 - Irritating to respiratory system. R39/23/24/25 - Toxic: danger of very serious irreversible effects through inhalation, in contact with

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Other information	
	skin and if swallowed. R43 - May cause sensitisation by skin contact. R50 - Very toxic to aquatic organisms.
Text of Hazard Statements in Section 3	Skin Corr. 1B: H314 - Causes severe skin burns and eye damage. Aquatic Acute 1: H400 - Very toxic to aquatic life. Flam. Liq. 2: H225 - Highly flammable liquid and vapour. Acute Tox. 3: H301 - Toxic if swallowed. Acute Tox. 3: H311 - Toxic in contact with skin. Acute Tox. 3: H331 - Toxic if inhaled. STOT SE 1: H370 - Causes damage to organs . Acute Tox. 4: H302 - Harmful if swallowed. Skin Corr. 1A: H314 - Causes severe skin burns and eye damage. Skin Sens. 1: H317 - May cause an allergic skin reaction. STOT SE 3: H335 - May cause respiratory irritation.
Maximum content of VOC	15 g/l.