Release Date: 11/28/12

REF ADD List Number	Product Name
99644-01	***CELL-DYN Enzymatic Cleaner Concentrate***

Components:

93641-01	**CELL-DYN Enzymatic Cleaner Concentrate**

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 MSDSs, please contact your local Safety Representative.

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

· **Product name:** CELL-DYN Enzymatic Cleaner Concentrate

· **ADD List number:** 93641-01

· **Application of the substance / mixture:** For In Vitro Diagnostic Use

· **Manufacturer / Supplier:**
Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

· **Department issuing SDS:** Abbott Diagnostics Safety, Health and Environmental Assurance

· **Emergency telephone number:**
Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week):
- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.
- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.

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2 Hazards identification

· Classification of the substance or mixture

Resp. Sens. 1	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Eye Dam. 1	H318	Causes serious eye damage.
Skin Irrit. 2	H315	Causes skin irritation.
STOT SE 3	H335	May cause respiratory irritation.

· **Classification system:**
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 company and/or literature data.

· 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 labelling:**
Subtilisin

· **Hazard statements:**
H315 Causes skin irritation.
H318 Causes serious eye damage.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335 May cause respiratory irritation.

· **Precautionary statements:**
P285 In case of inadequate ventilation wear respiratory protection.

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P261	Avoid breathing mist / vapours / spray.
P280	Wear protective gloves / protective clothing / eye protection.
P264	Wash hands 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.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing and wash before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	This material and its container must be disposed of in a safe way.

· **Additional information:** Refer to section 15 for labeling per Directives 67/548/EEC or 1999/45/EC.

· **Routes of Exposure:**
Skin
Eye
Inhalation

· **National Fire Protection Association (NFPA) ratings (scale 0-4)**
Health = 2
Fire = 0
Reactivity = 0

· **Hazard Overview**
· **Health:**
May cause irreversible eye damage
Sensitizer by inhalation
Causes skin irritation
Irritant by inhalation
Causes eye irritation
· **Fire:** Noncombustible
· **Reactivity:** Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.

· **Carcinogenicity information**

· **OSHA (Occupational Safety and Health Administration)**
None of the ingredients is listed.

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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):**		
77-86-1	Tris hydroxymethyl aminomethane	22.33%
57-55-6	1,2-propylene glycol	8.83%
9002-92-0	Brij 35	5.30%
9014-01-1	Subtilisin	3.808%

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141-53-7	sodium formate	1.56%
10035-04-8	Calcium chloride dihydrate	0.78%
122-99-6	2-Phenoxyethanol	0.32%

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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:**
Rinse open eye(s) cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention and appropriate follow-up. Wash hands after handling.

· **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.

· **Information for Medical Personnel**

· **Most important symptoms and effects, both acute and delayed:**
Kidney effects
Changes in blood parameters
Breathing difficulty
Coughing
Asthma attacks
Skin irritation
Eye irritation
Irreversible eye damage
Respiratory irritation
Possibly immune response

· **Medical conditions aggravated by exposure:**
Pre-existing eye ailments
Pre-existing kidney ailments
Pre-existing blood ailments
Pre-existing respiratory ailments
Pre-existing skin ailments
Respiratory allergies

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5 Firefighting 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.

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· **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.
· **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**
Ensure adequate ventilation.
Blot up small volumes of spilled or spattered product with paper towels or similar materials.
Contain larger spills by placing absorbants 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.

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7 Handling and storage

· **Precautions for safe handling:**
Ensure good ventilation in the workplace.
Prevent formation of aerosols or vapors.
Avoid contact with skin.
Avoid contact with eyes.
Avoid inhalation.

· **Information about protection against explosions and fires:** No special measures required.

· **Requirements to be met by storerooms and receptacles:**
Store only in the original container.
Refer to the package insert or product label for additional information on storage conditions for product quality.

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

· **Further information about storage conditions:**
Keep containers tightly sealed.

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Protect from heat and direct sunlight.

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8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**

57-55-6 1,2-propylene glycol (8.83%)	
WEEL	10 mg/m³
9014-01-1 Subtilisin (3.808%)	
REL	STEL/C: 0.00006* mg/m³ *60-min
TLV	C 0.00006 mg/m³ as crystalline active enzyme

· **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.

· **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.

· **Eye protection:**
Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

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· **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.

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9 Physical and chemical properties

· **Form:**	Liquid
· **Color:**	Colorless
· **Odor:**	Odorless
· **pH-value at 20°C (68 °F)**	8.2
· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Flash point**	Not applicable
· **Flammability (solid, gaseous)**	Not applicable
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product does not present an explosion hazard.
· **Explosion limits**	
· **Lower:**	Not determined
· **Upper:**	Not determined
· **Density**	Not determined
· **Evaporation rate:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Water:**	56.6 %

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10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided**
No decomposition if used 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.

· **Hazardous decomposition products:** No dangerous decomposition products known.

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11 Toxicological information

· **Acute toxicity**

· **LD50/LC50 values for hazardous ingredients per OSHA criteria:**

· **Ingredients (100% pure substance/s):**		
77-86-1 Tris hydroxymethyl aminomethane		
Oral	LD50	5900 mg/kg (rat)
	LDLo	1000 mg/kg (rabbit)
57-55-6 1,2-propylene glycol		
Oral	LD50	10000-33700 mg/kg (mammal)
Dermal	LD50	20800 mg/kg (rabbit)
	Target Organ Effects	See comment (mammal) Heinz body formation or erythrocytes destruction found in animals at repeated dosages of 500 mg/kg or more.
9002-92-0 Brij 35		
Oral	LD50	384 mg/kg (guinea pig) > 1000 mg/kg (mouse) 1000 mg/kg (rat)
9014-01-1 Subtilisin		
Oral	LD50	2000 mg/kg (rat)
141-53-7 sodium formate		
Oral	LD50	11200 mg/kg (mouse) LDLo = 4000 mg/kg in dogs.

· **Primary toxicological effects of the final product:**

· **Skin irritation:** Irritating to skin and mucous membranes.

· **Eye irritation:**
Strong irritant, with the danger of severe eye injury.
Irritating.

· **Sensitization:** Sensitization possible through inhalation.

· **Additional toxicological information:** None

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

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

· **Target organs/systems:**
Eye
Kidneys
Blood
Skin
Immune system

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Respiratory tract

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12 Ecological information

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

· **Additional ecological information**

· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course, or sewage system.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable
· **vPvB:** Not applicable

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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.

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14 Transport information

· **UN-Number**
· **DOT, ADN, IMDG, IATA** none

· **UN proper shipping name**
· **DOT, ADR, ADN, IMDG, IATA** none

· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**
· **Class** none
· **DOT, IMDG, IATA** none

· **Environmental hazards**
· **Marine pollutant:** No

· **Additional information**

· **DOT**
· **Remarks:** Not restricted for transportation.
· **ADR**
· **Remarks:** Not restricted for transportation.

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· **IMDG**
· **Remarks:** Not restricted for transportation.

· **IATA**
· **Remarks:** Not restricted for transportation.

· **UN "Model Regulation"** -

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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):**
The product does not contain listed substances.

· **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.

· **Labelling according to Directives 67/548/EEC or 1999/45/EC**

· **Hazard designation of product:**



Xn Harmful

· **Hazard determining substance/s of labeling:**
Subtilisin
· **Risk phrases:**
36/37/38 Irritating to eyes, respiratory system and skin.
42 May cause sensitization by inhalation.
· **Safety phrases:**
23 Do not breathe gas/fumes/vapour/spray.
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
35 This material and its container must be disposed of in a safe way.
36/37 Wear suitable protective clothing and gloves.
46 If swallowed, seek medical advice immediately and show this container or label.

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16 Other information

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· **Department issuing MSDS**

- 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

· **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 Organization
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
NFPA: National Fire Protection Association (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative