

Specimen Validity Test ControlsVersion
1.11Revision Date:
03-22-2022Date of last issue: 10-11-2021
Date of first issue: 12-09-2015**SECTION 1. IDENTIFICATION**

Product name : Specimen Validity Test Controls

Product code : 05122953190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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Address : 9115 Hague Road
Indianapolis, IN 46250
USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC

1-800-424-9300 (U.S. or Ca-
nada)
1-703-527-3887 (Internatio-
nal)**Recommended use of the chemical and restrictions on use**

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section GHS Label elements contains the resulting labelling for the kit

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**SVT Control 2****GHS Classification**

Not a hazardous substance or mixture.

Components

Chemical name	CAS-No.	Concentration (% w/w)
Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-	56-75-7	< 0.1

Actual concentration is withheld as a trade secret

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SECTION 4. FIRST AID MEASURES

General advice	: Do not leave the victim unattended.
If inhaled	: Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	: If on skin, rinse well with water.
In case of eye contact	: Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	: Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	: None known.
Notes to physician	: The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during fire fighting	: No information available.
Further information	: Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special protective equipment for fire-fighters	: Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Refer to protective measures listed in sections 7 and 8.
Environmental precautions	: Local authorities should be advised if significant spillages cannot be contained.

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Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Advice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

SVT Control 2

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-	56-75-7	IOEL	0.1 mg/m ³	Roche Industrial Hygiene Committee (RIHC)
		TWA	0.5 mg/m ³	US WEEL

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

In case of contact through splashing:

Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0.11 mm

In case of full contact:

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Material	:	butyl-rubber
Break through time	:	> 480 min
Glove thickness	:	> 0.4 mm
Remarks	:	Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Eye protection	:	Safety glasses
Skin and body protection	:	Protective suit
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**SVT Control 2**

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	3.6
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available

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Relative density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.

SECTION 11. TOXICOLOGICAL INFORMATION**SVT Control 2****Acute toxicity**

Not classified based on available information.

Components:**Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-:**

Acute oral toxicity : LD50 Oral (Rat): 2,500 mg/kg

LD50 Oral (Mouse): 1,500 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-:**

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Remarks : This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-:**

Remarks : This information is not available.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:**Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-:**

Germ cell mutagenicity - Assessment : In vivo tests showed mutagenic effects

Carcinogenicity

Not classified based on available information.

Components:**Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-:**

Carcinogenicity - Assessment : Presumed to have carcinogenic potential for humans

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.**Reproductive toxicity**

Not classified based on available information.

Components:**Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-:**

Reproductive toxicity - Assessment : Suspected of damaging the unborn child., Suspected human reproductive toxicant

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Not classified based on available information.

Components:**Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure

Not classified based on available information.

Components:**Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:**Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-:**

No data available

SECTION 12. ECOLOGICAL INFORMATION**SVT Control 2****Ecotoxicity****Components:****Acetamide, 2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-:**Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 345 mg/l
Exposure time: 48 h**Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Persistence and degradability

No data available

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octanol/water : Remarks: Not applicable**Mobility in soil**

No data available

Other adverse effects

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**Waste from residues : Can be disposed as waste water, when in compliance with
local regulations.Contaminated packaging : Empty containers should be taken to an approved waste
handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable

Domestic regulation**49 CFR**

Not regulated as a dangerous good

Special precautions for userRemarks : Not dangerous goods in the meaning of ADR/RID, ADN,
IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION**SVT Control 2**

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CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Hydrochloric acid	7647-01-0	>= 0 - < 0.1 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Hydrochloric acid	7647-01-0	>= 0 - < 0.1 %
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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

Acetamide, (hydroxymethyl)-2-(4-nitrophenyl)ethyl]-	2,2-dichloro-N-[(1R,2R)-2-hydroxy-1-	56-75-7
Hydrochloric acid		7647-01-0

Pennsylvania Right To Know

Water		7732-18-5
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Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The ingredients of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

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DSL	:	All components of this product are on the Canadian DSL
NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	On the inventory, or in compliance with the inventory
PICCS	:	On the inventory, or in compliance with the inventory
IECSC	:	On the inventory, or in compliance with the inventory
TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	All substances listed as active on the TSCA inventory
TECI	:	Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SVT Control 2**GHS label elements**

Not a hazardous substance or mixture.

SECTION 16. OTHER INFORMATION**Further information**

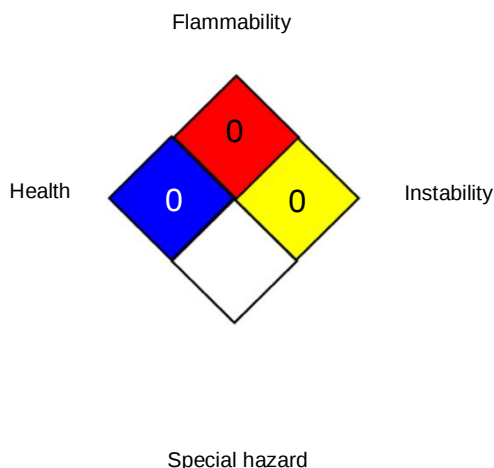
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NFPA 704:



HMIS® IV:

HEALTH	/	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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US / Z8 / 2104