

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product Name Rubella (HPV77 Strain) Purified Virus, UV-Inactivated
Catalog Number 10-270-000

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

There are no other hazards not otherwise classified that have been identified. After treatment with ultraviolet (UV) light irradiation, this preparation of UV-Inactivated Rubella was specifically tested for residual infectivity and no infectious virus was detected.

Results of PBT and vPvB assessment

PBT	Not applicable
vPvB	Not applicable

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description: Mixture consisting of the following components with Rubella Virus, UV-Inactivated

Components		Concentration/Amount
Dulbecco's Phosphate Buffered Saline (DPBS) Components		(1X)
Sodium Phosphate, Dibasic Synonym: Disodium hydrogenorthophosphate	CAS: 7558-79-4 EC No: 231-448-7	
Potassium Phosphate, Monobasic Synonym: Potassium dihydrogenorthophosphate	CAS: 7778-77-0 EC No: 231-913-4	
Sodium Chloride	CAS: 7647-14-5 EC No: 231-598-3	
Potassium Chloride	CAS: 7447-40-7 EC No: 231-211-8	
Sucrose	CAS: 57-50-1 EC No: 200-334-9	250 mM
Gentamicin, Sulfate	CAS: 1405-41-0 EC No: 215-778-9	25 µg/mL
Rubella Virus, UV-Inactivated		

SECTION 4: First aid measures

4.1 Description of first aid measures

After inhalation Supply fresh air; consult doctor in case of complaints.
After skin contact Immediately wash with water and soap and rinse thoroughly.
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.

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.

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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

This inactivated biological preparation should be handled in accordance with Good Laboratory Practices and any applicable local guidelines. 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.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace

Sucrose: OSHA PEL TWA 15mg/m³ (total) TWA 5mg/m³ (respirable fraction)

NIOSH REL TWA 10mg/m³ (total) TWA 5mg/m³ (respirable fraction)

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.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance	Form: Liquid Color: Slightly Whitish
Odor	Odorless
Odor Threshold	Does not apply, as substance is odorless.
pH	7.4
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.

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.

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SECTION 12: Ecological information

12.1 Toxicity	No further relevant information available.
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.

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 3% hydrogen peroxide followed by 70% isopropyl alcohol.

SECTION 14: Transport information

14.1 UN number	
DOT, ADR, IMDG, IATA	Not Regulated
14.2 UN proper shipping name	
DOT, ADR, IMDG, IATA	Not Regulated
14.3 Transport hazard class(es)	
DOT, ADR, IMDG, IATA Class	Not Regulated
14.4 Packing group	
DOT, ADR, IMDG, IATA	Not Regulated
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

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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

None of the ingredients are listed.

SARA Section 313 (Specific toxic chemical listings)

Sodium Phosphate, Dibasic is listed, but is present below the CERCLA RQ.

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

Sucrose is listed.

Canada - Canadian Domestic Substances List (DSL)

Gentamicin is not listed.

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.

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

NIOSH: National Institute for Occupational Safety and Health

OSHA: Occupational Safety and Health Administration

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

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

SARA: Superfund Amendments and Reauthorization Act

STEL: Short Term Exposure Limit

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.