

SAFETY DATA SHEET

Product Identifier: Cisplatin Conjugated Proteins with Preservatives
Catalog ID numbers: Cat# 319XXXX & TIS-00001

SDS ID: SDS-00025 Rev 01

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

Contact information

General	Fluidigm Corporation 2 Tower Place, Suite 2000, 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	Cisplatin Conjugated Proteins with Preservatives
Synonyms	None identified
Trade names	None identified
Chemical family	Mixture - contains a polypeptide.

Relevant identified uses of the substance or mixture and uses advised against *For Research Use Only.*

Note This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture. Workers manufacturing this product/mixture should consult the SDS of each hazardous ingredient for hazard information and handling recommendations.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture The classification and labeling listed below is for bulk formulation.

Globally Harmonized System [GHS] Not classified

Label elements

GHS hazard pictogram None required

GHS signal word None required

GHS hazard statements None required

GHS precautionary statements None required

Other hazards Cisplatin conjugated protein with preservatives is an antibody-based mixture. In a workplace setting, the likelihood of systemic effects following an accidental ingestion is low, due to the rapid breakdown of proteins in the digestive system. Based on the large molecular weight of proteins, systemic absorption following inhalation or dermal contact is anticipated to be low. The mixture contains bovine serum albumin, which has been associated with occupational sensitization.

Note This mixture does not meet criteria for classification 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).

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SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Antibodies	N/A	N/A	<0.1%	Not classified
Cisplatin	15663-27-1	239-733-8	<0.01%	ATO2: H300; STOT-S1: H370; STOT-S3: H335; STOT-R1: H372; RT1A: H360FD; GCM1B: H340; Carc1B: H350; SC1: H314; EC1: H318
Bovine serum albumin	9048-46-8	N/A	0.1 – 0.6%	RSS1:H317; RS1:H334

Note The primary ingredient of this mixture is sterile water (~98%). The substance listed above is not classified but is listed because it is the key component and its toxicologic properties have not yet been fully characterized. The remaining components are not hazardous and/or present at amounts below reportable limits.

Amounts are listed as ranges; the exact percentage of composition is withheld as a trade secret. See Section 16 for full text of GHS classifications.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed

No. If exposed or concerned: Get medical advice/attention.

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

Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

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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, and other cadmium- chlorine-, phosphorus-, sulfur- and sodium-containing compounds.
Flammability/ Explosivity	No explosivity data identified. As product is an aqueous solution, it is not expected to be flammable.
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 vapors/mist/spray.
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	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 vapor/mist/spray.
Conditions for safe storage including any incompatibilities	Store at 2-8°C in tightly closed container. Avoid strong oxidizers. Store in sealed containers that are appropriately labeled.
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Note Wash hands, face and other potentially exposed areas immediately in the event of physical contact.

Control Parameters/Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Antibodies	--	--	--
Cisplatin	ACGIH	TLV	2 µg/m ³

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

	OSHA	PEL	2 µg/m ³
	Belgium, Hungary, New Zealand	TWA	2 µg/m ³
	Japan	OEL	1 µg/m ³
	Switzerland	MAK	2 µg/m ³
	United Kingdom	TWA	20 µg/m ³
Bovine serum albumin	--	--	--

Exposure/Engineering controls None required for normal handling of packaged product. If handling bulk product: Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. If vials are crushed or broken, or if handling bulk formulation: Utilize closed and sealed systems whenever possible. Solutions used for procedures where aerosolization may occur (e.g., pipetting, spraying, pumping, open transfers,) must be handled using a control device such as a ventilated enclosure. Control the potential for spills and leaks by securing all connections. Use clean-in-place systems.

Respiratory protection None required for normal handling of packaged product. If handling bulk formulation: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls.

Hand protection None required for normal handling of packaged product. If handling bulk formulation: Wear disposable nitrile or other impervious gloves. Double gloves should be worn for direct handling of solutions. When the material is diluted in an organic solvent, wear gloves that provide protection against the solvent.

Skin protection None required for normal handling of packaged product. If handling bulk formulation: Wear disposable outer garment appropriate to the task, booties, two pairs of gloves and safety glasses with side shields. Employees must be trained in proper gowning and degowning practices. An anteroom or transition area is recommended for gowning and degowning.

Eye/face protection None required for normal handling of packaged product. If handling bulk formulation: 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 product, 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	Aqueous solution.
Color	Clear.
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.

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Vapor density	Not applicable.
Relative density	No information identified.
Water solubility	Soluble.
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 formula	Not applicable (Mixture)
Molecular weight	Not applicable (Mixture)

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SECTION 10 - STABILITY AND REACTIVITY

Reactivity No information identified.

Chemical stability No information identified.

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 for this product/mixture were identified. The following data describe the individual ingredients where applicable.

Information on toxicological effects

Route of entry Large proteins are unlikely to be absorbed through inhalation, skin contact, or ingestion.

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Antibodies	--	--	--	--
Cisplatin	LD50	Oral	Rat	14.5 mg/kg
	LD50	Oral	Mouse	32.7 mg/kg
	LD50	Intravenous (IV)	Rat	8 mg/kg
	LD50	Intravenous (IV)	Mouse	11 mg/kg
	LC50	Inhalation	Rat	40250 ppm
Bovine serum albumin	--	--	--	--

Irritation/Corrosion No studies identified. Cisplatin can cause eye, skin and/or respiratory tract irritation.

Sensitization No studies identified.

STOT-single exposure No studies identified. In rats, single intraperitoneal (IP) injections up to 12.2 mg/kg cisplatin caused leukopenia (characterized by decreases in neutrophils, lymphocytes, and platelets) and bone marrow depression, generalized lymphoid depletion, and intestinal/renal tubular injury, which were most severe 2-4 days post-injection. Similar target organ effects were noted in dogs following single IV doses of 2.5 mg/kg or 5 consecutive intravenous (IV) doses of 0.75 mg/kg/day. Heart effects and sperm degeneration were also seen in monkeys following acute exposure.

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

Reproductive toxicity No studies identified. Similar adverse effects on spermatogenesis seen in humans were noted in monkeys administered cisplatin (additional details not provided).

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SECTION 11 - TOXICOLOGICAL INFORMATION...continued

Developmental toxicity	<p>No studies identified. In rats, IP doses of cisplatin ≥ 0.25 mg/kg/day before mating through gestation increased the number of resorptions and decreased the post-natal viability and exploratory behavior of surviving offspring; doses of 0.5 mg/kg/day caused embryoletality and growth retardation.</p> <p>In rabbits, embryoletality was noted at IP doses > 0.125 mg/kg/day, but no teratogenic effects were seen at doses up to 0.5 mg/kg/day.</p> <p>In mice, IP doses of 10 mg/day administered during organogenesis led to retarded growth and bone formation but caused no major malformations. A single IP dose of ≈ 3 mg/kg of cisplatin on day 8 of pregnancy was fetal to $\approx 30\%$ of fetuses. Surviving offspring showed growth retardation and had a number of minor skeletal abnormalities.</p>
Genotoxicity	<p>No studies identified. Cisplatin was mutagenic in bacteria and produced chromosomal aberrations, micronuclei, and sister chromatid exchanges (SCEs) in cultured animal and human cells. It also induced SCEs <i>in vivo</i> in rodents but did not cause <i>in vivo</i> dominant lethal mutations in mice.</p>
Carcinogenicity	<p>Weekly IP injections of a 0.85% cisplatin solution in mice (delivering cisplatin doses equivalent to 1.62 mg/kg) for 16 weeks significantly increased lung adenomas; skin papillomas were increased when cisplatin was co-administered with croton oil as a promoter twice weekly for 52 weeks. In two rat studies, multiple IP injections (3 times 1 mg/kg/week for 3 weeks) induced leukemia. Overall, cisplatin was carcinogenic to rodents at low, occupationally relevant doses. Cisplatin is also listed as a carcinogen by OSHA, IARC (Group 2A - "Probably carcinogenic to humans"), and NTP ("Reasonably anticipated to be a human carcinogen").</p>
Aspiration hazard	No data available.
Human health data	See "Section 2 - Other Hazards"

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Antibodies	--	--	--
Cisplatin	LC ₅₀ (96 h)	Fish	34 g/L
Bovine serum albumin	--	--	--

Persistence and Degradability	Polypeptides are expected to degrade rapidly when released into the environment.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Results of PBT and vPvB assessment	Not performed.
Other adverse effects	No data available.
Note	No special precautions are necessary.

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.
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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	This product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for users	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	Not listed.
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 and GHS classifications	Not applicable.
Sources of data	Information from published literature and internal company data.

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SECTION 16 - OTHER INFORMATION...continued

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; 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; NIOSH - The National Institute for Occupational Safety and Health; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Issue Date

Nov 2020

Revisions

This is the first version of this SDS.

Disclaimer

The information and recommendations in this safety data sheet are, to the best of Supplier's knowledge, accurate as of the date of issue. Supplier gives no warranty whatsoever, including the warranties of merchantability or of fitness for a particular purpose. Any product purchased is sold on the assumption the purchaser shall determine the quality and suitability of the product. Supplier expressly disclaims any and all liability for incidental, consequential or any other damages arising out of the use or misuse of this product. No information provided shall be deemed to be a recommendation to use any product in conflict with any existing patent rights. Read the Safety Data Sheet before handling product. For Research Use Only. Not for use in diagnostic procedures.