

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Product Name HIV-1 (Ba-L Strain) Direct Pelleted Virus (500X)
Catalog Number 10-177-250

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

SU24 Scientific research and development

1.3 Details of the supplier of the safety data sheet

Manufacturing Supplier Advanced Biotechnologies, Inc
1545 Progress Way
Eldersburg, MD 21784
Telephone (410) 792-9779

1.4 Emergency telephone number

24 Hour Emergency Number ChemTel, Inc 1-800-255-3924

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

This product is not classified as hazardous according to the Regulation (EC) No 1272/2008 and subsequent amendments.

This product is not classified as hazardous according to the Globally Harmonized System (GHS).

This product is not classified as hazardous according to OSHA GHS regulations within the U.S.

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008**

This product does not have a classification according to the CLP regulation.

This product is not classified as hazardous according to the OSHA GHS regulations within the U.S.

GHS Elements	Not Regulated
Hazard Pictograms	Not Regulated
Signal Word	Not Regulated
Hazard-determining components of labelling	None
Hazard statements	Not Regulated

2.3 Other hazards**Hazards Not Otherwise Classified (HNOC) or covered by GHS**

This preparation of HIV-1 is a BIOHAZARDOUS material containing ACTIVE VIRUS and should be handled in accordance with biosafety guidelines defined in the BMBL, NIH-CDC HHS publication No. (CDC) 21-1112.

Category: WHO Risk Group 3

Emergency Overview: Biohazardous

Pathogenicity: AIDS is characterized by symptoms and infections caused by the breakdown of the immune system due to HIV infection. HIV can infect many types of cells, mainly lymphocytes, but also macrophages, and microglia in the brain, and other neurological cells, resulting in profound asthenia, dementia and damage to the peripheral nervous system. Due to immunodeficiency, patients succumb to various fungi, parasites, bacteria, and/or viruses and are prone to certain tumors. Globally, *Mycobacterium tuberculosis* is the most common cause of death of HIV-infected individuals.

Potential Health Effects: The clinical features of HIV infection vary depending on the stage of the disease. Acute infection is accompanied by non-specific “flu-like” and “mononucleosis-like” symptoms such as myalgia, arthralgia, diarrhea, nausea, vomiting, headache, hepatosplenomegaly, weight loss and neurological symptoms. Early-stage disease refers to the period of clinical latency between the time of the primary infection and the development of symptoms indicative of advanced immunodeficiency. Typically, when the patient’s CD4+ T-cell count falls below 500 cells/ μ l,

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syndromes indicative of depressed cell mediated immunity can appear. Examples include oropharyngeal and recurrent vulvovaginal candidiasis, bacillary angiomatosis, recurrent or multidermatomal herpes zoster, listeriosis, infections due to *Rhodococcus equi*, pelvic inflammatory disease, oral hairy leukoplakia associated with Epstein-Barr virus, cervical dysplasia, long lasting diarrhea, idiopathic thrombocytopenic purpura and peripheral neuropathy. Late-stage disease refers to the period when the patient's CD4+ T-cell count falls below 200 cells/ μ l. The loss of the integrity of cell-mediated immune responses allows ubiquitous environmental organisms with limited virulence to become life threatening pathogens. Examples of conditions (as set out by the U.S. Centers for Disease Control and Prevention) include candidiasis of bronchi, trachea, lungs or oesophagus, invasive cervical cancer, coccidioidomycosis, cryptococcosis, cryptosporidiosis, cytomegalovirus disease (other than liver, spleen or nodes) cytomegalovirus retinitis (with loss of vision), HIV-related encephalopathy, herpes simplex, histoplasmosis, isosporiasis, Kaposi's sarcoma, Burkitt's lymphoma, immunoblastic lymphoma, primary lymphoma of the brain, *Mycobacterium avium* complex, *Mycobacterium tuberculosis*, *Pneumocystis jiovecii* pneumonia, recurrent pneumonia, progressive multifocal leukoencephalopathy, recurrent salmonella septicaemia, toxoplasmosis of the brain and wasting syndrome due to HIV. (Original Pathogen Safety Data Sheet and Risk Assessment located at publichealth.gc.ca)

Host Range: Humans.

Results of PBT and vPvB assessment

PBT Not applicable

vPvB Not applicable

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture consisting of the following components with Human Immunodeficiency Virus Type 1.

Components		Concentration/Amount
CAS: N/A EC No: N/A	Dulbecco's Modified Eagle's Medium (DMEM)	1X
CAS: N/A EC No: N/A	Fetal Bovine Serum (FBS)	20%
CAS: 1405-41-0 EC No: 215-778-9	Gentamicin, Sulfate	25 μ g/mL
	Human Immunodeficiency Virus Type 1	

SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation Supply fresh air and seek medical advice.
After skin contact Immediately wash with water and soap and rinse thoroughly. Seek medical advice.
After eye contact Rinse immediately with plenty of water and seek medical advice.
After swallowing If swallowed, seek medical advice immediately and show the container/label/SDS.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Use fire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

Protective equipment: No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

To minimize contact, wear a laboratory coat, nitrile or latex gloves, and protective glasses.

6.2 Environmental precautions

Disinfect material before disposal.

6.3 Methods and material for containment and cleaning up

Take up with absorbent material. Disinfect area with 3% hydrogen peroxide followed by 70% isopropyl alcohol.

6.4 Reference to other sections

See Section 7 for Safe Handling.

See Section 8 for Exposure Controls.

See Section 13 for Disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

As per the Biosafety in Microbiological and Biomedical Laboratories (BMBL), activities such as producing research-laboratory-scale quantities, manipulating concentrated virus preparations, and conducting procedures that may produce droplets or aerosols, are performed in a BSL-2 facility, using BSL-3 practices. Activities involving large-scale volumes or preparation of concentrated HIV are conducted at BSL-3. Wear appropriate protective equipment (see Section 8). Practice good work hygiene.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature $\leq -70^{\circ}\text{C}$ in well-sealed receptacle.

7.3 Specific end use(s)

No further relevant information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls

Personal protective equipment

General protective/hygienic measures

The usual precautionary measures are to be adhered to when handling chemicals and biological material.

Ventilation

Work in a biological safety cabinet to reduce the possibility of exposure.

Respiratory protection

Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard, if a risk assessment indicates this is necessary.

Protection of hands

Protective gloves (i.e. nitrile or equivalent).

Eye protection

Safety glasses or safety goggles, as appropriate.

Body protection

Protective work clothing and laboratory coats.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance

Form: Liquid

Color: Reddish

Odor

Odorless

Odor Threshold

Does not apply, as substance is odorless.

pH

Not determined

Change in condition

Melting point/Melting range: Not determined

Boiling point/Boiling range: Not determined

Flash point

Not applicable

Evaporation rate

Not determined

Flammability (solid, gaseous)

Does not apply, substance is a liquid.

Auto/Self-ignition temperature

Not determined

Decomposition temperature

Not determined

Self-igniting

Product is not self-igniting.

Danger of explosion

Product does not present an explosion hazard.

Vapor pressure/density

Not determined

Density

Not determined

Viscosity

Not determined

Solubility in/Miscibility with Water

Soluble

9.2 Other information

No further relevant information available.

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SECTION 10: Stability and reactivity

10.1 Reactivity	No further relevant information available.
10.2 Chemical stability	No further relevant information available.
10.3 Possibility of hazardous reactions	No dangerous reactions known.
10.4 Conditions to avoid	No further relevant information available.
10.5 Incompatible materials	No further relevant information available.
10.6 Hazardous decomposition products	No further relevant information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity	Based on available data, the classification criteria are not met.
LD/LC50 values relevant for classification	Unknown
Primary irritant effect	
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)	
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
STOT-single exposure	Based on available data, the classification criteria are not met.
STOT-repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity	
Aquatic toxicity	No further relevant information available.
12.2 Persistence and degradability	No further relevant information available.
12.3 Bioaccumulative potential	No further relevant information available.
12.4 Mobility in soil	No further relevant information available.
Other Information	The ecological effects have not been thoroughly investigated, but none have been identified.
General notes	Avoid release to the environment.
12.5 Results of PBT and vPvB assessment	
PBT	None of the substances present are considered PBT.
vPvB	None of the substances present are considered vPvB.
12.6 Other adverse effects	No further relevant information available.

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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Recommendation

The user of this product has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state, and federal laws and regulations regarding treatment, storage, and disposal for hazardous and nonhazardous wastes.

Uncleaned packaging recommendation

Disposal must be made according to official regulations.

Recommended cleansing agents

Disinfection with 10% sodium hypochlorite (bleach) or 1:256 Lysol IC Quaternary Disinfectant Cleaner.

SECTION 14: Transport information

14.1 UN number

DOT, ADR, IMDG, IATA

UN 2814

14.2 UN proper shipping name

DOT, ADR, IMDG, IATA

Infectious substance, affecting humans

14.3 Transport hazard class(es)

DOT, ADR, IMDG, IATA Class

Class 6, Division 6.2

14.4 Packing group

DOT, ADR, IMDG, IATA

Intentionally Blank for Category A Infectious Substances

14.5 Environmental hazards

Marine Pollutant

Mixture Not Classified Marine Pollutant

14.6 Special precautions for user

Not Applicable

14.7 Transport in bulk according to

Annex II of Marpol and the IBC Code

Not Applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

Unites States (USA)

SARA Section 355 (extremely hazardous substances)

None of the ingredients are listed.

SARA Section 313 (Specific toxic chemical listings)

None of the ingredients are listed.

TSCA (Toxic Substances Control Act)

All chemicals are listed.

Proposition 65 (California)

None of the ingredients are listed.

Chemicals known to cause Cancer

None of the ingredients are listed.

Chemicals known to cause reproductive toxicity for females

None of the ingredients are listed.

Chemicals known to cause developmental toxicity

None of the ingredients are listed.

Carcinogenic Categories

EPA (Environmental Protection Agency)

None of the ingredients are listed.

IARC (International Agency for Research on Cancer)

None of the ingredients are listed.

NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients are listed.

Canada - Canadian Domestic Substances List (DSL)

Gentamicin is not listed.

International Regulations

WHO/HSE/GCR/2015.2: UN2814

Other regulations, limitations and prohibitive regulations

Seveso III Directive (2012/18/EU)

None of the ingredients are listed.

Substances of very high concern (SVHC)

None of the ingredients are listed.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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SECTION 16: Other information

Disclaimer

The above information is believed to be accurate but does not purport to be all inclusive and shall be used only as a guide. Advanced Biotechnologies, Inc. shall not assume any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that these are the only hazards that exist.

Abbreviations and acronyms

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DOT: US Department of Transportation

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

IATA: International Air Transport Association

IMDG: International Maritime Code for Dangerous Goods

LC50/LD50: Lethal concentration, 50 percent/Lethal dose, 50 percent

OSHA: Occupational Safety and Health Administration

PBT/vPvB: Persistent, Bioaccumulative and Toxic/very Persistent and very Bioaccumulative

PEL/REL: Permissible Exposure Limit/Recommended Exposure Limit

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals (EC 1907/2006)

SARA: Superfund Amendments and Reauthorization Act

STOT: Specific Target Organ Toxicity

SVHC: Candidate List of Substances of Very High Concern

TWA: Time Weighted Average

Date of Preparation

The effective date in the header of this document is the date of preparation and/or last revision.