

1 PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name and number	Warfarin Signal Buffer	KT020540
	CF Signal Buffer	KT020656
	TRT Signal Buffer	KT020937
	2C19 Signal Buffer	KT021147
	HCV Genotyping Test Signal Buffer	KT021413
	HCVg <i>Direct</i> Test Signal Buffer	KT021502
	3A4/3A5 Genotyping Test Signal Buffer	KT021507
	RVP Signal Buffer	KT021622

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

1.4 Emergency telephone number

1-800-424-9300

2 HAZARD IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral (Category 4)

Skin irritation (Category 2)

Eye irritation (Category 2A)

2.2 GHS label elements

Pictogram



Signal Word

Warning

Hazard statement(s)

H302

Harmful if swallowed.

H315

Causes skin irritation

H319

Causes serious eye irritation.

Precautionary statement(s)

P264

Wash skin thoroughly after handling.

P270

Do not eat, drink or smoke when using this product.

P280

Wear protective gloves/ protective clothing/ eye protection/ face protection.

P301 + P312

IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.

P302 + P352

IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P332 + P313

If skin irritation occurs: Get medical advice/ attention.

P337 + P313
P362 + P364
P501

If eye irritation persists: Get medical advice/ attention.
Take off contaminated clothing and wash before reuse.
Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified or not covered by GHS

None

3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

<u>Chemical Name</u>	<u>CAS-No</u>	<u>EC-No</u>	<u>Concentration</u>
Guanidine Hydrochloride (Synonyms: Guanidinium chloride, Aminoromamidinehydrochloride, guanidium chloride)	50-01-1	200-002-3	30-60% *

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4 FIRST AID MEASURES

4.1 Description of first aid measures

General advice

Move out of dangerous area. Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

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

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

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. Evacuate personnel to safe areas. Avoid breathing dust. 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**
Contain spillage, soak up with inert absorbent material or then collect by wetbrushing and place in container for disposal according to local regulations (see section 13). 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
N/A
- 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
Odour	no data available
Odour 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

Inhalation	May cause irritation of respiratory tract.
Eye Contact	Contact with eyes may cause serious eye irritation based on the components present within the product.
Skin Contact	Expected to be an irritant based on components
Ingestion	Harmful if swallowed.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Guanidine hydrochloride	= 475 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization	Did not cause sensitization on laboratory animals.
Mutagenic Effects	In vitro tests did not show mutagenic effects.
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.
Chronic Toxicity	Avoid repeated exposure.
Target Organ Effects	Liver. Eyes. Skin. Blood. Gastrointestinal tract (GI).
Aspiration Hazard	No information available.

12 ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish	static test LC50 - Danio rerio (zebra fish) - > 1,000 mg/l - 96 h (OECD Test Guideline 203)
Toxicity to daphnia and other aquatic invertebrates	static test EC50 - Daphnia magna (Water flea) - > 100 mg/l - 48 h (OECD Test Guideline 202)
Toxicity to algae	Toxicity to algae static test EC50 - Pseudokirchneriella subcapitata - > 435.7 mg/l - 72 h (OECD Test Guideline 201)

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

Bioaccumulation	Bioaccumulation Danio rerio (zebra fish)
	Bioconcentration factor (BCF): 0.06 - 0.14

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
Dispose of contents/containers in accordance with applicable regional, national and local laws and regulations.

14 TRANSPORT INFORMATION

IATA, ADR, DOT

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

15 REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
International Inventories
TSCA – All components of this product are either listed or are exempt on the TSCA inventory.
DSL – Sustances 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	Yes
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 INFORMATIONHMIS Rating

Health hazard:	2
Chronic Health Hazard:	*
Flammability:	0
Physical Hazard:	2

NFPA Rating

Health hazard:	2
Fire Hazard:	0
Reactivity Hazard:	0

General Disclaimer

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End of Safety Data Sheet