

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier Adacel®
Product Name

Other means of identification

- Product Information**
- Syringe, without needle, 1 dose (NDC 49281-400-88) in package of 5 syringes, (NDC 49281-400-15)
 - Syringe, without needle, 1 dose (NDC 49281-400-89) in package of 5 syringes, (NDC 49281-400-20)
 - Vial, 1 dose (NDC 49281-400-58) in package of 5 vials (NDC 49281-400-05)
 - Vial, 1 dose (NDC 49281-400-58) in package of 10 vials (NDC 49281-400-10)

Synonyms Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed

Recommended use of the chemical and restrictions on use

Recommended Use Active booster immunization against tetanus, diphtheria and pertussis.
Uses advised against Not available.

Details of the supplier of the safety data sheet

Supplier Address
 Sanofi Pasteur
 1 Discovery Drive
 Swiftwater, PA 18370

Emergency telephone number

Company Phone Number 1-800-VACCINE (1-800-822-2463)
24 Hour Emergency Phone Number 1-570-957-4400
Emergency Telephone 1-570-957-4400

2. HAZARDS IDENTIFICATION

Classification

Health Hazards

Not classified.

Physical Hazards

Not classified.

OSHA Regulatory Status

This product is a vaccine that is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows throughout the sheet.

Label elements

Emergency Overview

Normal precautions common to safe manufacturing practice should be followed in handling and storage.

Appearance Uniform, white, cloudy suspension	Physical State Liquid	Odor Not available.
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Hazards not otherwise classified (HNOC)

Not available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed.

Chemical Name	CAS No.	Weight-%
Tetanus Toxoid Adsorbed	N/A	N/A
Diphtheria Toxoid Adsorbed	N/A	N/A
Pertussis (acellular, component)	N/A	0.0005
Fimbriae Types 2 and 3 Adsorbed (FIM)	N/A	0.001
Filamentous Haemagglutinin Adsorbed (FHA)	N/A	0.001
Pertactin Adsorbed	N/A	0.0006
Water	7732-18-5	q.s to 100

Note: Ingredients below reportable levels are not listed.

4. FIRST AID MEASURES

First aid measures

Eye Contact

In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin Contact

In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation

In case of inhalation, remove to fresh air. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion

In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-Protection of the First Aider

Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms

Common effects of the vaccine include the following: pain, swelling, and erythema of the injection site; headache; body ache or muscle weakness; tiredness.

Indication of any immediate medical attention and special treatment needed

Note to physicians

Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media None known.

Specific hazards arising from the chemical

Not available.

Hazardous Combustion Products Not available.

Explosion data

Sensitivity to Mechanical Impact Not available.

Sensitivity to Static Discharge None known.

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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions Wear appropriate personal protective equipment (see Section 8).

Environmental precautions

Environmental Precautions See Section 12 for additional ecological information.

Methods and material for containment and cleaning up

Methods for Containment Prevent further leakage or spillage if safe to do so.

Methods for Cleaning up

Wipe up with absorbent material (e.g. cloth) for disposal. Area where spill occurred can be cleaned with the regular cleaning materials designated for the area.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on Safe Handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Store at 2° to 8°C (35° to 46°F). Do not freeze.

Incompatible Materials Not available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Controls Used as supplied, no special engineering controls are needed when administering the vaccine.

Individual protection measures, such as personal protective equipment

Eye/face Protection In laboratory or industrial settings, safety glasses with side shields are recommended.

Skin and Body Protection

In laboratory or industrial settings, gloves and lab coats are recommended.

Respiratory Protection

Used as supplied, general room ventilation is acceptable and no special respiratory protection is needed when administering the vaccine.

General Hygiene Considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid	Odor	Not available.
Appearance	Uniform, white cloudy suspension.	Odor Threshold	Not available.
Color	Not available.		

<u>Property</u>	<u>Values</u>	<u>Remarks</u>
pH	Not available.	
Melting Point/Freezing Point	Not available.	
Boiling Point / Boiling Range	Not available.	
Flash Point	Not available.	
Evaporation Rate	Not available.	
Flammability (Solid, gas)	Not available.	
Flammability Limit in Air		
Upper Flammability Limit:	Not available.	
Lower Flammability Limit:	Not available.	
Vapor Pressure	Not available.	
Vapor Density	Not available.	
Specific Gravity	Not available.	
Water Solubility	Not available.	
Solubility in Other Solvents	Not available.	
Partition Coefficient	Not available.	
Autoignition Temperature	Not available.	
Decomposition Temperature	Not available.	
Kinematic Viscosity	Not available.	
Dynamic Viscosity	Not available.	
Explosive Properties	Not available.	
Oxidizing Properties	Not available.	

Other Information

Softening Point	Not available.
Molecular Weight	Not available.
VOC Content (%)	Not available.
Density	Not available.
Bulk Density	Not available.

10. STABILITY AND REACTIVITY

Reactivity

Not available.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

Not available.

Incompatible materials

Not available.

Hazardous decomposition products

None under normal use conditions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Symptoms Common effects of the vaccine include the following: pain, swelling, and erythema of the injection site; headache; body ache or muscle weakness; tiredness.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin Corrosion/Irritation	Not available.
Serious Eye Damage/Eye Irritation	Not available.
Irritation	Not available.
Corrosivity	Not available.
Sensitization	Not available.
Germ Cell Mutagenicity	Not available.
Carcinogenicity	Not available.
Reproductive Toxicity	Pregnancy Category C: Animal reproduction studies have not been conducted with Adacel vaccine. It is also not known whether Adacel vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Animal fertility studies have not been conducted with Adacel vaccine. The effects of Adacel vaccine on embryo-fetal and pre-weaning development was evaluated in two developmental toxicity studies using pregnant rabbits. No adverse effects on pregnancy, parturition, lactation, embryo-fetal or pre-weaning development were observed. There were no vaccines related fetal malformations or other evidence of teratogenicity noted in this study. It is not known whether Adacel vaccine is excreted in human milk.
Developmental Toxicity	Not available.
Teratogenicity	Not available.
STOT - Single Exposure	Not classified.
STOT - Repeated Exposure	Not classified.
Chronic Toxicity	Not available.
Subchronic Toxicity	Not available.
Target Organ Effects	Not available.
Neurological Effects	Not available.
Other Adverse Effects	Not available.
Aspiration Hazard	Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity
Not available.

Persistence and degradability
Not available.

Bioaccumulation
Not available.

Mobility

Not available.

Other adverse effects

Not available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of Wastes

Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated Packaging

Disposal should be in accordance with applicable regional, national and local laws and regulations.

US EPA Waste Number

Not applicable.

California Hazardous Waste Codes

Not applicable.

14. TRANSPORT INFORMATION

DOT

Not regulated.

TDG

Not regulated.

MEX

Not regulated.

ICAO (air)

Not regulated.

IATA

Not regulated.

IMDG

Not regulated.

RID

Not regulated.

ADR

Not regulated.

ADN

Not regulated.

15. REGULATORY INFORMATION

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355).

US State Regulations

California Proposition 65

Component (Formaldehyde) is on Proposition 65 list; however, based on percentage of formulation it is not considered hazardous.

U.S. State Right-to-Know Regulations

This drug is regulated by the Food and Drug Administration and is therefore exempt from State Right-to-Know Regulations.

16. OTHER INFORMATION

Prepared By	IES Engineers
Issue Date	17-Apr-2015
Revision Date	26-Oct-2017
Revision Note	Updated Product Information.

Disclaimer

Sanofi Pasteur considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. Sanofi Pasteur cannot be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet