

## 1. Identification

**Product identifier** RSV PreF3 VACCINE

**Other means of identification**  
**Synonyms** AREXVY \* DS-CAV1 VACCINE \* NDC 58160-848-11 (US) \* RSV PreF3, FORMULATED PRODUCT

**Recommended use** Medicinal Product.

This safety data sheet (SDS) has been prepared in accordance with workplace safety standards which require identification of all known hazards of the material regardless of potential risk. The information is intended for people handling the material in the workplace. Warnings included may not apply in all cases. Needs may vary depending upon the potential for exposure in the workplace. The SDS is not intended to provide information relevant to final use of the material for the purpose intended. Consumers/Patients should consult prescribing information/package insert/product label or consult their chemist or physician.

**Recommended restrictions** No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

**COMPANY NAME** GSK

**Address:** 410 Blackwell Street  
 Durham, NC, 27701

**Telephone:** +1-888-825-5249 (GSK General Inquiries)  
 +1-877-844-8872 (ViiV General Inquiries)

**Email:** msds@gsk.com

**Website:** www.gsk.com

### EMERGENCY CONTACTS

**Telephone:** 3E GLOBAL INCIDENT RESPONSE  
 +(1) 760 476 3971 (In country)  
 +(1) 760 476 3962 or +(1) 866 519 4752 (International)  
 24/7; multi-language response

**Contract Number:** 334878

## 2. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Not classified.

**Environmental hazards** Not classified.

**OSHA defined hazards** Combustible dust

### Label elements

**Hazard symbol** None.

**Signal word** Warning

**Hazard statement** May form combustible dust concentrations in air.

**Precautionary statement**

**Prevention** Prevent dust accumulation to minimize explosion hazard. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Ground/bond container and receiving equipment.

**Response** Take off contaminated clothing and wash it before reuse. In case of fire: Use appropriate media to extinguish.

**Storage** Store away from incompatible materials.

**Disposal** Dispose of waste and residues in accordance with local authority requirements.

**Hazard(s) not otherwise classified (HNOC)**

Assume that this material is capable of sustaining combustion.  
 Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.

**Supplemental information**

95.64% of the mixture consists of component(s) of unknown acute oral toxicity. 95.64% of the mixture consists of component(s) of unknown acute dermal toxicity. 96.35% of the mixture consists of component(s) of unknown acute inhalation toxicity. 97.53% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 97.53% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

**3. Composition/information on ingredients****Mixtures**

Chemical name	Common name and synonyms	CAS number	%
POTASSIUM PHOSPHATE MONOBASIC	POTASSIUM ACID PHOSPHATE POTASSIUM DIPHOSPHATE POTASSIUM BIPHOSPHATE POTASSIUM ORTHOPHOSPHATE MONOPOTASSIUM PHOSPHATE POTASSIUM DIHYDROGEN PHOSPHATE E POTASSIUM DIHYDROGEN ORTHOPHOSPHATE POTASSIUM PHOSPHATE, MONOBASIC	7778-77-0	1.89
POTASSIUM PHOSPHATE DIBASIC	PHOSPHORIC ACID, DIPOTASSIUM SALT DIBASIC POTASSIUM PHOSPHATE DIPOTASSIUM HYDROGEN PHOSPHATE E DIPOTASSIUM MONOHYDROGEN PHOSPHATE DIPOTASSIUM MONOPHOSPHATE DIPOTASSIUM ORTHOPHOSPHATE DIPOTASSIUM PHOSPHATE HYDROGEN DIPOTASSIUM PHOSPHATE E POTASSIUM BIPHOSPHATE POTASSIUM MONOHYDROGEN PHOSPHATE POTASSIUM MONOPHOSPHATE DKP DIPOTASSIUM HYDROGENORTHOPHOSPHATE DIPOTASSIUM HYDROGEN ORTHOPHOSPHATE POTASSIUM PHOSPHATE, DIBASIC, ANHYDROUS POTASSIUM HYDROGEN ORTHOPHOSPHATE POTASSIUM HYDROGEN PHOSPHATE	7758-11-4	1.7
RSV PreF3	DS-CAV1		0.77
Other components below reportable levels			< 95.5

**4. First-aid measures**

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	Dusts may irritate the respiratory tract, skin and eyes.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

**5. Fire-fighting measures**

**Suitable extinguishing media** Water. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers. Apply extinguishing media carefully to avoid creating airborne dust.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted. May form combustible dust concentrations in air.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate protective equipment and clothing during clean-up. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter.  Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.  Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal.  Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Minimize dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Combustible dust clouds may be created where operations produce fine material (dust). Handling and processing operations should be conducted in accordance with 'best practices' (e.g. NFPA-654). Explosion-proof general and local exhaust ventilation. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

<b>GSK Components</b>	<b>Type</b>	<b>Value</b>	<b>Form</b>
POTASSIUM PHOSPHATE DIBASIC (CAS 7758-11-4)	8 HR TWA	5000 mcg/m3	
	OHC	1	
POTASSIUM PHOSPHATE MONOBASIC (CAS 7778-77-0)	OHC	1	>1000 - <=/5000 mcg/m3
RSV PreF3	OHC	3	>10 - <=/100 mcg/m3 PROVISIONAL

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
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## Exposure guidelines

### Appropriate engineering controls

Explosion-proof general and local exhaust ventilation. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. Use only appropriately classified electrical equipment and powered industrial trucks.

### Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	Not normally needed. Wear safety glasses with side shields (or goggles). Eye wash fountain is recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Not normally needed. Wear appropriate chemical resistant gloves.
<b>Other</b>	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required. If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

When using, do not eat, drink or smoke. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Vial Powder. and Vial Solution
<b>Color</b>	White. Powder. and Colorless to Pale brownish. Diluent
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.

**Viscosity** Not available.

**Other information**

**Explosive properties** Not established.

**Oxidizing properties** Not established.

**Percent volatile** 90 % estimated

## 10. Stability and reactivity

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Keep away from heat, sparks and open flame. Contact with incompatible materials. Minimize dust generation and accumulation.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

**Inhalation** Dust may irritate respiratory system. Prolonged inhalation may be harmful.

**Skin contact** No adverse effects due to skin contact are expected.

**Eye contact** Direct contact with eyes may cause temporary irritation.

**Ingestion** May cause discomfort if swallowed. Expected to be a low ingestion hazard.

**Symptoms related to the physical, chemical and toxicological characteristics** Dusts may irritate the respiratory tract, skin and eyes.

### Information on toxicological effects

**Acute toxicity** Not known. Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
POTASSIUM PHOSPHATE MONOBASIC (CAS 7778-77-0)		

**Acute**

**Dermal**

LD50 Rabbit > 300 mg/kg, 24 Hours

**Oral**

LD50 Mouse 1700 mg/kg

**Skin corrosion/irritation** Due to partial or complete lack of data the classification is not possible. No adverse effects due to skin contact are expected.

**Serious eye damage/eye irritation** Dust or powder may irritate eye tissue.

**Respiratory or skin sensitization** Due to partial or complete lack of data the classification is not possible. Health injuries are not expected as a result of occupational exposure or intended use.

**Respiratory sensitization** Due to partial or complete lack of data the classification is not possible. Health injuries are not expected as a result of occupational exposure or intended use.

**Skin sensitization** Due to partial or complete lack of data the classification is not possible.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Carcinogenicity** No data available to indicate product or any components present at greater than 0.1% are carcinogenic. Carcinogenic effects are not expected as a result of occupational exposure.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)**

Not listed.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity** Due to partial or complete lack of data the classification is not possible. Health injuries are not expected as a result of occupational exposure or intended use.

<b>Specific target organ toxicity - single exposure</b>	Not assigned. Based on available data, the classification criteria are not met.
<b>Specific target organ toxicity - repeated exposure</b>	Not assigned. Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Not likely, due to the form of the product. Due to partial or complete lack of data the classification is not possible.
<b>Chronic effects</b>	Not established. Prolonged inhalation may be harmful.
<b>Further information</b>	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

## 12. Ecological information

<b>Ecotoxicity</b>	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
<b>Persistence and degradability</b>	No data is available on the degradability of any ingredients in the mixture.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Other adverse effects</b>	Not available.

## 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

## 14. Transport information

### DOT

Not regulated as a dangerous good.  
Read safety instructions, SDS and emergency procedures before handling.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

### Toxic Substances Control Act (TSCA)

#### TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

### SARA 304 Emergency release notification

Not regulated.

### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories** Combustible dust

**SARA 313 (TRI reporting)**  
Not regulated.

#### Other federal regulations

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

#### US state regulations

**California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

#### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

**Issue date** 04-18-2018

**Revision date** 07-17-2023

**Version #** 07

**Further information** Refer to:  
OSHA 3371-08 2009, Hazard Communication Guidance for Combustible Dusts  
NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids

**HMIS® ratings** Health: 1  
Flammability: 1  
Physical hazard: 0

**NFPA ratings** Health: 1  
Flammability: 1  
Instability: 0

**References** GSK Hazard Determination.

**Disclaimer** The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**Revision information**

Product and Company Identification: Synonyms  
Physical and chemical properties: Color  
Physical and chemical properties: Form  
Toxicological information: Acute toxicity  
Toxicological information: Aspiration hazard  
Toxicological information: Carcinogenicity  
Toxicological information: Corrosivity  
Toxicological information: Eye contact  
Toxicological information: Reproductivity  
Toxicological information: Respiratory or skin sensitization  
Toxicological information: Respiratory sensitization  
Toxicological information: Skin contact