

FectoVIR®-AAV reference standard

Safety Data Sheet dated January 30, 2024, version E.

In compliance with the requirement of the Regulation (EC) N°1907/2006.

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

1.1. Product Identifier

Trade name: **Reference Standard FectoVIR®-AAV powder**
 Polymer class term: Cationic polymer
 Reference number: 101000137

1.2. Relevant identified uses of the substance/mixture and uses advised against

Recommended use: For analysis as reference standard
 Uses advised against: Not intended for human diagnostic or therapeutic use.

1.3. Details of the supplier of the safety data sheet

Company:
 POLYPLUS-TRANSFECTION SA
 75, rue Marguerite Perey
 67400 ILLKIRCH
 FRANCE
 Tel: +33 (0)3 90 40 61 80
 Fax: +33 (0)3 90 40 61 81
 Email: support@polyplus-transfection.com

1.4. Emergency telephone number

I.N.R.S.: +33 (0)1 40 44 30 00
 On-line information database TOXBASE (www.toxbase.org)

SECTION 2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:
 Acute toxicity, Oral (Category 4), H302, H312, H315, H319, H332.
 For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2. Label elements

Labelling according Regulation (EC) No 1272/2008 [CLP]:

Symbols:



Warning

Hazard statements:

H302 Harmful if swallowed.
 H312 Harmful in contact with skin.
 H315 Causes skin irritation
 H319 Causes serious eye irritation.
 H332 Harmful if inhaled.

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
 P264 Wash hands thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P271 Use only outdoors or in a well-ventilated area
 P280 Wash hands thoroughly after handling.
 P281 Use personal protective equipment as required.
 P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
 P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
 P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

FectoVIR®-AAV reference standard

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P312 Call a POISON CENTER or doctor/physician if you feel unwell.

P330 Rinse mouth.

P332 + P313 If skin irritation occurs: Get medical advice/ attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P362 Take off contaminated clothing and wash before reuse.

2.3. Other hazards

vPvB and PBT Substances:

This substance/mixture does not contain components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Endocrine disrupting properties:

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 % by weight.

Other Hazards:

No other hazards.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Substance	Classification	Concentration (% w/w)
Name: Reference Standard FectoVIR®-AAV powder CAS-No.: none EC-No.: N.A.	Acute Tox.4; H302, H312, H315, H319, H332	100%

For the full text of the H-Statements mentioned in this Section, see Section 16.

3.2. Mixtures

None.

SECTION 4. FIRST AID MEASURES

4.1. Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Remove contaminated clothing and shoes. Consult a physician.

In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Consult a physician.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Call a POISON CENTER or doctor/physician.

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

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

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

N.A.

SECTION 5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media:

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products formed under fire conditions. Carbon monoxide, Carbon dioxide, Hydrogen chloride gas, and Nitrogen oxides (NOx).

5.3. Advice for fire-fighters

Wear self-contained breathing apparatus for fire-fighting if necessary.

5.4. Further information

N.A.

FectoVIR®-AAV reference standard

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Avoid breathing dust. Ensuring personal safety, mark out contaminated area with signs and prevent unauthorised access. Personal involved in clean-up should wear appropriate personal protective equipment.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

See also section 8 and 13.

SECTION 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Do not eat or drink while working.

7.2. Conditions for safe storage, including any incompatibilities

Store in cool place. Keep light-resistant container tightly closed in a dry and well-ventilated place. Recommended storage temperature: $-20\pm 5^{\circ}\text{C}$. Hygroscopic. Handle and store under inert gas.

7.3. Specific end use(s)

None in particular.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

None.

8.2. Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and immediately after handling the product.

Personal protective equipment

Eye/face protection:

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166(EU).

Skin protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body protection:

Complete suits protecting against chemicals. The type of body protection must be selected according to the amount and concentration of the dangerous substance at the workplace.

Respiratory protection:

For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEK-P2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure:

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Unless otherwise indicated, tests have been carried out at 20°C and at normal atmospheric pressure (760 mm Hg - 1 atm).

9.1. Information on basic physical and chemical properties

Appearance and colour:	Form: solid Colour: white
Odour:	N.A.
Odour threshold:	N.A.
pH:	2-3

FectoVIR®-AAV reference standard

Melting point / freezing point:	Melting point: 276-281°C
Initial boiling point and boiling range:	N.A.
Solid/gas flammability:	N.A.
Upper/lower flammability or explosive limits:	N.A.
Vapour density:	N.A.
Flash point:	N.A.
Evaporation rate:	N.A.
Vapour pressure:	N.A.
Relative density:	N.A.
Solubility in water:	Soluble
Lipid solubility:	N.A.
Partition coefficient (n-octanol/water):	N.A.
Particle characteristics:	N.A.
Auto-ignition temperature:	N.A.
Decomposition temperature:	N.A.
Viscosity:	N.A.
Explosive properties:	N.A.
Oxidizing properties:	N.A.

9.2. Other information

N.A.

SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity

N.A.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None.

10.4. Conditions to avoid

None in particular.

10.5. Incompatible materials

Strong oxidizing agent.

10.6. Hazardous decomposition products

Other decomposition product: N.A.

In the event of fire: see section 5.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Accute toxicity

N.A.

Skin corrosion/irritation

N.A.

Serious eye damage/eye irritation

N.A.

Respiratory or skin sensitisation

N.A.

Germ cell mutagenicity

N.A.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

N.A.

Specific target organ toxicity - single exposure

N.A.

Specific target organ toxicity - repeated exposure

N.A.

Aspiration hazard

N.A.

Additional information

RTECS: N.A.

FectoVIR®-AAV reference standard

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

11.2. Information on other hazards

11.2.1 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 % by weight.

SECTION 12. ECOLOGICAL INFORMATION

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

Since no ecotoxicological data about the powder is available, the concentration of each substance must be considered to assess the ecotoxicological effects resulting from exposure to the mixture.

12.2. Persistence and degradability

N.A.

12.3. Bioaccumulative potential

N.A.

12.4. Mobility in soil

N.A.

12.5. Results of PBT and vPvB assessment

N.A.

12.6. Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 % by weight.

12.7. Other adverse effects

None.

SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14. TRANSPORT INFORMATION

14.1. UN number or ID Number

Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

N.A.

14.3. Transport hazard class(es)

N.A.

14.4. Packing Group

N.A.

14.5. Environmental hazards

Marine pollutant: No

14.6. Special Precautions for User

N.A.

14.7. Maritime transport in bulk according to IMO instruments

No.

SECTION 15. REGULATORY INFORMATION

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

Where applicable, refer to the following regulatory provisions:

Directive 98/24/EC (Risks related to chemical agents at work).

Directive 2000/39/EC (Occupational exposure limit values).

Directive 2012/18/EU (control of major-accident hazards involving dangerous substances) and subsequent amendments.

Regulation (EC) nr 648/2004 (detergents).

Directive 2010/75/EU ((integrated pollution prevention and control).

15.2. Chemical Safety Assessment

No.

SECTION 16. OTHER INFORMATION

FectoVIR[®]-AAV reference standard

Full text of phrases referred to in Section 3:

- H302 Harmful if swallowed.
- H312 Harmful in contact with skin.
- H315 Causes skin irritation
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.

Main bibliographic sources:

- ECHA CHEM (European Chemicals Agency)
- eCHEMPORTAL (OECD Global Portal of Information on Chemical Substances)
- GESTIS International Limit Values (IFA)
- TOXNET (Hazardous Substances Data Bank)
- ESIS (European chemical Substances Information System) - European Commission/Joint Research Centre/Institute for Health and Consumer Protection
- ACToR (Aggregated Computational Toxicology Resource - EPA's database on chemical toxicity)
- CCR DATA (Ecological Categorization Results from the Canadian Domestic Substance List)

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This safety data sheet has been completely updated in compliance with Regulation (CE) 1907/2006.

This document supersedes any previous version.

CAS:	Chemical Abstracts Service (division of the American Chemical Society).
CLP:	Classification, Labeling, Packaging.
EC50:	Median effective concentration.
LC50:	Lethal concentration, for 50 percent of test population.
N.A.:	Not Available
PBT:	Persistent, Bioaccumulative and Toxic.
vPvB:	very Persistent and very Bioaccumulative.

End of the safety data sheet.