SAFETY DATA SHEET

ALTL

Version	Revision Date:	Date of last issue: 05/19/2017
1.2	11/12/2018	Date of first issue: 12/20/2016

SECTION 1. IDENTIFICATION

Product name : ALTL

Product code : 04718569190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostic Canada
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Address : 201 Boulevard Armand-Frappier
H7V 4A2 Laval, QC, Canada
QC
Canada

Telephone : 1-877-273-3433
Telefax : 1-877-686-1598
E-mail address : laval.techinfo@roche.com
Emergency telephone
In case of emergencies: : CHEMTREC 1-800-424-9300

Centre for detoxification: : Canadian Association of Poison Control Centres http://www.capcc.ca

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations

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

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

R1 (A / B)

GHS Classification

Not a hazardous substance or mixture.

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Sodium azide (Na(N3))	26628-22-8	>= 0 - < 0.1

D(-)-Lactate dehydrogenase from Lactobacillus leichmannii	9028-36-8	>= 0 - < 0.1

R2 (B /C)/R3(C)

GHS Classification

Not a hazardous substance or mixture.

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Sodium azide (Na(N3))	26628-22-8	>= 0 - < 0.1
Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1

SECTION 4. FIRST AID MEASURES

General advice	:	Do not leave the victim unattended.
If inhaled	:	Move to fresh air. If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	No information available.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during fire fighting	:	No information available.
Further information	:	Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.

Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.

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

SECTION 7. HANDLING AND STORAGE

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

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

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

Materials to avoid : No materials to be especially mentioned.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

R1 (A / B)

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sodium azide (Na(N3))	26628-22-8	C	0.11 ppm 0.3 mg/m3	CA QC OEL
		(c)	0.29 mg/m3 (Sodium azide)	CA AB OEL
		(c)	0.11 ppm 0.3 mg/m3 (hydrazoic acid vapour)	CA AB OEL
		C	0.29 mg/m3	CA BC OEL

			(Sodium azide)	
		C	0.11 ppm (hydrazoic acid vapour)	CA BC OEL
		C (Vapor)	0.11 ppm (Hydrazoic acid)	ACGIH
		C	0.29 mg/m3 (Sodium azide)	ACGIH
		C (Vapour)	0.11 ppm (Hydrazoic acid)	ACGIH
		C	0.29 mg/m3 (Sodium azide)	ACGIH
D(-)-Lactate dehydrogenase from Lactobacillus leichmannii	9028-36-8	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

R2 (B /C)/R3(C)

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sodium azide (Na(N3))	26628-22-8	C	0.11 ppm 0.3 mg/m3	CA QC OEL
		(c)	0.29 mg/m3 (Sodium azide)	CA AB OEL
		(c)	0.11 ppm 0.3 mg/m3 (hydrazoic acid vapour)	CA AB OEL
		C	0.29 mg/m3 (Sodium azide)	CA BC OEL
		C	0.11 ppm (hydrazoic acid vapour)	CA BC OEL
		C (Vapor)	0.11 ppm (Hydrazoic acid)	ACGIH
		C	0.29 mg/m3 (Sodium azide)	ACGIH
		C (Vapour)	0.11 ppm (Hydrazoic acid)	ACGIH
		C	0.29 mg/m3 (Sodium azide)	ACGIH
Sodium hydroxide (Na(OH))	1310-73-2	(c)	2 mg/m3	CA AB OEL
		C	2 mg/m3	CA BC OEL
		C	2 mg/m3	CA QC OEL
		C	2 mg/m3	ACGIH
		C	2 mg/m3	ACGIH

Engineering measures : No data available

Personal protective equipment

Respiratory protection	:	No personal respiratory protective equipment normally required.
Hand protection		
Material	:	Protective gloves
Remarks	:	The selected protective gloves have to satisfy the specifications of EU Directive 89/689/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the material safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.
Eye protection	:	Safety glasses
Skin and body protection	:	Protective suit
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

R1 (A / B)

Appearance	:	liquid
Color	:	No data available
Odor	:	none
Odor Threshold	:	No data available
pH	:	7.4 - 7.8
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	The product is not flammable.
Flammability (liquids)	:	Does not sustain combustion.

Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

R2 (B /C)/R3(C)

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	10.0 - 10.4 (25 °C)
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available

Flammability (solid, gas)	:	The product is not flammable.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION

R1 (A / B)

Acute toxicity

Not classified based on available information.

Components:

Sodium azide (Na(N3)):

Acute oral toxicity	:	LD50 Oral (Rat): 27 mg/kg
Acute dermal toxicity	:	LD50 Dermal (Rat): 50 mg/kg

D(-)-Lactate dehydrogenase from Lactobacillus leichmannii:

Acute oral toxicity	:	Acute toxicity estimate: > 5,001 mg/kg Method: Expert judgment
Acute inhalation toxicity	:	Acute toxicity estimate: > 30 mg/l Test atmosphere: dust/mist Method: Expert judgment
Acute dermal toxicity	:	Acute toxicity estimate: > 5,001 mg/kg Method: Expert judgment

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

Components:

Sodium azide (Na(N3)):

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

D(-)-Lactate dehydrogenase from Lactobacillus leichmannii:

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

STOT-repeated exposure

Not classified based on available information.

Components:

Sodium azide (Na(N3)):

Assessment : May cause damage to organs through prolonged or repeated exposure.

D(-)-Lactate dehydrogenase from Lactobacillus leichmannii:

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

Aspiration toxicity

Not classified based on available information.

Components:

D(-)-Lactate dehydrogenase from Lactobacillus leichmannii:

No data available

R2 (B /C)/R3(C)

Acute toxicity

Not classified based on available information.

Components:

Sodium azide (Na(N3)):

Acute oral toxicity : LD50 Oral (Rat): 27 mg/kg

Acute dermal toxicity : LD50 Dermal (Rat): 50 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Sodium hydroxide (Na(OH)):

Result : Causes severe burns.
Remarks : Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Sodium hydroxide (Na(OH)):

Result	:	Risk of serious damage to eyes.
Remarks	:	May cause irreversible eye damage.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Sodium hydroxide (Na(OH)):

Genotoxicity in vitro	:	Test Type: Ames test Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

Components:

Sodium azide (Na(N3)):

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

STOT-repeated exposure

Not classified based on available information.

Components:

Sodium azide (Na(N3)):

Assessment	:	May cause damage to organs through prolonged or repeated exposure.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

R1 (A / B)

Ecotoxicity

Components:

Sodium azide (Na(N3)):

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1 mg/l Exposure time: 96 h LC50 (Lepomis macrochirus (Bluegill sunfish)): < 8 mg/l Exposure time: 96 h LC50 (Fish): 0.7 mg/l
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia pulex (Water flea)): 4.2 mg/l Exposure time: 96 h
Toxicity to algae	:	IC50 (Scenedesmus quadricauda (Green algae)): 272 mg/l Exposure time:
Toxicity to microorganisms	:	EC50 (Photobacterium phosphoreum): > 43 mg/l EC50 (Photobacterium phosphoreum): < 66 mg/l

Ecotoxicology Assessment

Acute aquatic toxicity	:	Very toxic to aquatic life.
Chronic aquatic toxicity	:	Very toxic to aquatic life with long lasting effects.
Toxicity Data on Soil	:	Not expected to adsorb on soil.

D(-)-Lactate dehydrogenase from Lactobacillus leichmannii:

Toxicity to fish	:	LC50 (Fish): > 100 mg/l Exposure time: 96 h
Toxicity to fish (Chronic toxicity)	:	> 1 mg/l

Ecotoxicology Assessment

Acute aquatic toxicity	:	This product has no known ecotoxicological effects.
Chronic aquatic toxicity	:	This product has no known ecotoxicological effects.
Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Sodium azide (Na(N3)):

Partition coefficient: n-octanol/water : log Pow: 0.3

D(-)-Lactate dehydrogenase from Lactobacillus leichmannii:

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

Mobility in soil

No data available

Other adverse effects

No data available

R2 (B /C)/R3(C)

Ecotoxicity

Components:

Sodium azide (Na(N3)):

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): < 8 mg/l
Exposure time: 96 h

LC50 (Fish): 0.7 mg/l

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex (Water flea)): 4.2 mg/l
Exposure time: 96 h

Toxicity to algae : IC50 (Scenedesmus quadricauda (Green algae)): 272 mg/l
Exposure time:

Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): > 43 mg/l

EC50 (Photobacterium phosphoreum): < 66 mg/l

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

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

Sodium hydroxide (Na(OH)):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 45.4 mg/l
Exposure time: 96 h

LC50 (Leuciscus idus (Golden orfe)): ca. 7 mg/l

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 40.38 mg/l
Exposure time: 48 h

Ecotoxicology Assessment

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

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Sodium azide (Na(N3)):

Partition coefficient: n-octanol/water : log Pow: 0.3

Sodium hydroxide (Na(OH)):

Partition coefficient: n-octanol/water : Remarks: Not applicable

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable

Domestic regulation

TDG

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

R1 (A / B)

WHMIS Classification : Not controlled.

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

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. D(-)-Lactate dehydrogenase from Lactobacillus leichmannii
AICS	:	Not in compliance with the inventory
NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	Not On TSCA Inventory

Canadian lists

No substances are subject to a Significant New Activity Notification.

R2 (B /C)/R3(C)

WHMIS Classification : Not controlled.

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

DSL	:	All components of this product are on the Canadian DSL
AICS	:	On the inventory, or in compliance with the inventory
NZIoC	:	On the inventory, or in compliance with the inventory

ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	Not On TSCA Inventory

Canadian lists

No substances are subject to a Significant New Activity Notification.

R1 (A / B)

GHS label elements

Not a hazardous substance or mixture.

R2 (B /C)/R3(C)

GHS label elements

Not a hazardous substance or mixture.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level;

NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Revision Date : 11/12/2018

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

CA / Z8 / 1711