Roche Diagnostics Corporation 9115 Hague Road Tel.+1-800-428-5074 PO Box 50457

Indianapolis, IN 46250-0457

USA







1. PRODUCT IDENTIFICATION

Product Name.....: COBAS-FP TDM Multianalyte Controls

Business Unit...... Near Patient Testing

Part Number......: N/A Product Line.....: Calibrator/Control/Standard Mira

Component Part No..: N/A Instrument Type:

Catalog Number.....: 43286

Preparation Date.....: 11/3/2000

Contact/Preparatory: Don Pearson Last Update......: 6/26/2002

Information Number: 1-800-428-5074 (x7425)

Emergency Number..: 1-800-424-9300 (U.S. or Canada)

1-703-527-3887 (International)

NOTE: CHEMTREC is used as the emergency number and to be used only in emergencies involving a chemical accident, spill, leak, fire or exposure. Collect calls are accepted.

2. COMPOSITION / INFORMATION ON HAZARDOUS INGREDIENTS

CHEMICAL NAME	CAS #	% W/V	EXPOSURE LIMITS IN AIR						
			ACGIH		OSHA		OTHER		
			TLV	STEL	PEL	STEL			

Reagent 1: TDM Controls

Human serum	N/A	50-100%	N/A	N/A	N/A	N/A	N/A
Sodium Acetate	127-09-3	20-35%	N/A	N/A	N/A	N/A	N/A

Reagent 2: Continued

Sodium Chloride	7647-14-5	5-10%	N/A	N/A	N/A	N/A	N/A

Reagent 3: N/A

Reagent 5: N/A								
Reagent 6: N/A								

3. HAZARD IDENTIFICATION

Primary Routes of Entry:

Reagent 4: N/A

Inhalation, ingestion, skin and/or eye contact.

Inhalation:

May cause irritation to respiratory tract.

Ingestion:

May cause nausea or vomiting.

Skin Contact:

May irritate skin with prolonged contact.

Eye Contact:

May irritate the eye on contact.

Chronic Exposure:

N/A

Medical Conditions Aggravated by Exposure:

N/A

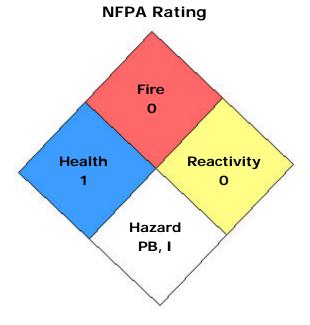
Health Effects:

No adverse health effects should occur from routine use of this material in the manner specified by the manufacturer's instructions. The above health effects may be associated with overexposure to this product. With FDA liscensed tests, the human source material in this product has been tested and is not reactive for Hepatitis B surface antigen, anti-Hepatitis C, and anti HIV 1/HIV-2. It is recommended to handle this product in accordance with Universal Precautions and the OSHA Bloodborne Pathogen Standard (29CFR1910.1030).

4. FIRST AID MEASURES

Inhalation:

If breathing becomes difficult, remove victim to fresh air. Seek medical assistance immediately.



Ingestion:

If product is swallowed get medical attention. If professional advice is not available, do not induce vomiting. Never give anything by mouth to an unconcious person.

Skin Contact:

If contact with this product leads to reddening, inflammation, or irritation, flush the exposed area with running water. Get medical attention.

Eye Contact:

Immediately flush eye(s) with large volumes of water for at least 15 minutes, occasionally lifting the lower and upper lids. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

Flash Point (Method used): N/A Flammable Limits-LEL: N/A UEL: N/A

Extinguishing Media:

Use fire extinguishing media appropriate for site conditions.

Special Fire Procedures:

Structural firefighting gear and self-contained breathing apparatus will provide adequate protection if this product is in a fire area.

Unusual Fire and Explosion Hazards:

N/A

6. ACCIDENTIAL RELEASE MEASURES

Steps to be Taken in Case Material is Released or Spilled:

Use Universal Precautions. Wash contaminated area with disinfectant and water, Use proper personal protective equipment as indicated in Section 8. Sweep up (if powder) or absorb material (if liquid), then place into a suitable clean, dry, closed container, and label for disposal. Avoid making dusty conditions (if powder).

7. HANDLING AND STORAGE

Store vials as directed in the product insert. Avoid splashing or spraying this product's components. All employees who handle this material should be trained to handle it safely.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Ventilation Data:

Supplemental ventilation such as general exhaust ventilation should be adequate under normal use of this product.

Respiratory Protection:

Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow OSHA respirator regulations (29CFR1910.134) and, if necessary, wear a NIOSH approved respirator. Select respirator based on its suitability to provide worker protection for given working conditions, level of airborne concentration, and presence of sufficient oxygen.

Protective Gloves:

Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly. Consistent with Universal Precautions, avoid the use of sharps with this product.

Other Protective Equipment:

Wear appropriate eye protection to prevent eye contact. Wear appropriate body protection to prevent skin contact.

Other Engineering Controls:

Eye wash stations and deluge showers.

Work Practices:

Good laboratory technique should be used when handling this product. Observe appropriate chemical hygiene. Avoid contact with skin or eyes. Do not place in mouth.

Hygienic Practices:

Do not eat, drink, or smoke while working with product. Upon completion of work activities involving this product, wash hands thoroughly with soap and water.

9. PHYSICAL AND CHEMICAL PROPERTIES

For All Components Unless Otherwise Indicated

Relative Vapor Density (air = 1): N/A Evaporation Rate (nBuAc = 1): N/A

Specific Gravity (water = 1) N/A Freezing/Melting Point: N/A

Solubility in Water: Soluble in water Boiling Point: N/A

Vapor Pressure, mm Hg @ 20°C: N/A pH: 7.6

Odor and Appearance Information

or and Appearance miormatic
Reagent 1:
Light yellow, lyophilized cake
Reagent 2:
N/A
Reagent 3:
N/A
Decreed 4
Reagent 4:
N/A
Reagent 5:

10. STABILITY AND REACTIVITY

Incompatibility (Materials to Avoid):

Unknown

N/A

N/A

Reagent 6:

Hazardous Decomposition Products:

N/A

Hazardous polymerization will not occur.

Conditions to Avoid/Polymerization:

N/A

Is the Product Stable?

Stable under normal handling and storage conditions.

Conditions to Avoid/Stability:

N/A

11. TOXICOLOGICAL INFORMATION

Toxicity Data:

Sodium Acetate: LD50(rat,oral) = 3530mg/kg.

Reproductive Effects:

N/A

Target Organ Effects:

Eyes, skin, gastrointestinal system.

Carcinogenicity: No

			NTP Car			
CHEMICAL NAME	CAS #	% W/V	Known	Anticipated	IARC	OSHA
N/A						

12. ECOLOGICAL INFORMATION

Environmental Fate/Stability:

N/A

Effect of Material on Plants or Animals:

N/A

Effect of Chemical on Aquatic Life:

N/A

13. DISPOSAL CONSIDERATIONS

EPA Waste Number and Proper Waste Disposal Method:

Please consult local, state and federal regulations for additional guidance on disposal.

14. TRANSPORATION INFORMATION

Is this Material Hazardous? Not regulated under transportation regulations.

Proper Shipping Name: N/A

Hazard Class Number: N/A Packing Group: N/A UN Number: N/A

15. REGULATORY INFORMATION

U.S. SARA 313 Notice Requirement (40 CFR 372):

N/A

U.S. SARA Reportable Quantity (EHS RQ)/Threshold Planning Quantity (SARA 302;40 CFR 355,App. A):

N/A

U.S. CERCLA Reportable Quantity (SARA 304; 40CFR Table 302.4):

N/A

U.S. TSCA Inventory Status:

All hazardous components listed are in TSCA.

Other U.S. Federal Regulations:

N/A

California Safe Drinking Water and Toxic Enforment Act (Proposition 65):

No component of this product is on the California Proposition 65 List.

16. OTHER INFORMATION

Other Comments:

DISCLAIMER

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