



MATERIAL SAFETY DATA SHEET

While we believe the information provided herein is accurate and current, JHP Pharmaceuticals makes no representation or warranties, either explained or implied, and assume no responsibility for any damage or injuries of any kind, which may result from use or reliance upon this information.

SECTION 1 MATERIAL IDENTIFICATION

PRODUCT NAME: Aplisol[®] (Tuberculin Purified Protein Derivative, diluted) **DATE OF ISSUE:** 3/26/08

FORMULA: Solution **SUPERCEDES:** NA **REVISION:** 1.0
SYNONYMS: Tuberculin PPD, diluted

NDC #: 42023-104-01 Aplisol[®] (Tuberculin Purified Protein Derivative, diluted) 5TU/0.1mL, 1mL MDV
42023-104-05 Aplisol[®] (Tuberculin Purified Protein Derivative, diluted) 5TU/0.1mL, 5mL MDV

MANUFACTURING DIVISION:	ADDRESS:	PHONE :
JHP Pharmaceuticals, LLC.	870 Parkdale Road Rochester, MI 48307	Emergency: 248-656-5400 Medical Affairs: 866-923-2474

SECTION 2 INGREDIENT (S)

CAS #: Not Assigned **INGREDIENT NAME:** Tuberculin PPD

EXPOSURE LIMITS/ GUIDELINES: No occupational exposure limits established.
OSHA PEL: ND
ACGIH TLV: ND
OTHER: ND
LISTED AS CARCINOGEN: No

SECTION 3 HAZARD IDENTIFICATION

MAJOR HEALTH HAZARD: No significant target effects reported.

POTENTIAL HEALTH EFFECTS:

INHALATION:
SHORT TERM EXPOSURE: No information on significant adverse effects.
LONG TERM EXPOSURE: No information on significant adverse effects.

SKIN CONTACT:
SHORT TERM EXPOSURE: Allergic reactions.
LONG TERM EXPOSURE: Allergic reactions.

SECTION 3**HAZARD IDENTIFICATION cont.****EYE CONTACT:**

SHORT TERM EXPOSURE: No information on significant adverse effects.

LONG TERM EXPOSURE: No information on significant adverse effects.

INGESTION:

SHORT TERM EXPOSURE: No information on significant adverse effects.

LONG TERM EXPOSURE: No information on significant adverse effects.

SECTION 4**FIRST AID INFORMATION**

THERAPEUTIC CLASS: Diagnostic Agent

EYES: Flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.

SKIN: Wash exposed skin with soap and water for at least 15 minutes while removing contaminated clothes and shoes. Get medical attention. Thoroughly clean and dry contaminated clothing and shoes before reuse.

INHALATION: If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. If breathing is difficult, oxygen should be administered by qualified personnel. Get immediate medical attention.

INGESTION: If large amount is swallowed, get medical attention.

SECTION 5**FIRE AND EXPLOSION DATA**

FLASH POINT AND METHOD: >200°F (>93.3°C)

FLAMMABILITY CLASS (OSHA): III B

EXTINGUISHING MEDIUM: Carbon dioxide, regular dry chemical, regular foam, water.

SPECIAL FIRE PROCEDURES: Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS: Thermal decomposition products or combustion: oxides of carbon.

FIRE HAZARDS: Slight

EXPLOSION HAZARDS: Slight

SECTION 6**ACCIDENTAL RELEASE MEASURES****ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:**

Stop leak if possible without personal risk. Small Spills: Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal.

SECTION 7**HANDLING AND STORAGE**

STORAGE: Store and handle in accordance with all current regulations and standards. Store between 2°C and 8°C. Avoid contact with light. See original container for storage recommendations. Keep separated from incompatible substances.

SECTION 8**SPECIAL PROTECTION INFORMATION**

VENTILATION: Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

EYE PROTECTION: Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

CLOTHING: Wear appropriate chemical resistant clothing.

GLOVES: Wear appropriate chemical resistant gloves.

RESPIRATOR: Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.

Any chemical cartridge respirator with organic vapor cartridges(s)

Any chemical cartridge respirator with a full face piece and organic vapor cartridge(s).

Any air-purifying respirator with a full face piece and organic vapor canister

For Unknown Concentrations or Immediately Dangerous to Life or Health-

Any supplied-air respirator with full face piece and operated in a pressure-demand or other positive –pressure mode in combination with a separate escape supply.

Any self-contained breathing apparatus with a full face piece.

SECTION 9**PHYSICAL AND CHEMICAL DATA**

PHYSICAL STATE: Liquid

APPEARANCE: Clear

CHARACTERISTIC ODOR: NA

SPECIFIC GRAVITY: NA

SOLUBILITY:

pH: NA

WATER: Soluble

SECTION 10**STABILITY AND REACTIVITY**

REACTIVITY: Stable at normal temperature and pressure

CONDITIONS TO AVOID: Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

INCOMPATIBLES: Oxidizing materials.

POLYMERIZATION: Will not polymerize.

SECTION 11**TOXICOLOGY****TOXICITY INFORMATION:**

The following information pertains to the ingredient(s) individually and not to the product as marked. Included will be any data which emphasize the potential effects that may occur with the occupational handling (by inhalation or by dermal or by ocular contact) of this product.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Allergic reactions.

ADDITIONAL DATA: This product may be administered intradermally as an aid in the detection of infection with Mycobacterium tuberculosis. An inflammatory response in the skin with redness and swelling may occur at the injection site. Highly sensitive individuals may experience blistering, ulceration and necrosis.

(Refer to package insert for further information)

SECTION 12**ECOLOGICAL INFORMATION**

Not available

SECTION 13**DISPOSAL**

Dispose in accordance with all applicable regulations.

SECTION 14**TRANSPORTATION****SHIPPING REQUIREMENTS AND LIMITATIONS**

PROPER SHIPPING NAME: NA **ID/UN NUMBER:** NA **CONTAINER SPECIFICATION:** NA

HAZARD CLASS: NA **LABEL:** NA **PACKAGING GROUP:** NA

SHIPPING LIMITATIONS: NA **MARKING:** NA **OTHER COMMENTS:** NA

U.S REGULATIONS:**CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):** Not regulated.**SARA TITLE III SECTIONS 302/304 EXTREMELY HAZARDOUS SUBSTANCES:** Not regulated.**SARA TITLE III SECTIONS 311/312 HAZARDOUS CATEGORIES:** Not regulated.

ACUTE: No

CHRONIC: No

FIRE: No

REACTIVE: No

SUDDEN RELEASE: No

SARA TITLE II SECTION 313: Not regulated.**OSHA PROCESS SAFETY:** Not regulated.**STATE REGULATIONS:****California Proposition 65:** Not regulated**NATIONAL INVENTORY STATUS:****U.S. INVENTORY (TSCA):** This product is exempt.**TSCA 12(b) EXPORT NOTIFICATION:** Not listed.

NA – NOT APPLICABLE**ND – NO DATA FOUND**

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company to make sure the sheet is the latest one issued.