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## **SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

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**Contact information****General**

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**Product identifier** cfDNA in Depleted EDTA Plasma

**Part Number** 60100102, 60100104, 60133501, 60133502, 60133503, 60100501, 60100502, 60100503, 60100504, 60100001, 60100002, 60100003, 60100012, 601XXX13, 601XXX18, 601XXX21, 601XXX24, 601XXX25, 601XXX26, and 601XXX27, 601005XX (Note: "X" is any number)

**Trade names** Multiplexed ctDNA Standard 3% AF for Amplicon-Based Assay, Multiplexed ctDNA Standard 3% AF, Normal Male cfgDNA in Plasma, Normal Female cfgDNA in Plasma, Normal Patient cfgDNA in Plasma, 5% Trisomy 13 Standards, 5% Trisomy 18 Standards, 5% Trisomy 21 Standards, 5% Trisomy 13, 18 and 21 Standards, Trisomy 13 Controls, Trisomy 18 Controls, Trisomy 21 Controls, SCA 45-X Controls, SCA 47-XYY Controls, SCA 47-XXY Controls, and SCA 47-XXX Controls, Extraction Sensitivity Controls

**Chemical family** Mixture

**Relevant identified uses of the substance or mixture and uses advised against** Molecular PCR assays

**Note** The pharmacological, toxicological, and ecological properties of this product/mixture have not been fully characterized. This data sheet will be updated as more data become available.

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## **SECTION 2 - HAZARDS IDENTIFICATION**

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**Classification of the substance or mixture**

**Globally Harmonized System [GHS]**

**Label elements**

**GHS hazard pictogram** None required

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## SECTION 2 - HAZARDS IDENTIFICATION ...continued

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<b>GHS signal word</b>	
<b>GHS hazard statements</b>	None required
<b>GHS precautionary statements</b>	None required
<b>Other hazards</b>	<p>The potential health hazards associated with exposure/handling of this mixture are unknown; no data specific for the mixture were identified. The following data describe the hazards of individual ingredients, where applicable.</p> <p>This product/mixture contains human plasma and should be treated/handled as a potential biohazard. All such human source material has been derived from donors tested individually and shown by FDA approved methods to be free from antibodies to Human Immune Deficiency Virus and Hepatitis B and C. As no test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions. Products may contain active pathogens. Please refer to package insert for additional information, and handle product as potentially biohazardous</p>
<b>Note</b>	This mixture is classified as non-hazardous according to Hazardous Products Regulations (HPR) of Canada, Regulation EC No 1272/2008 (EU CLP) and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological and ecological properties of this mixture have not been fully characterized.

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## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

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<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN CS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Human Source Material	N/A	N/A	>99%	Not classified
Tromethamine (Tris {hydroxymethyl} aminomethane)	77-86-1	201-064-4	≤0.2%	SI2: H315; EI2: H319; STOT-SE3: H335
Ethylenediaminetetraacetic acid tetrasodium salt (EDTA)	60-00-4	200-449-4	≤0.04%	ATO4: H302; SC2: H315; ED2A: H319; STOT-SE3: H335
Sodium Azide	26628-22-8	247-852-1	0 – 0.05%	ATO2: H300; AA1: H400 , CA1: H410; EUH032

<b>Note</b>	The ingredient(s) listed above are considered non-hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. Product contains trace levels of unencapsulated DNA. Although unencapsulated DNA is not known to be dangerous, it is recommended that the product be handled as potentially biohazardous. See Section 16 for full text of CLP/GHS classifications. The GHS classification is based on Regulation (EC) 1272/2008 and Hazard Communication Standard No. 1910.1200.
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## SECTION 4 - FIRST AID MEASURES

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### Description of first aid measures

<b>Immediate Medical Attention Needed</b>	Yes
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<b>Eye Contact</b>	Immediately flush eyes with copious quantities of water for at least 15 minutes. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

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## SECTION 4 - FIRST AID MEASURES ...continued

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<b>Inhalation</b>	Immediately move exposed subject to fresh air. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
<b>Ingestion</b>	If swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt, or waistband. Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

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## SECTION 5 - FIREFIGHTING MEASURES

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<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	May emit toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.
<b>Flammability/Explosivity</b>	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
<b>Advice for firefighters</b>	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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<b>Personal precautions, protective equipment and emergency procedures</b>	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES ...continued

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**Methods and material for containment and cleaning up** DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Neutralize the residue with a dilute solution of acetic acid. Decontaminate the area twice with an appropriate solvent (see Section 9).

**Reference to other sections** See Sections 8 and 13 for more information.

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## SECTION 7 - HANDLING AND STORAGE

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**Precautions for safe handling** Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing mist/spray. Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material.

**Conditions for safe storage including any incompatibilities** Store unopened bottles at -20°C or below. Open bottles are stable for up to 30 days at 2-8°C. Store in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed.

**Specific end use(s)** No information identified.

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## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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### Control

### Parameters/Occupational

### Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Human Source Material	--	--	--
Tromethamine (Tris {hydroxymethyl} aminomethane)	--	--	--
Ethylenediaminetetraacetic acid tetrasodium salt (EDTA)	--	--	--
Sodium Azide	ACGIH, Australia, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, U.S.-California OSHA, United	OEL-STEL	0.3 mg/m <sup>3</sup>

## Kingdom

New Zealand,	Ceiling	0.29 mg/m <sup>3</sup>
Portugal		
ACGIH,	OEL-TWA	0.1 mg/m <sup>3</sup>
Australia,		
Austria,		
Belgium,		
Bulgaria,		
Croatia,		
Cyprus, Czech		
Republic,		
Denmark,		
Estonia,		
Finland,		
France, Greece,		
Hungary,		
Ireland, Italy,		
Latvia,		
Lithuania,		
Malta,		
Netherlands,		
Poland,		
Romania,		
Slovakia,		
Slovenia,		
Spain, Sweden,		
U.S.-California		
OSHA, United		
Kingdom		
NIOSH,	Ceiling	0.3 mg/m <sup>3</sup>
U.S.-California		
OSHA		
Germany	OEL-STEL	0.4 mg/m <sup>3</sup>
Germany	OEL-TWA	0.2 mg/m <sup>3</sup>

### Exposure/Engineering controls

Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/ or enclosure at aerosol/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling.

### Respiratory protection

Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. An approved and properly fitted air-purifying respirator with HEPA filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls.

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## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued

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<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
<b>Skin protection</b>	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, dust respirator, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

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## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

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### Information on basic physical and chemical properties

<b>Appearance</b>	Liquid
<b>Color</b>	Yellowish Brown
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	6-8
<b>Melting point/freezing point</b>	No information identified.
<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.

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## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

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<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	Miscible in water
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (<i>n</i>-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular weight</b>	No information identified.
<b>Molecular formula</b>	No information identified.

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## SECTION 10 - STABILITY AND REACTIVITY

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<b>Reactivity</b>	High concentration of sodium azide may react with lead or copper plumbing to form highly explosive metal azides.
<b>Chemical stability</b>	Stable when stored as recommended.
<b>Possibility of hazardous reactions</b>	Not expected to occur.
<b>Conditions to avoid</b>	Avoid temperatures $\geq 25^\circ \text{ C}$ .
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition products</b>	No information identified.

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## SECTION 11 - TOXICOLOGICAL INFORMATION

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### Information on toxicological effects

<b>Route of entry</b>	May be absorbed by inhalation, skin contact and ingestion.			
<b>Acute toxicity</b>				
<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Human Source Material	--	--	--	--
Sodium azide	LD <sub>50</sub>	Oral	Rat	27 mg/kg
	LD <sub>50</sub>	Oral	Mouse	27 mg/kg
	LD <sub>50</sub>	Dermal	Rabbit	20 mg/kg
<b>Additional acute toxicity information</b>	No studies identified.			
<b>Irritation/Corrosion</b>	No studies identified.			
<b>Sensitization</b>	No studies identified.			
<b>STOT-single exposure</b>	No studies identified.			
<b>STOT-repeated exposure/Repeat-dose toxicity</b>	No studies identified.			
<b>Reproductive toxicity</b>	No studies identified.			
<b>Developmental toxicity</b>	No studies identified.			
<b>Genotoxicity</b>	No studies identified.			
<b>Carcinogenicity</b>	No studies identified. This mixture is not listed by NTP, IARC, ACGIH or OSHA as a carcinogen.			
<b>Aspiration hazard</b>	No data available.			
<b>Human health data</b>	See "Section 2 - Other Hazards"			
<b>Additional information</b>	The toxicological properties of this mixture have not been fully characterized.			

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## SECTION 12 - ECOLOGICAL INFORMATION

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**Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Human Source Material	--	--	--
Sodium azide	LC <sub>50</sub> /96h	Oncorhynchus mykiss	0.8 mg/L
	LC <sub>50</sub> /96h	Lepomis macrochirus	0.7 mg/L
	LC <sub>50</sub> /96h	Pimephales promelas	5.46 mg/L
<b>Additional toxicity information</b>	Sodium azide is toxic to aquatic organisms and should not be allowed to accumulate in metal piping as it has the potential to form explosive mixtures.		
<b>Persistence and Degradability</b>	No data available.		
<b>Bioaccumulative potential</b>	No data available.		
<b>Mobility in soil</b>	No data available.		
<b>Results of PBT and vPvB assessment</b>	No data available.		
<b>Other adverse effects</b>	No data available.		
<b>Note</b>	The environmental characteristics of this product/mixture have not been fully investigated. The above data are for the active ingredient and/or any other ingredient(s) where applicable. Although present at low concentrations, disposal should consider that sodium azide is present. Releases to the environment should be avoided.		

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## SECTION 13 - DISPOSAL CONSIDERATIONS

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<b>Waste treatment methods</b>	Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.
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## SECTION 14 - TRANSPORT INFORMATION

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<b>Transport</b>	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
<b>UN number</b>	None assigned.
<b>UN proper shipping name</b>	None assigned.

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## SECTION 14 - TRANSPORT INFORMATION ...continued

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**Transport hazard classes and packing group** None assigned.

**Environmental hazards** Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.

**Special precautions for users** Mixture not fully tested - avoid exposure.

**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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## SECTION 15 - REGULATORY INFORMATION

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**Safety, health and environmental regulations/legislation specific for the substance or mixture** This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.

**Chemical safety assessment** Not conducted.

**WHMIS classification** This product/mixture has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.

**TSCA status** Not listed

**SARA section 313** Not listed.

**California proposition 65** Not listed.

**Additional information** No other information identified.

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## SECTION 16 - OTHER INFORMATION

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**Full text of H phrases and GHS classifications** SC1B - Skin corrosion Category 1. H314 - Causes severe skin burns and eye damage. ED1 - Eye Damage Category 1. H318 - Causes serious eye damage. SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. AA1- Aquatic toxicity (acute) - Category 1. H400 - Very toxic to aquatic life. CA1 - Chronic Aquatic Toxicity Category 1. H410 - Very toxic to aquatic life with long lasting effects. H412 - Harmful to aquatic life with long lasting effects. SI2 - Skin irritant Category 2. H315 - Causes skin irritation. EI2 - Eye irritant Category 2. H319 - Causes serious eye irritation. STOT-SE3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H335 - May cause respiratory irritation.

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## SECTION 16 - OTHER INFORMATION ...continued

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<b>Sources of data</b>	Information from published literature and internal company data.
<b>Abbreviations</b>	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
<b>Issue Date</b>	April 30th, 2024
<b>Revisions</b>	Version 2
<b>Disclaimer</b>	<p>The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical/diagnostic product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.</p>