

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**Product identifier****Product Name** TUBERSOL®**Other means of identification****Product Information** 10-test vial, 1 mL
50-test vial, 5 mL**Synonyms** Tuberculin Purified Protein Derivative (Mantoux)**Recommended use of the chemical and restrictions on use****Recommended Use** Aid diagnosis of tuberculosis infection (TB) in persons at increased risk of developing active disease.**Uses advised against** Not available.**Details of the supplier of the safety data sheet****Supplier Address**Sanofi Pasteur
Discovery Drive
Swiftwater, PA 18370
Phone: 1-800-822-2463 (1-800-VACCINE)**Emergency telephone number****24 Hour Emergency Phone** 1-703-741-5970 / 1-800-424-9300 CCN # 2118 (CHEMTREC)**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 through the sheet.

Label elements**Emergency Overview**

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

Appearance Clear colorless liquid**Physical state** Liquid**Odor** Not available.**Hazards not otherwise classified (HNOC)**

Not classified as a hazardous substance.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms Tuberculin Purified Protein Derivative (Mantoux)

| Chemical Name | CAS No. | Weight-% |
|---|---------|------------|
| Purified Protein derivative of Mycobacterium tuberculosis | N/A | N/A |
| Sterile isotonic phosphate buffered saline | N/A | 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 if needed. 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

Induration at test site if test is positive for TB.

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. Protect from light.

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 | Clear colorless liquid | Odor threshold | Not available. |
| Color | Clear | | |

Property

| | | |
|-------------------------------------|----------------|-------------------------|
| pH | Values | Remarks • Method |
| Melting point/freezing point | Not available. | |
| | 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. |
| | |
| <u>Other Information</u> | |
| 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 reactive under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of Hazardous Reactions

None under normal handling.

| | |
|---------------------------------|--|
| 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 likely routes of exposure

| | |
|----------------------------|---|
| Product Information | No data available. |
| | |
| Inhalation | No impact known or expected under normal use. |
| | |
| Eye contact | No impact known or expected under normal use. |
| | |
| Skin Contact | No impact known or expected under normal use. |

Ingestion No impact known or expected under normal use.

Information on toxicological effects

Symptoms Induration at test site if test is positive for TB.

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 | TUBERSOL has not been evaluated for its mutagenic potential. |
| Carcinogenicity | TUBERSOL has not been evaluated for its carcinogenic potential. |
| Reproductive toxicity | Pregnancy Category C: Animal reproduction studies have not been conducted with TUBERSOL. It is also not known whether TUBERSOL can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity |
| 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. |

Numerical measures of toxicity - Product Information

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

| | |
|--------------------------|----------------|
| <u>DOT</u> | Not regulated. |
| <u>TDG</u> | Not regulated. |
| <u>MEX</u> | Not regulated. |
| <u>ICAO (air)</u> | Not regulated. |
| <u>IATA</u> | Not regulated. |
| <u>IMDG</u> | Not regulated. |
| <u>RID</u> | Not regulated. |
| <u>ADR</u> | Not regulated. |
| <u>ADN</u> | 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

No component is on the Proposition 65 list.

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

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|----------------------|--|
| Prepared By | IES Engineers |
| Issue Date | 24-Apr-2015 |
| Revision Date | 22-Jan-2019 |
| Revision Note | Updated Sanofi Pasteur address. Revised by Sanofi Pasteur. |

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