1. PRODUCT AND COMPANY IDENTIFICATION

1.1. Product identifiers

Commercial name: SARS-CoV-2 pseudovirus D614G variant
Biological name: viral vector
Brand: IVANO Bioscience

1.2. Identification of the biological product or preparation

Biological Product: 3rd generation lentivirus-based viral vector, infectious, non-replicative, and non-toxic.
Pseudotyping: Spike glycoprotein from the SARS-CoV-2 virus, D614G variant

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

Recommended use: For research use only.
Uses advised against: Not to be used in humans or animal food. Not for use in diagnostic procedures. Not meant for resale.

1.4. Details of the supplier of the safety data sheet

Headquarters: IVANO Bioscience
737 Avenue du Chateau, Room 23
Quebec, QC, G1X 3P4, Canada

Biomanufacturing laboratory: IVANO Bioscience
1065, Avenue de la Medecine, PLT-0596
Quebec, QC, G1V 0A6, Canada

Telephone: +1 581-986-2808.

1.5. Emergency telephone number

Telephone: +1 581-986-2808 or +1 418-271-2272

1.6. Issue date:

February 12th, 2024.

2. HAZARDS IDENTIFICATION

Pseudoviruses must be handled as a biohazardous material under Biosafety Level 2.
For information on BSL-2 handling, see Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition. Contact your local institutional biosafety office for accurate regional information.

2.1. Pathogenicity

Lentivirus-derived non-replicating vectors derived from HIV-1, do not encode the viral proteins or genome required for viral replication. Replication-defective lentiviral vectors are not known to cause any diseases in humans or animals. However, they can integrate into the cell genome and thus pose some risk of insertional mutagenesis.

These pseudoviruses are lentiviral vectors defined by the presence of HIV-derived cis elements flanked by lentiviral long terminal repeats (LTRs). The removal of the viral structural genes renders the vector replication-defective and dependent upon a helper vector(s) or packaging cell line. Lentiviruses are enveloped viruses and upon leaving the producer cell line, the viral capsid becomes enclosed in a lipid membrane derived from the host cell. The pseudoviruses contain only 10% of the lentiviral genome sequence, notably excluding the essential viral tat gene required for wild-type replication. The vector employs a split-genome packaging system to reduce the risk of recombination during plasmid amplification and viral vector production. Chimeric 5' LTRs have been engineered in the transfer vector, making the lentiviral promoter Tat-independent by replacing the U3 region of the 5' LTR with a strong tat-independent constitutive promoter. An altered 3' LTR renders the vector "self-inactivating" to prevent integrated genes from being repackaged, significantly limiting genome mobility and potential recombination in host cells. The lentiviral vectors are pseudotyped with a custom envelope protein to mimic another virus surface.

2.2. Classification of the substance or mixture

Pseudoviruses are biological materials and are therefore outside the scope of the Globally Harmonized System of Classification and Labelling (GHS), so it CANNOT be classified in accordance with this system. The toxicological properties of this material have not been fully investigated. As with any chemical product of unknown toxicity, take precautions to prevent contact with eye, skin and mucous membranes. Use good industrial hygiene practices to prevent accidental exposure. IVANO Bioscience recommends that all lentiviral vectors and cultures be handled by qualified individuals using appropriate safety procedures and precautions. Appropriate containment facilities for all activities involving the vector and vector-administered cells, tissues and fluids. This includes BSL2 practices (including animal housing). For information on BSL-2 handling, see Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition.

2.3. Biohazard Classification

In accordance with the NIH recommended guidelines, replication-incompetent lentiviral particles are to be handled as Risk Group-Level 2 (RGL2) (https://ivanobioscience.com/wp-content/uploads/2024/09/NIH-Containment-Guidance-Lentiviral-vector.pdf)

2.4. Hazards not otherwise classified (HNOC) or not covered by GHS

Handle as if capable of transmitting infectious agents. Replication-defective lentiviral vectors are not known to cause disease in humans or animals. However, lentiviruses can integrate into the host cell genome and may pose some risk of insertional mutagenesis.

2.5. Precautionary Statements

- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Do not get in eyes, on skin, or on clothing.
- Wash hands thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Wear protective gloves, eye protection, face protection, and protective clothing.
- Contaminated clothing must not be allowed out of the workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Biological Product

Virus name: Pseudovirus or lentiviral vector
Type: 3rd generation lentiviral vector
Promoter: CMV
Replicative: No
LTR: HIV 5' LTRs have been engineered in the transfer vector, making the lentiviral promoter Tat-independent by replacing the U3 region of the 5' LTR with a strong tat-independent constitutive promoter. An altered 3' LTR renders the vector "self-inactivating" to prevent integrated genes from being repackaged, significantly limiting genome mobility and potential recombination in host cells.

4. FIRST AID MEASURES

4.1. Description of first aid measures

4.1.1. Inhalation

Move people into fresh air. If not breathing, give artificial respiration and obtain medical attention.

4.1.2. Ingestion

If swallowed, rinse your mouth with water. Do not induce vomiting. Immediately get medical advice/attention.

4.1.3. Skin contact

Wash immediately with plenty of soap and water. If skin irritation occurs, get medical advice/attention. Take off contaminated clothing and wash before reusing.

4.1.4. Eye contact

Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if soreness or redness persists. Contact lenses are not recommended when handling viral vectors.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media.
Substance is non-flammable. Use an extinguishing agent suitable for surrounding fire.

5.2. Special hazards arising from the substance or mixture
None known.

5.3. Advice for firefighters
As in any fire, wearing self-contained breathing apparatus and full protective gear if necessary.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions
Should not be released into the environment.

6.3. Methods and materials for containment and cleaning up
Spill: Contain spill and decontaminate the area using a disinfectant such as chlorine bleach (10% f.c.), Wescodyne, or detergent-based disinfectant and allow sufficient contact time (30 min) before cleaning up disposal (Decontaminate all wastes before disposal).

7. HANDLING AND STORAGE

7.1. Precautions for safe handling
Handle in accordance with good industrial hygiene and safety practices. Use personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. This product should be handled at a biosafety level 2 or enhanced biosafety level 2 (BSL2) as required by OSHA Bloodborne Pathogen Rule (29 CFR 1910.1030).

7.2. Conditions for safe storage, including any incompatibilities
- Keep the container tightly closed.
- Store at -80°C.
- Storage class (TRGS 510): Infectious substances.
- The store is locked up in accordance with biosafety level 2 containment requirements.

7.3. Specific end use(s)
See Section 1.3.

7.4. Shipping information
- Product classification: category B (UN3373)
- Use Dry ice (UN1845)
- HS Code: 3002.90

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

8.1.1. Components with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

General industrial hygiene practice.

8.2.2. Collective protection

BLS-2 containment and BSC-2 biosafety cabinet-2.

8.2.3. Personal protective equipment

Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards.

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Body Protection**:** Laboratory coat.

Respiratory protection: Respiratory protection is not required. If there is a risk of exposure or insufficient ventilation, wear suitable respiratory equipment that has been tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	red/orange
Form	Liquid
Decomposition temperature	No data available
Odor	No data available
Odor Threshold	No data available
pH	No data available
Melting point/range	No data available
Boiling point/range	No data available
Flash point	No data available
Evaporation rate	No data available
Explosion limits	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Partition coefficient	No data available

Autoignition temperature	No data available
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available

9.2. Other safety information
No data available.

10. STABILITY AND REACTIVITY

10.1. Reactivity
No data available.

10.2. Chemical stability
Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions
No data available.

10.4. Conditions to avoid
No data available.

10.5. Incompatible materials
No data available.

10.6. Hazardous decomposition products
No data available. In the event of fire, see section 5.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

11.1.1. Acute toxicity
No data available.

11.1.2. Skin corrosion/irritation
No data available.

11.1.3. Serious eye damage/eye irritation
No data available.

11.1.4. Respiratory or skin sensitization
No data available.

11.1.5. Germ cell mutagenicity
Lentiviruses can integrate into the host cell genome and may pose some risk of insertional mutagenesis.

11.1.6. Carcinogenicity
Lentiviruses can integrate into the host cell genome and may pose some risk of oncogenic insertional mutagenesis. This product has not been evaluated in animal carcinogenicity studies and is not listed on the NTP, IARC or OSHA database.

11.1.7. Reproductive toxicity
No data available.

11.1.8. Specific target organ toxicity - single exposure
No data available.

11.1.9. Specific target organ toxicity - repeated exposure
No data available.

11.1.10. Aspiration hazard
No data available.

11.1.11. Additional Information
RTECS: Not available.

12. ECOLOGICAL INFORMATION

12.1. Toxicity
No data available.

12.2. Persistence and degradability
No data available.

12.3. Bioaccumulative potential
No data available.

12.4. Mobility in soil
No data available.

12.5. Results of PBT and vPvB assessment
PBT/vPvB assessment is not available as chemical safety assessment is not required.

12.6. Other adverse effects
No data available.

13. DISPOSAL CONSIDERATIONS

13.1. Disposal methods
Waste Disposal: Dispose of viral stock by autoclaving at 121°C for 30-45 minutes. Dispose of infected liquid cultures by decontamination with chlorine bleach (10% f.c.) for 10 minutes and then dispose of in sink. Dispose of infected animal carcasses or tissues by incineration.
Follow all Federal, State, and Local regulations.

14. TRANSPORT INFORMATION

Product must be shipped on DRY ICE.
UN number: 1845
Class: 9
Proper Shipping Name: CARBON DIOXIDE, SOLID

Non replicative viral vector, pseudovirus is a biological substance **category B**
UN number: 3373
Class: 6.2
Proper shipping name: viral vector non-replicative and non-toxic
Marine pollutant: No
Poison Inhalation Hazard: No

15. REGULATORY INFORMATION

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

Non-applicable.

15.2. Chemical safety assessment

A Chemical Safety Assessment (CSA) has not been conducted.

15.3. Classification

Biohazard Biosafety level BSL-2.

16. OTHER INFORMATION

Disclaimer
The above information is accurate to the best of IVANO Bioscience's knowledge and experience but does not claim to be all inclusive and should only be used as a guide. The information in this document is applicable to the product regarding appropriate safety precautions. The user should exercise independent judgment as to the hazards based on all sources of information available. The information herein does not show any guarantee of the properties of the product. IVANO Bioscience shall not be held liable for any damage resulting from handling, from use or from contact with the above product.

Safety Data Sheet Preparation
Headquarters
IVANO Bioscience
737 avenue du Chateau, Room 23
Quebec, QC, G1X 3P4, Canada

Manufacturing Laboratory
IVANO Bioscience
1065, Avenue de la Medecine, PLT-0596
Quebec, Qc, G1V 0A6, Canada