Document Title:	TUDRIQEV™ Safety Data Sheet

SECTION I - IDENTIFICATION

NAME:	**TUDRIQEV™**
SYNONYMS:	vusolimogene oderparepvec; vusolimogene oderparepvec-wtpg; RP1
ACTIVE INGREDIENT:	rHSV-1hGM-CSF/GALV-GP-R$^-$
CAS #:	2305659-09-8
MANUFACTURED BY:	Replimune, Inc 33 New York Ave Framingham, MA 01701 USA
PRODUCT INFORMATION & EMERGENCY TELEPHONE NUMBER	+1-877-375-0095 (USA)

DESCRIPTION:

TUDRIQEV (vusolimogene oderparepvec) is a fusion-enhanced herpes simplex virus, type 1 (HSV-1) oncolytic immunotherapy that is administered intratumorally. TUDRIQEV encodes a fusogenic glycoprotein derived from gibbon ape leukemia virus with the R sequence deleted (GALV-GP-R$^-$) and human granulocyte-macrophage colony-stimulating factor (GM-CSF). TUDRIQEV is a non-pathogenic version of HSV-1 with the neurovirulence factor ICP34.5 deleted so that replication occurs selectively in tumors and not in healthy tissue.

SECTION II – HAZARD IDENTIFICATION

Classification:	This product is not considered hazardous under the Hazard Communication Standard as defined in 29 CFR 1910.1200 Sections (c) & (d).
Hazard Pictograms:	None
Signal word:	None
Hazard statements:	None
Precautionary statement:	Use standard precautions (inclusive of inclusive of universal precautions) with proper personal protective equipment, proper engineering controls and use within the parameters of the purchaser's safety program.
Unknown acute toxicity:	None

SECTION III – COMPOSITION/INFORMATON ON INGREDIENTS

Component Name	CAS Number	Concentration	Classification
rHSV-1hGM-CSF/GALV-GP-R--	2305659-09-8	1 x 10^6 PFU/mL	Not a hazardous substance
rHSV-1hGM-CSF/GALV-GP-R--	2305659-09-8	1 x 10^7 PFU/mL	Not a hazardous substance
disodium hydrogen phosphate dihydrate	10028-24-7	**7.0 mg/mL**	Not a hazardous substance
Sodium dihydrogen phosphate dihydrate	13472-35-0	**1.4 mg/mL**	Not a hazardous substance
sodium chloride	7647-14-5	**1.3 mg/mL**	Not a hazardous substance
myo-inositol	87-89-8	**39.0 mg/mL**	Not a hazardous substance
d-sorbitol	50-70-4	**19.5 mg/mL**	Not a hazardous substance
human serum albumin	70024-90-7	**5.1 mg/mL**	Not a hazardous substance

SECTION IV – FIRST AID MEASURES

FIRST AID/TREATMENT:

In case of inhalation:	Move to fresh air
In case of skin contact:	Remove contaminated clothing and rinse skin with water, followed by washing with soap and water.
In case of contact with eyes or mucous membranes:	Remove contact lenses. Flush with clean water for at least 15 minutes.
In case of exposure to broken skin or a needle stick:	Thoroughly clean the site with soap and water or use a disinfectant. See a physician for monitoring for signs of infection.
In case of ingestion:	Do not induce vomiting. Rinse mouth with water. Get medical attention if symptoms occur.

Notes to physician:	TUDRIQEV is sensitive to the antiviral agents such as the thymidine kinase inhibitor acyclovir.

SECTION V – FIRE AND EXPLOSION MEASURES

Extinguishing media:	Use an extinguishing agent suitable for the surrounding area.
Specific hazards arising from the chemical:	Thermal decomposition can lead to release of irritating gases and vapors. Keep product and empty container away from heat and sources of ignition.
Protective equipment and precautions for firefighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION VI – ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:	Use personal protective equipment and appropriate laboratory procedures.
Methods and material for containment and cleaning up:	Allow aerosols to settle; wearing protective clothing, gently cover spill with paper towel or lint-free wipe. Apply either 70% isopropanol or Decon90 (5%) and allow to sit for 30 seconds to ensure decontamination. Allow sufficient contact time for absorption before removing towel or wipe. Materials used for cleaning should be disposed of as biohazardous waste.
Environmental precautions:	Although HSV-1 does not persist in natural ecosystems, avoid release of TUDRIQEV into the environment.

SECTION VII – HANDLING AND STORAGE

Precautions for safe handling:	Handle in accordance with Biosafety Level 1 procedures. Standard precautions are recommended for healthcare facilities preparing and administering the product with single dose vials. When working with volumes greater than 10L (eg, manufacturing) use of Biosafety Level 2 practices is recommended for work tasks.
Storage conditions:	Protect TUDRIQEV from light. Store vials in the original carton until use.
Storage:	Store at -70°C to -90°C (-94°F to -130°F). Once thawed:

- TUDRIQEV 10^6 PFU/mL vial may be stored at 2°C to 8°C (36°F to 46°F) for up to 2 days
- TUDRIQEV 10^7 PFU/mL vial may be stored at 2°C to 8°C (36°F to 46°F) for up to 10 days.
- Do not refreeze.

SECTION VIII – EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure guidelines:	This product does not contain any hazardous materials with occupational exposure limits established by the region-specific regulatory bodies.
Engineering controls:	Use standard precautions (inclusive of universal precautions). Maintain adequate ventilation.
Personal protective equipment:	Use laboratory coat, protective gloves, safety glasses and suitable protective clothing.

SECTION IX – PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Liquid at room temperature
Appearance/color:	Translucent to opaque, colorless
Odor/odor threshold:	No Data Available.
Melting point:	-2.4 ºC
Freezing point:	-16.3 ºC
Boiling point:	No Data Available.
Flash point:	No Data Available.
Flammability:	No Data Available.
Upper/lower flammability or explosive limits:	No Data Available.
Auto-ignition temperature:	No Data Available.
Decomposition temperature:	No Data Available.
pH:	7.2 to 7.5
Viscosity:	1.2 (based on formulation buffer)
Solubility(ies):	No Data Available.
Partition coefficient:	No Data Available.
Vapor pressure/evaporation rate:	No Data Available.
Vapor density:	No Data Available.
Relative density:	1.03 g/mL

Particle characteristics	Subvisible
Other information:	May settle. Swirl gently before use.

SECTION X – STABILITY AND REACTIVITY

Reactivity:	No data available.
Chemical stability:	The product is stable.
Possibility of hazardous reactions:	Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid:	No data available.
Incompatible materials:	No data available.
Hazardous decomposition products:	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION XI – TOXICOLOGICAL INFORMATION

Acute toxicity:

Component:	L**D50 Oral**	L**D50 Dermal**	L**C50 Inhalation**
rHSV-1hGM-CSF/GALV	Not listed	Not listed	Not listed
disodium hydrogen phosphate dihydrate	LD50 = 17 g/kg (Rat)	Not listed	Not listed
Sodium dihydrogen phosphate dihydrate	LD50 = 8290 mg/kg (Rat)	LD50 > 7940 mg/kg (Rabbit)	LC50 > 0.83 mg/L (Rat) 4 h
sodium chloride	LD50 = 3 g/kg (Rat)	LD50 > 10000 mg/kg (Rabbit)	LC50 > 42 mg/L (Rat) 1 h
myo-inositol	Not listed	Not listed	Not listed
d-sorbitol	LD50 = 15900 mg/kg (Rat)	Not listed	Not listed
human serum albumin	Not listed	Not listed	Not listed

Repeat dose toxicity:

Species:	Rat
NOAEL:	10^7 PFU
Administration route:	SC
Exposure time:	12 weeks
Remarks:	no significant adverse effects were reported

Species:	Rat
NOAEL:	10^6 PFU
Administration route:	SC
Exposure time:	6 months
Remarks:	No significant adverse effects were reported

Development effects:

Species:	Rat
NOAEL:	10^6 PFU/rat
Administration route:	IV
Exposure time:	Gestation days 4, 7, 10, 13, and 16
Remarks:	No significant adverse effects were reported. No evidence of placental transfer was found.

Carcinogen status:

None of the components of this formulation are listed as a carcinogen by IARC NTP or OSHA.

SECTION XII – ECOLOGICAL INFORMATION

Ecotoxicity:	Do not empty into drains.
Persistence and degradability:	Persistence is unlikely based on information available.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.
Other adverse effects:	No data available.

SECTION XIII – DISPOSAL CONSIDERATIONS

Waste disposal recommendations:	Dispose of material in accordance with local, State and Federal waste disposal regulations. Decontaminate before disposal with steam sterilization, chemical disinfection, or incineration.

SECTION XIV – TRANSPORT INFORMATION

UN number	UN3245 (UN1845 if shipping samples in dry ice)
UN proper shipping name	Genetically Modified Organisms (GMO)
Hazard Class	9
Packing group	Products manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for personal health care by medical professionals or individuals are not subject to IATA Dangerous Goods Regulations.
Environmental hazards	No data available.
Special precautions	Maintain temperature at -70°C to -90°C (-94°F to -130°F).

SECTION XV – REGULATORY INFORMATON

SECTION XVI – OTHER INFORMATION

Version	Effective date	Description of Changes / Reason for Change
03	Xx Jul 2025	Revision for commercial product; aligned with SDS standards
02	30 Jan 2017	Administrative changes, new header and footer
01	24 May 2016	New