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 (NDC 49281-752-78); package of 1 vial, (NDC 49281-752-21)
50-test vial, 5 mL (NDC 49281-752-98); package of 1 vial, (NDC 49281-752-22)

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
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 skin test antigen 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

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Physical state</th>
<th>Odor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear colorless liquid</td>
<td>Liquid</td>
<td>Not available</td>
</tr>
</tbody>
</table>

Hazard not otherwise classified (HNOC)
Not classified as a hazardous substance.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purified Protein derivative of Mycobacterium tuberculosis</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Sterile isotonic phosphate buffered saline</td>
<td>N/A</td>
<td>q.s to 100</td>
</tr>
</tbody>
</table>

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

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
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 test.

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 test.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appearance</td>
<td>Clear colorless liquid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Color</td>
<td>Clear</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Odor</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Property</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 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.

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

<table>
<thead>
<tr>
<th>Skin corrosion/irritation</th>
<th>Not available.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Not available.</td>
</tr>
<tr>
<td>Irritation</td>
<td>Not available.</td>
</tr>
<tr>
<td>Corrosivity</td>
<td>Not available.</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Not available.</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>TUBERSOL has not been evaluated for its mutagenic potential.</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>TUBERSOL has not been evaluated for its carcinogenic potential.</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>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. It is not known whether TUBERSOL is excreted in human milk.</td>
</tr>
</tbody>
</table>

Developmental Toxicity

Teratogenicity

STOT - single exposure

STOT - repeated exposure

Chronic toxicity

Subchronic toxicity

Target Organ Effects

Neurological effects

Other adverse effects

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

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute health hazard</td>
<td>No</td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Fire hazard</td>
<td>No</td>
</tr>
<tr>
<td>Sudden release of pressure hazard</td>
<td>No</td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>

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
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations
This product does not contain any substances regulated by state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number  
Not applicable.
16. OTHER INFORMATION

Revision Date
Revision Note
Not available.

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