

## 1 PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifiers

Product name and number	Warfarin PCR Mix	KT020525
	CF PCR Mix	KT020652
	TRT PCR Mix	KT020936
	2C19 PCR Mix	KT021148
	HCVg PCR Mix	KT021408
	HCVg <i>Direct</i> Test RT-PCR Mix	KT021500
	3A4/3A5 Genotyping Test PCR Mix	KT021506
	RVP PCR Mix	KT021621

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

Identified uses                      In vitro diagnostic use, investigational use and for research use

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

Company	GenMark Diagnostics	
	5964 La Place Court	
	Carlsbad, CA 92008	
Telephone	+1 800-373-6767	
	+1 760-448-4300	
	HCVg PCR Mix	KT021408

### 1.4 Emergency telephone number

1-800-424-9300

## 2 HAZARD IDENTIFICATION

### 2.1 Classification of the substance or mixture

This chemical is not considered hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

### 2.2 GHS label elements

None

### 2.3 Hazards not otherwise classified or not covered by GHS

None

## 3 COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

The product contains no substances which at their given concentration, are considered to be hazardous to health.

## 4 FIRST AID MEASURES

### 4.1 Description of first aid measures

#### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

#### In case of skin contact

Wash off with soap and plenty of water.

#### In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

#### If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

### 4.2 Most important symptoms and effects both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

- 4.3 Indication of any immediate medical attention and special treatment needed**  
No data available

## 5 FIRE-FIGHTING MEASURES

- 5.1 Extinguishing media**  
Suitable extinguishing media  
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide
- 5.2 Special hazards arising from the substance or mixture**  
Hydrogen chloride gas, Sodium oxides, carbon oxides, nitrogen oxides (NOx)
- 5.3 Advice for firefighters**  
Wear self contained breathing apparatus for fire fighting if necessary.

## 6 ACCIDENTAL RELEASE MEASURES

- 6.1 Personal precautions, protective equipment and emergency procedures**  
Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. For personal protection see section 8.
- 6.2 Environmental precautions**  
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.
- 6.3 Methods and material for containment and cleaning up**  
Keep in suitable, closed containers for disposal.
- 6.4 Reference to other sections**  
For disposal see section 13.

## 7 HANDLING AND STORAGE

- 7.1 Precautions for safe handling**  
Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.  
For precautions see section 2.2.
- 7.2 Conditions for safe storage, including any incompatibilities**  
Keep container tightly closed in a dry and well-ventilated place.
- 7.3 Specific end use(s)**  
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

## 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

- 8.1 Control parameters**  
Components with limit values that require monitoring at the workplace  
Contains no substances with occupational exposure limit values.
- 8.2 Exposure controls**  
Appropriate engineering controls  
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
- 8.3 Individual protection measures, such as personal protective equipment (PPE)**  
  
Eye/face protection  
Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**Skin protection**

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

**Body Protection**

Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection**

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**Control of environmental exposure**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

**9 PHYSICAL AND CHEMICAL PROPERTIES****9.1 Information on basic physical and chemical properties**

Appearance	Form: liquid Color: colorless
Odor	no data available
Odor Threshold	no data available
pH	no data available
Melting point/freezing point	no data available
Initial boiling point and boiling range	no data available
Flash point	no data available
Evaporation rate	no data available
Flammability (solid, gas)	no data available
Upper/lower flammability or explosive limits	no data available
Vapour pressure	no data available
Vapour density	no data available
Relative density	no data available
Water solubility	no data available
Partition coefficient: n-octanol/water	no data available
Auto-ignition temperature	no data available
Decomposition temperature	no data available
Viscosity	no data available
Oxidizing properties	no data available

**9.2 Other safety information**

no data available

**10 STABILITY AND REACTIVITY****10.1 Reactivity**

No data available

**10.2 Chemical stability**

Stable under recommended storage conditions.

**10.3 Possibility of hazardous reactions**

No data available

- 10.4 Conditions to avoid**  
No data available
- 10.5 Incompatible materials**  
Strong oxidizing agents
- 10.6 Hazardous decomposition products**  
Other decomposition products - no data available  
In the event of fire: see section 5

## 11 TOXICOLOGICAL INFORMATION

- 11.1 Information on likely routes of exposure**
- |                     |   |
|---------------------|---|
| Product Information | Product does not present an acute toxicity hazard based on known or supplied information. |
| Inhalation          | There is no data available for this product.  |
| Eye Contact         | There is no data available for this product.  |
| Skin Contact        | There is no data available for this product.  |
| Ingestion           | There is no data available for this product.  |
- 11.2 Symptoms related to the physical, chemical and toxicological characteristics**
- |          |            |
|----------|------------|
| Symptoms | None known |
|----------|------------|
- 11.3 Delayed and immediate effects and also chronic effects from short and long term exposure**
- |                          |   |
|--------------------------|---|
| Sensitization            | No information available.   |
| Mutagenic Effects        | No information available  |
| Carcinogenicity          | Contains no ingredients above reportable quantities listed as a carcinogen. |
| Reproductive Toxicity    | No information available.   |
| STOT - single exposure   | No information available.   |
| STOT - repeated exposure | No information available.   |
| Aspiration Hazard        | No information available.   |

## 12 ECOLOGICAL INFORMATION

- 12.1 Toxicity**  
no data available
- 12.2 Persistence and degradability**  
no data available
- 12.3 Bioaccumulative potential**  
no data available
- 12.4 Mobility in soil**  
no data available
- 12.5 Results of PBT and vPvB assessment**  
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
- 12.6 Other adverse effects**  
no data available

## 13 DISPOSAL CONSIDERATION

- 13.1 Disposal methods**  
This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or

if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

## 14 TRANSPORT INFORMATION

IATA, ADR, DOT

<b>14.1</b>	<b>UN Number</b>	Not a dangerous good in sense of these transport regulations.
<b>14.2</b>	<b>UN Proper shipping name</b>	None
<b>14.3</b>	<b>Transport hazard class(es)</b>	None
<b>14.4</b>	<b>Packing group</b>	None
<b>14.5</b>	<b>Additional information</b>	None

## 15 REGULATORY INFORMATION

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

#### International Inventories

TSCA – Complies

DSL – Substances comply or are exempt

#### Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

#### U.S. Federal Regulations

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### SARA 311/312 Hazard Categories

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

#### Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### U.S. State Regulations

##### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### U.S. State Right-to-Know Regulations

This product does not contain any substances regulated by state right-to-know regulations.

#### U.S. EPA Label Information

EPA Pesticide Registration Number: Not applicable

**16 OTHER INFORMATION**HMIS Rating

Health hazard:	1
Chronic Health Hazard:	*
Flammability:	0
Physical Hazard:	0

NFPA Rating

Health hazard:	1
Fire Hazard:	0
Reactivity Hazard:	0

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**End of Safety Data Sheet**