

## Safety Data Sheet

According to 29 CFR 1910.1200(g)

### Unyvero M1 Master Mix

Print date: 30.01.2018

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#### 1. Identification

##### Product identifier

Unyvero M1 Master Mix

##### Recommended use of the chemical and restrictions on use

###### **Use of the substance/mixture**

In vitro diagnostic medical device.

###### **Uses advised against**

Any non-intended use.

##### Details of the supplier of the safety data sheet

Company name:	Curetis GmbH		
Street:	Max-Eyth-Str. 42		
Place:	71088 Holzgerlingen, Germany		
Telephone:	+49-(0)7031 – 49195-55	Telefax:	+49-(0)7031 - 4919519
Responsible Department:	Dr. Gans-Eichler	e-mail:	info@tge-consult.de
	Chemieberatung GmbH	Tel.:	+49 (0)251/924520-60
	Raesfeldstr. 22		
	48149 Muenster		

**Emergency phone number:** Poison Information Center Mainz, Germany, Tel: +49(0)6131/19240

#### 2. Hazard(s) identification

##### Classification of the chemical

###### **29 CFR Part 1910.1200**

This mixture is not classified as hazardous according to Regulation 29 CFR 1910.1200(d).

##### Label elements

###### **Additional advice on labelling**

Label elements GHS: none

##### Hazards not otherwise classified

No risks worthy of mention. Please observe the information on the safety data sheet at all times.

#### 3. Composition/information on ingredients

##### Mixtures

###### **Chemical characterization**

The product does not contain dangerous substances to be mentioned in Chapter 3.

#### 4. First-aid measures

##### Description of first aid measures

###### **General information**

In case of accident or illness, seek medical attention immediately. Show this safety data sheet to the doctor in attendance.

###### **After inhalation**

In case of accident by inhalation, remove subject to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

###### **After contact with skin**

Gently wash with plenty of soap and warm water. In case of skin irritation, seek medical attention.

###### **After contact with eyes**

Rinse cautiously with soap and warm water for several minutes. In case of troubles or persistent symptoms, consult

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ophthalmologist.

**After ingestion**

Rinse mouth thoroughly with water. Drink water in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical attention.

**Most important symptoms and effects, both acute and delayed**

No information available.

**Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

## 5. Fire-fighting measures

**Extinguishing media****Suitable extinguishing media**Carbon dioxide (CO<sub>2</sub>). Dry extinguishing powder. Alcohol resistant foam. Atomized water.**Unsuitable extinguishing media**

High power water jet.

**Specific hazards arising from the chemical**In case of fire, the following chemicals may be released: Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>).**Special protective equipment and precautions for fire-fighters**

Wear a self-contained breathing apparatus and chemical protective clothing.

**Additional information**

Collect contaminated fire extinguishing water separately. Do not allow contaminated water to enter drains or surface water.

## 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**

See protective measures under point 7 and 8.

**Environmental precautions**

Discharge into the environment must be avoided.

**Methods and material for containment and cleaning up**

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid or universal binding agents).

Treat the recovered material as prescribed in the section on waste disposal.

Clean contaminated articles and floor according to the environmental legislation.

**Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

## 7. Handling and storage

**Precautions for safe handling****Advice on safe handling**

Wear suitable protective clothing and equipment for receiving, handling and storage of frozen consumables shipped on dry ice (See section 8). Shipping and handling procedures should be in accordance with UN 1845 for the handling of dry ice which is subject to dangerous goods classification.

**Advice on protection against fire and explosion**

Usual measures for fire prevention.

**Further information on handling**

General protection and hygiene measures: refer to chapter 8

**Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Store frozen at ≤-20°C in temperature monitored freezer.

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#### Advice on storage compatibility

Do not store together with: Explosives, oxidizing solids, oxidizing liquids, radioactive substances, infectious substances or food.

#### Further information on storage conditions

Keep the packing frozen and in a well-sealed, temperature monitored freezer to prevent contamination, experiencing freeze-thaw cycles and absorption of humidity. Recommended storage temperature:  $\leq -20^{\circ}\text{C}$ . If Master Mix should thaw, which is to go from a frozen state to a liquid, it can be stored at refrigerated temperatures ( $4-8^{\circ}\text{C}$ ) for 4-7 days. After 7 days at refrigerated temperatures, Master Mix is to be disposed of according to state and federal waste regulations. Protect against: Light, UV-radiation, sunlight, heat and moisture.

## 8. Exposure controls/personal protection

### Control parameters

#### Exposure limits

CAS No.	Substance	ppm	mg/m <sup>3</sup>	f/cc	Category	Origin
56-81-5	Glycerin (mist) respirable fraction	-	5		TWA (8 h)	PEL

### Exposure controls

#### Appropriate engineering controls

No special measures are necessary.

#### Protective and hygiene measures

Always close containers tightly after the removal of product. When using, do not eat, drink, smoke or sniff. Wash hands with soap and warm water before and after removal of personal protective equipment upon handling frozen

#### Eye/face protection

Wear safety glasses or chemical goggles (if splashing is possible). Standards: EN 166 or 29 CFR 1910.133

#### Hand protection

Always avoid direct contact with skin when handling frozen consumables or shipping/receiving consumables on dry ice.

Wear suitable dry ice gloves and personal protective equipment.

Suitable material:

FKM (fluororubber). - Thickness of glove material (0,4 mm)

Breakthrough time  $\geq 8$  h

Butyl rubber: Thickness of glove material (0,5 mm)

Breakthrough time  $\geq 8$  h

CR (polychloroprenes, Chloroprene rubber): Thickness of glove material: 0,5 mm

Breakthrough time  $\geq 8$  h

NBR (Nitrile rubber): Thickness of glove material (0,35 mm)

Breakthrough time  $\geq 8$  h

PVC (Polyvinyl chloride): Thickness of glove material (0,5 mm)

Breakthrough time  $\geq 8$  h

Standards: EN 374

Before using, check leak tightness and impermeability. In the case of wanting to use the gloves again, clean them before taking off and dry them well.

#### Skin protection

Suitable protective clothing: Lab apron, dry ice handling gloves for shipping and receiving consumables. Latex gloves for handling of frozen product in freezer.

#### Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

#### Environmental exposure controls

No special precautionary measures are necessary.

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## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state:	Liquid at room temperature
Color:	Not determined
Odor:	Characteristic

#### Test method

pH-Value:	Not determined
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#### Changes in the physical state

Melting point/freezing point:	Not determined
Initial boiling point and boiling range:	Not determined
Sublimation point:	Not determined
Softening point:	Not determined
Pour point:	Not determined
Flash point:	Not determined
Sustaining combustion:	Not sustaining combustion

#### Explosive properties

Non

Lower explosion limits:	Not determined
Upper explosion limits:	Not determined
Ignition temperature:	Not determined

#### Auto-ignition temperature

Gas:

Not determined

Decomposition temperature:	Not determined
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#### Oxidizing properties

Non

Vapor pressure:	Not determined
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Density:	Not determined
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Water solubility:	Not determined
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#### Solubility in other solvents

Not determined

Partition coefficient:	Not determined
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Viscosity / dynamic:	Not determined
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Viscosity / kinematic:	1.847 mm <sup>2</sup> /s	DIN 51562
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Flow time:	Not determined
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Vapor density:	Not determined
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Evaporation rate:	Not determined
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Solvent separation test:	Not determined
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Solvent content:	Not determined
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#### Other information

Solid content:	Not determined
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## 10. Stability and reactivity

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#### **Reactivity**

No information available.

#### **Chemical stability**

Stability: Stable

The product is chemically stable under recommended conditions of storage, use and temperature.

#### **Possibility of hazardous reactions**

Hazardous reactions: Will not occur

No information available.

#### **Conditions to avoid**

Protect against UV-radiation, sunlight and heat.

#### **Incompatible materials**

Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

#### **Hazardous decomposition products**

In case of fire, the following chemicals may be released: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>).

## 11. Toxicological information

### **Information on toxicological effects**

#### **Route(s) of Entry**

Ingestion may be harmful. Inhalation may be harmful. Skin contact may cause mild irritation. Eye contact may cause irritation.

#### **Toxicokinetics, metabolism and distribution**

No data available.

#### **Acute toxicity**

Based on available data, the classification criteria are not met.

#### **Irritation and corrosivity**

Based on available data, the classification criteria are not met.

#### **Sensitizing effects**

Based on available data, the classification criteria are not met.

#### **Carcinogenic/mutagenic/toxic effects for reproduction**

Based on available data, the classification criteria are not met.

#### **Specific target organ toxicity (STOT) - single exposure**

Based on available data, the classification criteria are not met.

#### **Specific target organ toxicity (STOT) - repeated exposure**

Based on available data, the classification criteria are not met.

#### **Carcinogenicity (NTP):**

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

#### **Carcinogenicity (IARC):**

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

#### **Carcinogenicity (OSHA):**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

#### **Aspiration hazard**

Based on available data, the classification criteria are not met.

#### **Specific effects in experiment on an animal**

No data available.

## 12. Ecological information

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#### Ecotoxicity

No data available.

#### Persistence and degradability

No data available.

#### Bioaccumulative potential

No indication of bioaccumulation potential.

#### Mobility in soil

No data available.

#### Other adverse effects

No data available.

#### Further information

Do not allow to enter into surface water or drains.

### 13. Disposal considerations

#### Waste treatment methods

##### Advice on disposal

Dispose in accordance with all applicable regulations. In addition, observe any national regulations! Consult the local waste disposal expert about waste disposal. Non-contaminated packages may be recycled.

##### Contaminated packaging

Since emptied containers may retain product residue, follow warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

### 14. Transport information

#### **US DOT 49 CFR 172.101**

##### Proper shipping name:

Master Mix is to be stored frozen at  $\leq -20^{\circ}\text{C}$  and shipped on dry ice. Dry ice shipments are designated as UN 1845 and are characterized as hazardous material with respect to these transport regulations and controlled under DOT.

#### **Marine transport (IMDG)**

##### UN number:

UN 1845

##### UN proper shipping name:

Dry Ice – UN 1845

##### Transport hazard class(es):

Class 9

##### Packing group:

Group III

#### **Air transport (ICAO)**

##### UN number:

UN 1845

##### UN proper shipping name:

Dry Ice – UN 1845

##### Transport hazard class(es):

Class 9

##### Packing group:

Group III

#### Environmental hazards

Environmentally Hazardous:

No

#### Special precautions for user

Refer to chapter 6-8

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

### 15. Regulatory information

#### U.S. Regulations

##### **National Inventory TSCA**

Glycerol is listed in the TSCA inventory.

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No TSCA 12(b) components exist in this product.

#### State Regulations

##### Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65, State of California)

This product contains no chemicals known to the State of California to cause cancer, birth defects or other reproductive harm.

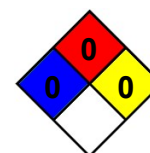
#### 16. Other information

##### Hazardous Materials Information Label (HMIS)

Health:	0
Flammability:	0
Physical Hazard:	0
Personal Protection:	-

##### NFPA Hazard Ratings

Health:	0
Flammability:	0
Reactivity:	0
Unique Hazard:	-



##### Changes

Revision date:	30.01.2018
Revision No:	2.0
Rev. 1.0; Initial release:	05.08.2015
Rev.: 2.0	Editorial changes

##### Abbreviations and acronyms

CAS: Chemical Abstracts Service  
 CFR: Code of Federal Regulations  
 DOT: Department of Transportation  
 IARC: International Agency for Research on Cancer  
 IBC: Intermediate Bulk Container  
 IMDG: International Maritime Code for Dangerous Goods  
 IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)  
 ICAO: International Civil Aviation Organization  
 ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)  
 GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
 MARPOL: marine pollution  
 NTP: National Toxicology Program  
 OSHA: Occupational Safety and Health Administration  
 TSCA: Toxic Substances Control Act  
 UN: United Nations

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#### Other data

Classification according regulation 29 CFR Part 1910.1200 (GHS): Classification procedure:

Health hazards: Calculation method.

Environmental hazards: Calculation method.

Physical hazards: On basis of test data and/or calculated and/or estimated.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*