SAFETY DATA SHEET

Product Identifier: Advanta™ Immuno-Oncology Gene Expression Reagent Kit - 2 IFC **SDS ID: 101-6423**
Catalog ID numbers: 101-6081, 101-6082, 101-6083, 101-6084 **Rev A1**

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

Contact information

General	Fluidigm Corporation 7000 Shoreline Court Suite 100, South San Francisco, CA 94080 Main (U.S.): +1 (650) 266-6000 E-mail: techsupport@fluidigm.com
Emergency telephone number	+ (650) 266-6100 (outside US) + (866) 358-4354 (toll free)

Product identifier	Advanta™ Immuno-Oncology Gene Expression Reagent Kit - 2 IFC
Synonyms	None identified
Trade names	None identified
Chemical family	Mixture – bovine serum albumin or formamide
Relevant identified uses of the substance or mixture and uses advised against	*For Research Use Only. Not for use of diagnostic procedures.*
Note	This SDS is written to address potential health and safety issues associated with the handling of the formulated product.

SECTION 2 - HAZARDS IDENTIFICATION

This product contains ten (10) parts. The following provides the hazard classification for each part.

Part 1: 20x GE Sample Loading Reagent (Part #: 100-6311)

Classification of the substance or mixture

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

Label elements

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. P302 + P352 - IF ON SKIN: Wash with plenty of soap and water. P304 + P340 - IF INHALED: 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. P362 + P364 - Take off contaminate clothing and wash it before reuse. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.
Other hazards	Mixture - contains bovine serum albumin. May cause respiratory sensitization. Part/mixture not yet fully tested.

Note This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological, and ecological properties of this part/mixture have not been fully characterized.

Part 2: Rgt Kit, Advanta™ Immuno-Oncology Gene Expression Assay - Panel A (Part #: 101-6145)
Part 3: Rgt Kit, Advanta™ Immuno-Oncology Gene Expression Assay - Panel B (Part #: 101-6146)

Classification of the substance or mixture

Globally Harmonized System [GHS] Reproductive Toxicity - Category 1B.

Label elements

GHS hazard pictogram

GHS signal word Danger

GHS hazard statements H360FD - May damage fertility. May damage the unborn child.

GHS precautionary statements P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves/eye protection/face protection. P308 + P313 - IF exposed or concerned: get medical advice/attention. P405 - Store locked up. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Other hazards Mixture - contains formamide. May cause irritation. Part/mixture not yet fully tested.

Note This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological, and ecological properties of this part/mixture have not been fully characterized.

Part description and number	GHS Hazard Classification
Part 4: Tube, 2X Assay Loading Reagent(85000736)	None required.
Part 5: Tube, PreAmp Master Mix (100-5744)	None required.
Part 6: Tube, PCR Water (100-5941)	None required.
Part 7: Tube, Reverse Transcription Master Mix (100-6297)	None required.
Part 8: Bottle, DNA Dilution Reagent (100-9167)	None required.
Part 9: Tube, Gene Expression Master Mix (2x) (101-5852)	None required.
Part 10: 96.96 Control Line Fluid Kit – 2 IFC (101-6334)	None required.

Other hazards Parts of the kit may cause irritation. Part/mixture not yet fully tested.

Note Parts 4-10 are not classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA). The pharmacological, toxicological, and ecological properties of this part/mixture have not been fully characterized.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Part 1: 20x GE Sample Loading Reagent (Part #: 100-6311)

Ingredient	CAS #	EINECS/ ELINCS#	Amount	GHS Classification
Bovine serum albumin	9048-46-8	N/A	5-10%	SS1: H317; RS1: H334

Note Bovine serum albumin is considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications.

Part 2: Rgt Kit, Advanta™ Immuno-Oncology Gene Expression Assay - Panel A (Part #: 101-6145)
Part 3: Rgt Kit, Advanta™ Immuno-Oncology Gene Expression Assay - Panel A (Part #: 101-6146)

Ingredient	CAS #	EINECS/ ELINCS#	Amount	GHS Classification
Formamide	75-12-7	200-842-0	≤0.5%	Carc2:H351; RT1B:H360FD; STOT-R2:H373

Note Formamide is considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications.

Part 4-10

Tube Description	CAS #	EINECS/ ELINCS#	Amount	GHS Classification
Part 4: Tube, 2X Assay Loading Reagent(Part #: 85000736)	N/A (mixture)	N/A	~100%	Not classified
Part 5: Tube, PreAmp Master Mix (Part #: 100-5744)	N/A (mixture)	N/A	~100%	Not classified
Part 6: Tube, PCR Water (Part #: 100-5941)	N/A (mixture)	N/A	~100%	Not classified
Part 7: Tube, Reverse Transcription Master Mix (Part #: 100-6297)	N/A (mixture)	N/A	~100%	Not classified
Part 8: Bottle, DNA Dilution Reagent (Part #: 100-9167)	N/A (mixture)	N/A	~100%	Not classified
Part 9: Tube, Gene Expression Master Mix (2x) (Part #: 101-5852)	N/A (mixture)	N/A	~100%	Not classified
Part 10: 96.96 Control Line Fluid Kit – 2 IFC (Part #: 101-6334)	N/A (mixture)	N/A	~100%	Not classified

Note The components within Parts 4-10 are non-hazardous and/or present at amounts below reportable limits.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

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 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	Certain parts of the kit contain low levels of bovine serum albumin or formamide. 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 carbon monoxide, carbon dioxide, oxides of nitrogen and sulfur, metal-containing compounds, and other nitrogen-, sulfur- or fluorine-containing compounds.
Flammability/Explosivity	No information identified.
Advice for firefighters	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. 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. Do not breathe mist/vapors/spray.

SECTION 6 - ACCIDENTAL RELEASE MEASURES …continued

Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	If vials are crushed or broken, 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.
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	Avoid breathing dust/mist/vapor/spray. Do not permit eating/drinking/smoking near this material.
Conditions for safe storage including any incompatibilities	Store in a well-ventilated area; keep container upright and tightly closed.
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note Dispose of broken tubes/syringes in a sharps container.

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Bovine serum albumin	--	--	--
Formamide	ACGIH, British Columbia, Ontario	TWA	10 ppm (15 mg/m³) skin
	NIOSH	REL	10 ppm (15 mg/m³) skin

	United Kingdom	TWA	20 ppm (37 mg/m³)
	United Kingdom	STEL	30 ppm (56 mg/m³)
	France	VME	30 mg/m³

Exposure/Engineering controls

None required for normal handling of packaged product. 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. Use engineered local exhaust ventilation (LEV) and/or enclosure for procedures where aerosolization may occur such as opened transfers, pumping, and spraying. Solutions can be handled outside a containment system or without LEV during procedures with no potential for aerosolization. All containers for solutions and slurries must be covered while being transferred.

Respiratory protection

None required for normal handling of packaged product. If vials are crushed or broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. At a minimum, a tight-fitting full-face respirator with HEPA filters is required when performing aerosol generating operations. A powered air-purifying respirator (PAPR) with HEPA filters and head cover is required for spill cleanup.

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is diluted 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 substance, 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).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Liquids (supplied as individually packaged reagents)
Color	No information identified.
Odor	No information identified.
Odor threshold	No information identified.
pH	No information identified.
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	No information identified.
Flash point	No information identified.

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	No information identified.
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	Not applicable (Mixture)
Molecular formula	Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	Stable when stored as recommended.
Possibility of hazardous reactions	No information identified.
Conditions to avoid	No information identified.
Incompatible materials	No information identified.
Hazardous decomposition products	No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note No data were identified for the product/mixture. The following information is for the individual hazardous ingredients contained in some parts of the kit.

Information on toxicological effects

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

Acute toxicity

Compound	Type	Route	Species	Dose
Bovine serum albumin	--	--	--	--
Formamide	LD_{50}	Oral	Rat	4000 mg/kg
	LD_{50}	Oral	Mouse	2450 mg/kg
	LD_{50}	IV	Rat	5600 mg/kg

	LD_{50}	IV	Mouse	5100 mg/kg
	LD_{50}	Inhalation	Rat	>3900 ppm/6H
	LD_{50}	Inhalation	Mouse	11000 mg/m³
	LD_{50}	Dermal	Rabbit	6000 mg/kg

Irritation/Corrosion Formamide was not irritating to rabbit skin and caused a mild, temporary eye irritation.

Sensitization 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 In a 3-month oral study in rats with formamide, dose-related increases in hematocrit values, hemoglobin concentrations, and red blood cell counts were reported at 10-160 mg/kg, 5 days/week. The incidences of degeneration of the germinal epithelium of the testes and epididymis were significantly increased in 160 mg/kg males. In a 3-month oral study in mice with formamide, no adverse effects were reported at any dose up to a maximum of 160 mg/kg, 5 days per week.

In a 2-week rat inhalation study with formamide, histopathological changes in the kidneys, and reduced platelet counts were seen at 1500 ppm, 6 hours/day, 5 day/week (highest dose). Rats at 500 ppm showed reduced platelet counts only. The no-observed-adverse-effect concentration (NOAEC) was 100 ppm (~0.19 mg/kg).

Reproductive toxicity In a 2-generation oral study in mice with formamide, dietary doses of 750 ppm (~200 mg/kg/day) decreased female fertility across several generations. The reported NOAELs in female and males were ~100 and ~200 mg/kg/day, respectively.

Developmental toxicity Formamide was administered orally to pregnant rats in two studies during gestation days (GD) 6-19. In the first study, reduced fetal body weights were reported at ≥125 mg/kg/day, with maternal toxicity at ≥250 mg/kg/day. The developmental and maternal NOAELs were 62 and 125 mg/kg/day, respectively. In the second study, embryofetal malformations and/or variations, increased resorptions and fetal loss, and reduced litter sizes were reported at ≥100 mg/kg/day, with maternal toxicity at 200 mg/kg/day. The developmental and maternal NOAELs were 50 and 100 mg/kg/day, respectively.

Genotoxicity Formamide was negative for mutagenicity in an Ames assay with and without metabolic activation. *In vivo*, an increased incidence of micronuclei was reported in mice at high doses (≥900 mg/kg). Overall, the weight of evidence suggests a low potential for genotoxicity.

Carcinogenicity In a 2-year study in mice with formamide, liver hemangiosarcoma was reported at oral doses ≥40 mg/kg/day. At 80 mg/kg/day, increased incidences of benign and malignant liver tumors were reported. No carcinogenic effects were observed in a 2-year rat study at oral doses up to a maximum of 80 mg/kg/day. The ingredients in this product/mixture are not listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard No data available.

Human health data See Section 2 - "Other hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Bovine serum albumin	--	--	--
Formamide	--	--	--

Persistence and Degradability No data identified.

Bioaccumulative potential No data identified.

Mobility in soil No data identified.

Results of PBT and vPvB assessment	Not performed.
Other adverse effects	No data identified.
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. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods	Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. 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.

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	No special precautions needed. Avoid release to the environment.
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 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.
TSCA status	Formamide is listed. The remaining components of this product/mixture are not listed.
SARA section 313	Not listed.
California proposition 65	Formamide is considered, but not listed. The remaining components of this product/mixture are not listed.
Component Analysis – State	Formamide is listed as hazardous in CA, HI, MA, MI, MN, NJ, PA, RI, VT, and WA. The remaining components of this product/mixture are not listed.
Component Analysis – Chemical Inventory	Bovine serum albumin and formamide are listed in the chemical inventory of the following countries: Australia, Canada, China, EU, New Zealand, and the Philippines.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

NFPA Ratings	**Bovine serum albumin**	**Health:** 1	**Fire:** 0	**Reactivity:** 0
	Formamide	**Health:** 2	**Fire:** 1	**Reactivity:** 0

Full text of H phrases and GHS classifications

SS1 - Skin sensitizer Category 1. H317 – May cause an allergic skin sensitization. RS1 - Respiratory Sensitizer Category 1. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. Carc2 - Carcinogenicity Category 2. H351 - Suspected of causing cancer. RT1B - Reproductive toxicity Category 1B. H360FD - May damage fertility. May damage the unborn child. STOT-R2 - Specific Target Organ Toxicity Following Repeated Exposure Category 2. H373 - May cause damage to organs through prolonged or repeated exposure.

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; CA – California; 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; HI – Hawaii; 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; MA – Massachusetts; MN – Minnesota; NJ – New Jersey; 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; PA – Pennsylvania; PNEC - Predicted No Effect Concentration; RI – Rhode Island; 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; VT – Vermont; WA – Washington; WHMIS - Workplace Hazardous Materials Information System

Issue Date

3/7/17

Revisions

This is the first version of this SDS.

Disclaimer

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