

Revision date:
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Version: 0

Material Safety Data Sheet



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product name: COBAS TaqMan HCV Test, v2.0 US-IVD
Product number: 05989060190
Business area: Molecular Diagnostics.
Supplier: Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876-3733
Technical Support: 1-800-526-1247
Emergency telephone number:
CHEMTREC:
1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Description 1: Master Mix

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
Potassium acetate	127-08-2	1-5	NA	NA	NA	NA
Tricine	5704-04-1	1-5	NA	NA	NA	NA
Dimethyl Sulfoxide (DMSO)	67-68-5	5-20	NA	NA	NA	NA
Glycerol	56-81-5	5-20	15 mg/m ³	NA	10 mg/m ³	NA

Description 2: Manganese Acetate

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
Manganese acetate tetrahydrate	6156-78-1	1-5	NA	NA	NA	NA

Description 3: Control Solutions

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
Human plasma	NONE	99-100	NA	NA	NA	NA

Description 4: All other solutions

Components	CAS Number	Weight %	OSHA PEL:	OSHA STEL:	ACGIH TLV:	ACGIH STEL:
No hazardous components >1%, >0.1% carcinogen	NONE	NA	NA	NA	NA	NA

3. HAZARDS IDENTIFICATION

Emergency Overview

NFPA Ratings:

Master Mix and Manganese Acetate Health= 1 Flammability= 0 Reactivity= 0 Special= I

Control Solutions Health= 1 Flammability= 0 Reactivity= 0 Special= PB

All other solutions Health= 0 Flammability= 0 Reactivity= 0

Special Definitions: A=Allergen CA=Carcinogen CO=Corrosive F=Flammable H=Harmful I=Irritant Ox=Oxidizer PB=Potential Biohazard
R=Reproductive S=Sensitizer T=Toxic T+=Highly Toxic W=Water Reactive

Principle routes of exposure: Ingestion, skin and/or eye contact

Inhalation: Avoid breathing vapors or mists. May cause irritation of respiratory tract. DMSO - Symptoms may include coughing, shortness of breath. May cause allergic reaction in sensitive individuals.

Ingestion: Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea

Skin contact: DMSO - Repeated or prolonged skin contact may cause dried skin or dermatitis. Readily absorbed through the skin. Garlic-like taste and odor may develop on the breath and skin. Transient disturbances of color vision, photophobia, headache, diarrhea, and dermatitis may result from skin applications. May result in the increased skin absorption of other more toxic materials.

Eye contact: Contact with eyes may cause irritation

Sensitization or Odor threshold: The following chemical(s) may cause sensitization, be absorbed via skin, and/or has an odor threshold for detection:

Medical conditions aggravated by exposure: None known

Additional information: With FDA approved methods, the human source material in this product has been tested and is shown to be free from HBsAg and antibodies to HCV and HIV. All human material should be considered potentially infectious. 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: Consult a physician. Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen

Skin contact: Rinse with plenty of water. If skin irritation persists, call a physician. Remove and wash contaminated clothing before re-use

Ingestion: Consult a physician. Do not induce vomiting without medical advice

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice

Notes to physician: None determined

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use dry chemical, CO₂, water spray or 'alcohol' foam

Unusual hazards: None known

Special protective equipment for firefighters: Wear self contained breathing apparatus for fire fighting if necessary

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Evacuate personnel to safe areas

Environmental precautions: Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

Methods for cleaning up: Never return spills in original containers for re-use. Sweep up or vacuum (if powder) or soak up with inert absorbent material (if liquid), then place into a suitable clean, dry, closed container, and label for disposal

7. HANDLING AND STORAGE

Handling: Protect from contamination. Wear personal protective equipment

Storage: No special precautions required

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering measures: Not applicable

Personal Protective Equipment

Respiratory protection: Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation, 29CFR1910.134. Always use a NIOSH approved respirator when necessary

Hand protection: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly

Skin and body protection: Wear appropriate body protection to prevent skin contact

Eye protection: Wear appropriate eye protection to prevent eye contact

Hygiene measures: Avoid contact with skin, eyes and clothing

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: Quantitation standard = red. Control solutions = yellow. Other solutions = colorless.

Odor: Master mix = garlic odor.

pH: 6.3-7.8

Physical state: Liquid.

Solubility in water: Soluble.

10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions
Polymerization:	Not applicable
Hazardous decomposition products:	DMSO - Upon heating above 100C (212F), sulfur dioxide is evolved from this substance. Hazardous thermo-oxidative degradation products from DMSO include formaldehyde, methyl mercaptan and sulfur dioxide. ALL OTHER SOLUTIONS... Carbon oxides.
Materials to avoid:	DMSO - Strong oxidants, acylhalides, arylhalides, bromobenzoyl acetanilide, magnesium perchlorate, perchloric acid and sodium hydroxide. ALL OTHER SOLUTIONS - strong acids, strong bases, strong oxidising agents, and strong water reactive substances.

11. TOXICOLOGICAL INFORMATION

Components	NIOSH - Selected LD50s and LC50s:	NIOSH Pocket Guide - Target Organs:
Potassium acetate	=3250 mg/kg Oral LD50 Rat	
Dimethyl Sulfoxide (DMSO)	=14500 mg/kg Oral LD50 Rat =40 g/kg Dermal LD50 Rat	
Glycerol	>21900 mg/kg Dermal LD50 Rat >570 mg/m ³ Inhalation LC50 Rat 1h =12600 mg/kg Oral LD50 Rat	respiratory system skin eyes kidneys

Components	NIOSH - Selected LD50s and LC50s:	NIOSH Pocket Guide - Target Organs:
Manganese acetate tetrahydrate	=3730 mg/kg Oral LD50 Rat	

Inhalation:	No additional data available
Skin:	No additional data available
Oral:	No additional data available
Mutagenic effects:	No data is available on the product itself
Reproductive toxicity:	No data is available on the product itself

12. ECOLOGICAL INFORMATION

Bioaccumulation:	Components of this product will degrade in the environment to smaller organic and inorganic constituents.
Aquatic toxicity:	Because of the small volume of solutions in this product, no unusual effects on aquatic plants or animals are expected if this product is released into the environment.
Ecotoxicity effects:	No data is available on the product itself

U.S. EPA, RCRA, CERCLA, SARA, or DGC information on persistent, bioaccumulative, and toxic chemicals (PBTs):
The following chemicals are listed under the U.S. EPA regulations of RCRA, CERCLA, SARA, or DGC:

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products:	Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. Residue from fires extinguished with this material may be hazardous
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14. TRANSPORT INFORMATION

Is product hazardous to ship?	No
DOT	

Proper shipping name: None			
UN Number: Not applicable	Hazard class: Not applicable	Subsidiary risk: Not applicable	Packing group: Not applicable

ICAO/IATA

Proper shipping name: None			
UN Number: Not applicable	Hazard class: Not applicable	Subsidiary risk: Not applicable	Packing group: Not applicable

15. REGULATORY INFORMATION

Product number: 05989060190

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15. REGULATORY INFORMATION

U.S. Regulations:

U.S. CERCLA/SARA/TSCA Regulatory Information: The following chemicals are listed under the following TSCA/SARA/CERCLA lists. Refer to TSCA regulation if you need a definition for acronyms that may be shown in the TSCA Inventory field in the table below

Components	CERCLA/SARA 302 RQ and TPQ (40 CFR 355, App.A)	CERCLA/SARA 304 RQ (40 CFR Table 302.4)	SARA 313 Emission reporting	TSCA Inventory
Potassium acetate				Present
Tricine				Present
Dimethyl Sulfoxide (DMSO)				Present
Glycerol				Present

U.S. Clean Water Act (CWA)/ California Proposition 65: The following chemicals are listed under the CWA and/or California Proposition 65:

Canadian Regulations:

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.

Components	Canada - WHMIS: Classifications of Substances:
Potassium acetate	Uncontrolled product according to WHMIS classification criteria
Dimethyl Sulfoxide (DMSO)	B3
Glycerol	Uncontrolled product according to WHMIS classification criteria

16. OTHER INFORMATION

Reason for revision: Not applicable
References: None
Additional advice: None
Prepared by: Roche Diagnostics, Health & Safety Department, MSDS Contact: 317-521-7425 or 317-521-7505

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End of Safety Data Sheet