



## Safety Data Sheet (SDS)

acc. to OSHA HazCom Standard 29 CFR 1910.1200(g) and Canada WHMIS 2015

Issue date 11/28/2018

Reviewed on 11/28/2018

### \* 1 Product and Company Identification

- **Product Identifier**
- **Trade Name: Positive Control**
- **Index number:** 5035P
- **Relevant identified uses of the substance or mixture and uses advised against:**  
No further relevant information available.
- **Application of the substance / the mixture:** Kit Component
- **Details of the Supplier of the Safety Data Sheet:**
- **Manufacturer/Supplier:**  
Company, Manufacturer:  
TECHLAB, Inc.  
2001 Kraft Drive  
Blacksburg, VA 24060, USA

Distributed by:

Alere North America, LLC

30 South Keller Road

Orlando, Florida 32810, US

- **Emergency telephone number:** +(207) 730-5750

### 2 Hazard(s) Identification

- **Classification of the substance or mixture:**



Skin Sens. 1B H317 May cause an allergic skin reaction.

- **Hazard description:** Refer to the information found in this Safety Data Sheet.
- **Information concerning particular hazards for human and environment:**  
Not applicable.  
The product has to be labeled due to the calculation procedure of international guidelines.
- **Classification system:**  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- **Label elements:**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms:**



GHS07

- **Signal word:** Warning
- **Hazard statements:**  
H317 May cause an allergic skin reaction.
- **Precautionary statements:**  
P261 Avoid breathing dust/fume/gas/mist/vapors/spray.  
P272 Contaminated work clothing must not be allowed out of the workplace.

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- P280 Wear protective gloves.
- P302+P352 If on skin: Wash with plenty of water.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P321 Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

• **Unknown acute toxicity:**

This value refers to knowledge of known, established toxicological or ecotoxicological values.  
3 % of the mixture consists of component(s) of unknown toxicity.

• **Hazard(s) not otherwise classified (HNOC):** None known

• **Results of PBT and vPvB assessment**

• **PBT:** Not applicable.

• **vPvB:** Not applicable.








### 3 Composition/Information on ingredients:

• **Chemical characterization: Mixtures**

• **Description:**

Mixture of substances listed below with non-hazardous additions.  
Mixture: consisting of non-regulated material.

• **Dangerous Components:**

ProClin® 300	≤1%
 C R35;  Xn R22;  Xi R43;  N R50/53	
 Skin Corr. 1C, H314;  Aquatic Chronic 1, H410;  Acute Tox. 4, H302; Skin Sens. 1, H317	
Giardia Antigen	≤1%
Cryptosporidium Positive Stool (Heat Inactivated)	≤1%

• **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First-Aid Measures

• **Description of first aid measures**

• **After inhalation:**

In case of unconsciousness place patient stably in side position for transportation.  
Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.

• **After skin contact:**

Remove contaminated clothes and shoes.  
Immediately wash with water and soap and rinse thoroughly.  
If skin irritation occurs, consult a doctor.

• **After eye contact:**

Rinse opened eye for several minutes under running water.  
Seek immediate medical advice.  
If eye irritation occurs, consult a doctor.

• **After swallowing:**

Call a doctor immediately.  
Do not induce vomiting without medical advice.

• **Information for doctor**

• **Most important symptoms and effects, both acute and delayed:**

Prolonged exposure may cause an allergic reaction.

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- **Indication of any immediate medical attention and special treatment needed:**  
No further relevant information available.

### 5 Fire-Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO2, extinguishing powder or water spray. Fight larger fires with water spray.  
Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** No further relevant information.
- **Special hazards arising from the substance or mixture:** No further relevant information available.
- **Advice for firefighters**
- **Special protective equipment for firefighters:** No special measures required.

### 6 Accidental Release Measures:

- **Personal precautions, protective equipment and emergency procedures:**  
Do not breathe vapor.  
Avoid contact with skin, eyes and clothing.
- **Environmental precautions:** Do not allow to enter sewers/surface or ground water.
- **Methods and material for containment and cleaning up:**  
Dispose of the collected material according to regulations.
- **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

- **Handling**
- **Precautions for safe handling:**  
Avoid contact with skin, eyes and clothing  
Wear protective equipment.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**  
Protect from heat and direct sunlight.  
Store in a cool, dry place.  
Store in the original container.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s):** No further relevant information available.

### 8 Exposure Controls/Personal Protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters:**
- **Components with occupational exposure limits:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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- **Additional information:** The lists that were valid during the creation of this SDS were used as basis.
- **Exposure controls:**
- **Personal protective equipment**
- **General protective and hygienic measures:**  
Immediately remove all soiled and contaminated clothing and wash before reuse.  
Wash hands before breaks and at the end of work.
- **Breathing equipment:**  
Have self-contained breathing apparatus, positive pressure, MSHA/NIOSH (approved or equivalent) available in case of spillage or equipment failure.
- **Protection of hands:**



Protective gloves

- **Material of gloves:** Nitrile rubber, NBR
- **Penetration time of glove material:** Not applicable.
- **Eye protection:**



Safety goggles

- **Body protection:**



Protective work clothing

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
  - Form:** Liquid
  - Color:** Colorless to brown
- **pH-value:** Not applicable.
- **Change in condition**
  - Melting point/Melting range:** Not determined.
  - Boiling point/Boiling range:**  $\geq 100$  °C ( $\geq 212$  °F)
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not determined.  
Not applicable.
- **Ignition temperature:** Not applicable
- **Decomposition temperature:** Not determined.
- **Auto igniting:** Product is not self-igniting.

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- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**
  - Lower:** Not determined.
  - Upper:** Not determined.
- **Vapor pressure @ 20 °C (68 °F):** ≤23 hPa (≤17.3 mm Hg)
- **Density:**
  - Relative density:** Not determined.
  - Vapor density:** Not applicable.
  - Evaporation rate:** Not applicable.
- **Solubility in / Miscibility with:**
  - Water:** Miscible
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
  - Dynamic:** Not applicable.
  - Kinematic:** Not applicable.
- **Solvent content:**
  - Water:** 89.0 %
  - Solids content:** 0.0 %
- **Other information:** No further relevant information available.

### 10 Stability and reactivity

- **Reactivity:** Stable under normal conditions.
- **Chemical stability:** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
  - Incompatibilities, flames, ignition sources.
  - High temperatures.
  - Keep out of direct sunlight.
- **Incompatible materials:** Strong acids, strong bases, strong oxidizing agents and strong reducing agents.
- **Hazardous decomposition products:** Oxides

### 11 Toxicological information

- **Information on toxicological effects:**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:** No data available.
- **Primary irritant effect:**
- **On the skin:** May be irritating.
- **On the eye:** May be irritating.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

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### • **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

## 12 Ecological information

### • **Toxicity:**

• **Aquatic toxicity:** No further relevant information available.

• **Persistence and degradability:** No further relevant information available.

### • **Behavior in environmental systems:**

• **Bioaccumulative potential:** No further relevant information available.

• **Mobility in soil:** No further relevant information available.

### • **Additional ecological information:**

### • **General notes:**

Do not allow undiluted product or product that has not been neutralized to reach ground water, water course or sewage system.

### • **Results of PBT and vPvB assessment:**

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

• **Other adverse effects:** No further relevant information available.

## 13 Disposal considerations

### • **Waste treatment methods**

### • **Recommendation:**

Observe all federal, state and local environmental regulations when disposing of this material.

### • **Uncleaned packaging**

• **Recommendation:** Dispose of as unused product.

## 14 Transport information

### • **UN-Number:**

• **ADR/ADN, ADN, IMDG, IATA**

Non-Regulated Material

### • **UN proper shipping name:**

• **ADR/ADN, ADN, IMDG, IATA**

Non-Regulated Material

### • **Transport hazard class(es):**

• **ADR/ADN, ADN, IMDG, IATA**

### • **Class:**

Non-Regulated Material

### • **Packing group:**

• **ADR/ADN, IMDG, IATA**

Non-Regulated Material

### • **Environmental hazards:**

Not applicable.

### • **Special precautions for user:**

Not applicable.

### • **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:**

Not applicable.

### • **UN "Model Regulation":**

Non-Regulated Material

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### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
- **SARA (Superfund Amendments and Reauthorization):**

- **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

- **TSCA (Toxic Substances Control Act):**

7732-18-5 Highly Purified Water

7647-14-5 Sodium Chloride

7758-11-4 Dipotassium Hydrogenorthophosphate

7778-77-0 Potassium Phosphate

- **TSCA new (21st Century Act) (Substances not listed)**

Giardia Antigen

Cryptosporidium Positive Stool (Heat Inactivated)

ProClin® 300

- **Chemicals known to cause cancer:**

None of the ingredients are listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

- **New Jersey Right-to-Know List:**

None of the ingredients are listed.

- **New Jersey Special Hazardous Substance List:**

None of the ingredients are listed.

- **Pennsylvania Right-to-Know List:**

None of the ingredients are listed.

- **Pennsylvania Special Hazardous Substance List:**

None of the ingredients are listed.

- **Carcinogenic categories:**

- **EPA (Environmental Protection Agency):**

None of the ingredients are listed.

- **TLV (Threshold Limit Value established by ACGIH):**

None of the ingredients are listed.

- **NIOSH-Ca (National Institute for Occupational Safety and Health):**

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• **Canadian substance listings:**

• **Canadian Domestic Substances List (DSL):**

7732-18-5	Highly Purified Water
7647-14-5	Sodium Chloride
7758-11-4	Dipotassium Hydrogenorthophosphate
7778-77-0	Potassium Phosphate

• **Canadian Ingredient Disclosure list (limit 0.1%):**

None of the ingredients are listed.

• **Canadian Ingredient Disclosure list (limit 1%):**

None of the ingredients are listed.

• **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

• **Hazard pictograms:**



GHS07

• **Signal word:** Warning

• **Hazard statements:**

H317 May cause an allergic skin reaction.

• **Precautionary statements:**

P261 Avoid breathing dust/fume/gas/mist/vapors/spray.

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

P280 Wear protective gloves.

P302+P352 If on skin: Wash with plenty of water.

P362+P364 Take off contaminated clothing and wash it before reuse.

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

P321 Specific treatment (see supplementary first aid instructions on this Safety Data Sheet).

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

• **National regulations:**

None of the ingredients are listed.

• **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 16 Other information:

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

• **Relevant phrases:**

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H410 Very toxic to aquatic life with long lasting effects.

R22 Harmful if swallowed.

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R35 Causes severe burns.

R43 May cause sensitisation by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

• **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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

NIOSH: National Institute for Occupational Safety and Health

OSHA: Occupational Safety & Health Administration

Acute Tox. 4: Acute toxicity – Category 4

Skin Corr. 1C: Skin corrosion/irritation – Category 1C

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

• **\* Data compared to the previous version altered.**

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