



SAFETY DATA SHEET COVER SHEET

Part Number: 303-2748
Revision A

Product Information

Product Name Xpert® PML-RARA RUO
Product Code RPMLRARA-10

Safety Data Sheets

| Description | |
|------------------|---|
| USA | Xpert® PML-RARA RUO (Kit)_US Xpert® HemOnc Lysis Reagents_US Xpert® HemOnc Proteinase K_US Xpert® HemOnc Wash Reagent_US |
| Australia | Xpert® PML-RARA RUO (Kit)_AU Xpert® HemOnc Lysis Reagents_AU Xpert® HemOnc Proteinase K_AU Xpert® HemOnc Wash Reagent_AU |



Xpert[®] PML-RARA RUO (Kit)

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
Issue date: 2023-12 Supersedes Date: Not Applicable Version: A

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Xpert[®] PML-RARA RUO
Product code : RPMLRARA-10

1.2. Recommended use and restrictions on use

Recommended use : Laboratory use
Restrictions on use : No information available

1.3. Supplier

Cepheid
904 E. Caribbean Drive
Sunnyvale, Santa Clara, CA 94089
USA
T 1-888-838-3222
techsupport@cepheid.com - www.cepheid.com

1.4. Emergency telephone number

Emergency number : For Chemical Emergency Call INFOTRAC 24hr/day 7days/week
Within USA and Canada: 1-800-535-5053
Outside USA and Canada: 1-352-323-3500
(collect calls accepted)

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

| | | |
|--|------|----------------------------|
| Flammable liquids Category 3 | H226 | Flammable liquid and vapor |
| Skin corrosion/irritation Category 2 | H315 | Causes skin irritation |
| Serious eye damage/eye irritation Category 1 | H318 | Causes serious eye damage |

Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) : Danger

Hazard statements (GHS US) : H226 - Flammable liquid and vapor
H315 - Causes skin irritation
H318 - Causes serious eye damage

Precautionary statements (GHS US) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P264 - Wash hands, forearms and face thoroughly after handling.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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P310 - Immediately call a poison center or doctor.

P370+P378 - In case of fire: Use Dry chemical, carbon dioxide (CO₂), Water spray, alcohol resistant foam to extinguish.

P403+P235 - Store in a well-ventilated place. Keep cool.

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | % | GHS US classification |
|---|---------------------|---------|--|
| guanidine,hydrochloride | CAS-No.: 50-01-1 | 15 – 20 | Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 3, H412 |
| ethanol | CAS-No.: 64-17-5 | 5 – 10 | Flam. Liq. 2, H225 |
| guanidine thiocyanate | CAS-No.: 593-84-0 | 1 – 5 | Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332 Skin Corr. 1C, H314 Eye Dam. 1, H318 Aquatic Chronic 3, H412 |
| sodium dodecyl sulphate, bulk density ≥400g/l | CAS-No.: 151-21-3 | <3 | Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 3, H412 |
| proteinase K | CAS-No.: 39450-01-6 | < 1 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 STOT SE 3, H335 |
| sodium azide | CAS-No.: 26628-22-8 | < 1 | Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |

Full text of hazard classes and H-statements : see section 16

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SECTION 4: First-aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|---|
| First-aid measures general | : Seek medical attention immediately. If possible, show the doctor this safety data sheet. Failing this, show the doctor the packaging or label. |
| First-aid measures after inhalation | : Remove person to fresh air and keep comfortable for breathing. Get medical attention if symptoms occur. |
| First-aid measures after skin contact | : Wash off with soap and plenty of water. Remove/Take off immediately all contaminated clothing. Seek medical attention if irritation develops. |
| First-aid measures after eye contact | : Rinse immediately with plenty of water, also under the eyelids. Do not rub affected area. Get immediate medical advice/attention. Remove contact lenses, if present and easy to do. Continue rinsing. |
| First-aid measures after ingestion | : Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician immediately. |

4.2. Most important symptoms and effects (acute and delayed)

| | |
|-------------------------------------|---------------------------|
| Symptoms/effects | : Burning sensation. |
| Symptoms/effects after skin contact | : Irritation. |
| Symptoms/effects after eye contact | : Serious damage to eyes. |

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

| | |
|--------------------------------|--|
| Suitable extinguishing media | : Dry chemical. Carbon dioxide. Water spray. Alcohol-resistant foam. |
| Unsuitable extinguishing media | : No information available. |

5.2. Specific hazards arising from the chemical

| | |
|--|--|
| Fire hazard | : Flammable liquid and vapor. |
| Hazardous decomposition products in case of fire | : Toxic fumes may be released. Carbon oxides (CO, CO ₂). |

5.3. Special protective equipment and precautions for fire-fighters

| | |
|--------------------------------|--|
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |
|--------------------------------|--|

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

| | |
|----------------------|--|
| Protective equipment | : Wear recommended personal protective equipment. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. |
| Emergency procedures | : Evacuate area. Use personal protective equipment as required. See section 8 of the SDS for more information on personal protective equipment. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Keep upwind. No flames, no sparks. Eliminate all sources of ignition. Take precautionary measures against static discharge. All equipment used when handling the product must be grounded. Do not touch or walk on the spilled product. |

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6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. Prevent further leakage or spillage if safe to do so. Do not allow to enter drains or water courses. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Stop leak, if possible without risk. Do not touch or walk on the spilled product. Absorb spilled material with sand or earth.

Methods for cleaning up : Take precautionary measures against static discharges. Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapors may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Always wash hands after handling the product. Avoid contact with skin, eyes and clothing. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Ground/bond container and receiving equipment.

Storage conditions : Store tightly closed in a dry, cool and well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store in accordance with local, regional, national or international regulations. Store locked up. Keep out of reach of children.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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No additional information available

sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3)

No additional information available

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| sodium azide (26628-22-8) | |
|---|---------------------------|
| USA - ACGIH - Occupational Exposure Limits | |
| ACGIH OEL C | 0.29 mg/m ³ |
| ACGIH OEL C [ppm] | 0.11 ppm |
| proteinase K (39450-01-6) | |
| USA - ACGIH - Occupational Exposure Limits | |
| ACGIH OEL C | 0.00006 mg/m ³ |
| guanidine,hydrochloride (50-01-1) | |
| No additional information available | |
| guanidine thiocyanate (593-84-0) | |
| No additional information available | |
| ethanol (64-17-5) | |
| USA - ACGIH - Occupational Exposure Limits | |
| ACGIH OEL STEL [ppm] | 1000 ppm |

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

| |
|--|
| Hand protection: |
| Protective gloves |
| Eye protection: |
| Safety glasses |
| Skin and body protection: |
| Wear suitable protective clothing |
| Respiratory protection: |
| In case of insufficient ventilation, wear suitable respiratory equipment |

Personal protective equipment symbol(s):



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear liquid.

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| | |
|---|---------------------|
| Color | : Colorless |
| Odor | : odorless |
| Odor threshold | : No data available |
| pH | : No data available |
| Melting point | : 0 °C |
| Freezing point | : No data available |
| Boiling point | : 66.2 °C |
| Flash point | : 29 – < 40 °C |
| Relative evaporation rate (butyl acetate=1) | : No data available |
| Flammability (solid, gas) | : Not applicable. |
| Vapor pressure | : No data available |
| Relative vapor density at 20°C | : No data available |
| Relative density | : No data available |
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosion limits | : No data available |
| Explosive properties | : No data available |
| Oxidizing properties | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Flammable liquid and vapor.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified

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Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|---|
| LD50 oral rat | 1200 mg/kg body weight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rat | > 2000 mg/kg body weight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal, 14 day(s)) |
| LD50 dermal rabbit | 600 mg/kg Source: cal, SIDS |
| ATE US (oral) | 1200 mg/kg body weight |
| ATE US (dermal) | 600 mg/kg body weight |
| sodium azide (26628-22-8) | |
| LD50 oral rat | 27 mg/kg body weight (Rat, Experimental value, Oral) |
| LD50 dermal rabbit | 19 – 48 mg/kg body weight (Rabbit, Inconclusive, insufficient data, Dermal) |
| LC50 Inhalation - Rat | 0.05 – 0.52 mg/l (EPA OPPTS 870.1300: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (dust), 14 day(s)) |
| ATE US (oral) | 27 mg/kg body weight |
| ATE US (dermal) | 19 mg/kg body weight |
| ATE US (vapors) | 0.05 mg/l/4h |
| ATE US (dust, mist) | 0.05 mg/l/4h |
| guanidine,hydrochloride (50-01-1) | |
| LD50 oral rat | 774 – 907 mg/kg body weight (Equivalent or similar to OECD 401, Rat, Male / female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rabbit | > 2000 mg/kg body weight (Equivalent or similar to OECD 402, 24 h, Rabbit, Male / female, Experimental value, Dermal, 14 day(s)) |
| LC50 Inhalation - Rat | 5.32 mg/l (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (aerosol), 14 day(s)) |
| ATE US (oral) | 774 mg/kg body weight |
| ATE US (vapors) | 5.32 mg/l/4h |
| ATE US (dust, mist) | 5.32 mg/l/4h |
| guanidine thiocyanate (593-84-0) | |
| LD50 oral rat | 593 mg/kg body weight (OECD 401: Acute Oral Toxicity, Rat, Female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rabbit | > 2000 mg/kg body weight (24 h, Rabbit, Male / female, Experimental value, Skin, 14 day(s)) |
| LC50 Inhalation - Rat | > 0.853 mg/l air (Equivalent or similar to OECD 403, 4 h, Rat, Male / female, Experimental value, Inhalation (dust), 14 day(s)) |
| ATE US (oral) | 593 mg/kg body weight |
| ATE US (gases) | 4500 ppmV/4h |
| ATE US (vapors) | 11 mg/l/4h |
| ATE US (dust, mist) | 1.5 mg/l/4h |

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| ethanol (64-17-5) | |
|---------------------------------|--|
| LD50 oral rat | 10470 mg/kg body weight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s)) |
| LD50 oral | 6200 mg/kg |
| LD50 dermal rabbit | > 15800 mg/kg body weight (Rabbit, Experimental value, Dermal) |
| LD50 dermal | 20000 mg/kg |
| LC50 Inhalation - Rat | 124.7 mg/l air (Equivalent or similar to OECD 403, 4 h, Rat, Male / female, Experimental value, Inhalation (vapours), 14 day(s)) |
| LC50 Inhalation - Rat (Vapours) | 116.9 mg/l Source: ECHA |
| ATE US (oral) | 6200 mg/kg body weight |
| ATE US (dermal) | 20000 mg/kg body weight |
| ATE US (vapors) | 116.9 mg/l/4h |

Skin corrosion/irritation : Causes skin irritation.

| sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3) | |
|---|-----------|
| pH | 9.1 (1 %) |

| sodium azide (26628-22-8) | |
|----------------------------------|-------------------------------------|
| pH | No data available in the literature |

| proteinase K (39450-01-6) | |
|----------------------------------|-------------------------------------|
| pH | No data available in the literature |

| guanidine,hydrochloride (50-01-1) | |
|--|------------------|
| pH | 4.5 – 6 (57.3 %) |

| guanidine thiocyanate (593-84-0) | |
|---|----------------|
| pH | 4.5 – 7 (70 %) |

| ethanol (64-17-5) | |
|--------------------------|--------------------|
| pH | 7 (789 g/l, 20 °C) |

Serious eye damage/irritation : Causes serious eye damage.

| sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3) | |
|---|-----------|
| pH | 9.1 (1 %) |

| sodium azide (26628-22-8) | |
|----------------------------------|-------------------------------------|
| pH | No data available in the literature |

| proteinase K (39450-01-6) | |
|----------------------------------|-------------------------------------|
| pH | No data available in the literature |

| guanidine,hydrochloride (50-01-1) | |
|--|------------------|
| pH | 4.5 – 6 (57.3 %) |

| guanidine thiocyanate (593-84-0) | |
|---|----------------|
| pH | 4.5 – 7 (70 %) |

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| ethanol (64-17-5) | |
|---|---|
| pH | 7 (789 g/l, 20 °C) |
| Respiratory or skin sensitization | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| ethanol (64-17-5) | |
| IARC group | 1 - Carcinogenic to humans |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| proteinase K (39450-01-6) | |
| STOT-single exposure | May cause respiratory irritation. |
| STOT-repeated exposure | : Not classified |
| ethanol (64-17-5) | |
| NOAEL (subchronic,oral,animal/male,90 days) | < 9700 mg/kg body weight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents) |
| NOAEL (subchronic,oral,animal/female,90 days) | > 9400 mg/kg body weight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents) |
| Aspiration hazard | : Not classified |
| Viscosity, kinematic | : No data available |
| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
| Viscosity, kinematic | Not applicable (solid) |
| sodium azide (26628-22-8) | |
| Viscosity, kinematic | Not applicable (solid) |
| proteinase K (39450-01-6) | |
| Viscosity, kinematic | Not applicable (solid) |
| guanidine thiocyanate (593-84-0) | |
| Viscosity, kinematic | No data available in the literature |
| ethanol (64-17-5) | |
| Viscosity, kinematic | 1.6 mm ² /s (20 °C) |
| Symptoms/effects | : Burning sensation. |
| Symptoms/effects after skin contact | : Irritation. |
| Symptoms/effects after eye contact | : Serious damage to eyes. |

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|--|
| LC50 - Fish [1] | 29 mg/l (Equivalent or similar to OECD 203, 96 h, Pimephales promelas, Flow-through system, Fresh water, Experimental value, Lethal) |

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| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|--|
| EC50 - Crustacea [1] | 6 mg/l Source: ECOTOX |
| EC50 - Other aquatic organisms [1] | 11.1 mg/l Test organisms (species): other aquatic crustacea: |
| EC50 72h - Algae [1] | 53 mg/l (DIN 38412: German standard methods for the examination of water, waste water and sludge, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, Biomass) |
| EC50 72h - Algae [2] | 53 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) |
| EC50 96h - Algae [1] | 1.2 mg/l Source: ECOTOX |
| NOEC chronic fish | ≥ 1.357 mg/l Test organisms (species): Pimephales promelas Duration: '42 d' |
| NOEC chronic crustacea | 0.88 mg/l |
| sodium azide (26628-22-8) | |
| LC50 - Fish [1] | 2.75 – 3.28 mg/l (Equivalent or similar to OECD 203, 96 h, Oncorhynchus mykiss, Flow-through system, Fresh water, Experimental value) |
| EC50 96h - Algae [1] | 0.35 mg/l (Equivalent or similar to OECD 201, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, Cell numbers) |
| guanidine,hydrochloride (50-01-1) | |
| LC50 - Fish [1] | 1758 mg/l (DIN 38412-15, 48 h, Leuciscus idus, Experimental value, GLP) |
| EC50 - Crustacea [1] | 70.2 mg/l (Equivalent or similar to OECD 202, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect) |
| ErC50 algae | 33.5 mg/l (EU Method C.3, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, GLP) |
| guanidine thiocyanate (593-84-0) | |
| LC50 - Fish [1] | 89.1 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Poecilia reticulata, Static system, Fresh water, Experimental value) |
| EC50 - Crustacea [1] | 42.4 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect) |
| ErC50 algae | 130 mg/l (DIN 38412: German standard methods for the examination of water, waste water and sludge, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, Growth rate) |
| ethanol (64-17-5) | |
| LC50 - Fish [1] | 15300 mg/l (US EPA, 96 h, Pimephales promelas, Flow-through system, Fresh water, Experimental value, Lethal) |
| EC50 - Crustacea [1] | 5463 mg/l |
| EC50 72h - Algae [1] | 275 mg/l (Equivalent or similar to OECD 201, Chlorella vulgaris, Static system, Fresh water, Experimental value, Growth rate) |
| ErC50 algae | 275 mg/l Source: ECHA |
| NOEC (chronic) | 9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d' |
| NOEC chronic crustacea | 9.6 mg/l |

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12.2. Persistence and degradability

sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3)

| | |
|-------------------------------|---------------------------------|
| Persistence and degradability | Readily biodegradable in water. |
|-------------------------------|---------------------------------|

sodium azide (26628-22-8)

Not rapidly degradable

| | |
|-------------------------------|-----------------------------------|
| Persistence and degradability | Biodegradability: not applicable. |
|-------------------------------|-----------------------------------|

| | |
|------------------------------|----------------------------|
| Chemical oxygen demand (COD) | Not applicable (inorganic) |
|------------------------------|----------------------------|

| | |
|------|----------------------------|
| ThOD | Not applicable (inorganic) |
|------|----------------------------|

proteinase K (39450-01-6)

| | |
|-------------------------------|---|
| Persistence and degradability | Biodegradability in water: no data available. |
|-------------------------------|---|

guanidine,hydrochloride (50-01-1)

Not rapidly degradable

| | |
|-------------------------------|-------------------------------------|
| Persistence and degradability | Not readily biodegradable in water. |
|-------------------------------|-------------------------------------|

guanidine thiocyanate (593-84-0)

Not rapidly degradable

| | |
|-------------------------------|---------------------------|
| Persistence and degradability | Inherently biodegradable. |
|-------------------------------|---------------------------|

ethanol (64-17-5)

| | |
|-------------------------------|--|
| Persistence and degradability | Biodegradable in the soil. Readily biodegradable in water. |
|-------------------------------|--|

| | |
|---------------------------------|---|
| Biochemical oxygen demand (BOD) | 0.8 – 0.967 g O ₂ /g substance |
|---------------------------------|---|

| | |
|------------------------------|-----------------------------------|
| Chemical oxygen demand (COD) | 1.7 g O ₂ /g substance |
|------------------------------|-----------------------------------|

| | |
|------|-----------------------------------|
| ThOD | 2.1 g O ₂ /g substance |
|------|-----------------------------------|

12.3. Bioaccumulative potential

sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3)

| | |
|---|---|
| Partition coefficient n-octanol/water (Log Pow) | < 2.03 (Estimated value, EU Method A.8: Partition Coefficient, 20 °C) |
|---|---|

| | |
|---------------------------|--|
| Bioaccumulative potential | Low potential for bioaccumulation (Log Kow < 4). |
|---------------------------|--|

sodium azide (26628-22-8)

| | |
|---|--------------------|
| Partition coefficient n-octanol/water (Log Pow) | 0.16 Source: NIOSH |
|---|--------------------|

| | |
|---------------------------|----------------------|
| Bioaccumulative potential | Not bioaccumulative. |
|---------------------------|----------------------|

proteinase K (39450-01-6)

| | |
|---------------------------|------------------------------------|
| Bioaccumulative potential | No bioaccumulation data available. |
|---------------------------|------------------------------------|

guanidine,hydrochloride (50-01-1)

| | |
|---|---|
| Partition coefficient n-octanol/water (Log Pow) | < -1.7 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C) |
|---|---|

| | |
|---------------------------|----------------------|
| Bioaccumulative potential | Not bioaccumulative. |
|---------------------------|----------------------|

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| guanidine thiocyanate (593-84-0) | |
|---|--|
| Partition coefficient n-octanol/water (Log Pow) | -1.11 (Estimated value, EU Method A.8: Partition Coefficient, 25 °C) |
| Bioaccumulative potential | Not bioaccumulative. |
| ethanol (64-17-5) | |
| Partition coefficient n-octanol/water (Log Pow) | -0.35 (Experimental value, Equivalent or similar to OECD 107, 24 °C) |
| Bioaccumulative potential | Not bioaccumulative. |

12.4. Mobility in soil

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|---|
| Surface tension | 25.2 mN/m (23 °C, 1 g/l) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 2.28 (log Koc, Experimental value) |
| Ecology - soil | Low potential for adsorption in soil. |
| sodium azide (26628-22-8) | |
| Surface tension | No data available (test not performed) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 2.63 (log Koc, Calculated value) |
| Ecology - soil | Low potential for adsorption in soil. |
| proteinase K (39450-01-6) | |
| Ecology - soil | No (test)data on mobility of the substance available. |
| guanidine,hydrochloride (50-01-1) | |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 1.358 (log Koc, SRC PCKOCWIN v2.0, Calculated value) |
| Ecology - soil | Highly mobile in soil. |
| guanidine thiocyanate (593-84-0) | |
| Ecology - soil | No (test)data on mobility of the substance available. |
| ethanol (64-17-5) | |
| Surface tension | 22.31 mN/m (20 °C, 100 %) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 0.2 (log Koc, Experimental value) |
| Ecology - soil | Highly mobile in soil. |

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

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Additional information : Flammable vapors may accumulate in the container.

SECTION 14: Transport information

In accordance with DOT / IMDG / IATA

| DOT | IMDG | IATA |
|---|---|---|
| 14.1. UN number | | |
| 1993 | 1993 | 1993 |
| 14.2. Proper Shipping Name | | |
| Flammable liquids, n.o.s. (ethanol) | FLAMMABLE LIQUID, N.O.S. (ethanol) | Flammable liquid, n.o.s. (ethanol) |
| 14.3. Transport hazard class(es) | | |
| 3 | 3 | 3 |
|  |  |  |
| 14.4. Packing group | | |
| III | III | III |
| 14.5. Environmental hazards | | |
| Dangerous for the environment: No | Dangerous for the environment: No Marine pollutant: No | Dangerous for the environment: No |
| No supplementary information available | | |

14.6. Special precautions for user

| | |
|---|---|
| DOT | |
| UN-No.(DOT) | : UN1993 |
| DOT Special Provisions (49 CFR 172.102) | : B1 - If the material has a flash point at or above 38 C (100 F) and below 93 C (200 F), then the bulk packaging requirements of 173.241 of this subchapter are applicable. If the material has a flash point of less than 38 C (100 F), then the bulk packaging requirements of 173.242 of this subchapter are applicable. B52 - Notwithstanding the provisions of 173.24b of this subchapter, non-reclosing pressure relief devices are authorized on DOT 57 portable tanks. IB3 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1 and 31HA2, 31HB2, 31HN2, 31HD2 and 31HH2). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized, except for UN2672 (also see Special Provision IP8 in Table 2 for UN2672). T4 - 2.65 178.274(d)(2) Normal..... 178.275(d)(3) TP1 - The maximum degree of filling must not exceed the degree of filling determined by the following: Degree of filling = $97 / 1 + a (tr - tf)$ Where: tr is the maximum mean bulk temperature during transport, and tf is the temperature in degrees celsius of the liquid during filling. TP29 - A portable tank having a minimum test pressure of 1.5 bar (150.0 kPa) may be used provided the calculated test pressure is 1.5 bar or less based on the MAWP of the hazardous materials, as defined in 178.275 of this subchapter, where the test pressure is 1.5 times the MAWP. |
| DOT Packaging Exceptions (49 CFR 173.xxx) | : 150 |
| DOT Packaging Non Bulk (49 CFR 173.xxx) | : 203 |

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| | |
|--|---|
| DOT Packaging Bulk (49 CFR 173.xxx) | : 242 |
| DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) | : 60 L |
| DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) | : 220 L |
| DOT Vessel Stowage Location | : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel. |

IMDG

| | |
|---------------------------------|---|
| Special provision (IMDG) | : 223, 274, 955 |
| Limited quantities (IMDG) | : 5 L |
| Excepted quantities (IMDG) | : E1 |
| Packing instructions (IMDG) | : LP01, P001 |
| IBC packing instructions (IMDG) | : IBC03 |
| Tank instructions (IMDG) | : T4 |
| Tank special provisions (IMDG) | : TP1, TP29 |
| EmS-No. (Fire) | : F-E - FIRE SCHEDULE Echo - NON-WATER-REACTIVE FLAMMABLE LIQUIDS |
| EmS-No. (Spillage) | : S-E - SPILLAGE SCHEDULE Echo - FLAMMABLE LIQUIDS, FLOATING ON WATER |
| Stowage category (IMDG) | : A |

IATA

| | |
|--|--------|
| PCA Excepted quantities (IATA) | : E1 |
| PCA Limited quantities (IATA) | : Y344 |
| PCA limited quantity max net quantity (IATA) | : 10L |
| PCA packing instructions (IATA) | : 355 |
| PCA max net quantity (IATA) | : 60L |
| CAO packing instructions (IATA) | : 366 |
| CAO max net quantity (IATA) | : 220L |
| Special provision (IATA) | : A3 |
| ERG code (IATA) | : 3L |

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

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

| | | |
|--------------|--------------------|------|
| proteinase K | CAS-No. 39450-01-6 | < 1% |
|--------------|--------------------|------|

Chemical(s) subject to the reporting requirements of Section 313 or Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 and 40 CFR Part 372.

| | | |
|--------------|--------------------|------|
| sodium azide | CAS-No. 26628-22-8 | < 1% |
|--------------|--------------------|------|

sodium azide (26628-22-8)

| | |
|--|---------|
| CERCLA RQ | 1000 lb |
| RQ (Reportable quantity, section 304 of EPA's List of Lists) | 1000 lb |

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sodium azide (26628-22-8)

| | |
|--|--------|
| SARA Section 302 Threshold Planning Quantity (TPQ) | 500 lb |
|--|--------|

15.2. International regulations

CANADA

sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3)

Listed on the Canadian DSL (Domestic Substances List)

sodium azide (26628-22-8)

Listed on the Canadian DSL (Domestic Substances List)

proteinase K (39450-01-6)

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

guanidine,hydrochloride (50-01-1)

Listed on the Canadian DSL (Domestic Substances List)

guanidine thiocyanate (593-84-0)

Listed on the Canadian DSL (Domestic Substances List)

ethanol (64-17-5)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

sodium azide (26628-22-8)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

guanidine,hydrochloride (50-01-1)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

ethanol (64-17-5)

Listed on IARC (International Agency for Research on Cancer)
Listed on INSQ (Mexican National Inventory of Chemical Substances)

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15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

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| Full text of H-phrases | |
|------------------------|--|
| H225 | Highly flammable liquid and vapor |
| H226 | Flammable liquid and vapor |
| H300 | Fatal if swallowed |
| H302 | Harmful if swallowed |
| H310 | Fatal in contact with skin |
| H311 | Toxic in contact with skin |
| H314 | Causes severe skin burns and eye damage |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H332 | Harmful if inhaled |
| H334 | May cause an allergy or asthma symptoms or breathing difficulties if inhaled |
| H335 | May cause respiratory irritation |
| H400 | Very toxic to aquatic life |
| H410 | Very toxic to aquatic life with long lasting effects |
| H412 | Harmful to aquatic life with long lasting effects |

Safety Data Sheet (SDS), USA

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



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Issue date: 2023-12 Supersedes Date: Not Applicable Version: A

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Xpert[®] HemOnc Lysis Reagents

1.2. Recommended use and restrictions on use

Recommended use : Laboratory use
Restrictions on use : No information available

1.3. Supplier

Cepheid
904 E. Caribbean Drive
Sunnyvale, Santa Clara, CA 94089
USA
T 1-888-838-3222
techsupport@cepheid.com - www.cepheid.com

1.4. Emergency telephone number

Emergency number : For Chemical Emergency Call INFOTRAC 24hr/day 7days/week
Within USA and Canada: 1-800-535-5053
Outside USA and Canada: 1-352-323-3500
(collect calls accepted)

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

| | | |
|--|------|-------------------------------|
| Acute toxicity (oral) Category 4 | H302 | Harmful if swallowed |
| Skin corrosion/irritation Category 2 | H315 | Causes skin irritation |
| Serious eye damage/eye irritation Category 2 | H319 | Causes serious eye irritation |

Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) : Warning

Hazard statements (GHS US) : H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation

Precautionary statements (GHS US) : P264 - Wash hands, forearms and face thoroughly after handling.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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P321 - Specific treatment (see supplemental first aid instruction on this label).
P501 - Dispose of contents/container to an approved waste disposal plant.

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | % | GHS US classification |
|---|--------------------|---------|--|
| guanidine,hydrochloride | CAS-No.: 50-01-1 | 35 – 40 | Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 3, H412 |
| sodium dodecyl sulphate, bulk density ≥400g/l | CAS-No.: 151-21-3 | ≤ 2 | Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 3, H412 |

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|--|
| First-aid measures general | : If possible, show the doctor this safety data sheet. Failing this, show the doctor the packaging or label. |
| First-aid measures after inhalation | : Remove person to fresh air and keep comfortable for breathing. Get medical attention if symptoms occur. Give oxygen or artificial respiration if necessary. |
| First-aid measures after skin contact | : Wash skin with plenty of water. Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. |
| First-aid measures after eye contact | : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Rinse immediately with plenty of water, also under the eyelids. Do not rub affected area. If irritation persists, consult a doctor/medical service. |
| First-aid measures after ingestion | : If swallowed, seek medical advice immediately and show this container or label. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. |

4.2. Most important symptoms and effects (acute and delayed)

| | |
|-------------------------------------|-------------------|
| Symptoms/effects after skin contact | : Irritation. |
| Symptoms/effects after eye contact | : Eye irritation. |

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

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SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : No information available.

5.2. Specific hazards arising from the chemical

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear personal protective clothing (see chapter 8). Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Wear recommended personal protective equipment. Avoid breathing dust, mist or spray.
Emergency procedures : Use personal protective equipment as required.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Prevent entry to sewers and public waters. Prevent further leakage or spillage if safe to do so. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Prevent further leakage or spillage if safe to do so.
Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Ensure good ventilation of the work station. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse. Avoid breathing vapors, mist. Wear personal protective equipment.
Hygiene measures : Avoid contact with skin, eyes and clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store tightly closed in a dry, cool and well-ventilated place. Keep out of reach of children. Store locked up.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Xpert® HemOnc Lysis Reagents

No additional information available

guanidine,hydrochloride (50-01-1)

No additional information available

sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3)

No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear liquid.
Color : White clear
Odor : odorless
Odor threshold : No data available

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| | |
|---|---------------------|
| pH | : 6.4 |
| Melting point | : Not applicable |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Relative evaporation rate (butyl acetate=1) | : No data available |
| Flammability (solid, gas) | : Not applicable. |
| Vapor pressure | : No data available |
| Relative vapor density at 20°C | : No data available |
| Relative density | : No data available |
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosion limits | : No data available |
| Explosive properties | : No data available |
| Oxidizing properties | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|-----------------------------|-------------------------|
| Acute toxicity (oral) | : Harmful if swallowed. |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |

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| Xpert® HemOnc Lysis Reagents | |
|---|--|
| ATE US (oral) | 1959.494 mg/kg body weight |
| guanidine,hydrochloride (50-01-1) | |
| LD50 oral rat | 774 – 907 mg/kg body weight (Equivalent or similar to OECD 401, Rat, Male / female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rabbit | > 2000 mg/kg body weight (Equivalent or similar to OECD 402, 24 h, Rabbit, Male / female, Experimental value, Dermal, 14 day(s)) |
| LC50 Inhalation - Rat | 5.32 mg/l (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (aerosol), 14 day(s)) |
| ATE US (oral) | 774 mg/kg body weight |
| ATE US (vapors) | 5.32 mg/l/4h |
| ATE US (dust, mist) | 5.32 mg/l/4h |
| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
| LD50 oral rat | 1200 mg/kg body weight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rat | > 2000 mg/kg body weight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal, 14 day(s)) |
| LD50 dermal rabbit | 600 mg/kg Source: cal, SIDS |
| ATE US (oral) | 1200 mg/kg body weight |
| ATE US (dermal) | 600 mg/kg body weight |
| Skin corrosion/irritation | : Causes skin irritation. pH: 6.4 |
| guanidine,hydrochloride (50-01-1) | |
| pH | 4.5 – 6 (57.3 %) |
| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
| pH | 9.1 (1 %) |
| Serious eye damage/irritation | : Causes serious eye irritation. pH: 6.4 |
| guanidine,hydrochloride (50-01-1) | |
| pH | 4.5 – 6 (57.3 %) |
| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
| pH | 9.1 (1 %) |
| Respiratory or skin sensitization | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |
| Viscosity, kinematic | : No data available |

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| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|------------------------|
| Viscosity, kinematic | Not applicable (solid) |

Symptoms/effects after skin contact : Irritation.
Symptoms/effects after eye contact : Eye irritation.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

| guanidine,hydrochloride (50-01-1) | |
|--|--|
| LC50 - Fish [1] | 1758 mg/l (DIN 38412-15, 48 h, Leuciscus idus, Experimental value, GLP) |
| EC50 - Crustacea [1] | 70.2 mg/l (Equivalent or similar to OECD 202, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect) |
| ErC50 algae | 33.5 mg/l (EU Method C.3, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, GLP) |

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|---|
| LC50 - Fish [1] | 29 mg/l (Equivalent or similar to OECD 203, 96 h, Pimephales promelas, Flow-through system, Fresh water, Experimental value, Lethal) |
| EC50 - Crustacea [1] | 6 mg/l Source: ECOTOX |
| EC50 - Other aquatic organisms [1] | 11.1 mg/l Test organisms (species): other aquatic crustacea: |
| EC50 72h - Algae [1] | 53 mg/l (DIN 38412: German standard methods for the examination of water, waste water and sludge, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, Biomass) |
| EC50 72h - Algae [2] | 53 mg/l Test organisms (species): Desmodesmus subspicatus (previous name: Scenedesmus subspicatus) |
| EC50 96h - Algae [1] | 1.2 mg/l Source: ECOTOX |
| NOEC chronic fish | ≥ 1.357 mg/l Test organisms (species): Pimephales promelas Duration: '42 d' |
| NOEC chronic crustacea | 0.88 mg/l |

12.2. Persistence and degradability

| guanidine,hydrochloride (50-01-1) | |
|--|-------------------------------------|
| Not rapidly degradable | |
| Persistence and degradability | Not readily biodegradable in water. |

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|---------------------------------|
| Persistence and degradability | Readily biodegradable in water. |

12.3. Bioaccumulative potential

| guanidine,hydrochloride (50-01-1) | |
|---|---|
| Partition coefficient n-octanol/water (Log Pow) | < -1.7 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C) |
| Bioaccumulative potential | Not bioaccumulative. |

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| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|---|
| Partition coefficient n-octanol/water (Log Pow) | < 2.03 (Estimated value, EU Method A.8: Partition Coefficient, 20 °C) |
| Bioaccumulative potential | Low potential for bioaccumulation (Log Kow < 4). |

12.4. Mobility in soil

| guanidine,hydrochloride (50-01-1) | |
|--|--|
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 1.358 (log Koc, SRC PCKOCWIN v2.0, Calculated value) |
| Ecology - soil | Highly mobile in soil. |

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|---------------------------------------|
| Surface tension | 25.2 mN/m (23 °C, 1 g/l) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 2.28 (log Koc, Experimental value) |
| Ecology - soil | Low potential for adsorption in soil. |

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations : Dispose of in accordance with applicable federal, state, and local regulations.

SECTION 14: Transport information

In accordance with DOT / IMDG / IATA

| DOT | IMDG | IATA |
|---|---------------|---------------|
| 14.1. UN number | | |
| Not regulated for transport | | |
| 14.2. Proper Shipping Name | | |
| Not regulated | Not regulated | Not regulated |
| 14.3. Transport hazard class(es) | | |
| Not regulated | Not regulated | Not regulated |
| 14.4. Packing group | | |
| Not regulated | Not regulated | Not regulated |
| 14.5. Environmental hazards | | |
| Not regulated | Not regulated | Not regulated |
| No supplementary information available | | |

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14.6. Special precautions for user

DOT

Not regulated

IMDG

Not regulated

IATA

Not regulated

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

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

guanidine,hydrochloride (50-01-1)

Listed on the Canadian DSL (Domestic Substances List)

sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

guanidine,hydrochloride (50-01-1)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

Xpert[®] HemOnc Lysis Reagents

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date : 12/12/2023

| Full text of H-phrases | |
|------------------------|---|
| H302 | Harmful if swallowed |
| H311 | Toxic in contact with skin |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H412 | Harmful to aquatic life with long lasting effects |

Safety Data Sheet (SDS), USA

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Xpert[®] HemOnc Proteinase K

1.2. Recommended use and restrictions on use

Recommended use : Laboratory use
Restrictions on use : No information available

1.3. Supplier

Cepheid
904 E. Caribbean Drive
Sunnyvale, Santa Clara, CA 94089
USA
T 1-888-838-3222
techsupport@cepheid.com - www.cepheid.com

1.4. Emergency telephone number

Emergency number : For Chemical Emergency Call INFOTRAC 24hr/day 7days/week
Within USA and Canada: 1-800-535-5053
Outside USA and Canada: 1-352-323-3500
(collect calls accepted)

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS US classification

Respiratory sensitization, Category 1 H334 May cause an allergy or asthma symptoms or breathing difficulties if inhaled

Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US) :



Signal word (GHS US) : Danger
Hazard statements (GHS US) : H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled
Precautionary statements (GHS US) : P261 - Avoid breathing mist, vapors, spray.
P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.
P501 - Dispose of contents/container to an approved waste disposal plant.

2.3. Other hazards which do not result in classification

No additional information available

Xpert[®] HemOnc Proteinase K

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

2.4. Unknown acute toxicity (GHS US)

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | % | GHS US classification |
|--------------|---------------------|-------|---|
| proteinase K | CAS-No.: 39450-01-6 | 1 – 5 | Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 STOT SE 3, H335 |

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|---|
| First-aid measures general | : If possible, show the doctor this safety data sheet. Failing this, show the doctor the packaging or label. |
| First-aid measures after inhalation | : Get immediate medical advice/attention. Give oxygen or artificial respiration if necessary. Remove person to fresh air. Do not apply mouth-to-mouth resuscitation. |
| First-aid measures after skin contact | : Wash off with soap and plenty of water. May cause an allergic skin reaction. If skin irritation occurs: Get medical advice/attention. |
| First-aid measures after eye contact | : Rinse immediately with plenty of water, also under the eyelids. |
| First-aid measures after ingestion | : May produce an allergic reaction. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention. |

4.2. Most important symptoms and effects (acute and delayed)

| | |
|-----------------------------------|--|
| Symptoms/effects after inhalation | : May cause an allergy or asthma symptoms or breathing difficulties if inhaled. Coughing. Itching. |
|-----------------------------------|--|

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

| | |
|--------------------------------|---|
| Suitable extinguishing media | : Use extinguishing media appropriate for surrounding fire. |
| Unsuitable extinguishing media | : No information available. |

5.2. Specific hazards arising from the chemical

| | |
|--|---|
| Hazardous decomposition products in case of fire | : Product is or contains a sensitiser. May cause sensitisation by inhalation. |
|--|---|

5.3. Special protective equipment and precautions for fire-fighters

| | |
|--------------------------------|--|
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |
|--------------------------------|--|

Xpert® HemOnc Proteinase K

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate unnecessary personnel. Keep upwind.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Prevent further leakage or spillage if safe to do so.
Methods for cleaning up : Take up mechanically (sweeping, shoveling) and collect in suitable container for disposal.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Ensure good ventilation of the work station.
Hygiene measures : Avoid contact with skin, eyes and clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Take off immediately all contaminated clothing and wash it before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of reach of children.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Xpert® HemOnc Proteinase K

No additional information available

proteinase K (39450-01-6)

USA - ACGIH - Occupational Exposure Limits

| | |
|-------------|---------------------------|
| ACGIH OEL C | 0.00006 mg/m ³ |
|-------------|---------------------------|

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

Xpert® HemOnc Proteinase K

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

[In case of inadequate ventilation] wear respiratory protection.

Personal protective equipment symbol(s):



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|---------------------|
| Physical state | : Liquid |
| Appearance | : Clear liquid. |
| Color | : Colorless |
| Odor | : odorless |
| Odor threshold | : No data available |
| pH | : 7.5 |
| Melting point | : Not applicable |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Relative evaporation rate (butyl acetate=1) | : No data available |
| Flammability (solid, gas) | : Not applicable. |
| Vapor pressure | : No data available |
| Relative vapor density at 20°C | : No data available |
| Relative density | : No data available |
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosion limits | : No data available |
| Explosive properties | : No data available |
| Oxidizing properties | : No data available |

9.2. Other information

No additional information available

Xpert[®] HemOnc Proteinase K

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|-----------------------------|------------------|
| Acute toxicity (oral) | : Not classified |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |
| Skin corrosion/irritation | : Not classified |
| | pH: 7.5 |

proteinase K (39450-01-6)

| | |
|----|-------------------------------------|
| pH | No data available in the literature |
|----|-------------------------------------|

| | |
|-------------------------------|------------------|
| Serious eye damage/irritation | : Not classified |
| | pH: 7.5 |

proteinase K (39450-01-6)

| | |
|----|-------------------------------------|
| pH | No data available in the literature |
|----|-------------------------------------|

| | |
|-----------------------------------|---|
| Respiratory or skin sensitization | : May cause an allergy or asthma symptoms or breathing difficulties if inhaled. |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |

proteinase K (39450-01-6)

| | |
|----------------------|-----------------------------------|
| STOT-single exposure | May cause respiratory irritation. |
|----------------------|-----------------------------------|

| | |
|------------------------|---------------------|
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |
| Viscosity, kinematic | : No data available |

proteinase K (39450-01-6)

| | |
|----------------------|------------------------|
| Viscosity, kinematic | Not applicable (solid) |
|----------------------|------------------------|

Xpert® HemOnc Proteinase K

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Symptoms/effects after inhalation : May cause an allergy or asthma symptoms or breathing difficulties if inhaled. Coughing. Itching.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

12.2. Persistence and degradability

proteinase K (39450-01-6)

| | |
|-------------------------------|---|
| Persistence and degradability | Biodegradability in water: no data available. |
|-------------------------------|---|

12.3. Bioaccumulative potential

proteinase K (39450-01-6)

| | |
|---------------------------|------------------------------------|
| Bioaccumulative potential | No bioaccumulation data available. |
|---------------------------|------------------------------------|

12.4. Mobility in soil

proteinase K (39450-01-6)

| | |
|----------------|---|
| Ecology - soil | No (test)data on mobility of the substance available. |
|----------------|---|

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Product/Packaging disposal recommendations : This material and its container must be disposed of as hazardous waste.

SECTION 14: Transport information

In accordance with DOT / IMDG / IATA

| DOT | IMDG | IATA |
|---|---------------|---------------|
| 14.1. UN number | | |
| Not regulated for transport | | |
| 14.2. Proper Shipping Name | | |
| Not regulated | Not regulated | Not regulated |
| 14.3. Transport hazard class(es) | | |
| Not regulated | Not regulated | Not regulated |
| 14.4. Packing group | | |
| Not regulated | Not regulated | Not regulated |

Xpert[®] HemOnc Proteinase K

Safety Data Sheet

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| DOT | IMDG | IATA |
|--|---------------|---------------|
| 14.5. Environmental hazards | | |
| Not regulated | Not regulated | Not regulated |
| No supplementary information available | | |

14.6. Special precautions for user

DOT

Not regulated

IMDG

Not regulated

IATA

Not regulated

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

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

| | | |
|--------------|--------------------|--------|
| proteinase K | CAS-No. 39450-01-6 | 1 – 5% |
|--------------|--------------------|--------|

This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

proteinase K (39450-01-6)

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

EU-Regulations

No additional information available

National regulations

No additional information available

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

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Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

| Full text of H-phrases | |
|------------------------|--|
| H315 | Causes skin irritation |
| H319 | Causes serious eye irritation |
| H334 | May cause an allergy or asthma symptoms or breathing difficulties if inhaled |
| H335 | May cause respiratory irritation |

Safety Data Sheet (SDS), USA

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



Xpert[®] HemOnc Wash Reagent

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
Issue date: 2023-12 Supersedes Date: Not Applicable Version: A

SECTION 1: Identification

1.1. Identification

Product form : Mixture
Product name : Xpert[®] HemOnc Wash Reagent

1.2. Recommended use and restrictions on use

Recommended use : Laboratory use
Restrictions on use : No information available

1.3. Supplier

Cepheid
904 E. Caribbean Drive
Sunnyvale, Santa Clara, CA 94089
USA
T 1-888-838-3222
techsupport@cepheid.com - www.cepheid.com

1.4. Emergency telephone number

Emergency number : For Chemical Emergency Call INFOTRAC 24hr/day 7days/week
Within USA and Canada: 1-800-535-5053
Outside USA and Canada: 1-352-323-3500
(collect calls accepted)

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture



GHS US classification

| | | |
|--|------|---|
| Flammable liquids Category 3 | H226 | Flammable liquid and vapor |
| Skin corrosion/irritation Category 1C | H314 | Causes severe skin burns and eye damage |
| Serious eye damage/eye irritation Category 1 | H318 | Causes serious eye damage |

Full text of H statements : see section 16

2.2. GHS Label elements, including precautionary statements

GHS US labeling

Hazard pictograms (GHS US) :  

Signal word (GHS US) : Danger

Hazard statements (GHS US) : H226 - Flammable liquid and vapor
H314 - Causes severe skin burns and eye damage

Precautionary statements (GHS US) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 - Do not breathe mist, vapors, spray.
P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

P310 - Immediately call a poison center or doctor.

P370+P378 - In case of fire: Use Dry chemical, carbon dioxide (CO₂), Water spray, alcohol resistant foam to extinguish.

P403+P235 - Store in a well-ventilated place. Keep cool.

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | % | GHS US classification |
|-----------------------|--------------------|---------|--|
| ethanol | CAS-No.: 64-17-5 | 40 – 45 | Flam. Liq. 2, H225 |
| guanidine thiocyanate | CAS-No.: 593-84-0 | 15 – 20 | Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332 Skin Corr. 1C, H314 Eye Dam. 1, H318 Aquatic Chronic 3, H412 |

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|---|
| First-aid measures general | : Seek medical attention immediately. If possible, show the doctor this safety data sheet. Failing this, show the doctor the packaging or label. |
| First-aid measures after inhalation | : Remove person to fresh air and keep comfortable for breathing. Give oxygen or artificial respiration if necessary. Get immediate medical advice/attention. Do not apply mouth-to-mouth resuscitation. |
| First-aid measures after skin contact | : Wash off with soap and plenty of water. Remove/Take off immediately all contaminated clothing. Get immediate medical advice/attention. |
| First-aid measures after eye contact | : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately. |
| First-aid measures after ingestion | : Rinse mouth. Do not induce vomiting. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention. |

4.2. Most important symptoms and effects (acute and delayed)

| | |
|-------------------------------------|---------------------------|
| Symptoms/effects | : Burning sensation. |
| Symptoms/effects after skin contact | : Burns. |
| Symptoms/effects after eye contact | : Serious damage to eyes. |
| Symptoms/effects after ingestion | : Burns. |

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

Xpert® HemOnc Wash Reagent

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Dry chemical. Carbon dioxide. Water spray. Alcohol-resistant foam.
Unsuitable extinguishing media : No information available.

5.2. Specific hazards arising from the chemical

Fire hazard : Flammable liquid and vapor.
Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon oxides (CO, CO₂). Sulfur oxides (SO_x). Nitrogen oxides.

5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking. Ensure adequate ventilation. Do not breathe dust/fume/gas/mist/vapors/spray. Evacuate area. Use personal protective equipment as required. See section 8 of the SDS for more information on personal protective equipment. Avoid contact with skin, eyes and clothing. Keep upwind. No flames, no sparks. Eliminate all sources of ignition. Do not touch or walk on the spilled product. Take precautionary measures against static discharge. All equipment used when handling the product must be grounded. Corrosive materials.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. Prevent further leakage or spillage if safe to do so. Do not allow to enter drains or water courses. Prevent soil and water pollution. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Stop leak, if possible without risk. Do not touch or walk on the spilled product. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Absorb spilled material with sand or earth.
Methods for cleaning up : Take precautionary measures against static discharges. Soak up with inert absorbent material (for example sand, sawdust, a universal binder, silica gel). Notify authorities if product enters sewers or public waters.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8. For further information refer to section 13.

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Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapors may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Do not breathe vapors, mist. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.
- Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Wear suitable gloves and eye/face protection. Contaminated work clothing should not be allowed out of the workplace.

7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Ground/bond container and receiving equipment.
- Storage conditions : Store tightly closed in a dry, cool and well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store in accordance with local, regional, national or international regulations. Protect from moisture. Store locked up. Keep out of reach of children. Store away from other materials.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Xpert® HemOnc Wash Reagent

No additional information available

guanidine thiocyanate (593-84-0)

No additional information available

ethanol (64-17-5)

USA - ACGIH - Occupational Exposure Limits

| | |
|----------------------|----------|
| ACGIH OEL STEL [ppm] | 1000 ppm |
|----------------------|----------|

8.2. Appropriate engineering controls

- Appropriate engineering controls : Ensure good ventilation of the work station.
- Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Xpert® HemOnc Wash Reagent

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|---------------------|
| Physical state | : Liquid |
| Appearance | : Clear liquid. |
| Color | : Colorless |
| Odor | : odorless |
| Odor threshold | : No data available |
| pH | : No data available |
| Melting point | : 0 °C |
| Freezing point | : No data available |
| Boiling point | : 66.2 °C |
| Flash point | : 29 – < 40 °C |
| Relative evaporation rate (butyl acetate=1) | : No data available |
| Flammability (solid, gas) | : Not applicable. |
| Vapor pressure | : No data available |
| Relative vapor density at 20°C | : No data available |
| Relative density | : No data available |
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosion limits | : No data available |
| Explosive properties | : No data available |
| Oxidizing properties | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Flammable liquid and vapor.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

Xpert® HemOnc Wash Reagent

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified

Acute toxicity (dermal) : Not classified

Acute toxicity (inhalation) : Not classified

guanidine thiocyanate (593-84-0)

| | |
|-----------------------|---|
| LD50 oral rat | 593 mg/kg body weight (OECD 401: Acute Oral Toxicity, Rat, Female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rabbit | > 2000 mg/kg body weight (24 h, Rabbit, Male / female, Experimental value, Skin, 14 day(s)) |
| LC50 Inhalation - Rat | > 0.853 mg/l air (Equivalent or similar to OECD 403, 4 h, Rat, Male / female, Experimental value, Inhalation (dust), 14 day(s)) |
| ATE US (oral) | 593 mg/kg body weight |
| ATE US (gases) | 4500 ppmV/4h |
| ATE US (vapors) | 11 mg/l/4h |
| ATE US (dust, mist) | 1.5 mg/l/4h |

ethanol (64-17-5)

| | |
|---------------------------------|--|
| LD50 oral rat | 10470 mg/kg body weight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s)) |
| LD50 oral | 6200 mg/kg |
| LD50 dermal rabbit | > 15800 mg/kg body weight (Rabbit, Experimental value, Dermal) |
| LD50 dermal | 20000 mg/kg |
| LC50 Inhalation - Rat | 124.7 mg/l air (Equivalent or similar to OECD 403, 4 h, Rat, Male / female, Experimental value, Inhalation (vapours), 14 day(s)) |
| LC50 Inhalation - Rat (Vapours) | 116.9 mg/l Source: ECHA |
| ATE US (oral) | 6200 mg/kg body weight |
| ATE US (dermal) | 20000 mg/kg body weight |
| ATE US (vapors) | 116.9 mg/l/4h |

Skin corrosion/irritation : Causes severe skin burns.

guanidine thiocyanate (593-84-0)

| | |
|----|----------------|
| pH | 4.5 – 7 (70 %) |
|----|----------------|

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ethanol (64-17-5)

| | |
|----|--------------------|
| pH | 7 (789 g/l, 20 °C) |
|----|--------------------|

Serious eye damage/irritation : Causes serious eye damage.

guanidine thiocyanate (593-84-0)

| | |
|----|----------------|
| pH | 4.5 – 7 (70 %) |
|----|----------------|

ethanol (64-17-5)

| | |
|----|--------------------|
| pH | 7 (789 g/l, 20 °C) |
|----|--------------------|

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

ethanol (64-17-5)

| | |
|------------|----------------------------|
| IARC group | 1 - Carcinogenic to humans |
|------------|----------------------------|

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

ethanol (64-17-5)

| | |
|---|---|
| NOAEL (subchronic,oral,animal/male,90 days) | < 9700 mg/kg body weight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents) |
|---|---|

| | |
|---|---|
| NOAEL (subchronic,oral,animal/female,90 days) | > 9400 mg/kg body weight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents) |
|---|---|

Aspiration hazard : Not classified

Viscosity, kinematic : No data available

guanidine thiocyanate (593-84-0)

| | |
|----------------------|-------------------------------------|
| Viscosity, kinematic | No data available in the literature |
|----------------------|-------------------------------------|

ethanol (64-17-5)

| | |
|----------------------|--------------------------------|
| Viscosity, kinematic | 1.6 mm ² /s (20 °C) |
|----------------------|--------------------------------|

Symptoms/effects : Burning sensation.

Symptoms/effects after skin contact : Burns.

Symptoms/effects after eye contact : Serious damage to eyes.

Symptoms/effects after ingestion : Burns.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Before neutralisation, the product may represent a danger to aquatic organisms.

guanidine thiocyanate (593-84-0)

| | |
|-----------------|--|
| LC50 - Fish [1] | 89.1 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Poecilia reticulata, Static system, Fresh water, Experimental value) |
|-----------------|--|

| | |
|----------------------|--|
| EC50 - Crustacea [1] | 42.4 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect) |
|----------------------|--|

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| guanidine thiocyanate (593-84-0) | |
|----------------------------------|--|
| ErC50 algae | 130 mg/l (DIN 38412: German standard methods for the examination of water, waste water and sludge, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, Growth rate) |
| ethanol (64-17-5) | |
| LC50 - Fish [1] | 15300 mg/l (US EPA, 96 h, Pimephales promelas, Flow-through system, Fresh water, Experimental value, Lethal) |
| EC50 - Crustacea [1] | 5463 mg/l |
| EC50 72h - Algae [1] | 275 mg/l (Equivalent or similar to OECD 201, Chlorella vulgaris, Static system, Fresh water, Experimental value, Growth rate) |
| ErC50 algae | 275 mg/l Source: ECHA |
| NOEC (chronic) | 9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d' |
| NOEC chronic crustacea | 9.6 mg/l |

12.2. Persistence and degradability

| guanidine thiocyanate (593-84-0) | |
|----------------------------------|--|
| Not rapidly degradable | |
| Persistence and degradability | Inherently biodegradable. |
| ethanol (64-17-5) | |
| Persistence and degradability | Biodegradable in the soil. Readily biodegradable in water. |
| Biochemical oxygen demand (BOD) | 0.8 – 0.967 g O ₂ /g substance |
| Chemical oxygen demand (COD) | 1.7 g O ₂ /g substance |
| ThOD | 2.1 g O ₂ /g substance |

12.3. Bioaccumulative potential

| guanidine thiocyanate (593-84-0) | |
|---|--|
| Partition coefficient n-octanol/water (Log Pow) | -1.11 (Estimated value, EU Method A.8: Partition Coefficient, 25 °C) |
| Bioaccumulative potential | Not bioaccumulative. |
| ethanol (64-17-5) | |
| Partition coefficient n-octanol/water (Log Pow) | -0.35 (Experimental value, Equivalent or similar to OECD 107, 24 °C) |
| Bioaccumulative potential | Not bioaccumulative. |

12.4. Mobility in soil

| guanidine thiocyanate (593-84-0) | |
|--|--|
| Ecology - soil | No (test) data on mobility of the substance available. |
| ethanol (64-17-5) | |
| Surface tension | 22.31 mN/m (20 °C, 100 %) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 0.2 (log Koc, Experimental value) |

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ethanol (64-17-5)

Ecology - soil

Highly mobile in soil.

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods




: Dispose of contents/container in accordance with licensed collector's sorting instructions.

Additional information

: Flammable vapors may accumulate in the container.

SECTION 14: Transport information

In accordance with DOT / IMDG / IATA

| DOT | IMDG | IATA |
|---|--|--|
| 14.1. UN number | | |
| 2924 | 2924 | 2924 |
| 14.2. Proper Shipping Name | | |
| Flammable liquids, corrosive, n.o.s. (guanidine thiocyanate ; ethanol, aqueous solutions, 23°C≤F.P.<60°C) | FLAMMABLE LIQUID, CORROSIVE, N.O.S. (guanidine thiocyanate ; ethanol, aqueous solutions, 23°C≤F.P.<60°C) | Flammable liquid, corrosive, n.o.s. (guanidine thiocyanate ; ethanol, aqueous solutions, 23°C≤F.P.<60°C) |
| 14.3. Transport hazard class(es) | | |
| 3 (8) | 3 (8) | 3 (8) |
|  |  |  |
| 14.4. Packing group | | |
| III | III | III |
| 14.5. Environmental hazards | | |
| Dangerous for the environment: No | Dangerous for the environment: No Marine pollutant: No | Dangerous for the environment: No |
| No supplementary information available | | |

14.6. Special precautions for user

DOT

UN-No.(DOT)

: UN2924

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| | |
|--|---|
| DOT Special Provisions (49 CFR 172.102) | : B1 - If the material has a flash point at or above 38 C (100 F) and below 93 C (200 F), then the bulk packaging requirements of 173.241 of this subchapter are applicable. If the material has a flash point of less than 38 C (100 F), then the bulk packaging requirements of 173.242 of this subchapter are applicable. IB3 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1 and 31HA2, 31HB2, 31HN2, 31HD2 and 31HH2). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized, except for UN2672 (also see Special Provision IP8 in Table 2 for UN2672). T7 - 4 178.274(d)(2) Normal..... 178.275(d)(3) TP1 - The maximum degree of filling must not exceed the degree of filling determined by the following: Degree of filling = $97 / 1 + a (tr - tf)$ Where: tr is the maximum mean bulk temperature during transport, and tf is the temperature in degrees celsius of the liquid during filling. TP28 - A portable tank having a minimum test pressure of 2.65 bar (265 kPa) may be used provided the calculated test pressure is 2.65 bar or less based on the MAWP of the hazardous material, as defined in 178.275 of this subchapter, where the test pressure is 1.5 times the MAWP. |
| DOT Packaging Exceptions (49 CFR 173.xxx) | : 150 |
| DOT Packaging Non Bulk (49 CFR 173.xxx) | : 203 |
| DOT Packaging Bulk (49 CFR 173.xxx) | : 242 |
| DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) | : 5 L |
| DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) | : 60 L |
| DOT Vessel Stowage Location | : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel. |
| DOT Vessel Stowage Other | : 40 - Stow "clear of living quarters" |

IMDG

| | |
|------------------------------------|---|
| Special provision (IMDG) | : 223, 274 |
| Limited quantities (IMDG) | : 5 L |
| Excepted quantities (IMDG) | : E1 |
| Packing instructions (IMDG) | : P001 |
| IBC packing instructions (IMDG) | : IBC03 |
| Tank instructions (IMDG) | : T7 |
| Tank special provisions (IMDG) | : TP1, TP28 |
| EmS-No. (Fire) | : F-E - FIRE SCHEDULE Echo - NON-WATER-REACTIVE FLAMMABLE LIQUIDS |
| EmS-No. (Spillage) | : S-C - SPILLAGE SCHEDULE Charlie - FLAMMABLE CORROSIVE LIQUIDS |
| Stowage category (IMDG) | : A |
| Stowage and handling (IMDG) | : SW2 |
| Properties and observations (IMDG) | : Causes burns to skin, eyes and mucous membranes. |

IATA

| | |
|--|------------|
| PCA Excepted quantities (IATA) | : E1 |
| PCA Limited quantities (IATA) | : Y342 |
| PCA limited quantity max net quantity (IATA) | : 1L |
| PCA packing instructions (IATA) | : 354 |
| PCA max net quantity (IATA) | : 5L |
| CAO packing instructions (IATA) | : 365 |
| CAO max net quantity (IATA) | : 60L |
| Special provision (IATA) | : A3, A803 |
| ERG code (IATA) | : 3C |

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

Not applicable

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SECTION 15: Regulatory information

15.1. US Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

guanidine thiocyanate (593-84-0)

Listed on the Canadian DSL (Domestic Substances List)

ethanol (64-17-5)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

ethanol (64-17-5)

Listed on IARC (International Agency for Research on Cancer)
Listed on INSQ (Mexican National Inventory of Chemical Substances)

15.3. US State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

| Full text of H-phrases | |
|------------------------|---|
| H225 | Highly flammable liquid and vapor |
| H226 | Flammable liquid and vapor |
| H302 | Harmful if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H318 | Causes serious eye damage |
| H332 | Harmful if inhaled |
| H412 | Harmful to aquatic life with long lasting effects |

Safety Data Sheet (SDS), USA

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SECTION 1: Product identifier

1.1. GHS Product identifier

Product form : Mixture
Product name : Xpert® PML-RARA RUO
Product code : RPMLRARA-10

1.2. Other means of identification

No additional information available

1.3. Recommended use of the chemical and restrictions on use

Recommended use : Laboratory use
Restrictions on use : No information available

1.4. Details of manufacturer or importer

Supplier

Cepheid
904 E. Caribbean Drive
Sunnyvale Santa Clara CA 94089
USA
T 1-888-838-3222
techsupport@cepheid.com - www.cepheid.com

Distributor

Cepheid Holdings Pty Ltd
Suite 2, Level 3, Building A
11 Talavera Road
Macquarie Park New South Wales 2113
Australia
T 1800 107 884
TechSupportANZ@cepheid.com - www.cepheidinternational.com

1.5. Emergency phone number

Emergency number : For Chemical Emergency Call INFOTRAC 24hr/day 7days/week
Within USA and Canada: 1-800-535-5053
Outside USA and Canada: 1-352-323-3500
(collect calls accepted)

SECTION 2: Hazard identification

2.1. Classification of the hazardous chemical

Classification according to the model Work Health and Safety Regulations (WHS Regulations)

| | |
|---|------|
| Flammable liquids, Category 3 | H226 |
| Skin corrosion/irritation, Category 2 | H315 |
| Serious eye damage/eye irritation, Category 1 | H318 |

2.2. GHS Label elements, including precautionary statements

Hazard pictograms (GHS AU) :



Flame

Corrosion

Signal word (GHS AU) :

Danger

Contains :

guanidine,hydrochloride (15 – 20 %); guanidine thiocyanate (1 – 5 %); sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (<3 %)

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according to the Work Health and Safety (WHS) Regulations

| | |
|-----------------------------------|---|
| Hazard statements (GHS AU) | : H226 - Flammable liquid and vapour H315 - Causes skin irritation H318 - Causes serious eye damage |
| Precautionary statements (GHS AU) | : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P264 - Wash hands, forearms and face thoroughly after handling. |
| | P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 - Immediately call a POISON CENTER or doctor. P370+P378 - In case of fire: Use Dry chemical, carbon dioxide (CO ₂), Water spray, alcohol resistant foam to extinguish. P403+P235 - Store in a well-ventilated place. Keep cool. |

2.3. Other hazards which do not result in classification

No additional information available

SECTION 3: Composition and information on ingredients

| Name | CAS-No. | % | Classification according to the model Work Health and Safety Regulations (WHS Regulations) |
|---|----------|---------|---|
| guanidine,hydrochloride | 50-01-1 | 15 – 20 | Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Aquatic Chronic 3, H412 |
| guanidine thiocyanate | 593-84-0 | 1 – 5 | Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Skin Corr. 1C, H314 Eye Dam. 1, H318 Aquatic Chronic 3, H412 |
| sodium dodecyl sulphate, bulk density ≥400g/l | 151-21-3 | <3 | Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 3, H412 |
| Other substances (not contributing to the classification of this product) | - | 72 – 84 | - |

SECTION 4: First aid measures

4.1. Description of necessary first-aid measures

| | |
|---------------------------------------|--|
| First-aid measures general | : Seek medical attention immediately. If possible, show the doctor this safety data sheet. Failing this, show the doctor the packaging or label. |
| First-aid measures after inhalation | : Remove person to fresh air and keep comfortable for breathing. Get medical attention if symptoms occur. |
| First-aid measures after skin contact | : Wash off with soap and plenty of water. Remove/Take off immediately all contaminated clothing. Seek medical attention if irritation develops. |

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| | |
|--------------------------------------|---|
| First-aid measures after eye contact | : Rinse immediately with plenty of water, also under the eyelids. Do not rub affected area. Get immediate medical advice/attention. Remove contact lenses, if present and easy to do. Continue rinsing. |
| First-aid measures after ingestion | : Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician immediately. |

4.2. Symptoms caused by exposure

| | |
|------------------|----------------------|
| Symptoms/effects | : Burning sensation. |
|------------------|----------------------|

4.3. Medical attention and special treatment

| | |
|-----------------------------------|--------------------------|
| Other medical advice or treatment | : Treat symptomatically. |
|-----------------------------------|--------------------------|

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

| | |
|--------------------------------|--|
| Suitable extinguishing media | : Dry chemical. Carbon dioxide. Water spray. Alcohol-resistant foam. |
| Unsuitable extinguishing media | : No information available. |

5.2. Specific hazards arising from the chemical

| | |
|--|--|
| Hazardous decomposition products in case of fire | : Toxic fumes may be released. Carbon oxides (CO, CO ₂). |
|--|--|

5.3. Special protective equipment and precautions for fire-fighters

| | |
|--------------------------------|--|
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |
| Hazchem Code | : * 3Y |

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

| | |
|----------------------|--|
| Protective equipment | : Wear recommended personal protective equipment. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. |
| Emergency procedures | : Evacuate area. Use personal protective equipment as required. See section 8 of the SDS for more information on personal protective equipment. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Keep upwind. No flames, no sparks. Eliminate all sources of ignition. Take precautionary measures against static discharge. All equipment used when handling the product must be grounded. Do not touch or walk on the spilled product. |

6.1.2. For emergency responders

| | |
|----------------------|---|
| Protective equipment | : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection". |
|----------------------|---|

6.2. Environmental precautions

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. Prevent further leakage or spillage if safe to do so. Do not allow to enter drains or water courses. Avoid release to the environment.

6.3. Methods and materials for containment and cleaning up

| | |
|-----------------|---|
| For containment | : Stop leak without risks if possible. Do not touch or walk on the spilled product. Absorb spilled material with sand or earth. |
|-----------------|---|

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according to the Work Health and Safety (WHS) Regulations

- Methods for cleaning up : Take precautionary measures against static discharges. Take up liquid spill into absorbent material.
- Reference to other sections (13) : For further information refer to section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.
- Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Always wash hands after handling the product. Avoid contact with skin, eyes and clothing. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store tightly closed in a dry, cool and well-ventilated place. Store in accordance with local, regional, national or international regulations. Store locked up. Keep out of reach of children.

SECTION 8: Exposure controls and personal protection

8.1. Control parameters - exposure standards

No additional information available

8.2. Monitoring methods

No additional information available

8.3. Engineering controls

- Appropriate engineering controls : Ensure good ventilation of the work station.

8.4. Individual protection measures, such as personal protective equipment (PPE)

- Hand protection : Protective gloves
- Eye protection : Safety glasses
- Skin and body protection : Wear suitable protective clothing
- Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s)



- Environmental exposure controls : Avoid release to the environment.

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SECTION 9: Physical and chemical properties

| | |
|---|-----------------------|
| Physical state | : Liquid |
| Appearance | : Clear liquid. |
| Colour | : Colourless |
| Odour | : odourless |
| Odour threshold | : No data available |
| pH | : No data available |
| pH solution | : No data available |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point / Freezing point | : Melting point: 0 °C |
| Boiling point | : 66.2 °C |
| Flash point | : 29 – < 40 °C |
| Auto-ignition temperature | : No data available |
| Flammability | : No data available |
| Vapour pressure | : No data available |
| Relative density | : No data available |
| Density | : No data available |
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Explosive properties | : No data available |
| Explosive limits | : No data available |
| Minimum ignition energy | : No data available |
| Fat solubility | : No data available |

SECTION 10: Stability and reactivity

| | |
|------------------------------------|--|
| Reactivity | : The product is non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | : Stable under normal conditions. |
| Possibility of hazardous reactions | : No dangerous reactions known under normal conditions of use. |
| Conditions to avoid | : None under recommended storage and handling conditions (see section 7). |
| Incompatible materials | : No additional information available |
| Hazardous decomposition products | : Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

SECTION 11: Toxicological information

| | |
|-----------------------------|------------------|
| Acute toxicity (oral) | : Not classified |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|--|--|
| LD50 oral rat | 1200 mg/kg bodyweight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rat | > 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal, 14 day(s)) |
| LD50 dermal rabbit | 600 mg/kg Source: cal, SIDS |
| guanidine,hydrochloride (50-01-1) | |
| LD50 oral rat | 774 – 907 mg/kg bodyweight (Equivalent or similar to OECD 401, Rat, Male / female, Experimental value, Oral, 14 day(s)) |

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| guanidine,hydrochloride (50-01-1) | |
|-----------------------------------|---|
| LD50 dermal rabbit | > 2000 mg/kg bodyweight (Equivalent or similar to OECD 402, 24 h, Rabbit, Male / female, Experimental value, Dermal, 14 day(s)) |
| LC50 Inhalation - Rat | 5.32 mg/l (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (aerosol), 14 day(s)) |

| guanidine thiocyanate (593-84-0) | |
|----------------------------------|---|
| LD50 oral rat | 593 mg/kg bodyweight (OECD 401: Acute Oral Toxicity, Rat, Female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rabbit | > 2000 mg/kg bodyweight (24 h, Rabbit, Male / female, Experimental value, Skin, 14 day(s)) |
| LC50 Inhalation - Rat | > 0.853 mg/l air (Equivalent or similar to OECD 403, 4 h, Rat, Male / female, Experimental value, Inhalation (dust), 14 day(s)) |

| | |
|-----------------------------------|------------------------------|
| Skin corrosion/irritation | : Causes skin irritation. |
| Serious eye damage/irritation | : Causes serious eye damage. |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |

| sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3) | |
|---|------------------------|
| Viscosity, kinematic | Not applicable (solid) |

| guanidine thiocyanate (593-84-0) | |
|----------------------------------|-------------------------------------|
| Viscosity, kinematic | No data available in the literature |

SECTION 12: Ecological information

12.1. Ecotoxicity

| | |
|---|---|
| Ecology - general | : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. |
| Hazardous to the aquatic environment, short-term (acute) | : Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified |

| sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3) | |
|---|--|
| LC50 - Fish [1] | 29 mg/l (Equivalent or similar to OECD 203, 96 h, Pimephales promelas, Flow-through system, Fresh water, Experimental value, Lethal) |
| EC50 - Crustacea [1] | 6 mg/l Source: ECOTOX |
| EC50 - Other aquatic organisms [1] | 11.1 mg/l Test organisms (species): other aquatic crustacea: |
| NOEC chronic fish | ≥ 1.357 mg/l Test organisms (species): Pimephales promelas Duration: '42 d' |
| NOEC chronic crustacea | 0.88 mg/l |
| Partition coefficient n-octanol/water (Log Pow) | < 2.03 (Estimated value, EU Method A.8: Partition Coefficient, 20 °C) |

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| sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3) | |
|---|--|
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 2.28 (log Koc, Experimental value) |
| guanidine,hydrochloride (50-01-1) | |
| LC50 - Fish [1] | 1758 mg/l (DIN 38412-15, 48 h, Leuciscus idus, Experimental value, GLP) |
| EC50 - Crustacea [1] | 70.2 mg/l (Equivalent or similar to OECD 202, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect) |
| ErC50 algae | 33.5 mg/l (EU Method C.3, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, GLP) |
| Partition coefficient n-octanol/water (Log Pow) | < -1.7 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 1.358 (log Koc, SRC PCKOCWIN v2.0, Calculated value) |
| guanidine thiocyanate (593-84-0) | |
| LC50 - Fish [1] | 89.1 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Poecilia reticulata, Static system, Fresh water, Experimental value) |
| EC50 - Crustacea [1] | 42.4 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect) |
| ErC50 algae | 130 mg/l (DIN 38412: German standard methods for the examination of water, waste water and sludge, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, Growth rate) |
| Partition coefficient n-octanol/water (Log Pow) | -1.11 (Estimated value, EU Method A.8: Partition Coefficient, 25 °C) |

12.2. Persistence and degradability

| sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3) | |
|---|-------------------------------------|
| Persistence and degradability | Readily biodegradable in water. |
| guanidine,hydrochloride (50-01-1) | |
| Not rapidly degradable | |
| Persistence and degradability | Not readily biodegradable in water. |
| guanidine thiocyanate (593-84-0) | |
| Not rapidly degradable | |
| Persistence and degradability | Inherently biodegradable. |

12.3. Bioaccumulative potential

| sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ (151-21-3) | |
|---|---|
| Partition coefficient n-octanol/water (Log Pow) | < 2.03 (Estimated value, EU Method A.8: Partition Coefficient, 20 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 2.28 (log Koc, Experimental value) |
| Bioaccumulative potential | Low potential for bioaccumulation (Log Kow < 4). |

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| guanidine,hydrochloride (50-01-1) | |
|--|---|
| Partition coefficient n-octanol/water (Log Pow) | < -1.7 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 1.358 (log Koc, SRC PCKOCWIN v2.0, Calculated value) |
| Bioaccumulative potential | Not bioaccumulative. |

| guanidine thiocyanate (593-84-0) | |
|---|--|
| Partition coefficient n-octanol/water (Log Pow) | -1.11 (Estimated value, EU Method A.8: Partition Coefficient, 25 °C) |
| Bioaccumulative potential | Not bioaccumulative. |

12.4. Mobility in soil

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|---|
| Surface tension | 25.2 mN/m (23 °C, 1 g/l) |
| Ecology - soil | Low potential for adsorption in soil. |
| Partition coefficient n-octanol/water (Log Pow) | < 2.03 (Estimated value, EU Method A.8: Partition Coefficient, 20 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 2.28 (log Koc, Experimental value) |

| guanidine,hydrochloride (50-01-1) | |
|--|---|
| Ecology - soil | Highly mobile in soil. |
| Partition coefficient n-octanol/water (Log Pow) | < -1.7 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 1.358 (log Koc, SRC PCKOCWIN v2.0, Calculated value) |

| guanidine thiocyanate (593-84-0) | |
|---|--|
| Ecology - soil | No (test)data on mobility of the substance available. |
| Partition coefficient n-octanol/water (Log Pow) | -1.11 (Estimated value, EU Method A.8: Partition Coefficient, 25 °C) |

12.5. Other adverse effects

Ozone : Not classified
Other adverse effects : No additional information available

| Xpert® PML-RARA RUO (Kit) | |
|----------------------------------|-------|
| Fluorinated greenhouse gases | False |

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|---|-------|
| Fluorinated greenhouse gases | False |

| guanidine,hydrochloride (50-01-1) | |
|--|-------|
| Fluorinated greenhouse gases | False |

| guanidine thiocyanate (593-84-0) | |
|---|-------|
| Fluorinated greenhouse gases | False |

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SECTION 13: Disposal considerations

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADG / IMDG / IATA

| ADG | IMDG | IATA |
|---|---|--|
| 14.1. UN number | | |
| 1993 | 1993 | 1993 |
| 14.2. UN Proper Shipping Name | | |
| FLAMMABLE LIQUID, N.O.S. (ethanol) | FLAMMABLE LIQUID, N.O.S. (ethanol) | Flammable liquid, n.o.s. (ethanol) |
| Transport document description | | |
| Not applicable | UN 1993 FLAMMABLE LIQUID, N.O.S. (ethanol), 3, III | UN 1993 Flammable liquid, n.o.s. (ethanol), 3, III |
| 14.3. Transport hazard class(es) | | |
| 3 | 3 | 3 |
| | | |
| 14.4. Packing group | | |
| III - Substances presenting low danger | III | III |
| 14.5. Environmental hazards | | |
| Dangerous for the environment: No | Dangerous for the environment: No Marine pollutant: No | Dangerous for the environment: No |

14.6. Special precautions for user

Specific storage requirement : No data available
Shock sensitivity : No data available

14.7. Additional information

Other information : No supplementary information available

Transport by road and rail

UN-No. (ADG) : 1993
Special provision (ADG) : 223, 274
Limited quantities (ADG) : 5I
Excepted quantities (ADG) : E1
Packing instructions (ADG) : P001, IBC03, LP01
Portable tank and bulk container instructions (ADG) : T4
Portable tank and bulk container special provisions (ADG) : TP1, TP29

Transport by sea

UN-No. (IMDG) : 1993
Special provisions (IMDG) : 223, 274, 955

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| | |
|---------------------------------|---|
| Limited quantities (IMDG) | : 5 L |
| Excepted quantities (IMDG) | : E1 |
| Packing instructions (IMDG) | : LP01, P001 |
| IBC packing instructions (IMDG) | : IBC03 |
| Tank instructions (IMDG) | : T4 |
| Tank special provisions (IMDG) | : TP1, TP29 |
| EmS-No. (Fire) | : F-E - FIRE SCHEDULE Echo - NON-WATER-REACTIVE FLAMMABLE LIQUIDS |
| EmS-No. (Spillage) | : S-E - SPILLAGE SCHEDULE Echo - FLAMMABLE LIQUIDS, FLOATING ON WATER |
| Stowage category (IMDG) | : A |

Air transport

| | |
|--|--------|
| UN-No. (IATA) | : 1993 |
| PCA Excepted quantities (IATA) | : E1 |
| PCA Limited quantities (IATA) | : Y344 |
| PCA limited quantity max net quantity (IATA) | : 10L |
| PCA packing instructions (IATA) | : 355 |
| PCA max net quantity (IATA) | : 60L |
| CAO packing instructions (IATA) | : 366 |
| CAO max net quantity (IATA) | : 220L |
| Special provisions (IATA) | : A3 |
| ERG code (IATA) | : 3L |

14.8. Hazchem or Emergency Action Code

Hazchem Code : * 3Y

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations specific for the product in question

No additional information available

15.2. International agreements

No additional information available

SECTION 16: Other information

| Classification | |
|----------------|------|
| Flam. Liq. 3 | H226 |
| Skin Irrit. 2 | H315 |
| Eye Dam. 1 | H318 |

| Full text of H-statements | |
|---------------------------|---|
| Acute Tox. 3 (Dermal) | Acute toxicity (dermal), Category 3 |
| Acute Tox. 4 (Dermal) | Acute toxicity (dermal), Category 4 |
| Acute Tox. 4 (Inhalation) | Acute toxicity (inhal.), Category 4 |
| Acute Tox. 4 (Oral) | Acute toxicity (oral), Category 4 |
| Aquatic Chronic 3 | Hazardous to the aquatic environment – Chronic Hazard, Category 3 |
| Eye Dam. 1 | Serious eye damage/eye irritation, Category 1 |

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| Full text of H-statements | |
|---------------------------|---|
| Eye Irrit. 2A | Serious eye damage/eye irritation, Category 2A |
| Flam. Liq. 3 | Flammable liquids, Category 3 |
| Skin Corr. 1C | Skin corrosion/irritation, Category 1C |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| H226 | Flammable liquid and vapour |
| H302 | Harmful if swallowed |
| H311 | Toxic in contact with skin |
| H312 | Harmful in contact with skin |
| H314 | Causes severe skin burns and eye damage |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H332 | Harmful if inhaled |
| H412 | Harmful to aquatic life with long lasting effects |

Safety Data Sheet (SDS), Australia

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SECTION 1: Product identifier

1.1. GHS Product identifier

Product form : Mixture
Product name : Xpert® HemOnc Lysis Reagents

1.2. Other means of identification

No additional information available

1.3. Recommended use of the chemical and restrictions on use

Recommended use : Laboratory use
Restrictions on use : No information available

1.4. Details of manufacturer or importer

Supplier

Cepheid
904 E. Caribbean Drive
Sunnyvale Santa Clara CA 94089
USA
T 1-888-838-3222
techsupport@cepheid.com - www.cepheid.com

Distributor

Cepheid Holdings Pty Ltd
Suite 2, Level 3, Building A
11 Talavera Road
Macquarie Park New South Wales 2113
Australia
T 1800 107 884
TechSupportANZ@cepheid.com - www.cepheidinternational.com

1.5. Emergency phone number

Emergency number : For Chemical Emergency Call INFOTRAC 24hr/day 7days/week
Within USA and Canada: 1-800-535-5053
Outside USA and Canada: 1-352-323-3500
(collect calls accepted)

SECTION 2: Hazard identification

2.1. Classification of the hazardous chemical

Classification according to the model Work Health and Safety Regulations (WHS Regulations)

| | |
|--|------|
| Acute toxicity (oral), Category 4 | H302 |
| Skin corrosion/irritation, Category 2 | H315 |
| Serious eye damage/eye irritation, Category 2A | H319 |

2.2. GHS Label elements, including precautionary statements

Hazard pictograms (GHS AU) :



Exclamation
mark

Signal word (GHS AU) :

Warning

Contains :

guanidine,hydrochloride (35 – 40 %); sodium dodecyl sulphate, bulk density $\geq 400\text{g/l}$ ($\leq 2\%$)

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according to the Work Health and Safety (WHS) Regulations

| | |
|-----------------------------------|--|
| Hazard statements (GHS AU) | : H302 - Harmful if swallowed H315 - Causes skin irritation H319 - Causes serious eye irritation |
| Precautionary statements (GHS AU) | : P264 - Wash hands, forearms and face thoroughly after handling. P280 - Wear protective gloves, protective clothing, eye protection, face protection. P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. P302+P352 - IF ON SKIN: Wash with plenty of water. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P321 - Specific treatment (see supplemental first aid instruction on this label). P501 - Dispose of contents/container to an approved waste disposal plant. |

2.3. Other hazards which do not result in classification

No additional information available

SECTION 3: Composition and information on ingredients

| Name | CAS-No. | % | Classification according to the model Work Health and Safety Regulations (WHS Regulations) |
|---|----------|---------|--|
| guanidine,hydrochloride | 50-01-1 | 35 – 40 | Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Aquatic Chronic 3, H412 |
| sodium dodecyl sulphate, bulk density ≥400g/l | 151-21-3 | ≤ 2 | Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Skin Irrit. 2, H315 Eye Dam. 1, H318 Aquatic Chronic 3, H412 |
| Other substances (not contributing to the classification of this product) | - | 58 – 65 | - |

SECTION 4: First aid measures

4.1. Description of necessary first-aid measures

| | |
|---------------------------------------|---|
| First-aid measures after inhalation | : Remove person to fresh air and keep comfortable for breathing. Get medical attention if symptoms occur. Give oxygen or artificial respiration if necessary. Immediately consult a doctor/medical service. |
| First-aid measures after skin contact | : Wash skin with plenty of water. Wash off with soap and plenty of water. If irritation persists, consult a doctor/medical service. |
| First-aid measures after eye contact | : Remove contact lenses, if present and easy to do. Continue rinsing. Rinse immediately with plenty of water, also under the eyelids. Do not rub affected area. If irritation persists, consult a doctor/medical service. |
| First-aid measures after ingestion | : Rinse mouth out with water. If swallowed, seek medical advice immediately and show this container or label. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get medical advice/attention. |

4.2. Symptoms caused by exposure

No additional information available

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according to the Work Health and Safety (WHS) Regulations

4.3. Medical attention and special treatment

Other medical advice or treatment : Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : No information available.

5.2. Specific hazards arising from the chemical

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear personal protective clothing (see chapter 8). Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Wear recommended personal protective equipment. Avoid breathing dust, mist or spray.
Emergency procedures : Ventilate spillage area.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Prevent entry to sewers and public waters. Prevent further leakage or spillage if safe to do so. Avoid release to the environment.

6.3. Methods and materials for containment and cleaning up

For containment : Prevent further leakage or spillage if safe to do so.
Methods for cleaning up : Take up liquid spill into absorbent material.
Reference to other sections (13) : For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Ensure good ventilation of the work station. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse. Avoid breathing vapours, mist. Wear personal protective equipment.
Hygiene measures : Avoid contact with skin, eyes and clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store tightly closed in a dry, cool and well-ventilated place. Keep out of reach of children. Store locked up.

SECTION 8: Exposure controls and personal protection

8.1. Control parameters - exposure standards

No additional information available

8.2. Monitoring methods

No additional information available

8.3. Engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.

8.4. Individual protection measures, such as personal protective equipment (PPE)

Hand protection : Protective gloves
Eye protection : Safety glasses
Skin and body protection : Wear suitable protective clothing
Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s)



Environmental exposure controls : Avoid release to the environment.

SECTION 9: Physical and chemical properties

Physical state : Liquid
Appearance : Clear liquid.
Colour : White clear
Odour : odourless
Odour threshold : No data available
pH : 6.4
pH solution : No data available
Relative evaporation rate (butylacetate=1) : No data available
Melting point / Freezing point : Melting point: Not applicable
Boiling point : No data available
Flash point : No data available
Auto-ignition temperature : No data available
Flammability : No data available
Vapour pressure : No data available
Relative density : No data available
Density : No data available
Solubility : No data available
Partition coefficient n-octanol/water (Log Pow) : No data available
Explosive properties : No data available
Explosive limits : No data available
Minimum ignition energy : No data available

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Fat solubility : No data available

SECTION 10: Stability and reactivity

Reactivity : The product is non-reactive under normal conditions of use, storage and transport.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : No dangerous reactions known under normal conditions of use.
Conditions to avoid : None under recommended storage and handling conditions (see section 7).
Incompatible materials : No additional information available
Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Acute toxicity (oral) : Harmful if swallowed.
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

| Xpert[®] HemOnc Lysis Reagents | |
|---|---|
| ATE AU (oral) | 1959.494 mg/kg bodyweight |
| guanidine,hydrochloride (50-01-1) | |
| LD50 oral rat | 774 – 907 mg/kg bodyweight (Equivalent or similar to OECD 401, Rat, Male / female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rabbit | > 2000 mg/kg bodyweight (Equivalent or similar to OECD 402, 24 h, Rabbit, Male / female, Experimental value, Dermal, 14 day(s)) |
| LC50 Inhalation - Rat | 5.32 mg/l (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (aerosol), 14 day(s)) |
| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
| LD50 oral rat | 1200 mg/kg bodyweight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rat | > 2000 mg/kg bodyweight (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal, 14 day(s)) |
| LD50 dermal rabbit | 600 mg/kg Source: cal, SIDS |
| Skin corrosion/irritation | : Causes skin irritation. pH: 6.4 |
| Serious eye damage/irritation | : Causes serious eye irritation. pH: 6.4 |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |
| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
| Viscosity, kinematic | Not applicable (solid) |

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SECTION 12: Ecological information

12.1. Ecotoxicity

| | |
|---|---|
| Ecology - general | : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. |
| Hazardous to the aquatic environment, short-term (acute) | : Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified |

| guanidine,hydrochloride (50-01-1) | |
|--|--|
| LC50 - Fish [1] | 1758 mg/l (DIN 38412-15, 48 h, Leuciscus idus, Experimental value, GLP) |
| EC50 - Crustacea [1] | 70.2 mg/l (Equivalent or similar to OECD 202, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect) |
| ErC50 algae | 33.5 mg/l (EU Method C.3, 72 h, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, GLP) |
| Partition coefficient n-octanol/water (Log Pow) | < -1.7 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 1.358 (log Koc, SRC PCKOCWIN v2.0, Calculated value) |

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|--|--|
| LC50 - Fish [1] | 29 mg/l (Equivalent or similar to OECD 203, 96 h, Pimephales promelas, Flow-through system, Fresh water, Experimental value, Lethal) |
| EC50 - Crustacea [1] | 6 mg/l Source: ECOTOX |
| EC50 - Other aquatic organisms [1] | 11.1 mg/l Test organisms (species): other aquatic crustacea: |
| NOEC chronic fish | ≥ 1.357 mg/l Test organisms (species): Pimephales promelas Duration: '42 d' |
| NOEC chronic crustacea | 0.88 mg/l |
| Partition coefficient n-octanol/water (Log Pow) | < 2.03 (Estimated value, EU Method A.8: Partition Coefficient, 20 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 2.28 (log Koc, Experimental value) |

12.2. Persistence and degradability

| guanidine,hydrochloride (50-01-1) | |
|-----------------------------------|-------------------------------------|
| Not rapidly degradable | |
| Persistence and degradability | Not readily biodegradable in water. |

| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
|--|---------------------------------|
| Persistence and degradability | Readily biodegradable in water. |

12.3. Bioaccumulative potential

| guanidine,hydrochloride (50-01-1) | |
|---|---|
| Partition coefficient n-octanol/water (Log Pow) | < -1.7 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C) |

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| guanidine,hydrochloride (50-01-1) | |
|--|---|
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 1.358 (log Koc, SRC PCKOCWIN v2.0, Calculated value) |
| Bioaccumulative potential | Not bioaccumulative. |
| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
| Partition coefficient n-octanol/water (Log Pow) | < 2.03 (Estimated value, EU Method A.8: Partition Coefficient, 20 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 2.28 (log Koc, Experimental value) |
| Bioaccumulative potential | Low potential for bioaccumulation (Log Kow < 4). |

12.4. Mobility in soil

| guanidine,hydrochloride (50-01-1) | |
|--|---|
| Ecology - soil | Highly mobile in soil. |
| Partition coefficient n-octanol/water (Log Pow) | < -1.7 (Experimental value, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 20 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 1.358 (log Koc, SRC PCKOCWIN v2.0, Calculated value) |
| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
| Surface tension | 25.2 mN/m (23 °C, 1 g/l) |
| Ecology - soil | Low potential for adsorption in soil. |
| Partition coefficient n-octanol/water (Log Pow) | < 2.03 (Estimated value, EU Method A.8: Partition Coefficient, 20 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 2.28 (log Koc, Experimental value) |

12.5. Other adverse effects

Ozone : Not classified
Other adverse effects : No additional information available

| Xpert® HemOnc Lysis Reagents | |
|--|-------|
| Fluorinated greenhouse gases | False |
| guanidine,hydrochloride (50-01-1) | |
| Fluorinated greenhouse gases | False |
| sodium dodecyl sulphate, bulk density ≥400g/l (151-21-3) | |
| Fluorinated greenhouse gases | False |

SECTION 13: Disposal considerations

Waste treatment methods : Dispose of in accordance with applicable federal, state, and local regulations.
Product/Packaging disposal recommendations : Dispose of in accordance with applicable federal, state, and local regulations.

Xpert® HemOnc Lysis Reagents

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

SECTION 14: Transport information

In accordance with ADG / IMDG / IATA

| ADG | IMDG | IATA |
|---|---------------|---------------|
| 14.1. UN number | | |
| Not regulated for transport | | |
| 14.2. UN Proper Shipping Name | | |
| Not regulated | Not regulated | Not regulated |
| 14.3. Transport hazard class(es) | | |
| Not regulated | Not regulated | Not regulated |
| 14.4. Packing group | | |
| Not regulated | Not regulated | Not regulated |
| 14.5. Environmental hazards | | |
| Not regulated | Not regulated | Not regulated |

14.6. Special precautions for user

Specific storage requirement : No data available
Shock sensitivity : No data available

14.7. Additional information

Other information : No supplementary information available

Transport by road and rail

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

14.8. Hazchem or Emergency Action Code

Hazchem Code : Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations specific for the product in question

No additional information available

15.2. International agreements

No additional information available

Xpert[®] HemOnc Lysis Reagents

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according to the Work Health and Safety (WHS) Regulations

SECTION 16: Other information

| Classification | |
|---------------------|------|
| Acute Tox. 4 (Oral) | H302 |
| Skin Irrit. 2 | H315 |
| Eye Irrit. 2A | H319 |

| Full text of H-statements | |
|---------------------------|---|
| Acute Tox. 3 (Dermal) | Acute toxicity (dermal), Category 3 |
| Acute Tox. 4 (Oral) | Acute toxicity (oral), Category 4 |
| Aquatic Chronic 3 | Hazardous to the aquatic environment – Chronic Hazard, Category 3 |
| Eye Dam. 1 | Serious eye damage/eye irritation, Category 1 |
| Eye Irrit. 2A | Serious eye damage/eye irritation, Category 2A |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| H302 | Harmful if swallowed |
| H311 | Toxic in contact with skin |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H412 | Harmful to aquatic life with long lasting effects |

Safety Data Sheet (SDS), Australia

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



Xpert[®] HemOnc Proteinase K

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations
Issue date: 2023-12 Supersedes Date: Not Applicable Version: A

SECTION 1: Product identifier

1.1. GHS Product identifier

Product form : Mixture
Product name : Xpert[®] HemOnc Proteinase K

1.2. Other means of identification

No additional information available

1.3. Recommended use of the chemical and restrictions on use

Recommended use : Laboratory use
Restrictions on use : No information available

1.4. Details of manufacturer or importer

Supplier

Cepheid
904 E. Caribbean Drive
Sunnyvale Santa Clara CA 94089
USA
T 1-888-838-3222
techsupport@cepheid.com - www.cepheid.com

Distributor

Cepheid Holdings Pty Ltd
Suite 2, Level 3, Building A
11 Talavera Road
Macquarie Park New South Wales 2113
Australia
T 1800 107 884
TechSupportANZ@cepheid.com - www.cepheidinternational.com

1.5. Emergency phone number

Emergency number : For Chemical Emergency Call INFOTRAC 24hr/day 7days/week
Within USA and Canada: 1-800-535-5053
Outside USA and Canada: 1-352-323-3500
(collect calls accepted)

SECTION 2: Hazard identification

2.1. Classification of the hazardous chemical

Classification according to the model Work Health and Safety Regulations (WHS Regulations)

Respiratory sensitisation, Category 1 H334

2.2. GHS Label elements, including precautionary statements

Hazard pictograms (GHS AU) :



Health hazard

Signal word (GHS AU) :

Danger

Contains :

proteinase K (1 – 5 %)

Hazard statements (GHS AU) :

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary statements (GHS AU) :

P261 - Avoid breathing mist, vapours, spray.

P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

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

Xpert® HemOnc Proteinase K

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

2.3. Other hazards which do not result in classification

No additional information available

SECTION 3: Composition and information on ingredients

| Name | CAS-No. | % | Classification according to the model Work Health and Safety Regulations (WHS Regulations) |
|---|------------|---------|--|
| proteinase K | 39450-01-6 | 1 – 5 | Skin Irrit. 2, H315 Resp. Sens. 1, H334 STOT SE 3, H335 |
| Other substances (not contributing to the classification of this product) | - | 95 – 99 | - |

SECTION 4: First aid measures

4.1. Description of necessary first-aid measures

| | |
|---------------------------------------|---|
| First-aid measures after inhalation | : Give oxygen or artificial respiration if necessary. Get immediate medical advice/attention. Remove person to fresh air. |
| First-aid measures after skin contact | : Wash off with soap and plenty of water. May cause an allergic skin reaction. If skin irritation occurs: Get medical advice/attention. |
| First-aid measures after eye contact | : Rinse immediately with plenty of water, also under the eyelids. |
| First-aid measures after ingestion | : May produce an allergic reaction. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention. |

4.2. Symptoms caused by exposure

No additional information available

4.3. Medical attention and special treatment

| | |
|-----------------------------------|--------------------------|
| Other medical advice or treatment | : Treat symptomatically. |
|-----------------------------------|--------------------------|

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

| | |
|--------------------------------|---|
| Suitable extinguishing media | : Use extinguishing media appropriate for surrounding fire. |
| Unsuitable extinguishing media | : No information available. |

5.2. Specific hazards arising from the chemical

| | |
|--|--------------------------------|
| Hazardous decomposition products in case of fire | : Toxic fumes may be released. |
|--|--------------------------------|

5.3. Special protective equipment and precautions for fire-fighters

| | |
|--------------------------------|--|
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |
|--------------------------------|--|

Xpert® HemOnc Proteinase K

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate area. Keep upwind.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Avoid release to the environment.

6.3. Methods and materials for containment and cleaning up

For containment : Prevent further leakage or spillage if safe to do so.
Methods for cleaning up : Take up liquid spill into absorbent material.
Reference to other sections (13) : For further information refer to section 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Ensure good ventilation of the work station.
Hygiene measures : Do not eat, drink or smoke when using this product. Wear suitable gloves and eye/face protection. Take off immediately all contaminated clothing and wash it before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of reach of children.

SECTION 8: Exposure controls and personal protection

8.1. Control parameters - exposure standards

No additional information available

8.2. Monitoring methods

No additional information available

8.3. Engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.

8.4. Individual protection measures, such as personal protective equipment (PPE)

Hand protection : Protective gloves
Eye protection : Safety glasses
Skin and body protection : Wear suitable protective clothing
Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment

Xpert® HemOnc Proteinase K

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

Personal protective equipment symbol(s)



Environmental exposure controls : Avoid release to the environment.

SECTION 9: Physical and chemical properties

| | |
|---|---------------------------------|
| Physical state | : Liquid |
| Appearance | : Clear liquid. |
| Colour | : Colourless |
| Odour | : odourless |
| Odour threshold | : No data available |
| pH | : 7.5 |
| pH solution | : No data available |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point / Freezing point | : Melting point: Not applicable |
| Boiling point | : No data available |
| Flash point | : No data available |
| Auto-ignition temperature | : No data available |
| Flammability | : No data available |
| Vapour pressure | : No data available |
| Relative density | : No data available |
| Density | : No data available |
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Explosive properties | : No data available |
| Explosive limits | : No data available |
| Minimum ignition energy | : No data available |
| Fat solubility | : No data available |

SECTION 10: Stability and reactivity

| | |
|------------------------------------|--|
| Reactivity | : The product is non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | : Stable under normal conditions. |
| Possibility of hazardous reactions | : No dangerous reactions known under normal conditions of use. |
| Conditions to avoid | : None under recommended storage and handling conditions (see section 7). |
| Incompatible materials | : No additional information available |
| Hazardous decomposition products | : Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

SECTION 11: Toxicological information

| | |
|-----------------------------------|--|
| Acute toxicity (oral) | : Not classified |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |
| Skin corrosion/irritation | : Not classified pH: 7.5 |
| Serious eye damage/irritation | : Not classified pH: 7.5 |
| Respiratory or skin sensitisation | : May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Germ cell mutagenicity | : Not classified |

Xpert® HemOnc Proteinase K

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

| | |
|-----------------------|------------------|
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |

| | |
|----------------------------------|-----------------------------------|
| proteinase K (39450-01-6) | |
| STOT-single exposure | May cause respiratory irritation. |

| | |
|------------------------|------------------|
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |

| | |
|----------------------------------|------------------------|
| proteinase K (39450-01-6) | |
| Viscosity, kinematic | Not applicable (solid) |

SECTION 12: Ecological information

12.1. Ecotoxicity

| | |
|---|---|
| Ecology - general | : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. |
| Hazardous to the aquatic environment, short-term (acute) | : Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified |

12.2. Persistence and degradability

| | |
|----------------------------------|---|
| proteinase K (39450-01-6) | |
| Persistence and degradability | Biodegradability in water: no data available. |

12.3. Bioaccumulative potential

| | |
|----------------------------------|------------------------------------|
| proteinase K (39450-01-6) | |
| Bioaccumulative potential | No bioaccumulation data available. |

12.4. Mobility in soil

| | |
|----------------------------------|---|
| proteinase K (39450-01-6) | |
| Ecology - soil | No (test)data on mobility of the substance available. |

12.5. Other adverse effects

| | |
|-----------------------|---------------------------------------|
| Ozone | : Not classified |
| Other adverse effects | : No additional information available |

| | |
|-----------------------------------|-------|
| Xpert® HemOnc Proteinase K | |
| Fluorinated greenhouse gases | False |

| | |
|----------------------------------|-------|
| proteinase K (39450-01-6) | |
| Fluorinated greenhouse gases | False |

SECTION 13: Disposal considerations

| | |
|--|---|
| Waste treatment methods | : Dispose of contents/container in accordance with licensed collector's sorting instructions. |
| Product/Packaging disposal recommendations | : This material and its container must be disposed of as hazardous waste. |

Xpert[®] HemOnc Proteinase K

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

SECTION 14: Transport information

In accordance with ADG / IMDG / IATA

| ADG | IMDG | IATA |
|---|---------------|---------------|
| 14.1. UN number | | |
| Not regulated for transport | | |
| 14.2. UN Proper Shipping Name | | |
| Not regulated | Not regulated | Not regulated |
| 14.3. Transport hazard class(es) | | |
| Not regulated | Not regulated | Not regulated |
| 14.4. Packing group | | |
| Not regulated | Not regulated | Not regulated |
| 14.5. Environmental hazards | | |
| Not regulated | Not regulated | Not regulated |

14.6. Special precautions for user

Specific storage requirement : No data available
Shock sensitivity : No data available

14.7. Additional information

Other information : No supplementary information available

Transport by road and rail

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

14.8. Hazchem or Emergency Action Code

Hazchem Code : Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations specific for the product in question

No additional information available

15.2. International agreements

No additional information available

SECTION 16: Other information

Revision date : 13/12/2023

Xpert® HemOnc Proteinase K

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

| Classification | |
|----------------|------|
| Resp. Sens. 1 | H334 |

| Full text of H-statements | |
|---------------------------|--|
| Resp. Sens. 1 | Respiratory sensitisation, Category 1 |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| STOT SE 3 | Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation |
| H315 | Causes skin irritation |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled |
| H335 | May cause respiratory irritation |

Safety Data Sheet (SDS), Australia

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SECTION 1: Product identifier

1.1. GHS Product identifier

Product form : Mixture
Product name : Xpert[®] HemOnc Wash Reagent

1.2. Other means of identification

No additional information available

1.3. Recommended use of the chemical and restrictions on use

Recommended use : Laboratory use
Restrictions on use : No information available

1.4. Details of manufacturer or importer

Supplier

Cepheid
904 E. Caribbean Drive
Sunnyvale Santa Clara CA 94089
USA
T 1-888-838-3222
techsupport@cepheid.com - www.cepheid.com

Distributor

Cepheid Holdings Pty Ltd
Suite 2, Level 3, Building A
11 Talavera Road
Macquarie Park New South Wales 2113
Australia
T 1800 107 884
TechSupportANZ@cepheid.com - www.cepheidinternational.com

1.5. Emergency phone number

Emergency number : For Chemical Emergency Call INFOTRAC 24hr/day 7days/week
Within USA and Canada: 1-800-535-5053
Outside USA and Canada: 1-352-323-3500
(collect calls accepted)

SECTION 2: Hazard identification

2.1. Classification of the hazardous chemical

Classification according to the model Work Health and Safety Regulations (WHS Regulations)

| | |
|---|------|
| Flammable liquids, Category 3 | H226 |
| Skin corrosion/irritation, Category 1C | H314 |
| Serious eye damage/eye irritation, Category 1 | H318 |

2.2. GHS Label elements, including precautionary statements

Hazard pictograms (GHS AU) :



Flame

Corrosion

Signal word (GHS AU) : Danger
Contains : guanidine thiocyanate (15 – 20 %)
Hazard statements (GHS AU) : H226 - Flammable liquid and vapour
H314 - Causes severe skin burns and eye damage

Xpert[®] HemOnc Wash Reagent

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

Precautionary statements (GHS AU) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 - Do not breathe mist, vapours, spray.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 - Immediately call a POISON CENTER or doctor.
P370+P378 - In case of fire: Use Dry chemical, carbon dioxide (CO₂), Water spray, Alcohol-resistant foam to extinguish.
P403+P235 - Store in a well-ventilated place. Keep cool.

2.3. Other hazards which do not result in classification

No additional information available

SECTION 3: Composition and information on ingredients

| Name | CAS-No. | % | Classification according to the model Work Health and Safety Regulations (WHS Regulations) |
|---|----------|---------|---|
| ethanol | 64-17-5 | 40 – 45 | Flam. Liq. 2, H225 Skin Corr./Irrit. Not classified |
| guanidine thiocyanate | 593-84-0 | 15 – 20 | Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Skin Corr. 1C, H314 Eye Dam. 1, H318 Aquatic Chronic 3, H412 |
| Other substances (not contributing to the classification of this product) | - | 35 – 45 | - |

SECTION 4: First aid measures

4.1. Description of necessary first-aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Give oxygen or artificial respiration if necessary. Get immediate medical advice/attention. Do not apply mouth-to-mouth resuscitation.

First-aid measures after skin contact : Wash off with soap and plenty of water. Remove/Take off immediately all contaminated clothing. Get immediate medical advice/attention.

First-aid measures after eye contact : Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for several minutes. Call a physician immediately.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

4.2. Symptoms caused by exposure

Symptoms/effects : Burning sensation.

4.3. Medical attention and special treatment

Other medical advice or treatment : Treat symptomatically.

Xpert[®] HemOnc Wash Reagent

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media : Dry chemical. Carbon dioxide. Water spray. Alcohol-resistant foam.
Unsuitable extinguishing media : No information available.

5.2. Specific hazards arising from the chemical

Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon oxides (CO, CO₂). Sulfur oxides (SO_x). Nitrogen oxides.

5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Hazchem Code : * 3W

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking. Ensure adequate ventilation. Do not breathe dust/fume/gas/mist/vapours/spray. Evacuate area. Use personal protective equipment as required. See section 8 of the SDS for more information on personal protective equipment. Avoid contact with skin, eyes and clothing. Keep upwind. No flames, no sparks. Eliminate all sources of ignition. Do not touch or walk on the spilled product. Take precautionary measures against static discharge. All equipment used when handling the product must be grounded. Corrosive materials.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. Prevent further leakage or spillage if safe to do so. Do not allow to enter drains or water courses. Prevent soil and water pollution. Avoid release to the environment.

6.3. Methods and materials for containment and cleaning up

For containment : Stop leak without risks if possible. Do not touch or walk on the spilled product. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Absorb spilled material with sand or earth.
Methods for cleaning up : Take precautionary measures against static discharges. Soak up with inert absorbent material (for example sand, sawdust, a universal binder, silica gel). Notify authorities if product enters sewers or public waters.
Reference to other sections (13) : For further information refer to section 8. For further information refer to section 13.

Xpert® HemOnc Wash Reagent

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Avoid contact with skin, eyes and clothing. Do not breathe vapours, mist. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse.
- Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Wear suitable gloves and eye/face protection. Contaminated work clothing should not be allowed out of the workplace.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store tightly closed in a dry, cool and well-ventilated place. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Store in accordance with local, regional, national or international regulations. Protect from moisture. Store locked up. Keep out of reach of children. Store away from other materials.

SECTION 8: Exposure controls and personal protection

8.1. Control parameters - exposure standards

| ethanol (64-17-5) | |
|--|---|
| Australia - Occupational Exposure Limits | |
| Local name | Ethyl alcohol (Ethanol) |
| OES TWA [1] | 1880 mg/m ³ |
| OES TWA [2] | 1000 ppm |
| Regulatory reference | Workplace exposure standards for airborne contaminants (2022) |

8.2. Monitoring methods

No additional information available

8.3. Engineering controls

- Appropriate engineering controls : Ensure good ventilation of the work station.

8.4. Individual protection measures, such as personal protective equipment (PPE)

- Hand protection : Protective gloves
- Eye protection : Safety glasses
- Skin and body protection : Wear suitable protective clothing
- Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s)



- Environmental exposure controls : Avoid release to the environment.

Xpert[®] HemOnc Wash Reagent

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

SECTION 9: Physical and chemical properties

| | |
|---|-----------------------|
| Physical state | : Liquid |
| Appearance | : Clear liquid. |
| Colour | : Colourless |
| Odour | : odourless |
| Odour threshold | : No data available |
| pH | : No data available |
| pH solution | : No data available |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point / Freezing point | : Melting point: 0 °C |
| Boiling point | : 66.2 °C |
| Flash point | : 29 – < 40 °C |
| Auto-ignition temperature | : No data available |
| Flammability | : No data available |
| Vapour pressure | : No data available |
| Relative density | : No data available |
| Density | : No data available |
| Solubility | : No data available |
| Partition coefficient n-octanol/water (Log Pow) | : No data available |
| Explosive properties | : No data available |
| Explosive limits | : No data available |
| Minimum ignition energy | : No data available |
| Fat solubility | : No data available |

SECTION 10: Stability and reactivity

| | |
|------------------------------------|--|
| Reactivity | : The product is non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | : Stable under normal conditions. |
| Possibility of hazardous reactions | : No dangerous reactions known under normal conditions of use. |
| Conditions to avoid | : None under recommended storage and handling conditions (see section 7). |
| Incompatible materials | : No additional information available |
| Hazardous decomposition products | : Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

SECTION 11: Toxicological information

| | |
|-----------------------------|------------------|
| Acute toxicity (oral) | : Not classified |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |

| guanidine thiocyanate (593-84-0) | |
|---|---|
| LD50 oral rat | 593 mg/kg bodyweight (OECD 401: Acute Oral Toxicity, Rat, Female, Experimental value, Oral, 14 day(s)) |
| LD50 dermal rabbit | > 2000 mg/kg bodyweight (24 h, Rabbit, Male / female, Experimental value, Skin, 14 day(s)) |
| LC50 Inhalation - Rat | > 0.853 mg/l air (Equivalent or similar to OECD 403, 4 h, Rat, Male / female, Experimental value, Inhalation (dust), 14 day(s)) |
| ethanol (64-17-5) | |
| LD50 oral rat | 10470 mg/kg bodyweight (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s)) |

Xpert® HemOnc Wash Reagent

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

| ethanol (64-17-5) | |
|---------------------------------|--|
| LD50 oral | 6200 mg/kg |
| LD50 dermal rabbit | > 15800 mg/kg bodyweight (Rabbit, Experimental value, Dermal) |
| LD50 dermal | 20000 mg/kg |
| LC50 Inhalation - Rat | 124.7 mg/l air (Equivalent or similar to OECD 403, 4 h, Rat, Male / female, Experimental value, Inhalation (vapours), 14 day(s)) |
| LC50 Inhalation - Rat (Vapours) | 116.9 mg/l Source: ECHA |

| | |
|-----------------------------------|------------------------------|
| Skin corrosion/irritation | : Causes severe skin burns. |
| Serious eye damage/irritation | : Causes serious eye damage. |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |

| ethanol (64-17-5) | |
|--|--|
| NOAEL (subchronic, oral, animal/male, 90 days) | < 9700 mg/kg bodyweight Animal: mouse, Animal sex: male, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents) |
| NOAEL (subchronic, oral, animal/female, 90 days) | > 9400 mg/kg bodyweight Animal: mouse, Animal sex: female, Guideline: EPA OPPTS 870.3100 (90-Day Oral Toxicity in Rodents) |

Aspiration hazard : Not classified

| guanidine thiocyanate (593-84-0) | |
|----------------------------------|-------------------------------------|
| Viscosity, kinematic | No data available in the literature |

| ethanol (64-17-5) | |
|----------------------|--------------------------------|
| Viscosity, kinematic | 1.6 mm ² /s (20 °C) |

SECTION 12: Ecological information

12.1. Ecotoxicity

| | |
|---|---|
| Ecology - general | : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment. |
| Hazardous to the aquatic environment, short-term (acute) | : Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified |

| guanidine thiocyanate (593-84-0) | |
|----------------------------------|--|
| LC50 - Fish [1] | 89.1 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Poecilia reticulata, Static system, Fresh water, Experimental value) |
| EC50 - Crustacea [1] | 42.4 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, Locomotor effect) |
| ErC50 algae | 130 mg/l (DIN 38412: German standard methods for the examination of water, waste water and sludge, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Experimental value, Growth rate) |

Xpert® HemOnc Wash Reagent

Safety Data Sheet

according to the Work Health and Safety (WHS) Regulations

| guanidine thiocyanate (593-84-0) | |
|--|--|
| Partition coefficient n-octanol/water (Log Pow) | -1.11 (Estimated value, EU Method A.8: Partition Coefficient, 25 °C) |
| ethanol (64-17-5) | |
| LC50 - Fish [1] | 15300 mg/l (US EPA, 96 h, Pimephales promelas, Flow-through system, Fresh water, Experimental value, Lethal) |
| EC50 - Crustacea [1] | 5463 mg/l |
| ErC50 algae | 275 mg/l Source: ECHA |
| NOEC (chronic) | 9.6 mg/l Test organisms (species): Daphnia magna Duration: '9 d' |
| NOEC chronic crustacea | 9.6 mg/l |
| Partition coefficient n-octanol/water (Log Pow) | -0.35 (Experimental value, Equivalent or similar to OECD 107, 24 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 0.2 (log Koc, Experimental value) |

12.2. Persistence and degradability

| guanidine thiocyanate (593-84-0) | |
|----------------------------------|--|
| Not rapidly degradable | |
| Persistence and degradability | Inherently biodegradable. |
| ethanol (64-17-5) | |
| Persistence and degradability | Biodegradable in the soil. Readily biodegradable in water. |
| Biochemical oxygen demand (BOD) | 0.8 – 0.967 g O ₂ /g substance |
| Chemical oxygen demand (COD) | 1.7 g O ₂ /g substance |
| ThOD | 2.1 g O ₂ /g substance |

12.3. Bioaccumulative potential

| guanidine thiocyanate (593-84-0) | |
|--|--|
| Partition coefficient n-octanol/water (Log Pow) | -1.11 (Estimated value, EU Method A.8: Partition Coefficient, 25 °C) |
| Bioaccumulative potential | Not bioaccumulative. |
| ethanol (64-17-5) | |
| Partition coefficient n-octanol/water (Log Pow) | -0.35 (Experimental value, Equivalent or similar to OECD 107, 24 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 0.2 (log Koc, Experimental value) |
| Bioaccumulative potential | Not bioaccumulative. |

12.4. Mobility in soil

| guanidine thiocyanate (593-84-0) | |
|---|--|
| Ecology - soil | No (test) data on mobility of the substance available. |
| Partition coefficient n-octanol/water (Log Pow) | -1.11 (Estimated value, EU Method A.8: Partition Coefficient, 25 °C) |

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| ethanol (64-17-5) | |
|--|--|
| Surface tension | 22.31 mN/m (20 °C, 100 %) |
| Ecology - soil | Highly mobile in soil. |
| Partition coefficient n-octanol/water (Log Pow) | -0.35 (Experimental value, Equivalent or similar to OECD 107, 24 °C) |
| Organic Carbon Normalized Adsorption Coefficient (Log Koc) | 0.2 (log Koc, Experimental value) |

12.5. Other adverse effects

Ozone : Not classified
Other adverse effects : No additional information available

| Xpert® HemOnc Wash Reagent | |
|----------------------------------|-------|
| Fluorinated greenhouse gases | False |
| guanidine thiocyanate (593-84-0) | |
| Fluorinated greenhouse gases | False |
| ethanol (64-17-5) | |
| Fluorinated greenhouse gases | False |

SECTION 13: Disposal considerations

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADG / IMDG / IATA

| ADG | IMDG | IATA |
|---|--|--|
| 14.1. UN number | | |
| 2924 | 2924 | 2924 |
| 14.2. UN Proper Shipping Name | | |
| FLAMMABLE LIQUID, CORROSIVE, N.O.S. (guanidine thiocyanate ; ethanol, aqueous solutions, 23°C≤F.P.<60°C) | FLAMMABLE LIQUID, CORROSIVE, N.O.S. (guanidine thiocyanate ; ethanol, aqueous solutions, 23°C≤F.P.<60°C) | Flammable liquid, corrosive, n.o.s. (guanidine thiocyanate ; ethanol, aqueous solutions, 23°C≤F.P.<60°C) |
| Transport document description | | |
| Not applicable | UN 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (guanidine thiocyanate ; ethanol, aqueous solutions, 23°C≤F.P.<60°C), 3 (8), III | UN 2924 Flammable liquid, corrosive, n.o.s. (guanidine thiocyanate ; ethanol, aqueous solutions, 23°C≤F.P.<60°C), 3 (8), III |
| 14.3. Transport hazard class(es) | | |
| 3 (8) | 3 (8) | 3 (8) |
| | | |

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| ADG | IMDG | IATA |
|--|---|-----------------------------------|
| 14.4. Packing group | | |
| III - Substances presenting low danger | III | III |
| 14.5. Environmental hazards | | |
| Dangerous for the environment: No | Dangerous for the environment: No Marine pollutant: No | Dangerous for the environment: No |

14.6. Special precautions for user

Specific storage requirement : No data available
Shock sensitivity : No data available

14.7. Additional information

Other information : No supplementary information available

Transport by road and rail

UN-No. (ADG) : 2924
Special provision (ADG) : 223, 274
Limited quantities (ADG) : 5I
Excepted quantities (ADG) : E1
Packing instructions (ADG) : P001, IBC03
Portable tank and bulk container instructions (ADG) : T7
Portable tank and bulk container special provisions (ADG) : TP1, TP28

Transport by sea

UN-No. (IMDG) : 2924
Special provisions (IMDG) : 223, 274
Limited quantities (IMDG) : 5 L
Excepted quantities (IMDG) : E1
Packing instructions (IMDG) : P001
IBC packing instructions (IMDG) : IBC03
Tank instructions (IMDG) : T7
Tank special provisions (IMDG) : TP1, TP28
EmS-No. (Fire) : F-E - FIRE SCHEDULE Echo - NON-WATER-REACTIVE FLAMMABLE LIQUIDS
EmS-No. (Spillage) : S-C - SPILLAGE SCHEDULE Charlie - FLAMMABLE CORROSIVE LIQUIDS
Stowage category (IMDG) : A
Stowage and handling (IMDG) : SW2
Properties and observations (IMDG) : Causes burns to skin, eyes and mucous membranes.

Air transport

UN-No. (IATA) : 2924
PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y342
PCA limited quantity max net quantity (IATA) : 1L
PCA packing instructions (IATA) : 354
PCA max net quantity (IATA) : 5L
CAO packing instructions (IATA) : 365
CAO max net quantity (IATA) : 60L
Special provisions (IATA) : A3, A803
ERG code (IATA) : 3C

14.8. Hazchem or Emergency Action Code

Hazchem Code : * 3W

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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations specific for the product in question

No additional information available

15.2. International agreements

No additional information available

SECTION 16: Other information

| Classification | |
|----------------|------|
| Flam. Liq. 3 | H226 |
| Skin Corr. 1C | H314 |
| Eye Dam. 1 | H318 |

| Full text of H-statements | |
|----------------------------------|---|
| Acute Tox. 4 (Dermal) | Acute toxicity (dermal), Category 4 |
| Acute Tox. 4 (Inhalation) | Acute toxicity (inhal.), Category 4 |
| Acute Tox. 4 (Oral) | Acute toxicity (oral), Category 4 |
| Aquatic Chronic 3 | Hazardous to the aquatic environment – Chronic Hazard, Category 3 |
| Eye Dam. 1 | Serious eye damage/eye irritation, Category 1 |
| Flam. Liq. 2 | Flammable liquids, Category 2 |
| Flam. Liq. 3 | Flammable liquids, Category 3 |
| Skin Corr. 1C | Skin corrosion/irritation, Category 1C |
| Skin Corr./Irrit. Not classified | Skin corrosion/irritation Not classified |
| H225 | Highly flammable liquid and vapour |
| H226 | Flammable liquid and vapour |
| H302 | Harmful if swallowed |
| H312 | Harmful in contact with skin |
| H314 | Causes severe skin burns and eye damage |
| H318 | Causes serious eye damage |
| H332 | Harmful if inhaled |
| H412 | Harmful to aquatic life with long lasting effects |

Safety Data Sheet (SDS), Australia

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.