

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

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<p>Product identifier</p> <p>Synonyms</p>	<p>DRI® Technology SDS</p> <p>0017 DRI® Amphetamines Assay (100 mL) 0018 DRI® Amphetamines Assay (500 mL) 10014585 Indiko DRI® Amphetamine Assay (3 x 18 mL) 0225 DRI® Barbiturate Assay (100 mL) 0226 DRI® Barbiturate Assay (500 mL) 10015648 Indiko DRI® Barbiturate Assay (3 x 18 mL) 0039 DRI® Benzodiazepine Assay (100 mL) 0040 DRI® Benzodiazepine Assay (500 mL) 10015644 Indiko DRI® Benzodiazepine Assay (3 x 18 mL) 0055 DRI® Cocaine Metabolite Assay (100 mL) 0056 DRI® Cocaine Metabolite Assay (500 mL) 10014593 Indiko DRI® Cocaine Metabolite Assay (3 x 18 mL) 0394 DRI® Cotinine Assay (100 mL) 0395 DRI® Cotinine Assay (500 mL) 10018516 Indiko DRI® Cotinine Assay (3 x 18 mL) 100075 DRI® Ecstasy Assay (100 mL) 100076 DRI® Ecstasy Assay (500 mL) 10014681 DRI® Ecstasy Assay (3 x 18 mL) 10011297 DRI® Ethyl Glucuronide Assay (CE) (68 mL) 10011226 DRI® Ethyl Glucuronide Assay (CE) (500 mL) 10015626 Indiko DRI® Ethyl Glucuronide Assay (CE) (3 x 18 mL) 10011723 DRI® Ethyl Glucuronide Assay (CE) (18mL) 10015894 DRI® Ethyl Glucuronide Assay (CJF) (68 mL) 10015893 DRI® Ethyl Glucuronide Assay (CJF) (500 mL) 10016154 Indiko DRI® Ethyl Glucuronide Assay (CJF) (3 x 18 mL) 10016437 DRI® Fentanyl Assay (CE) (3 x 18mL) 10016006 DRI® Fentanyl Assay (CJF) (3 x 18mL) 10016005 DRI® Fentanyl Assay (CJF) (500 mL) 0596 DRI® Methadone Enzyme Immunoassay (100 mL) 0597 DRI® Methadone Enzyme Immunoassay (500 mL) 10016403 Indiko DRI® Methadone Enzyme Immunoassay (3 x 18mL) 100115 DRI® Methadone Metabolite Assay (100 mL) 100116 DRI® Methadone Metabolite Assay (500 mL) 10018522 Indiko DRI® Methadone Metabolite Assay (3 x 18 mL) 0514 DRI® Methaqualone (100 mL) 0515 DRI® Methaqualone (500 mL) 0135 DRI® Opiate Assay (100 mL) 0136 DRI® Opiate Assay (500 mL) 10014601 Indiko DRI® Opiate Assay (3 x 18 mL) 100248 DRI® Oxycodone Assay (68 mL) 100249 DRI® Oxycodone Assay (500 mL) 10015632 Indiko DRI® Oxycodone Assay (3 x 18 mL) 10012653 DRI® Oxycodone Assay for Synchron Systems</p>
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Synonyms, continued

0160 DRI® Phencyclidine (PCP) Assay (100 mL)
 0161 DRI® Phencyclidine (PCP) Assay (500 mL)
 10014673 Indiko DRI® Phencyclidine (PCP) Assay (3 x 18 mL)
 0432 DRI® Propoxyphene Assay (100 mL)
 0433 DRI® Propoxyphene Assay (500 mL)
 10018510 Indiko DRI® Propoxyphene Assay (3 x 18 mL)
 0185 DRI® THC (Cannabinoid) Assay (100 mL)
 0186 DRI® THC (Cannabinoid) Assay (500 mL)
 10014665 Indiko DRI® THC (Cannabinoid) Assay (3 x 18 mL)
 10018053 DRI® Hydrocodone Assay (500 mL)
 10018054 DRI® Hydrocodone Assay (3 x 18 mL)
 0911 DRI® Barbiturate Serum Tox Assay
 0920 DRI® Benzodiazepine Serum Tox Assay
 1128 DRI® Tricyclics Serum Tox Assay
 1086 DRI® Acetaminophen Serum Tox Assay

Trade names

DRI® Amphetamine, DRI® Barbiturate, DRI® Benzodiazepine, DRI® Cocaine Metabolite, DRI® Cotinine, DRI® Ecstasy, DRI® Ethyl Glucuronide, DRI® Fentanyl, DRI® Methadone, DRI® Methadone Metabolite, DRI® Methaqualone, DRI® Opiates, DRI® Oxycodone, DRI® Phencyclidine, DRI® Propoxyphene, DRI® THC, DRI® Hydrocodone, DRI® Barbiturate Serum Tox, DRI® Benzodiazepine Serum Tox, DRI® Tricyclics Serum Tox, DRI® Acetaminophen Serum Tox.

Chemical family Mixture

Relevant identified uses of the substance or mixture and uses advised against

In vitro diagnostic kit
 Criminal, Forensic & Justice Use kit

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.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Globally Harmonized System [GHS] Respiratory Sensitizer - Category 1. Skin Sensitizer - Category 1.

Other/Supplemental Mixture not yet fully tested.

Label elements

SECTION 2 - HAZARDS IDENTIFICATION ...continued

GHS hazard pictogram



GHS signal word

Danger

GHS hazard statements

H317 - May cause allergic skin reaction. H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

GHS precautionary statements

P261 - Avoid breathing mist or vapor. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/eye protection/ face protection. P285 - In case of inadequate ventilation wear respiratory protection. P302 + P352 - If on skin: Wash with plenty of soap and water. P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P363 - Wash contaminated clothing before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Other hazards

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.

Because the mixture contains a protein (bovine serum albumin) it may cause an allergic skin or respiratory reaction (e.g., potential to cause anaphylaxis). In a workplace setting, the likelihood of systemic effects following accidental ingestion is low, due to the rapid breakdown of proteins in the digestive tract. Bovine serum albumin has been associated with occupational sensitization. Although antibody particles are fairly large proteins, it is not known if systemic effects can occur following accidental inhalation. Proteins, in general, can cause skin and/or respiratory sensitization. Material produced in compliance with USDA and/or CPMP/BWP/1230/98 (Guidance on Minimizing the Risk of Transmitting Animal

SECTION 2 - HAZARDS IDENTIFICATION ...continued

Other hazards ...continued Spongiform Encephalopathy Agents via Medicinal Products). This is a CPMP/BWP/1230/98 Category IV material: it does not contain nor is it derived from specified risk materials as defined in Commission decision 97/534/EC (or successive amendments).

Note This mixture is classified as hazardous according to Directive 1999/45/EC, Regulation EC No 1272/2008 (EU CLP) and applicable US regulations. The pharmacological, toxicological, and ecological properties of this mixture have not been fully characterized. The CLP/ GHS classifications are based on Regulation (EC) 1272/2008 and on the revised OSHA hazard communication standard. The EU symbol/indicator of danger, R Phrases and Safety Advice are based on Directive 1999/45/EC.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN CS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Tris-Hydrochloride	1185-53-1	214-684-5	2–3%	SI2: H315; EI2: H319; STOT-SE3: H335
Tromethamine (Tris {hydroxymethyl} aminomethane)	77-86-1	201-064-4	1-2%	SI2: H315; EI2: H319; STOT-S3: H335
Drug-specific antibody	N/A	N/A	0.1–0.5%	SS1: H317; RS1: H334
Bovine serum albumin	9048-46-8	N/A	≤0.2%	SS1: H317, RS1: H334
Sodium azide	26628-22-8	247-852-1	≤0.09%	ATO2: H300; AA1: H400 , CA1: H410; EUH032

Note The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. Product also contains low levels of drug-specific antibody conjugates (≤0.20%). See Section 16 for full text of GHS classifications. The GHS classification is based on Regulation (EC) 1272/2008, WHMIS 2015 and Hazard Communication Standard No. 1910.1200.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

SECTION 4 - FIRST AID MEASURES ...continued

Immediate Medical Attention Needed	Yes
Eye Contact	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion	If swallowed, call a physician immediately. 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.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See Sections 2 and 11
Indication of immediate medical attention and special treatment needed, if necessary	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit toxic gases of carbon monoxide, carbon dioxide, and oxides of nitrogen.
Flammability/Explosivity	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
Advice for firefighters	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.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	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.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
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). Decontaminate the area twice with an appropriate solvent (see Section 9).
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing mist/spray.
Conditions for safe storage including any incompatibilities	Store at 2-8 °C in a well-ventilated area, away from incompatible materials. Keep container upright and tightly closed.
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters/Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Tris-Hydrochloride	--	--	--
Tromethamine (Tris {hydroxymethyl} aminomethane)	--	--	--
Drug-specific antibody	--	--	--
Bovine serum albumin	--	--	--

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

**Control
Parameters/Occupational
Exposure Limit Values
...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Sodium azide	ACGIH, 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	OEL-TWA	0.1 mg/m ³
	NIOSH, U.S.-California OSHA	Ceiling	0.3 mg/m ³
	Germany	OEL-STEL	0.4 mg/m ³
	Germany	OEL-TWA	0.2 mg/m ³

**Exposure/Engineering
controls**

Control exposures to below the OEL(s). Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Material should be handled inside a closed process, ventilated enclosure, biological safety cabinet, isolator or device of equivalent or better control that is suitable for mists and/or aerosols.

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

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. Use a powered air-purifying respirator equipped with HEPA filters or combination filters or a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.
Hand protection	Wear nitrile, rubber or other impervious gloves if skin contact is possible. If the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Skin protection	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.
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, 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.
Environmental Exposure Controls	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.
Other protective measures	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.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Clear liquid
Color	Colorless
Odor	No information identified.
Odor threshold	No information identified.
pH	5-8
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

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

SECTION 10 - STABILITY AND REACTIVITY

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

SECTION 10 - STABILITY AND REACTIVITY ...continued

Hazardous decomposition products No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Information on toxicological effects

Route of entry May be absorbed by inhalation, skin contact and ingestion.

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Tris-Hydrochloride	--	--	--	--
Tromethamine (Tris {hydroxymethyl} aminomethane)	LD ₅₀	Oral	Rat	5900 mg/kg
	LD ₅₀	Intravenous	Rat	1800 mg/kg
	LD ₅₀	Intravenous	Mouse	1210 mg/kg
Drug-specific antibody	--	--	--	--
Bovine serum albumin	--	--	--	--
Sodium azide	LD ₅₀	Oral	Rat	27 mg/kg
	LD ₅₀	Oral	Mouse	27 mg/kg
	LD ₅₀	Dermal	Rabbit	20 mg/kg

Additional acute toxicity information No studies identified.

Irritation/Corrosion No studies identified.

Sensitization No studies identified. As bovine serum albumin (BSA) is derived from animal (foreign) protein, there is potential for the material to cause an allergic response in humans. Occupational exposure to BSA has caused some cases of allergic sensitization in workers handling this material.

STOT-single exposure No studies identified.

STOT-repeated exposure/Repeat-dose toxicity No studies identified.

Reproductive toxicity No studies identified.

Developmental toxicity No studies identified.

Genotoxicity No studies identified.

Carcinogenicity No studies identified. This mixture is not listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard No data available.

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

Human health data See "Section 2 - Other Hazards"
Additional information The toxicological properties of this mixture have not been fully characterized.

SECTION 12 - ECOLOGICAL INFORMATION**Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Tris-Hydrochloride	--	--	--
Tromethamine (Tris {hydroxymethyl} aminomethane)	--	--	--
Drug-specific antibody	--	--	--
Bovine serum albumin	--	--	--
Sodium azide	LC ₅₀ /96h	Oncorhynchus mykiss	0.8 mg/L
	LC ₅₀ /96h	Lepomis macrochirus	0.7 mg/L
	LC ₅₀ /96h	Pimephales promelas	5.46 mg/L

Additional toxicity information 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.

Persistence and Degradability No data available.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Results of PBT and vPvB assessment No data available.

Other adverse effects No data available.

Note 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.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods Used product should be disposed of according to local, state, and federal regulations. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner.

SECTION 14 - TRANSPORT INFORMATION

Transport 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.

UN number None assigned.

UN proper shipping name None assigned.

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.

SECTION 15 - REGULATORY INFORMATION

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

Chemical safety assessment Not conducted.

SECTION 15 - REGULATORY INFORMATION ...continued

TSCA status	All components of mixture are on TSCA Inventory or are exempt.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional Information	No other information identified

SECTION 16 - OTHER INFORMATION

Full text of H phrases, P phrases and GHS classification SS1 - Skin sensitizer Category 1. H317 - May cause an allergic skin reaction. RS1 - Respiratory Sensitizer Category 1. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. ATO2 - Acute Toxicity (Oral) Category 2. H300 - Fatal 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. EUH032 - Contact with acids liberates very toxic gas. SI2 - Skin irritant Category 2. H315 - Causes skin irritation. H319 - Causes serious eye irritation. EI2 - Eye irritant Category 2. STOT-SE3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H335 - May cause respiratory irritation.

Sources of data Information from published literature and internal company data.

Abbreviations 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

SECTION 16 - OTHER INFORMATION ...continued

Abbreviations ...continued of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

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.