

## Section 1 Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

**Product name** System Calibrator

**Part number** 66300, 66300X

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

**Product use** For In Vitro Diagnostic Use. See product literature for details.

### 1.3 Details of the supplier of the safety data sheet

#### Manufacturer

Beckman Coulter Ireland Inc.  
Lismeehan  
O'Callaghan's Mills  
Co. Clare  
Ireland  
Tel: 353 (0)65 6831100

#### Supplier

Beckman Coulter, Inc.  
250 S. Kraemer Blvd  
Brea, CA 92821, U.S.A.  
Tel: 800-854-3633

CANADA  
Beckman Coulter Canada LP  
7075 Financial Drive  
Mississauga, ON L5N 6V8  
Canada  
1-800-463-7828

UNITED KINGDOM  
Beckman Coulter (UK) Ltd.  
Amersham Place  
Little Chalfont  
Buckinghamshire  
United Kingdom, HP7 9NA  
01494 441181

AUSTRALIA  
Beckman Coulter Australia Pty Ltd  
23-27 Chaplin Drive  
Lane Cove NSW 2066  
Australia  
ABN 81 002 011 672  
24 Hour emergency contact phone  
number:  
1800 060 881

NEW ZEALAND  
Beckman Coulter NZ  
Unit J, 33 Walmsley Road, Otahuhu,  
Auckland 1062, New Zealand  
Hours available: 08:30 - 17:00

SWITZERLAND  
Beckman Coulter Eurocenter SA  
22, rue Juste-Olivier, Case Postale  
1044,  
CH-1260 Nyon 1, Switzerland.  
Telephone: +41 (0)22 365 36 11  
Monday through Friday, 9:00 am to  
7:00pm)

ICELAND / ÍSLAND  
Beckman Coulter AB  
Ekbacksvägen 28  
168 69 Bromma  
Sweden  
Phone No.: +46 80564 85 900  
Hours available: 08.00-16.30

MALTA  
DX Distributor:  
Cherubino Ltd  
DELFI Building, Sliema Road, Gzira,  
GZR 1637  
Telephone: +356 21343270  
Hours available: 08:30 – 17:00

## Section 1 Identification of the substance/mixture and of the company/undertaking (Continued)

**e-mail address** SDSNT@beckman.com  
Further information Contact:  
Customer support Unit, Beckman Coulter Ireland Inc.  
Technical Service Department Tel. +001-800-854-3633 (PST)  
E-mail: Techsupportuk@beckman.com

### 1.4 Emergency telephone number

**Telephone number (24H)** Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001) 703-527-3887  
Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri (GMT) Tel +001-800-223-0130 (PST)

#### Distributor and emergency phone no.

Refer to attached list, Document ID: [472050](#), for local distributor and emergency phone numbers.

UNITED STATES - Emergency Phone (24h): Chemtrec (800) 424-9300, International (001) 703-527-3887

CANADA - Poison Centre: 1-844-764-7669; Centre antipoison du Québec: 1-800-463-5060

UNITED KINGDOM - For UK and Scotland: Emergency Call 999

IRELAND - National Poisons Information Centre Phone No.: Members of Public: +353 (01) 809 2166 (8:00 am to 10:00 pm 7 days a week); Healthcare Professionals: +353 (01) 809 2566 (24 hour service)

AUSTRALIA - 24 Hour emergency contact phone number: 1800 060 881

NEW ZEALAND - 24 Hour emergency number: 0800 446 109

## Section 2 Hazards identification

### 2.1 Classification of the substance or mixture

**Product description** In vitro diagnostic reagent.  
Yellow-brown; Lyophilized Powder; Characteristic odor

#### Classification according to EC 1272/2008 (CLP/GHS)

Not classified as hazardous per EC 1272/2008 (CLP/GHS)

#### Classification according to US-OSHA (HCS 29 CFR 1910.1200) and UN GHS

Skin Irritation Category 3

### 2.2 Label elements

#### According to EC 1272/2008 (CLP/GHS), US-OSHA and UN GHS

##### Hazardous ingredients

L-Lactic Acid

##### Pictogram

None

##### Signal word

WARNING

# SAFETY DATA SHEET

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Revision Date (year/month/day) 2025/10/09  
Last Revision Date (year/month/day) 2025/01/08

## Section 2 Hazards identification (Continued)

### Hazard statements

H316 Causes mild skin irritation.

### Precautionary statements

#### Prevention

None

#### Response

P332+P313 If skin irritation occurs: Get medical advice/attention.

#### Storage

None

#### Disposal

None

### 2.3 Other hazards

This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

## Section 3 Composition and information on ingredients

### 3.2 Mixtures

Hazardous ingredients:		Hazard classification of pure ingredients		
Chemical name	% by wt.	EU 1272/2008 CLP/GHS	GHS	Note
L-Lactic Acid CAS # 79-33-4 EINECS # 201-196-2 Index # Not available	0.1 - < 1	Eye Dam. 1, H318 Skin Corr. 1C, H314 EUH071	Eye Dam. 1, H318 Skin Corr. 1C, H314	REST

REST - Subject to Restriction as per Annex XVII of REACH Regulation (EC) No 1907/2006

See section 8 for available Occupational exposure limits

See Section 15 for additional regulatory information

See Section 16 for description of hazard class and hazard statements

## Section 4 First aid measures

### 4.1 Description of first aid measures

#### Inhalation

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration by trained personnel and obtain medical attention immediately.

#### Eye contact

If product enters eyes, rinse eyes gently with water as a precaution.

#### Skin contact

In case of skin contact, rinse with plenty of water. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical advice/attention.

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### Section 4 First aid measures (Continued)

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- Ingestion** If product is ingested, rinse mouth with water. If irritation or discomfort occurs, obtain medical attention immediately.
- 4.2 Most important symptoms and effects, both acute and delayed**  
May cause mild skin irritation.  
See Section 11 Toxicological Information for more detailed health information.
- 4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available. Refer to Section 4.1.

### Section 5 Firefighting measures

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- 5.1 Extinguishing media** In case of fire use carbon dioxide (CO<sub>2</sub>), dry chemical, water spray or foam.  
For large fires use extinguishing media suitable for surrounding fire.
- 5.2 Special hazards arising from the substance or mixture**  
**Special fire and explosion hazards**  
No special hazards determined.
- Hazardous combustion products**  
No combustion products posing significant hazards are expected from this product.
- 5.3 Advice for firefighters**  
**Protective equipment** Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.
- Additional information** No further relevant information available.

### Section 6 Accidental release measures

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- 6.1 Personal precautions, protective equipment and emergency procedures**  
**Personal precautions** This product contains material of human and animal origin and should be handled as though capable of transmitting infectious diseases. Observe general safety guidelines for protection during clean up procedures.  
Wear protective gloves, protective clothing and eye/face protection.
- 6.2 Environmental precautions** Contain spill to prevent migration.  
Do not allow the undiluted product to enter sewers/surface or ground water.
- 6.3 Methods and material for containment and cleaning up**  
**Spill and leak procedures** If the product is solid or lyophilized form, use vacuum or carefully sweep up spilled material and place in container for suitable disposal. Avoid generating dust.  
If the product is liquid form, as a precautionary measure, treat spilled material with a 1:10 bleach/water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.  
Dispose of all waste material in accordance with local guidelines.
- 6.4 Reference to other sections** Refer sections 8 and 13.

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## Section 7 Handling and storage

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- 7.1 Precautions for safe handling** This product should be handled as though capable of transmitting infectious diseases. Universal precautions should be followed when using this product.
- 7.2 Conditions for safe storage, including any incompatibilities**  
Store at 2 to 8°C, as directed on the product label.  
To maintain product quality, store according to the instructions in the product labeling.  
Store away from strong acids, strong bases, strong oxidizers and incompatible materials (section 10).
- 7.3 Specific end uses** No further relevant information available.

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## Section 8 Exposure controls and personal protection

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- 8.1 Control parameters**
- Exposure limits**
- |  |  |
|--|--|
| <b>US OSHA</b>                                 | None established   |
| <b>ACGIH</b>                                   | None established   |
| <b>ACGIH Biological Exposure Indices (BEI)</b> | None established   |
| <b>DFG MAK</b>                                 | None established   |
| <b>Ireland</b>                                 | None established   |
| <b>IOELVs</b>                                  | None established   |
| <b>NIOSH</b>                                   | None established   |
| <b>China</b>                                   | None established   |
| <b>Croatia</b>                                 |  |
| Zinc Chloride<br>CAS # 7646-85-7               | 1 mg/m <sup>3</sup> TWA [GVI] (fume); 2 mg/m <sup>3</sup> STEL [KGVI] (fume) |
| <b>Japan</b>                                   | None established   |
| <b>Sweden (AFS 2015:7 and amendments)</b>      | None established   |
| <b>Turkey</b>                                  | None established   |
- 8.2 Exposure controls**
- Engineering controls** No special engineering controls are required. Use with good general ventilation.
- Eye protection** Safety glasses or chemical goggles should be worn to prevent eye contact.  
Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.

## Section 8 Exposure controls and personal protection (Continued)

<b>Skin protection</b>	Wear impervious gloves such as Nitrile or equivalent and protective clothing. Refer to U.S. OSHA 29 CFR 1910.138, European Standard EN 374, EN 14605:2005+A1:2009 or appropriate government standards.
<b>Respiratory protection</b>	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

## Section 9 Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

<b>Physical state</b>	Lyophilized Powder	<b>Density and/or relative density</b>	Not determined
<b>Color</b>	Yellow-brown	<b>Solubility</b>	
<b>Odor</b>	Characteristic odor	<b>Water</b>	Soluble
<b>pH</b>	Not applicable	<b>Organic</b>	Not determined
<b>Melting Point</b>	Not determined	<b>Partition coefficient n-octanol/water (log value)</b>	Not applicable
<b>Boiling point or initial boiling point and boiling range</b>	Not applicable	<b>Auto-ignition temp.</b>	Not determined
<b>Flash point</b>	Not applicable	<b>Decomposition temperature</b>	Not determined
<b>Flammability</b>	Not determined	<b>Vapor pressure</b>	Not applicable
		<b>Kinematic viscosity</b>	Not applicable
<b>Lower and upper explosion limit</b>	Not determined		
<b>Relative vapor density</b>	Not applicable		
<b>Particle characteristics</b>	Not determined		

### 9.2 Other information

#### Information with regard to physical hazard classes

No further relevant information available.

#### Other safety characteristics

No further relevant information available.

## Section 10 Stability and reactivity

<b>10.1 Reactivity</b>	No further relevant information available.
<b>10.2 Chemical stability</b>	The product is stable in accordance with recommended storage conditions.

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## Section 10 Stability and reactivity (Continued)

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### 10.3 Possibility of hazardous reactions

No further relevant information available.

### 10.4 Conditions to avoid

To maintain product performance keep away from strong acids, strong bases, strong oxidizers.

Avoid exposure to heat and direct sunlight.

### 10.5 Incompatible materials

No further relevant information available.

### 10.6 Hazardous decomposition products

When stored as labeled, no known hazardous decomposition products are formed during the shelf-life of this product.

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## Section 11 Toxicological information

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### 11.1 Information on hazard classes

#### Toxicity data for hazardous ingredients

L-Lactic Acid  
CAS # 79-33-4

Dermal LD50 Rabbit >2000 mg/kg (no deaths occurred)(NICNAS); Inhalation LC50 Rat >7.94 mg/L 4 h (aerosol)(ECHA\_API); Oral LD50 Rat 3730 mg/kg (IUCLID)

#### Primary routes of exposure

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

#### Acute toxicity

Not classified based on available data.

#### Skin corrosion/irritation

May cause mild skin irritation.

#### Serious eye damage/irritation

Not classified based on available data.

#### Respiratory or skin sensitisation

Not classified based on available data.

#### Germ cell mutagenicity

Not classified based on available data.

#### Carcinogenicity

No ingredients in this product are listed as carcinogens by ACGIH, IARC, NTP, OSHA or 1272/2008 EC regulation.

#### Reproductive toxicity

Not classified based on available data.

#### Specific target organ toxicity (STOT) – single exposure

Not classified based on available data.

#### Specific target organ toxicity (STOT) – repeated exposure

Not classified based on available data.

#### Aspiration hazard

Not classified based on available data.

### 11.2 Information on other hazards

#### Endocrine disrupting properties

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## Section 11 Toxicological information (Continued)

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<b>Other information</b>	This product does not have substance(s) of endocrine disrupting properties for health according to REACH Article 57(f).
	This product contains materials of human and animal origins and should be considered as potentially capable of transmitting infectious diseases.

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## Section 12 Ecological information

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### 12.1 Toxicity

#### Fresh water species

L-Lactic Acid  
CAS # 79-33-4

LC50 96 h Brachydanio rerio: 320 mg/L [semi-static] (IUCLID); LC50 96 h Lepomis macrochirus: 100 - 180 mg/L [static] (EPA); LC50 96 h Oncorhynchus mykiss: 100 - 180 mg/L [static] (EPA)

#### Microtox/organisms

No information available.

#### Water flea

L-Lactic Acid  
CAS # 79-33-4

EC50 48 h Daphnia magna: 240 mg/L (IUCLID); EC50 48 h Daphnia magna: 180 - 320 mg/L [Static] (EPA)

#### Fresh water algae

No information available.

**12.2 Persistence and degradability** Not determined for the product.

**12.3 Bioaccumulative potential** Not determined for the product.

**12.4 Mobility in soil** Not determined for the product.

### 12.5 Results of PBT and vPvB assessment

Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

### 12.6 Endocrine disrupting properties

This product does not have substance(s) of endocrine disrupting properties for environment according to REACH Article 57(f).

**12.7 Other adverse effects** No further relevant information available.

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## Section 13 Disposal considerations

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### 13.1 Waste treatment methods

#### Product waste disposal

Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or approved waste-disposal company for information.

#### Package disposal

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

#### Additional information

Suggested European waste catalogue 18 01 03\* - wastes whose collection and disposal is subject to special requirements in order to prevent infection. Dispose in accordance with national, state and local waste regulations

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## Section 14 Transport information

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Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

- 14.1 **UN/ID number:** Not regulated for transportation
- 14.2 **UN proper shipping name:** Not regulated for transportation
- 14.3 **Transport hazard class(es):** Not regulated for transportation
- 14.4 **Packing group:** Not regulated for transportation
- 14.5 **Environmental hazards:** Not regulated for transportation
- 14.6 **Special precautions for user:** None
- 14.7 **Maritime transport in bulk according to IMO instruments:** Not applicable

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## Section 15 Regulatory information

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### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

#### US Federal and State Regulations

##### **SARA 313 (Section 313, Title III reporting requirements)**

No ingredients listed.

##### **CERCLA (The Comprehensive Environmental Response, Compensation, and Liability Act) 40 CFR 302.4**

CAS # 7758-94-3	Iron dichloride
CAS # 7646-85-7	Zinc Chloride

##### **California Proposition 65**

###### **Chemical which is known to the State of California to cause cancer**

No ingredients listed.

###### **Chemical which is known to the State of California to cause development toxicity**

No ingredients listed.

###### **Chemical which is known to the State of California to cause male reproductive toxicity**

No ingredients listed.

###### **Chemical which is known to the State of California to cause female reproductive toxicity**

No ingredients listed.

##### **Massachusetts Right To Know (RTK) List**

CAS # 7758-94-3	Iron dichloride
CAS # 7757-82-6	Sodium Sulfate
CAS # 7646-85-7	Zinc Chloride

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## Section 15 Regulatory information (Continued)

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### **New Jersey Dept. of Health Right To Know (RTK) List**

CAS # 7758-94-3      Iron dichloride

CAS # 7646-85-7      Zinc Chloride

### **Pennsylvania Right To Know (RTK) List**

CAS # 7758-94-3      Iron dichloride

CAS # 7757-82-6      Sodium Sulfate

CAS # 7646-85-7      Zinc Chloride

### **EU Regulations**

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

### **Water Hazard Class (Germany)**

WGK 1, low water endangering

### **Regulation (EU) 2019/1148 on the marketing and use of explosives precursors - Substances Subject to Suspicious Transactions Reporting**

No ingredients listed.

### **Regulation (EU) 2019/1148 on the marketing and use of explosives precursors - Restricted Explosives Precursors**

No ingredients listed.

### **REACH 1907/2006 EC - Candidate List of Substances of Very High Concern (SVHC)**

No ingredients listed.

### **REACH 1907/2006 EC - Annex XVII – Restrictions on Certain Dangerous Substances**

CAS # 79-33-4      L-Lactic Acid      Entry No.: 75

### **REACH 1907/2006 EC - Annex XIV - list of substances subject to authorisation**

No ingredients listed.

Refer to Section 3

### **UK Regulations**

### **UK REACH Regulation (as Amended) - List of substances subject to authorisation**

Refer to Section 3

### **Canada**

This product is exempt from WHMIS label and SDS requirements.

### **China**

### **Catalog of Hazardous Chemicals - Hazardous Chemicals**

CAS # 7646-85-7      Zinc Chloride

### **Inventory - China - Inventory of Existing Chemical Substances (IECSC)**

All ingredients are listed or exempted.

### **Turkey**

## Section 15 Regulatory information (Continued)

### Türkiye-REACH - KKDİK Regulation - Annex 17 – Restrictions

No ingredients listed.

### International

### UN/FAO/Rotterdam Convention - Chemicals Subject to Prior Informed Consent (PIC)

No ingredients listed.

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

*Some hazardous ingredients listed in Section 15 are below the cutoff limits of 0.1% for carcinogen, mutagen and reproductive toxin and 1% for other health hazards required for reporting in Section 3.*

## Section 16 Other information

<b>Beckman Coulter safety rating</b>	<b>Flammability: 0</b> <b>Health: 1</b> <b>Reactivity with water: 0</b> <b>Physical contact: 1</b>	Code 0=None 1=Slight 2=Caution 3=Severe
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### Revision changes

Updated Section 1.  
Update of product hazard classifications and label elements in Sec. 2.  
Updated hazardous ingredients in Section 3.  
Updated Section 12.  
Updated Section 4, 8, 11, 15, 16.

### Document version and issue/revision date

Revision Date (year/month/day) 2025/10/09  
Last Revision Date (year/month/day) 2025/01/08  
Document ID: 66300-75  
Version: 08

### Hazard Classification Procedure

This mixture was classified using the calculation method for human health and environmental hazards. Physical hazards were determined based on the specification.

### Description of hazard class and hazard statements from Section 3

Eye Dam. 1 - Eye Damage Category 1  
Skin Corr. 1C - Skin Corrosion Category 1C  
EUH071 - Corrosive to the respiratory tract.  
H314 - Causes severe skin burns and eye damage.  
H318 - Causes serious eye damage.

## Section 16 Other information (Continued)

### Abbreviations and acronyms

ACGIH - American Conference of Governmental Industrial Hygienists (ACGIH)  
ADR and RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road and Rail  
CLP - Classification, Labeling and Packaging  
DFGMAK - Republic Germany's maximum exposure limit  
EC50 - Concentration of a substance in an environmental medium expected to produce a certain effect in 50% of test organisms  
GHS - Globally Harmonized System of Classification and Labelling of Chemicals (GHS)  
HCS - Hazard Communication Standard  
IARC - International Agency for Research on Cancer  
IATA DGR - International Air Transport Association Dangerous Goods Regulation  
ICAO - International Civil Aviation Organization  
IDLH - Immediately Dangerous to Life or Health  
IMDG - International Maritime Dangerous Goods  
IMO - International Maritime Organization  
IOELVs - European Unions' Indicative Occupational Exposure Limit Values  
LC50 - Concentration of a substance in water causing death (50% of the tested population) to aquatic life  
LD50 - Lethal Dose 50%  
NIOSH - National Institute for Occupational Safety and Health  
NTP - National Toxicology Program  
OSHA - Occupational Safety and Health Administration  
PBT - Persistent Bioaccumulative and Toxic substances  
PEL - Permissible Exposure Limit  
SARA - Superfund Amendments and Reauthorization Act  
STEL – Short Term Exposure Limit  
STLV - Short Term Limit Value  
STV - Short Term Value  
TDG - Canadian Transportation of Dangerous Goods Regulations  
TLV - Threshold Limit Value  
TWA – Time Weighted Average  
UN GHS - United Nations Globally Harmonized System  
US DOT - United States Department of Transportation  
US OSHA - United States Occupational Safety and Health Administration  
vPvB - very Persistent and very Bioaccumulative substances  
WHMIS - Workplace Hazardous Material Information System

For further information, please contact your local Beckman Coulter, Inc. representative.

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