

SAFETY DATA SHEET



HIV Duo Elecsys E2G 10 x 300

Version
4.1

Revision Date:
08-29-2024

Date of last issue: 08-29-2024
Date of first issue: 04-16-2019

Cover letter for product:

Trade name : HIV Duo Elecsys E2G 10 x 300
Product code : 08836973162

The product is sold as a kit, and contains the following components:

- HIV DUO M1 E2G 100/300 R1
- HIV DUO M1 E2G 300 R2 V2
- SA COAT-BEAD ELECSYS (BOTTLE)
- HIV DUO M2 E2G 100/300 R1
- HIV DUO M2 E2G 300 R2 V2
- HIV DUO M1 ELECSYS CAL 1
- HIV DUO M1 ELECSYS CAL 2
- HIV DUO M2 ELECSYS CAL 3
- HIV DUO M2 ELECSYS CAL 4

The following is an overview of the labeling elements of the kit:

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements :

Prevention:

P261 Avoid breathing mist or vapors.

P272 Contaminated work clothing must not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

The product was evaluated per International Air Transport Association (IATA) specifications with the following outcome:

Not assigned by regulation



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SECTION 1. IDENTIFICATION

Product name : HIV DUO M1 E2G 100/300 R1

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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
Canada)
1-703-527-3887
(International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

No hazardous ingredients

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



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- 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.
- Hazardous combustion products : Gaseous hydrogen chloride (HCl).
Sodium oxides
- 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.
- Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.



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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

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

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:

- 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.



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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid

- Color : colorless

- Odor : odorless

- Odor Threshold : No data available

- pH : 6.4 - 6.6 (77 °F / 25 °C)

- 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

- Relative density : No data available

- Density : 1.026 g/cm³

- Solubility(ies)
 - Water solubility : completely miscible

 - Solubility in other solvents : No data available

- Partition coefficient: n-octanol/water : No data available



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| | | |
|---------------------------|---|--|
| 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 Expert judgment |
| 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 | : | No dangerous reaction known under conditions of normal use. Stable under recommended storage conditions. No hazards to be specially mentioned. |
| Conditions to avoid | : | Exposure to light. |
| Incompatible materials | : | Strong oxidizing agents |
| Hazardous decomposition products | : | No decomposition if stored and applied as directed. |

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Skin corrosion/irritation

Not classified due to lack of data.

Serious eye damage/eye irritation

Not classified due to lack of data.

Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.



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Respiratory sensitization

Not classified due to lack of data.

Germ cell mutagenicity

Not classified due to lack of data.

Carcinogenicity

Not classified due to lack of data.

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 due to lack of data.

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: 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).



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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 user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

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.



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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:

| | | |
|---------------------------|-----------|----------------|
| Sodium hydroxide (Na(OH)) | 1310-73-2 | >= 0.1 - < 1 % |
| Acetic acid | 64-19-7 | >= 0 - < 0.1 % |

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

| | | |
|---------------------------|-----------|----------------|
| Sodium hydroxide (Na(OH)) | 1310-73-2 | >= 0.1 - < 1 % |
| Acetic acid | 64-19-7 | >= 0 - < 0.1 % |

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

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

| | |
|---------------------------|-----------|
| Water | 7732-18-5 |
| Sodium hydroxide (Na(OH)) | 1310-73-2 |

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

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

PAK<->R-IGG(DET)

hydroxyl-2-pyridone

MAB / PAB

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- 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 : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not in compliance with the inventory

TSCA list

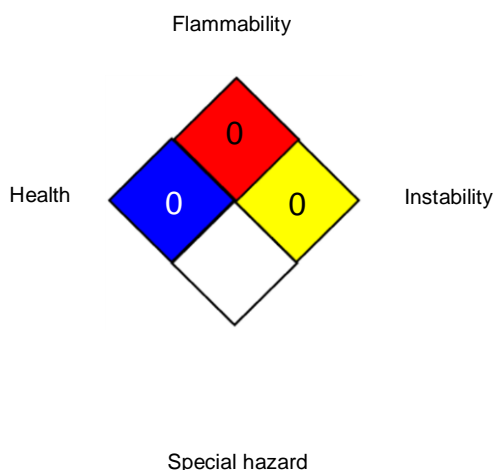
No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

Further information

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

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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; IECSC - 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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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2304



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SECTION 1. IDENTIFICATION

Product name : HIV DUO M1 E2G 300 R2 V2

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-

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
Canada)
1-703-527-3887
(International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

No hazardous ingredients

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



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- 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.
- Hazardous combustion products : Gaseous hydrogen chloride (HCl).
Sodium oxides
- 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.
- Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.



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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

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

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:

- 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.



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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|--|--------------------------------|
| Appearance | : liquid |
| Color | : colorless |
| Odor | : none |
| Odor Threshold | : No data available |
| pH | : 6.4 - 6.6 (77 °F / 25 °C) |
| 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 | : Not applicable |
| 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 |
| Relative density | : No data available |
| Density | : 1.026 g/cm ³ |
| Solubility(ies) | |
| Water solubility | : completely miscible |
| Solubility in other solvents | : No data available |
| Partition coefficient: n-octanol/water | : No data available |



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- 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
Expert judgment
- 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 : No dangerous reaction known under conditions of normal use.
Stable under recommended storage conditions.
No hazards to be specially mentioned.
- Conditions to avoid : Exposure to light.
- Incompatible materials : Strong oxidizing agents
- Hazardous decomposition products : No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Product:

- Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Skin corrosion/irritation

Not classified due to lack of data.

Serious eye damage/eye irritation

Not classified due to lack of data.

Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.



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Respiratory sensitization

Not classified due to lack of data.

Germ cell mutagenicity

Not classified due to lack of data.

Carcinogenicity

Not classified due to lack of data.

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 due to lack of data.

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: 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).



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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 user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

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.



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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:

| | | |
|------------------------------|-----------|----------------|
| Sodium hydroxide (Na(OH)) | 1310-73-2 | >= 0.1 - < 1 % |
|------------------------------|-----------|----------------|

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

| | | |
|------------------------------|-----------|----------------|
| Sodium hydroxide (Na(OH)) | 1310-73-2 | >= 0.1 - < 1 % |
|------------------------------|-----------|----------------|

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

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

| | |
|---------------------------|-----------|
| Water | 7732-18-5 |
| Sodium hydroxide (Na(OH)) | 1310-73-2 |

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

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

- MAB / PAB
- hydroxyl-2-pyridone
- Streptavidin Poly

NZIoC : On the inventory, or in compliance with the inventory

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- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not in compliance with the inventory

TSCA list

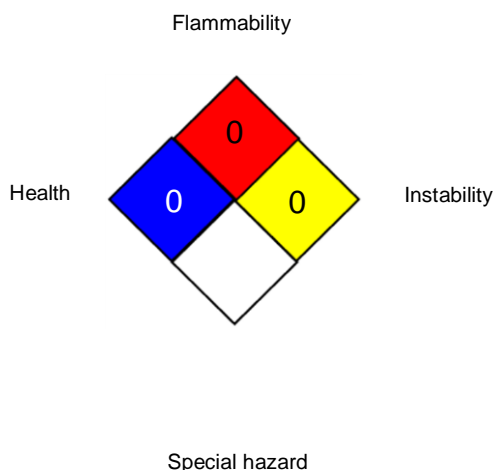
No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

Further information

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 -

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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; IECSC - 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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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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SECTION 1. IDENTIFICATION

Product name : SA COAT-BEAD ELECSYS (BOTTLE)

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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
Canada)
1-703-527-3887
(International)

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)

Skin sensitization : Category 1

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements :

Prevention:

P261 Avoid breathing mist or vapors.

P272 Contaminated work clothing must not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.



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P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--|------------|-----------------------|
| .alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl | 57-50-1 | >= 1 - < 5 |
| 1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)- | 7365-45-9 | >= 1 - < 5 |
| 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) | 26172-54-3 | >= 0.0015 - < 0.1 |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
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.
Keep eye wide open while rinsing.
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 : May cause an allergic skin reaction.



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delayed

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.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : No information available.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Sulfur oxides

Further information : The product itself does not burn.

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 : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
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 : Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.



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For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---------|--------------------------------|--|-----------|
| .alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl | 57-50-1 | TWA | 10 mg/m3 | ACGIH |
| | | TWA (Respirable) | 5 mg/m3 | NIOSH REL |
| | | TWA (total) | 10 mg/m3 | NIOSH REL |
| | | TWA (total dust) | 15 mg/m3 | OSHA Z-1 |
| | | TWA (respirable fraction) | 5 mg/m3 | OSHA Z-1 |
| | | TWA (Total dust) | 15 mg/m3 | OSHA P0 |
| | | TWA (respirable dust fraction) | 5 mg/m3 | OSHA P0 |

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of vapor formation use a respirator with an approved filter.

Hand protection

In case of contact through splashing:



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

In case of full contact:
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 : Eye wash bottle with pure water
Tightly fitting safety goggles
Skin and body protection : Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.
Hygiene measures : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid, Beads
Color : clear, colorless, red brown
Odor : odorless
Odor Threshold : No data available
pH : 7.1 - 7.4
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) : The product is not flammable., Does not sustain combustion.
Flammability (liquids) : Does not sustain combustion.
Self-ignition : Not applicable
Upper explosion limit / Upper : No data available



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- flammability limit
- Lower explosion limit / Lower flammability limit : No data available
- Vapor pressure : No data available
- Relative vapor density : No data available
- Relative density : No data available
- Density : 1.01 g/cm³ (68 °F / 20 °C)
- 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
Expert judgment
- 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 : No decomposition if stored and applied as directed.
- Conditions to avoid : No data available
- Incompatible materials : No data available
- Hazardous decomposition products : No decomposition if stored and applied as directed.
In case of fire hazardous decomposition products may be produced such as:
Carbon oxides

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Nitrogen oxides (NOx)
Sulfur oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Acute oral toxicity : LD50 Oral (Rat): 29,700 mg/kg

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Acute oral toxicity : LD50 Oral (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 423
GLP: yes
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402
GLP: yes
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: No mortality observed at this dose.

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg
Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Skin corrosion/irritation

Not classified due to lack of data.

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Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : No skin irritation
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Result : Causes severe burns.

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

Remarks : Vapors may cause irritation to the eyes, respiratory system and the skin.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rabbit
Result : No eye irritation
Exposure time : 30 s
Method : OECD Test Guideline 405
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Result : Risk of serious damage to eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified due to lack of data.

Product:

Remarks : Causes sensitization.

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Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Test Type : Maximization Test
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406
Result : Does not cause skin sensitization.
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Test Type : Local lymph node assay (LLNA)
Method : OECD Test Guideline 429
Result : The product is a skin sensitizer, sub-category 1A.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : positive
Remarks : Based on data from similar materials
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Germ cell mutagenicity

Not classified due to lack of data.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative

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GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Method: OECD Test Guideline 476
Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse (male and female)
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay
Species: Rat (male and female)
Application Route: Oral
Method: OECD Test Guideline 486
Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Carcinogenicity

Not classified due to lack of data.

Components:
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Remarks : 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.

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Remarks : 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.

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.

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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 due to lack of data.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Effects on fetal development : Species: Rat, female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Duration of Single Treatment: 14 d
General Toxicity Maternal: NOEL: 1,000 mg/kg body weight
Embryo-fetal toxicity.: NOEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Effects on fetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on fetal development.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

STOT-single exposure

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

Product:

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

Components:**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

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

STOT-repeated exposure

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

Product:

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

Components:**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Assessment : The substance or mixture is not classified as specific target

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organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rat, male and female
 NOEL : 1000 mg/kg
 Application Route : Oral
 Exposure time : 28 d
 Dose : 100, 300, 1000 mg/kg bw/day
 Method : OECD Test Guideline 407
 GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species : Rat
 NOEL : 94 mg/kg bw/day
 Application Route : Oral
 Exposure time : 90 d
 Method : OECD Test Guideline 408
 Remarks : No significant adverse effects were reported
 No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog
 NOAEL : 40.9 mg/kg bw/day
 Application Route : Oral
 Exposure time : 90 d
 Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Aspiration toxicity

Not classified due to lack of data.

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

No data available

Further information

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Remarks : Health injuries are not known or expected under normal use.

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SECTION 12. ECOLOGICAL INFORMATION
Ecotoxicity**Product:****Ecotoxicology Assessment**

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

Components:**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:****Ecotoxicology Assessment**

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

Chronic 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**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: yesToxicity to daphnia and other
aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yesToxicity to algae/aquatic
plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100
mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yesNOEC (Pseudokirchneriella subcapitata (green algae)): > 100
mg/l
End point: Growth rate
Exposure time: 72 h

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Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
End point: Respiration inhibition
Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Persistence and degradability
Components:
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Not readily biodegradable.

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Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Biodegradability : aerobic
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Partition coefficient: n- : log Pow: -3.7 (68 °F / 20 °C)
octanol/water

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Partition coefficient: n- : log Pow: < -3.85 (68 °F / 20 °C)
octanol/water Method: OECD Test Guideline 107
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n- : log Pow: ca. -0.44 (68 °F / 20 °C)
octanol/water Method: OECD Test Guideline 107

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: 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).

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Additional ecological : No data available
information



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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

- Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
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 user

- Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA 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** : Respiratory or skin sensitization



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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

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

Pennsylvania Right To Know

Water 7732-18-5
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

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

California Permissible Exposure Limits for Chemical Contaminants

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

hydroxyl-2-pyridone

Beads

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Impurity

- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not in compliance with the inventory

TSCA list

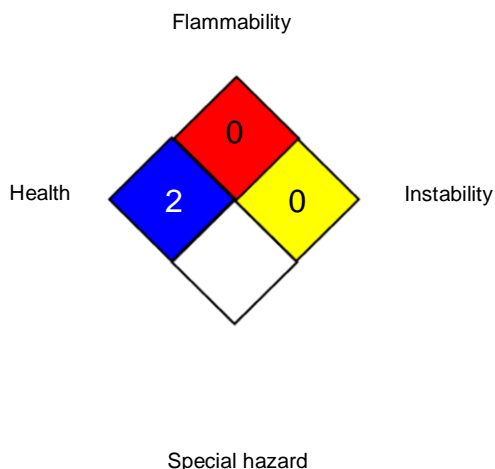
No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

| | | |
|------------------------|---|----------|
| HEALTH | / | 2 |
| 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

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| | | |
|-----------------|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| NIOSH REL | : | USA. NIOSH Recommended Exposure Limits |
| OSHA P0 | : | USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values) |
| OSHA Z-1 | : | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| NIOSH REL / TWA | : | Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |
| OSHA P0 / TWA | : | 8-hour time weighted average |
| OSHA Z-1 / TWA | : | 8-hour time weighted average |

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; IECSC - 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

Revision Date : 08-29-2024

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the

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specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2304

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SECTION 1. IDENTIFICATION

Product name : HIV DUO M2 E2G 100/300 R1

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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
Canada)
1-703-527-3887
(International)

Recommended use of the chemical and restrictions on use


Recommended use : Laboratory chemicals
Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin sensitization : Category 1

GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**
P261 Avoid breathing mist or vapors.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.



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P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|------------|-----------------------|
| 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) | 26172-54-3 | >= 0.0015 - < 0.1 |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
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.
Keep eye wide open while rinsing.
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 : May cause an allergic skin reaction.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.



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SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : Gaseous hydrogen chloride (HCl).
Sodium oxides
- 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 : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
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 : Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being



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- used.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of vapor formation use a respirator with an approved filter.

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:
 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 : Eye wash bottle with pure water
Tightly fitting safety goggles
- Skin and body protection : Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

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| | | |
|--|---|------------------------------|
| Color | : | colorless |
| Odor | : | odorless |
| Odor Threshold | : | No data available |
| pH | : | 7.2 - 7.4 (77 °F / 25 °C) |
| 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 |
| Relative density | : | No data available |
| Density | : | 1.026 g/cm ³ |
| 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 | | |

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|----------------------|---|--|
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive Expert judgment |
| 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 | : | No dangerous reaction known under conditions of normal use. No decomposition if stored and applied as directed. |
| Conditions to avoid | : | Exposure to light. |
| Incompatible materials | : | Strong oxidizing agents |
| Hazardous decomposition products | : | No decomposition if stored and applied as directed. |

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

| | | |
|---------------------------|---|--|
| Acute oral toxicity | : | LD50 Oral (Rat, female): 175 mg/kg Method: OECD Test Guideline 425 |
| Acute inhalation toxicity | : | LC50 (Rat, male and female): 0.11 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: Corrosive to the respiratory tract. Remarks: Based on data from similar materials The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one |
| Acute dermal toxicity | : | LD50 Dermal (Rat, male): 246 mg/kg Method: OECD Test Guideline 402 Remarks: Based on data from similar materials |



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The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Result : Causes severe burns.

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

Remarks : Vapors may cause irritation to the eyes, respiratory system and the skin.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Result : Risk of serious damage to eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified due to lack of data.

Product:

Remarks : Causes sensitization.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Test Type : Local lymph node assay (LLNA)
Method : OECD Test Guideline 429
Result : The product is a skin sensitizer, sub-category 1A.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : positive
Remarks : Based on data from similar materials

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The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Germ cell mutagenicity

Not classified due to lack of data.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Method: OECD Test Guideline 476
Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse (male and female)
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay
Species: Rat (male and female)
Application Route: Oral
Method: OECD Test Guideline 486
Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Carcinogenicity

Not classified due to lack of data.

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 due to lack of data.

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Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Effects on fetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on fetal development.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species : Rat
NOEL : 94 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 408
Remarks : No significant adverse effects were reported
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog
NOAEL : 40.9 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one



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- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Persistence and degradability

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

- Biodegradability : aerobic
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

- Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

- Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (68 °F / 20 °C)
Method: OECD Test Guideline 107

Mobility in soil

No data available

Other adverse effects

Product:

- Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: 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).



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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

- Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
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 user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

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 : Respiratory or skin sensitization



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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:

| | | |
|------------------------------|-----------|----------------|
| Sodium hydroxide (Na(OH)) | 1310-73-2 | >= 0.1 - < 1 % |
|------------------------------|-----------|----------------|

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

| | | |
|------------------------------|-----------|----------------|
| Sodium hydroxide (Na(OH)) | 1310-73-2 | >= 0.1 - < 1 % |
|------------------------------|-----------|----------------|

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

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

| | |
|---------------------------|-----------|
| Water | 7732-18-5 |
| Sodium chloride (NaCl) | 7647-14-5 |
| Sodium hydroxide (Na(OH)) | 1310-73-2 |

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

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

n-Octylglucoside



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hydroxyl-2-pyridone
HIV, gp41P2(SubO)-EEEX-Bi
4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride
Antigen / Protein, recombinant
Leupeptin hemisulfate
Aprotinin Trypsin inhibitor, pancreas type (BPTI) from bovine lung
HIV, gp36-EEEUZUX-Bi

- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on 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.

SECTION 16. OTHER INFORMATION

Further information

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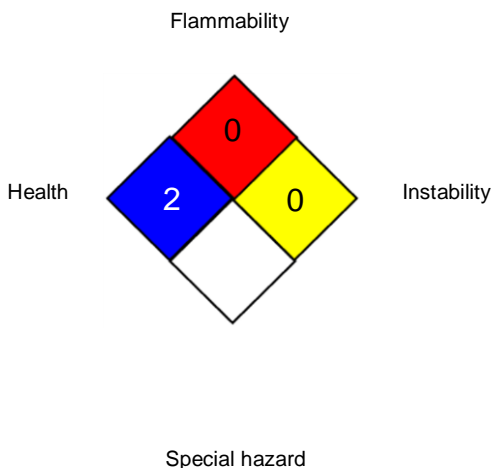
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NFPA 704:



HMIS® IV:

| | | |
|-----------------|---|---|
| HEALTH | / | 2 |
| 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; IECSC - 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; TECl - Thailand

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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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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2304

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SECTION 1. IDENTIFICATION

Product name : HIV DUO M2 E2G 300 R2 V2

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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
Canada)
1-703-527-3887
(International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin sensitization : Category 1

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements :

Prevention:

P261 Avoid breathing mist or vapors.

P272 Contaminated work clothing must not be allowed out of the workplace.

P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.



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P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|------------|-----------------------|
| 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) | 26172-54-3 | >= 0.0015 - < 0.1 |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
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.
Keep eye wide open while rinsing.
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 : May cause an allergic skin reaction.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.



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SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : Gaseous hydrogen chloride (HCl).
Sodium oxides
- 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 : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
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 : Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being



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- used.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of vapor formation use a respirator with an approved filter.

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:
 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 : Eye wash bottle with pure water
Tightly fitting safety goggles
- Skin and body protection : Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

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| | | |
|--|---|------------------------------|
| Color | : | colorless |
| Odor | : | none |
| Odor Threshold | : | No data available |
| pH | : | 7.2 - 7.4 (77 °F / 25 °C) |
| 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 | : | Not applicable |
| 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 |
| Relative density | : | No data available |
| Density | : | 1.026 g/cm ³ |
| 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 | | |

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| | | |
|----------------------|---|--|
| Viscosity, dynamic | : | No data available |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive Expert judgment |
| 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 | : | No dangerous reaction known under conditions of normal use. No decomposition if stored and applied as directed. |
| Conditions to avoid | : | Exposure to light. |
| Incompatible materials | : | Strong oxidizing agents |
| Hazardous decomposition products | : | No decomposition if stored and applied as directed. |

SECTION 11. TOXICOLOGICAL INFORMATION
Acute toxicity

Not classified due to lack of data.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

| | | |
|---------------------------|---|--|
| Acute oral toxicity | : | LD50 Oral (Rat, female): 175 mg/kg Method: OECD Test Guideline 425 |
| Acute inhalation toxicity | : | LC50 (Rat, male and female): 0.11 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: Corrosive to the respiratory tract. Remarks: Based on data from similar materials The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one |
| Acute dermal toxicity | : | LD50 Dermal (Rat, male): 246 mg/kg Method: OECD Test Guideline 402 Remarks: Based on data from similar materials |



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The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Result : Causes severe burns.

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

Remarks : Vapors may cause irritation to the eyes, respiratory system and the skin.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Result : Risk of serious damage to eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified due to lack of data.

Product:

Remarks : Causes sensitization.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Test Type : Local lymph node assay (LLNA)
Method : OECD Test Guideline 429
Result : The product is a skin sensitizer, sub-category 1A.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : positive
Remarks : Based on data from similar materials

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The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Germ cell mutagenicity

Not classified due to lack of data.

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Method: OECD Test Guideline 476
Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse (male and female)
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay
Species: Rat (male and female)
Application Route: Oral
Method: OECD Test Guideline 486
Result: negative
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Carcinogenicity

Not classified due to lack of data.

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 due to lack of data.

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Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Effects on fetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on fetal development.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species : Rat
NOEL : 94 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 408
Remarks : No significant adverse effects were reported
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog
NOAEL : 40.9 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

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- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Persistence and degradability
Components:
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

- Biodegradability : aerobic
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential
Components:
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

- Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).
- Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (68 °F / 20 °C)
Method: OECD Test Guideline 107

Mobility in soil

No data available

Other adverse effects
Product:

- Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: 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).



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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

- Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
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 user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

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 : Respiratory or skin sensitization



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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:

| | | |
|------------------------------|-----------|----------------|
| Sodium hydroxide (Na(OH)) | 1310-73-2 | >= 0.1 - < 1 % |
|------------------------------|-----------|----------------|

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

| | | |
|------------------------------|-----------|----------------|
| Sodium hydroxide (Na(OH)) | 1310-73-2 | >= 0.1 - < 1 % |
|------------------------------|-----------|----------------|

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

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

| | |
|---------------------------|-----------|
| Water | 7732-18-5 |
| Sodium chloride (NaCl) | 7647-14-5 |
| Sodium hydroxide (Na(OH)) | 1310-73-2 |

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

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

MAB / PAB



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n-Octylglucoside
hydroxyl-2-pyridone
4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride
Antigen / Protein, recombinant
Leupeptin hemisulfate
Aprotinin Trypsin inhibitor, pancreas type (BPTI) from bovine lung
HIV, gp36-SK(4)-BPRu(2)
HIV, gp41P2(SubO)-SK(4)-BPRu(2)
rec. Antigen-Conjugat

- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on 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.

SECTION 16. OTHER INFORMATION

Further information

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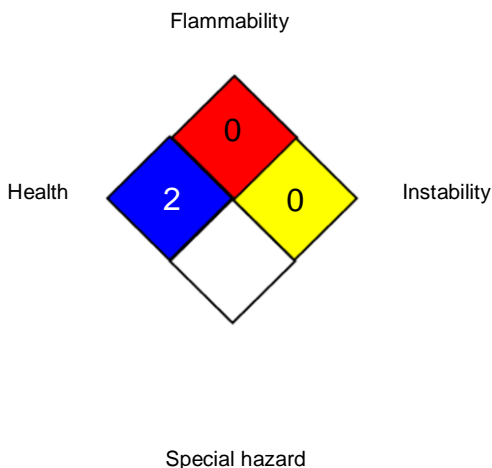
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NFPA 704:



HMIS® IV:

| | | |
|-----------------|---|---|
| HEALTH | / | 2 |
| 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; IECSC - 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; TECl - Thailand

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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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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2304

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SECTION 1. IDENTIFICATION

Product name : HIV DUO M1 ELECSYS CAL 1

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-

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
Canada)
1-703-527-3887
(International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.


SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Skin sensitization : Category 1

GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : May form combustible dust concentrations in air.
H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**
P261 Avoid breathing dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
Response:



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P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/
attention.
P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : Handle as potentially infectious.

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--|------------|-----------------------|
| 1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)- | 7365-45-9 | >= 5 - < 10 |
| 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) | 26172-54-3 | >= 0.1 - < 1 |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
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.
Keep eye wide open while rinsing.
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.



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Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.

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.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Sulfur oxides

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

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 : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.

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

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.



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Avoid contact with skin and eyes.
 For personal protection see section 8.
 Smoking, eating and drinking should be prohibited in the application area.
 Dispose of rinse water in accordance with local and national regulations.
 Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.

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:
 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 : Eye wash bottle with pure water
Tightly fitting safety goggles

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- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : (lyophilized)
- Color : white
- Odor : none
- Odor Threshold : Not applicable
- pH : Not applicable
- 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) : Sustains combustion
- Flammability (liquids) : Sustains 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 : Not applicable
- Relative density : No data available
- Solubility(ies)
Water solubility : soluble
- Solubility in other solvents : No data available



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- Partition coefficient: n-octanol/water : No data available
- Autoignition temperature : No data available
- Decomposition temperature : No data available
- Viscosity
 - Viscosity, dynamic : Not applicable
 - Viscosity, kinematic : Not applicable
- Explosive properties : Not explosive
Expert judgment
- 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 : No dangerous reaction known under conditions of normal use.
No decomposition if stored and applied as directed.
- Conditions to avoid : No data available
- Incompatible materials : Strong oxidizing agents
- Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Product:

- Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method
- Acute inhalation toxicity : Acute toxicity estimate: 15.37 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method
- Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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Components:
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Acute oral toxicity : LD50 Oral (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 423
GLP: yes
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402
GLP: yes
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: No mortality observed at this dose.

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg
Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : No skin irritation
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

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Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Result : Causes severe burns.

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rabbit
Result : No eye irritation
Exposure time : 30 s
Method : OECD Test Guideline 405
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Result : Risk of serious damage to eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified due to lack of data.

Product:

Remarks : Causes sensitization.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Test Type : Maximization Test
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406
Result : Does not cause skin sensitization.
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Test Type : Local lymph node assay (LLNA)
Method : OECD Test Guideline 429
Result : The product is a skin sensitizer, sub-category 1A.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test

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Species : Guinea pig
 Method : OECD Test Guideline 406
 Result : positive
 Remarks : Based on data from similar materials
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Germ cell mutagenicity

Not classified due to lack of data.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative
 GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Escherichia coli
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative
 GLP: yes

Test Type: Chromosome aberration test in vitro
 Test system: Human lymphocytes
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 473
 Result: negative
 GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative

Test Type: In vitro mammalian cell gene mutation test
 Test system: Chinese hamster ovary cells
 Method: OECD Test Guideline 476
 Result: negative
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test
 Species: Mouse (male and female)
 Application Route: Oral
 Method: OECD Test Guideline 474
 Result: negative
 The value is given in analogy to the following substances: 2-

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methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay

Species: Rat (male and female)

Application Route: Oral

Method: OECD Test Guideline 486

Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Carcinogenicity

Not classified due to lack of data.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Remarks : 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.

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 due to lack of data.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Effects on fetal development : Species: Rat, female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Duration of Single Treatment: 14 d
General Toxicity Maternal: NOEL: 1,000 mg/kg body weight
Embryo-fetal toxicity.: NOEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Effects on fetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on fetal development.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

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STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rat, male and female
NOEL : 1000 mg/kg
Application Route : Oral
Exposure time : 28 d
Dose : 100, 300, 1000 mg/kg bw/day
Method : OECD Test Guideline 407
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species : Rat
NOEL : 94 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 408
Remarks : No significant adverse effects were reported
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog
NOAEL : 40.9 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: yes

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- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
- NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
- Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
End point: Respiration inhibition
Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes

Ecotoxicology Assessment

- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

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Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Persistence and degradability

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Biodegradability : aerobic
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Partition coefficient: n-octanol/water : log Pow: < -3.85 (68 °F / 20 °C)
Method: OECD Test Guideline 107
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (68 °F / 20 °C)
Method: OECD Test Guideline 107

Mobility in soil

No data available



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Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: 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).

Additional ecological information : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Special treatment as infectious material is mandatory in
compliance with local regulations (disinfection and
incineration).
The product should not be allowed to enter drains, water
courses or the soil.
Do not contaminate ponds, waterways or ditches with
chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with
local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
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



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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 user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA 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 : Combustible dust
Respiratory or skin sensitization

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 I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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

No components are subject to the Massachusetts Right to Know Act.

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Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, lyophilized
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-

Not Assigned
7365-45-9

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
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Human serum /-plasma / -hemolysate, lyophilized

hydroxyl-2-pyridone
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on 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.

SECTION 16. OTHER INFORMATION

Further information

SAFETY DATA SHEET



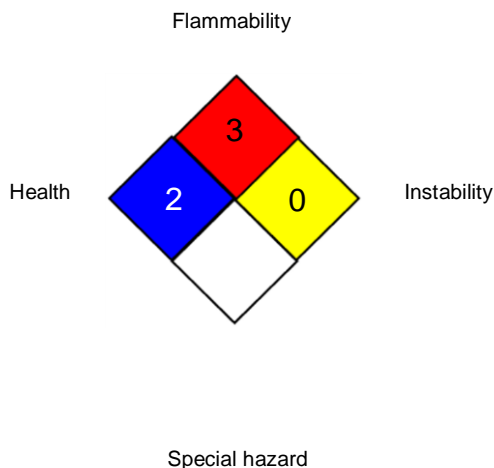
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NFPA 704:



HMIS® IV:

| | | |
|------------------------|---|----------|
| HEALTH | / | 2 |
| FLAMMABILITY | | 3 |
| 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; IECSC - 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; TECl - Thailand

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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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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2304

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SECTION 1. IDENTIFICATION

Product name : HIV DUO M1 ELECSYS CAL 2

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-

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
Canada)
1-703-527-3887
(International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.


SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Skin sensitization : Category 1

GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : May form combustible dust concentrations in air.
H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**
P261 Avoid breathing dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
Response:

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P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/
attention.
P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste
disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : Handle as potentially infectious.

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--|------------|-----------------------|
| 1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)- | 7365-45-9 | $\geq 5 - < 10$ |
| 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) | 26172-54-3 | $\geq 0.1 - < 1$ |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
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.
Keep eye wide open while rinsing.
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.



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Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.

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.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Sulfur oxides

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

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 : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.

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

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.



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Avoid contact with skin and eyes.
 For personal protection see section 8.
 Smoking, eating and drinking should be prohibited in the application area.
 Dispose of rinse water in accordance with local and national regulations.
 Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.

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:
 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 : Eye wash bottle with pure water
Tightly fitting safety goggles



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- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : (lyophilized)
- Color : white
- Odor : none
- Odor Threshold : Not applicable
- pH : Not applicable
- 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) : Sustains combustion
- Flammability (liquids) : Sustains 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 : Not applicable
- Relative density : No data available
- Solubility(ies)
Water solubility : soluble
- Solubility in other solvents : No data available



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- Partition coefficient: n-octanol/water : No data available
- Autoignition temperature : No data available
- Decomposition temperature : No data available
- Viscosity
 - Viscosity, dynamic : Not applicable
 - Viscosity, kinematic : Not applicable
- Explosive properties : Not explosive
Expert judgment
- 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 : No dangerous reaction known under conditions of normal use.
No decomposition if stored and applied as directed.
- Conditions to avoid : Exposure to light.
- Incompatible materials : Strong oxidizing agents
- Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Product:

- Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method
- Acute inhalation toxicity : Acute toxicity estimate: 15.38 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method
- Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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Acute oral toxicity : LD50 Oral (Rat, male and female): > 2,000 mg/kg
 Method: OECD Test Guideline 423
 GLP: yes
 Assessment: The substance or mixture has no acute oral toxicity
 Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg
 Method: OECD Test Guideline 402
 GLP: yes
 Assessment: The substance or mixture has no acute dermal toxicity
 Remarks: No mortality observed at this dose.

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg
 Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l
 Exposure time: 4 h
 Test atmosphere: dust/mist
 Method: OECD Test Guideline 403
 Assessment: Corrosive to the respiratory tract.
 Remarks: Based on data from similar materials
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg
 Method: OECD Test Guideline 402
 Remarks: Based on data from similar materials
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rabbit
 Exposure time : 4 h
 Method : OECD Test Guideline 404
 Result : No skin irritation
 GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

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Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Result : Causes severe burns.

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rabbit
Result : No eye irritation
Exposure time : 30 s
Method : OECD Test Guideline 405
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Result : Risk of serious damage to eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified due to lack of data.

Product:

Remarks : Causes sensitization.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Test Type : Maximization Test
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406
Result : Does not cause skin sensitization.
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Test Type : Local lymph node assay (LLNA)
Method : OECD Test Guideline 429
Result : The product is a skin sensitizer, sub-category 1A.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test

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Species : Guinea pig
 Method : OECD Test Guideline 406
 Result : positive
 Remarks : Based on data from similar materials
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Germ cell mutagenicity

Not classified due to lack of data.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative
 GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Escherichia coli
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative
 GLP: yes

Test Type: Chromosome aberration test in vitro
 Test system: Human lymphocytes
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 473
 Result: negative
 GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative

Test Type: In vitro mammalian cell gene mutation test
 Test system: Chinese hamster ovary cells
 Method: OECD Test Guideline 476
 Result: negative
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test
 Species: Mouse (male and female)
 Application Route: Oral
 Method: OECD Test Guideline 474
 Result: negative
 The value is given in analogy to the following substances: 2-

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methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay

Species: Rat (male and female)

Application Route: Oral

Method: OECD Test Guideline 486

Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Carcinogenicity

Not classified due to lack of data.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Remarks : 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.

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 due to lack of data.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Effects on fetal development : Species: Rat, female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Duration of Single Treatment: 14 d
General Toxicity Maternal: NOEL: 1,000 mg/kg body weight
Embryo-fetal toxicity.: NOEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Effects on fetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on fetal development.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

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STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rat, male and female
NOEL : 1000 mg/kg
Application Route : Oral
Exposure time : 28 d
Dose : 100, 300, 1000 mg/kg bw/day
Method : OECD Test Guideline 407
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species : Rat
NOEL : 94 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 408
Remarks : No significant adverse effects were reported
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog
NOAEL : 40.9 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: yes

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- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
- NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
- Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
End point: Respiration inhibition
Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

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Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Persistence and degradability

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Biodegradability : aerobic
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Partition coefficient: n-octanol/water : log Pow: < -3.85 (68 °F / 20 °C)
Method: OECD Test Guideline 107
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (68 °F / 20 °C)
Method: OECD Test Guideline 107

Mobility in soil

No data available



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Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: 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).

Additional ecological information : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Special treatment as infectious material is mandatory in
compliance with local regulations (disinfection and
incineration).
The product should not be allowed to enter drains, water
courses or the soil.
Do not contaminate ponds, waterways or ditches with
chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with
local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
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



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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 user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA 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 : Combustible dust
Respiratory or skin sensitization

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 I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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

No components are subject to the Massachusetts Right to Know Act.



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Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, lyophilized
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)- Not Assigned
7365-45-9

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:

- AICC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Human serum /-plasma / -hemolysate, lyophilized

hydroxyl-2-pyridone

4-(2-Aminoethyl)benzenesulfonyl Fluoride Hydrochloride

Leupeptin hemisulfate

AprotininTrypsin inhibitor, pancreas type (BPTI) from bovine lung

Antigen / Protein, recombinant
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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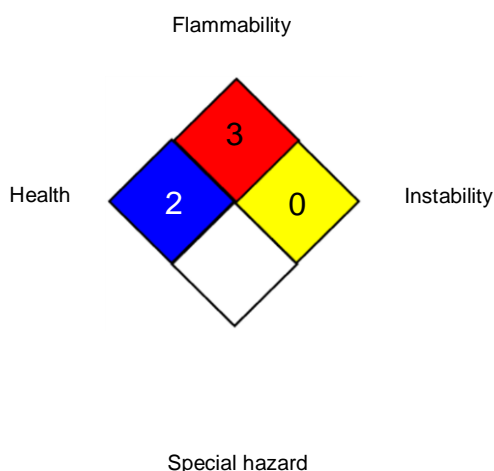
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No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

| | | |
|------------------------|---|----------|
| HEALTH | / | 2 |
| FLAMMABILITY | | 3 |
| 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; IECSC - 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 DATA SHEET



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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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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2304

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SECTION 1. IDENTIFICATION

Product name : HIV DUO M2 ELECSYS CAL 3

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-

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
Canada)
1-703-527-3887
(International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.


SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Skin sensitization : Category 1

GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : May form combustible dust concentrations in air.
H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**
P261 Avoid breathing dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
Response:

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P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/
attention.
P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : Handle as potentially infectious.

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--|------------|-----------------------|
| 1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)- | 7365-45-9 | $\geq 5 - < 10$ |
| 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) | 26172-54-3 | $\geq 0.1 - < 1$ |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
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.
Keep eye wide open while rinsing.
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.



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Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.

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.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Sulfur oxides

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

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 : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.

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

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.



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Avoid contact with skin and eyes.
 For personal protection see section 8.
 Smoking, eating and drinking should be prohibited in the application area.
 Dispose of rinse water in accordance with local and national regulations.
 Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.

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:
 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 : Eye wash bottle with pure water
Tightly fitting safety goggles



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- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : (lyophilized)
- Color : white
- Odor : none
- Odor Threshold : Not applicable
- pH : Not applicable
- 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) : Sustains combustion
- Flammability (liquids) : Sustains 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 : Not applicable
- Relative density : No data available
- Solubility(ies)
Water solubility : soluble
- Solubility in other solvents : No data available



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- Partition coefficient: n-octanol/water : No data available
- Autoignition temperature : No data available
- Decomposition temperature : No data available
- Viscosity
 - Viscosity, dynamic : Not applicable
 - Viscosity, kinematic : Not applicable
- Explosive properties : Not explosive
Expert judgment
- 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 : No dangerous reaction known under conditions of normal use.
No decomposition if stored and applied as directed.
- Conditions to avoid : No data available
- Incompatible materials : Strong oxidizing agents
- Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Product:

- Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method
- Acute inhalation toxicity : Acute toxicity estimate: 15.37 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method
- Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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Acute oral toxicity : LD50 Oral (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 423
GLP: yes
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402
GLP: yes
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: No mortality observed at this dose.

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg
Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : No skin irritation
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

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Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Result : Causes severe burns.

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rabbit
Result : No eye irritation
Exposure time : 30 s
Method : OECD Test Guideline 405
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Result : Risk of serious damage to eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified due to lack of data.

Product:

Remarks : Causes sensitization.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Test Type : Maximization Test
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406
Result : Does not cause skin sensitization.
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Test Type : Local lymph node assay (LLNA)
Method : OECD Test Guideline 429
Result : The product is a skin sensitizer, sub-category 1A.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test

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Species : Guinea pig
 Method : OECD Test Guideline 406
 Result : positive
 Remarks : Based on data from similar materials
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Germ cell mutagenicity

Not classified due to lack of data.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative
 GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Escherichia coli
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative
 GLP: yes

Test Type: Chromosome aberration test in vitro
 Test system: Human lymphocytes
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 473
 Result: negative
 GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative

Test Type: In vitro mammalian cell gene mutation test
 Test system: Chinese hamster ovary cells
 Method: OECD Test Guideline 476
 Result: negative
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test
 Species: Mouse (male and female)
 Application Route: Oral
 Method: OECD Test Guideline 474
 Result: negative
 The value is given in analogy to the following substances: 2-

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methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay

Species: Rat (male and female)

Application Route: Oral

Method: OECD Test Guideline 486

Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Carcinogenicity

Not classified due to lack of data.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Remarks : 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.

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 due to lack of data.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Effects on fetal development : Species: Rat, female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Duration of Single Treatment: 14 d
General Toxicity Maternal: NOEL: 1,000 mg/kg body weight
Embryo-fetal toxicity.: NOEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Effects on fetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on fetal development.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

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STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rat, male and female
NOEL : 1000 mg/kg
Application Route : Oral
Exposure time : 28 d
Dose : 100, 300, 1000 mg/kg bw/day
Method : OECD Test Guideline 407
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species : Rat
NOEL : 94 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 408
Remarks : No significant adverse effects were reported
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog
NOAEL : 40.9 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: yes

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- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
- NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
- Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
End point: Respiration inhibition
Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes

Ecotoxicology Assessment

- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

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Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Persistence and degradability

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Biodegradability : aerobic
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Partition coefficient: n-octanol/water : log Pow: < -3.85 (68 °F / 20 °C)
Method: OECD Test Guideline 107
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (68 °F / 20 °C)
Method: OECD Test Guideline 107

Mobility in soil

No data available



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Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: 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).

Additional ecological information : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Special treatment as infectious material is mandatory in
compliance with local regulations (disinfection and
incineration).
The product should not be allowed to enter drains, water
courses or the soil.
Do not contaminate ponds, waterways or ditches with
chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with
local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
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



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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 user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA 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 : Combustible dust
Respiratory or skin sensitization

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 I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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

No components are subject to the Massachusetts Right to Know Act.



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Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, lyophilized
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-

Not Assigned
7365-45-9

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
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Human serum /-plasma / -hemolysate, lyophilized

hydroxyl-2-pyridone
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on 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.

SECTION 16. OTHER INFORMATION

Further information

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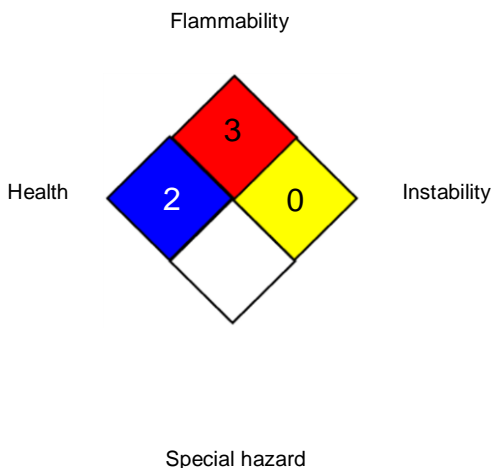
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NFPA 704:



HMIS® IV:

| | | |
|-----------------|---|---|
| HEALTH | / | 2 |
| FLAMMABILITY | | 3 |
| 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; IECSC - 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; TECl - Thailand

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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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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2304



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SECTION 1. IDENTIFICATION

Product name : HIV DUO M2 ELECSYS CAL 4

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-

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
Canada)
1-703-527-3887
(International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.


SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

Skin sensitization : Category 1

GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : May form combustible dust concentrations in air.
H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**
P261 Avoid breathing dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
Response:

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P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/
attention.
P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : Handle as potentially infectious.

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|--|------------|-----------------------|
| 1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)- | 7365-45-9 | $\geq 5 - < 10$ |
| 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1) | 26172-54-3 | $\geq 0.1 - < 1$ |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
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.
Keep eye wide open while rinsing.
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.



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Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.

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.

Unsuitable extinguishing media : High volume water jet

Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Sulfur oxides

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

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 : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.

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

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapors/dust.
Avoid exposure - obtain special instructions before use.



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Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.

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:
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 : Eye wash bottle with pure water
Tightly fitting safety goggles

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- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : (lyophilized)
- Color : white
- Odor : none
- Odor Threshold : Not applicable
- pH : Not applicable
- 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) : Sustains combustion
- Flammability (liquids) : Sustains 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 : Not applicable
- Relative density : No data available
- Solubility(ies)
Water solubility : soluble
- Solubility in other solvents : No data available



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- Partition coefficient: n-octanol/water : No data available
- Autoignition temperature : No data available
- Decomposition temperature : No data available
- Viscosity
 - Viscosity, dynamic : Not applicable
 - Viscosity, kinematic : Not applicable
- Explosive properties : Not explosive
Expert judgment
- 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 : No dangerous reaction known under conditions of normal use.
No decomposition if stored and applied as directed.
- Conditions to avoid : No data available
- Incompatible materials : Strong oxidizing agents
- Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Product:

- Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method
- Acute inhalation toxicity : Acute toxicity estimate: 15.37 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method
- Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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Acute oral toxicity : LD50 Oral (Rat, male and female): > 2,000 mg/kg
 Method: OECD Test Guideline 423
 GLP: yes
 Assessment: The substance or mixture has no acute oral toxicity
 Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg
 Method: OECD Test Guideline 402
 GLP: yes
 Assessment: The substance or mixture has no acute dermal toxicity
 Remarks: No mortality observed at this dose.

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg
 Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l
 Exposure time: 4 h
 Test atmosphere: dust/mist
 Method: OECD Test Guideline 403
 Assessment: Corrosive to the respiratory tract.
 Remarks: Based on data from similar materials
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg
 Method: OECD Test Guideline 402
 Remarks: Based on data from similar materials
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rabbit
 Exposure time : 4 h
 Method : OECD Test Guideline 404
 Result : No skin irritation
 GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

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Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Result : Causes severe burns.

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rabbit
Result : No eye irritation
Exposure time : 30 s
Method : OECD Test Guideline 405
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Result : Risk of serious damage to eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified due to lack of data.

Product:

Remarks : Causes sensitization.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Test Type : Maximization Test
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406
Result : Does not cause skin sensitization.
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Test Type : Local lymph node assay (LLNA)
Method : OECD Test Guideline 429
Result : The product is a skin sensitizer, sub-category 1A.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test

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Species : Guinea pig
 Method : OECD Test Guideline 406
 Result : positive
 Remarks : Based on data from similar materials
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Germ cell mutagenicity

Not classified due to lack of data.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative
 GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Escherichia coli
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative
 GLP: yes

Test Type: Chromosome aberration test in vitro
 Test system: Human lymphocytes
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 473
 Result: negative
 GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative

Test Type: In vitro mammalian cell gene mutation test
 Test system: Chinese hamster ovary cells
 Method: OECD Test Guideline 476
 Result: negative
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test
 Species: Mouse (male and female)
 Application Route: Oral
 Method: OECD Test Guideline 474
 Result: negative
 The value is given in analogy to the following substances: 2-

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methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay

Species: Rat (male and female)

Application Route: Oral

Method: OECD Test Guideline 486

Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Carcinogenicity

Not classified due to lack of data.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Remarks : 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.

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 due to lack of data.

Components:**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Effects on fetal development : Species: Rat, female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Duration of Single Treatment: 14 d
General Toxicity Maternal: NOEL: 1,000 mg/kg body weight
Embryo-fetal toxicity.: NOEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Effects on fetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on fetal development.
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

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STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Repeated dose toxicity

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Species : Rat, male and female
NOEL : 1000 mg/kg
Application Route : Oral
Exposure time : 28 d
Dose : 100, 300, 1000 mg/kg bw/day
Method : OECD Test Guideline 407
GLP : yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Species : Rat
NOEL : 94 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 408
Remarks : No significant adverse effects were reported
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog
NOAEL : 40.9 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: yes

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- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
- NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
- Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
End point: Respiration inhibition
Exposure time: 3 h
Test Type: static test
Analytical monitoring: no
Method: OECD Test Guideline 209
GLP: yes

Ecotoxicology Assessment

- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l
Exposure time: 96 h
Test Type: flow-through test
Method: OECD Test Guideline 203
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

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Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Persistence and degradability

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Biodegradability : aerobic
Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Partition coefficient: n-octanol/water : log Pow: < -3.85 (68 °F / 20 °C)
Method: OECD Test Guideline 107
GLP: yes

3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (68 °F / 20 °C)
Method: OECD Test Guideline 107

Mobility in soil

No data available



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Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: 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).

Additional ecological information : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

Components:

1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Special treatment as infectious material is mandatory in
compliance with local regulations (disinfection and
incineration).
The product should not be allowed to enter drains, water
courses or the soil.
Do not contaminate ponds, waterways or ditches with
chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with
local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
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



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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 user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA 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 : Combustible dust
Respiratory or skin sensitization

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 I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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

No components are subject to the Massachusetts Right to Know Act.



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Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, lyophilized
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-

Not Assigned
7365-45-9

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
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Human serum /-plasma / -hemolysate, lyophilized

hydroxyl-2-pyridone
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on 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.

SECTION 16. OTHER INFORMATION

Further information

SAFETY DATA SHEET



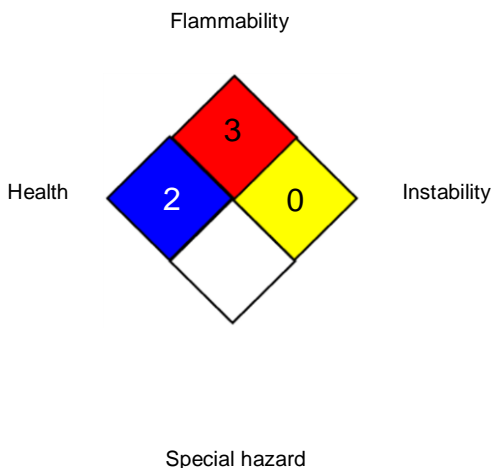
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NFPA 704:



HMIS® IV:

| | | |
|-----------------|---|---|
| HEALTH | / | 2 |
| FLAMMABILITY | | 3 |
| 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; IECSC - 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; TECl - Thailand

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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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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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