

SAFETY DATA SHEET

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

Contact information

General



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Product identifier

Part Number:
 102-0370

Bottle, Dilution Reagent 25mL

Synonyms

Reagent Kit, Advanta™ Dx SARS-CoV-2 RT-PCR Assay Module 2

Trade names

Advanta™ Dx SARS-CoV-2 RT-PCR Assay Reagent Kit, Module 2
 Advanta™ Dx Dilution Reagent, 25 mL (Part Number: 102-0353)

Chemical family

Mixture

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

In vitro Diagnostic kit For Emergency Use Authorization Only.

Note

This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Globally Harmonized System [GHS] Not classified

Label elements

GHS hazard pictogram None required

GHS signal word None required

SECTION 2 - HAZARDS IDENTIFICATION ...continued

GHS hazard statements None required

GHS precautionary statements None required

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.

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). Nevertheless, it should be handled with caution as it has not yet been fully tested.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ELIN CS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Non-Hazardous Reagent(s)	N/A	N/A	~100%	Not classified

Note The principal ingredient in this mixture is PCR water. Any remaining components are not hazardous and/or are present at amounts below reportable limits.

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 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. If signs/ symptoms occur, get medical attention.

SECTION 4 - FIRST AID MEASURES ...continued

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	In case of fire in the surroundings: Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, and chlorine-containing compounds.
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. Wash all equipment thoroughly 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.
Environmental precautions	Avoid release to the environment.
Methods and material for containment and cleaning up	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	Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with hands, eyes and other mucous membranes. Wash thoroughly after handling. Avoid breathing vapor/mist/spray.
Conditions for safe storage including any incompatibilities	Store at -15°C to -25°C.
Specific end use(s)	<i>In vitro</i> Diagnostic kit For Emergency Use Authorization Only.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Control Parameters/Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Non-Hazardous Reagent(s)	--	--	--

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 may be considered to provide ancillary protection based on the known or foreseeable limitations of existing engineering controls.
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered.
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).

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Liquid
Color	Clear, colorless
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	Miscible in water
Solvent solubility	No information identified.
Partition coefficient (<i>n</i>-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.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued

Other information

Molecular formula	Not applicable (Mixture)
Molecular weight	Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	No information identified.
Chemical stability	No information identified.
Possibility of hazardous reactions	Not expected to occur.
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 active ingredient and/or the individual ingredients where applicable.

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>
Non-Hazardous Reagent(s)	--	--	--	--

Irritation/Corrosion No data on product formulation.

Sensitization No data on product formulation.

STOT-single exposure No data on product formulation.

STOT-repeated exposure/Repeat-dose toxicity No data on product formulation.

Reproductive toxicity No data on product formulation.

Developmental toxicity No data on product formulation.

Genotoxicity No data on product formulation.

SECTION 11 - TOXICOLOGICAL INFORMATION ...continued

Carcinogenicity	No data on product formulation. None of the components of the product/mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
Aspiration hazard	No data on product formulation.
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>
Non-Hazardous Reagent(s)	--	--	--

Persistence and Degradability	No data on product formulation.
Bioaccumulative potential	No data on product formulation.
Mobility in soil	No data on product formulation.
Results of PBT and vPvB assessment	Not performed.
Other adverse effects	No data on product formulation.

Note The environmental characteristics of this product/mixture have not been fully investigated. 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. Do not discharge into sanitary drains (e.g. non-process drains) or 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

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.
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SECTION 14 - TRANSPORT INFORMATION ...continued

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	Due to lack of data, 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.

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; 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; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System
Issue Date	August 2020
Revisions	Revision 04: CHG-002241; Updated regulatory language. Revision 03: CHG-001895; Updated regulatory language. Revision 02: CHG-001826; Added temperature range to section 7. Revision 01: CHG-001778; This is the first version of this SDS.
Disclaimer	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 Material Safety Data Sheet before handling product. For <i>In Vitro</i> Diagnostic Use. For Emergency Use Authorization Only. RX only. This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of <i>in vitro</i> diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.