Release Date: 4/24/15

REF GTIN	Product Name
03H80-02 **00380740005160**	***CELL-DYN CN-FREE HGB / NOC LYSE***

Components:

03H80	**CELL-DYN CN-FREE HGB / NOC LYSE**

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

· **Product name:** CELL-DYN 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 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). 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.
- 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 Hazard(s) identification

· **Classification of the substance or mixture**

Skin Irrit. 2	H315	Causes skin irritation.
Eye Dam. 1	H318	Causes serious eye damage.
Skin Sens. 1	H317	May cause an allergic skin reaction.
Carc. 2	H351	Suspected of causing cancer.
STOT RE 2	H373	May cause damage to organs through prolonged or repeated exposure.

· **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:**
Hydroxylamine hydrochloride
Dodecyltrimethyl ammonium chloride (quaternary ammonium salt)

· **Hazard statements:**
H315 Causes skin irritation.
H318 Causes serious eye damage.
H317 May cause an allergic skin reaction.
H351 Suspected of causing cancer.
H373 May cause damage to organs through prolonged or repeated exposure.

· **Precautionary statements:**

P201	Obtain special instructions before use.
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/doctor.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P501	Dispose of contents / container in accordance with local regulations.

· **Routes of Exposure:**
Skin
Eye

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

· **Hazard Overview**
· **Health:**
May cause irreversible eye damage.
Sensitizer in contact with skin
Causes skin irritation
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)**
· **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.

· **Other hazards** This product may cause skin sensitization (allergic reactions) in some people.

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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):**

112-00-5	Dodecyltrimethyl ammonium chloride (quaternary ammonium salt)	3.57%
68391-01-5	Alkylbenzyldimethylammoniumchlorides, benzyl-C12-18-alkyldimethyl	3.57%
67-63-0	Isopropanol	2.86%
5470-11-1	Hydroxylamine hydrochloride	1.68%

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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.
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.

· **Information for Medical Personnel**

· **Most important symptoms and effects, both acute and delayed:**
Headache
Disorientation
Allergic reactions
Skin irritation
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 eye ailments
Pre-existing skin ailments
Skin allergies
Pre-existing nervous system ailments

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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.

· **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 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:**
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:** Protect from heat and direct sunlight.

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8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**

67-63-0 Isopropanol (2.86 %)	
PEL	TWA: 980 mg/m³, 400 ppm

REL	STEL/C: 1225 mg/m³, 500 ppm TWA: 980 mg/m³, 400 ppm
TLV	STEL/C: 984 mg/m³, 400 ppm TWA: 492 mg/m³, 200 ppm BEI
64-17-5 Ethanol (0.39 %)	
PEL	TWA: 1900 mg/m³, 1000 ppm
REL	TWA: 1900 mg/m³, 1000 ppm
TLV	STEL/C: 1880 mg/m³, 1000 ppm

· **Ingredients with biological limit values:**	
67-63-0 Isopropanol (2.86 %)	
BEI	40 mg/L Medium: urine Time: end of shift at end of workweek Parameter: Acetone (background, nonspecific)

· **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.

· **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

· **General Information**
· **Form:** Liquid
· **Color:** Colorless

· **Odor:** Odorless

· **pH-value at 20 °C (68 °F)** 3.9
· **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 at 20 °C (68 °F)** 0.993 g/cm³ (8.287 lbs/gal)
· **Evaporation rate:** Not determined

· **Solubility in / Miscibility with**
· **Water:** Fully miscible
· **Dynamic:** Not determined

· **Water:** 87.9 %

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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.

· **Hazardous decomposition products:** Hydrogen chloride (HCl)

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11 Toxicological information

· **Acute toxicity**

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

· **Ingredients (100% pure substance/s):**		
112-00-5 Dodecyltrimethyl ammonium chloride (quaternary ammonium salt)		
Oral	LD50	536 mg/kg (mouse) by analogy with stearyltrimethylammonium chloride.
Dermal	LD50	1600 mg/kg (mouse) by analogy with stearyltrimethylammonium chloride.
68391-01-5 Alkylbenzyldimethylammoniumchlorides, benzyl-C12-18-alkyldimethyl		
Oral	LD50	650 mg/kg (rat)
67-63-0 Isopropanol		
Oral	LD50	3600 - 6410 mg/kg (mammal) In rats, mice, dogs and rabbits
		4570 mg/kg (rat)
Dermal	LD50	12800 mg/kg (rabbit)
Inhalation	LC50 2 h	53 mg/l (mouse)
	LC50 4 h	27.2 mg/l (mouse)
		72.6 mg/l (rat)
	LC50 7 h	12800 - 16000 ppm (mammal) Vapor concentrations greater than 400 ppm causes eye nose and throat irritation upon exposure for 3 to 5 minutes.
		29-55 mg/l (rat)
Irritation of skin	Reported Effect	Mild irritant (rabbit)
Irritation of eyes	Reported Effect	Moderate-Severe (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.
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)

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		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	1500-2000 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. 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 > 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. > 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.
	Carcinogenicity	Category 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.
	Mutagenicity	Negative (Ames Assay) Positive in E. coli and S. cerevisiae mutagenicity assays. positive (mammalian cells) Positive in cell transformation assay. Negative in cultured human fibroblast unscheduled DNA synthesis assay and the sister chromatid assay.

· **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.
May cause eye damage based on the general properties of quaternary ammonium compound.

· **Sensitization:** Sensitization possible through skin contact.

· **Additional toxicological information:** None

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· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**		
67-63-0	Isopropanol	3

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

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

· **Target organs/systems:**
Eye
Nervous system
Skin
Immune system

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12 Ecological information

· **Aquatic toxicity:**	
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).

· **Additional ecological information**
· **General notes:** Do not allow product 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

· **DOT, ADN, IMDG, IATA** none

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

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

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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):**

67-63-0	Isopropanol

· **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:**

Harmful

· **Hazard determining substance/s of labeling:**
Hydroxylamine hydrochloride

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Dodecyltrimethyl ammonium chloride (quaternary ammonium salt)

· **Risk phrases:**
40 Limited evidence of a carcinogenic effect.
41 Risk of serious damage to eyes.
43 May cause sensitization by skin contact.

· **Safety phrases:**
24/25 Avoid contact with skin and eyes.
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.
37/39 Wear suitable gloves and eye/face protection.
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 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** 04/24/2015 / 62

· **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
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)
NFPA: National Fire Protection Association (USA)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

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PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
Carc. 2: Carcinogenicity, Hazard Category 2
STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2

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