



Abbott

Release Date: 7/17/24

REF	
GTIN	Product Name

03H80-02 00380740005160	<i>CELL-DYN Ruby CN-FREE HGB / NOC LYSE</i>
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Components:

03H80	CELL-DYN Ruby CN-FREE HGB / NOC LYSE
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Abbott Customers:

For additional information, please contact your Abbott Customer Support Center Representative by calling 1-800-527-1869, 1-800-323-9100, or 1-800-235-5396.

Abbott employees:

For additional information relative to the content of the SDSs, please contact your local Safety Representative.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Last alteration on 07/17/2024


1 Identification

- **Product name:** CELL-DYN Ruby CN-FREE HGB / NOC LYSE
- **ADD List number:** 03H80
- **Application of the substance / mixture:** For In Vitro Diagnostic Use
- **Manufacturer / Supplier:**
Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT
- **Department issuing SDS:** Abbott Diagnostics Environmental Health and Safety
- **Emergency telephone number**
Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.
Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

2 Hazard(s) identification

- **Classification of the substance or mixture**
The classification was made according to U.S. OSHA 29 CFR 1910.1200 and 1910.1030 and applicable European regulations, and is expanded upon from supplier company and/or literature data.

Eye Damage 1	H318 Causes serious eye damage.
Sensitization - Skin 1	H317 May cause an allergic skin reaction.
Carcinogenicity 1A	H350 May cause cancer.
Specific Target Organ Toxicity - Repeated Exposure 2	H373 May cause damage to organs through prolonged or repeated exposure.
Aquatic Acute 1	H400 Very toxic to aquatic life.
Aquatic Chronic 2	H411 Toxic to aquatic life with long lasting effects.
- **Additional information:** Testing has been done to determine the hazards of this material.
- **Label elements**
- **GHS label elements:** The product is labelled according to the Globally Harmonized System (GHS).
- **Hazard pictograms:**

- **Signal word:** Danger
- **Hazard-determining components of labeling:**
Dodecyltrimethyl ammonium chloride (quaternary ammonium salt)
Hydroxylamine hydrochloride



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Product name: CELL-DYN Ruby CN-FREE HGB / NOC LYSE

· Hazard statements:

- H318 Causes serious eye damage.
- H317 May cause an allergic skin reaction.
- H350 May cause cancer.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H400 Very toxic to aquatic life.
- H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements:

- P201 Obtain special instructions before use.
- P260 Do not breathe mist / vapors / spray.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- 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/physician.
- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P501 Dispose of contents / container in accordance with local regulations.

· Routes of Exposure:

- Skin
- Eye

· Health:

- May cause irreversible eye damage.
- Sensitizer in contact with skin
- Contains a suspect carcinogen.

· Fire: Noncombustible

· Reactivity: Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.

· IARC (International Agency for Research on Cancer) Group 3

· Interpretation of the IARC listing

Group 3: The substance or mixture listed above is not classifiable as to carcinogenicity in humans. Evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals.

3 Composition/information on ingredients

· Chemical characterization: Mixture of chemical and/or biological substances for in vitro diagnostic use.

· Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):

Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):		
CAS: 8001-54-5	Benzalkonium chloride	3.62%
CAS: 112-00-5	Dodecyltrimethyl ammonium chloride (quaternary ammonium salt)	3.57%
CAS: 67-63-0	Isopropanol	2.86%
CAS: 5470-11-1	Hydroxylamine hydrochloride	1.70%



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4 First-aid measures

- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:** Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.
- **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.
- **After eye contact:**
Symptoms (such as pain) may be delayed and lead to underestimating the possible damage. Provide medical observation for at least 48 hours after exposure.
- **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
- **Most important symptoms and effects, both acute and delayed:**
Headache
Disorientation
Allergic reactions
Irreversible eye damage
Possibly immune response
This product may cause skin sensitization reactions in some people. See Section 11 for additional information.
Dizziness
- **Medical conditions aggravated by exposure:**
Pre-existing respiratory ailments
Pre-existing eye ailments
Pre-existing skin ailments
Skin allergies
Pre-existing nervous system ailments

5 Fire-fighting measures

- **Suitable extinguishing agents**
Dry chemical, carbon dioxide (CO₂), water spray or regular foam.
 - Caution: CO₂ will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
 - For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.
- **Special hazards arising from the substance or mixture**
There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.
No further relevant information available.
- **Protective equipment**
For large fires, wear appropriate heat- and flame-resistant personal protective equipment and a NFPA/NIOSH approved positive-pressure, self-contained breathing apparatus.



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6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

Environmental precautions

Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

Methods and material for containment and cleaning up

Blot up small volumes of spilled or spattered product with paper towels or similar materials.

- Contain larger spills by placing absorbents around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

Precautions for safe handling:

Provide local exhaust ventilation if dust or vapor is formed.

Avoid contact with skin.

Avoid contact with eyes.

Avoid inhalation.

· **Information about protection against explosions and fires:** The product is not flammable.

· **Requirements to be met by storerooms and receptacles:** Store only in the original container.

· **Information about storage in one common storage facility:** Store in original packaging.

· **Further information about storage conditions:**

Refer to the package insert or product label for additional information on storage conditions for product quality.

8 Exposure controls/personal protection

Components with Occupational Exposure Limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

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Product name: CELL-DYN Ruby CN-FREE HGB / NOC LYSE

CAS: 67-63-0 Isopropanol (2.86 %)

PEL	TWA: 980 mg/m ³ , 400 ppm
REL	STEL/C: 1225 mg/m ³ , 500 ppm TWA: 980 mg/m ³ , 400 ppm
TLV	STEL/C: 400 ppm TWA: 200 ppm BEI, A4

CAS: 64-17-5 Ethanol (0.39 %)

PEL	TWA: 1900 mg/m ³ , 1000 ppm
REL	TWA: 1900 mg/m ³ , 1000 ppm
TLV	STEL/C: 1000 ppm A3

Ingredients with biological limit values:

CAS: 67-63-0 Isopropanol (2.86 %)

BEI	40 mg/L Medium: urine Time: end of shift at end of workweek Parameter: Acetone (background, nonspecific)
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General protective and hygienic measures:

Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the workshift.

- Avoid contact with the skin.
- Avoid contact with the eyes.
- Immediately remove all soiled and contaminated clothing.

Breathing equipment:

Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use appropriate NIOSH-approved air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use NIOSH/NFPA-approved respiratory protection.

Hand protection:

Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Material of gloves and breakthrough time of the glove material:

The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.



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Product name: CELL-DYN Ruby CN-FREE HGB / NOC LYSE

· **Eye protection:**

Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· **Body protection:**

Normal use: protect personal clothing from spatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution).

Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

9 Physical and chemical properties

· **General Information**

- **Color:** Colorless
- **Odor:** Odorless
- **Melting point/Melting range:** Not determined
- **Boiling point/Boiling range:** Not determined
- **Flammability (solid, gaseous)** Not applicable
- **Explosion limits**
- **Lower:** Not determined
- **Upper:** Not determined
- **Flash point** Not applicable
- **pH-value at 20 °C (68 °F)** 3.9
- **Dynamic:** Not determined
- **Solubility in / Miscibility with**
- **Water:** Fully miscible
- **Vapor pressure:**
- **Density at 20 °C (68 °F)** 0.9876 g/cm³ (8.2415 lbs/gal)
- **Form:** Liquid
- **Auto igniting** Product is not self-igniting.
- **Danger of explosion** Product does not present an explosion hazard.
- **Water:** 87.9 %
- **Solids content:** 0.0 %
- **Evaporation rate:** Not determined

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided**
No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.



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Product name: CELL-DYN Ruby CN-FREE HGB / NOC LYSE

Hazardous decomposition products: Hydrogen chloride (HCl)

11 Toxicological information

- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD50/LC50 values for hazardous ingredients per OSHA criteria:**

Ingredients (100% pure substance/s):

CAS: 8001-54-5 Benzalkonium chloride

Oral	LD50	300 mg/kg (rat) From EPA RED for ADBAC. EPA Guideline 870.1100, combined male/female LD50
Dermal	LD50	930 mg/kg (rat) From EPA RED for ADBAC. EPA Guideline 870.1200, combined male/female LD50
Inhalation	LC50 4 h	0.054 mg/l (rat) From EPA RED for ADBAC. EPA Guideline 870.1300, LC50 limit test 0.054-0.51 mg/L
Irritation of skin	Reported Effect	(rabbit) From EPA RED for ADBAC. EPA Guideline 870.2500, Primary dermal irritation results indicate substance is corrosive.
Irritation of eyes	Reported Effect	(rabbit) Substance is know corrosive mateiral to skin and probably eye corrosive. Confirmed by multiple primary eye irriation studies summarized in the Journal of Toxicology Cosmetic Ingredient Review for benzalkonium chloride (1989).
Sensitization	Reported Effect	(guinea pig) EPA RED for ADBAC (Aug 2006); Non-sensitizing in EPA 870.2600 guideline study, substance is not indicated as a sensitizer.
	EC50 48h	0.0059 mg/L (daphnia)
	EC50 72h	0.085 mg/L (algae)
	Mutagenicity	(rat) Journal of Americal College of Toxicology Final Report on the Safety Assessment of Benzalkonium Chloride (CIR) - substance is concluded to be non-mutagenic and non-genotoxic in multiple cell line assays.
	Carcinogenicity	(rat) Journal of Americal College of Toxicology Final Report on the Safety Assessment of Benzalkonium Chloride (CIR) - substance is concluded to be non-carcinogenic based on multiple animal studies.

CAS: 112-00-5 Dodecyltrimethyl ammonium chloride (quaternary ammonium salt)

Oral	LD50	536 mg/kg (mouse) by analogy with stearyltrimethylammonium chloride.
Dermal	LD50	1,600 mg/kg (mouse) by analogy with stearyltrimethylammonium chloride.



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Product name: CELL-DYN Ruby CN-FREE HGB / NOC LYSE

CAS: 67-63-0 Isopropanol

Oral	LD50	3,600-6,410 mg/kg (mammal) In rats, mice, dogs and rabbits 5,840 mg/kg (rat)
Dermal	LD50	12,800 mg/kg (rabbit)
Inhalation	LC50 4 h	27.2 mg/l (mouse) 72.6 mg/l (rat)
	LC50 2 h	53 mg/l (mouse)
	LC50 7 h	12,800-16,000 ppm (mammal) Vapor concentrations greater than 400 ppm causes eye nose and throat irritation upon exposure for 3 to 5 minutes.
Irritation of skin	LC50 7 h	29-55 mg/l (rat)
Irritation of eyes	Reported Effect	(rabbit)
	Reported Effect	(rabbit)
	Target Organ Effects	(rat) Induced central nervous system effects (i.e. drowsiness) at high concentrations in rats. Repeated exposure at high concentrations (at about 2.5% or greater in drinking water) induced a variety of reproductive, fertility and developmental effects in rats.

CAS: 5470-11-1 Hydroxylamine hydrochloride

Oral	LD50	200 mg/kg (mammal) Based on toxicology testing of hydroxylammonium sulfate. Species = cat Repeated vomiting, increased salivation, apathia, cyanosis. 2/6 cats died 2 days after application. BASF study Cited in ECBI/14/03 408 mg/kg (mouse) 141 mg/kg (rat) Angus (1982) values cited in ECBI/14/03: Oral LD50 = 545 mg/kg. At 250 mg/kg: temporary cyanosis At 500 mg/kg: marked cyanosis, convulsions; 2/5 rats died.
Dermal	LD50	100-500 mg/kg (rabbit) Cited in ECBI/14/03. Based on toxicology testing of hydroxylammonium sulfate. Occlusive. At 100 mg/kg: 2/10 rabbits died; 18.7% MetHb At 500 mg/kg: 9/10 rabbits died; 60.8% MetHb

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Product name: CELL-DYN Ruby CN-FREE HGB / NOC LYSE

	LD50	<p>>500 mg/kg (rat) Cited in ECBI/14/03. Based on toxicology testing of hydroxylammonium sulfate. No mortality; no cyanosis. Increase in methemoglobin (4%) at 500 mg/kg.</p>
	Mutagenicity	<p>1,500-2,000 gm/kg (mammal) Cited in ECBI/14/03. Based on toxicology testing of hydroxylammonium sulfate. Semi-occlusive. < or = 1500: all 10 animals survived. 2000: 7/10 died.</p> <p>>1 gm/kg (rabbit) Cited in ECBI/14/03. Based on toxicology testing of hydroxylammonium sulfate. Semi-occlusive. < or = 1000 mg/kg: 0/10 animals died (no mortality) 1000: 6.2% MetHb; in 3 animals Heinz bodies 4d postexposure. (Ames Assay) Positive in E. coli and S. cerevisiae mutagenicity assays. (mammalian cells) Positive in cell transformation assay. Negative in cultured human fibroblast unscheduled DNA synthesis assay and the sister chromatid assay.</p>
	Carcinogenicity	<p>3 (rat) Cited in ECBI/14/03. Based on toxicology testing of hydroxylammonium sulfate. Increased evidence of tumors of the spleen in male and female Wistar rats, after administration by oral route.</p>

- **Eye irritation:** Causes serious eye damage.
- **Sensitization:**
Sensitization possible through skin contact.
May cause an allergic skin reaction.
- **Carcinogenicity** May cause cancer.
- **Specific target organ toxicity - repeated exposure**
May cause damage to organs through prolonged or repeated exposure.
- **Aspiration hazard**
- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)		
CAS: 67-63-0	Isopropanol	3
CAS: 64-17-5	Ethanol	1

· NTP (National Toxicology Program)
None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients is listed.



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Product name: CELL-DYN Ruby CN-FREE HGB / NOC LYSE

· **Target organs/systems:**

- Eye
- Nervous system
- Skin
- Immune system

12 Ecological information

· **Aquatic toxicity:**

CAS: 8001-54-5 Benzalkonium chloride

LC50 96 h	0.28 mg/l (minnow)
	Chronic 34 day NOAEC = 0.032 (Chronic Cat 2)

CAS: 67-63-0 Isopropanol

LC50 96 h	6.12 mg/l (minnow)
	31-da-old Pimephales promelas (fathead minnows); water hardness 44.0 mg/l (CaCO3), temperature 24.6 deg C, pH 7.87, dissolved oxygen 6.7 mg/l, alkalinity 39.5 mg/l (CaCO3).

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable
- **vPvB:** Not applicable

· **Additional ecological information**

· **General notes:**

Do not allow product to reach ground water, water course or sewage system, even in small quantities.
 Very toxic for aquatic organisms
 Toxic for aquatic organisms

13 Disposal considerations

- **Recommendation for disposal of unused product:** Dispose in accordance with federal, state and local regulations.
- **Recommendation for disposal of packaging:**
 Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.
 For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.
- **Recommended cleansing agent:** Water with cleansing agents, if necessary.

14 Transport information

- | | |
|---------------------|--------|
| · DOT | none |
| · IMDG, IATA | UN3082 |

· **UN proper shipping name**

- | | |
|--------------|------|
| · DOT | none |
|--------------|------|



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Product name: CELL-DYN Ruby CN-FREE HGB / NOC LYSE

- **ADR, IATA** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dodecyltrimethyl ammonium chloride (quaternary ammonium salt))
- **IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dodecyltrimethyl ammonium chloride (quaternary ammonium salt)), MARINE POLLUTANT

Transport hazard class(es)

- **DOT**
- **Class** none
- **Class** 9 Miscellaneous dangerous substances and articles
- **IMDG, IATA**



- **Class** 9 Miscellaneous dangerous substances and articles
- **Label** 9
- **DOT** none
- **IMDG, IATA** III

Environmental hazards

- **Marine pollutant:** Symbol (fish and tree)
- **Special marking (IATA):** Symbol (fish and tree)
- **EMS Number:** F-A,S-F
- **Stowage Category** A

· **Additional information** Packages smaller than or equal to 5 kg / 5L; not dangerous goods of Class 9.

- **DOT**
- **Remarks:** Not restricted for transportation.
- **IMDG**
- **Remarks:** Not restricted for transportation.
- **IATA**
- **Remarks:** Not restricted for transportation.

15 Regulatory information

· SARA (Superfund Amendments and Reauthorization Act of 1986 - USA):

· Section 302/304 (40CFR355.30 / 40CFR355.40):

The product does not contain listed substances.

· Section 313 (40CFR372.65):

CAS: 67-63-0 | Isopropanol

· Hazardous Air Pollutants

None of the ingredients is listed.

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Product name: CELL-DYN Ruby CN-FREE HGB / NOC LYSE

· California Proposition 65 (USA):

· Chemicals known to cause cancer:

The product does not contain listed substances.

· Chemicals known to cause female reproductive toxicity:

None of the ingredients is listed.

· Chemicals known to cause male reproductive toxicity:

None of the ingredients is listed.

· Chemicals known to cause developmental reproductive toxicity:

None of the ingredients is listed.

16 Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

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The information in this Safety Data Sheet (SDS) reflects the most current hazard information for this product.

· Department issuing SDS

- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

· Contact

- General information about this product:

Abbott Diagnostics
Technical Support
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· Date of preparation / last revision 07/17/2024 / 10

· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association



Abbott

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EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
BEI: Biological Exposure Limit
Eye Damage 1: Serious eye damage/eye irritation – Category 1
Sensitization - Skin 1: Skin sensitisation – Category 1
Carcinogenicity 1A: Carcinogenicity – Category 1A
Specific Target Organ Toxicity - Repeated Exposure 2: Specific target organ toxicity (repeated exposure) – Category 2
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

· * Sections marked with an asterisk (*) have been altered since the previous version.