1. Identification

Product identifier: USP mAb 002, Monoclonal IgG1

Other means of identification
- Catalog number: 1445547
- Recommended use: Specified quality tests and assay use only.
- Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway, Rockville, MD 20852-1790
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300, CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Reproductive toxicity, Category 2

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

- Signal word: Warning
- Hazard statement: Suspected of damaging fertility or the unborn child.
- Precautionary statement
  - Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
  - Response: If exposed or concerned: Get medical advice/attention.
  - Storage: Store locked up.
  - Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): None known.

Supplemental information: Pharmacologically active material.

3. Composition/information on ingredients

Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td></td>
<td>7732-18-5</td>
<td>92.26</td>
</tr>
<tr>
<td>TREHALOSE DIHYDRATE</td>
<td></td>
<td>99-20-7</td>
<td>6</td>
</tr>
</tbody>
</table>
4. First-aid measures

**Inhalation**
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

**Skin contact**
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

**Eye contact**
Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion**
If ingestion of a large amount does occur, call a poison control center immediately. Get medical attention if symptoms occur.

**Most important symptoms/effects, acute and delayed**
Pharmacologically active material. Occupational exposure may cause physiological effects.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically.

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

**Suitable extinguishing media**

**Unsuitable extinguishing media**
Do not use water jet as an extinguisher, as this will spread the fire.

**Specific hazards arising from the chemical**
During fire, gases hazardous to health may be formed.

**Special protective equipment and precautions for firefighters**
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Fire fighting equipment/instructions**
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**
No unusual fire or explosion hazards noted.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of vapors. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

**Methods and materials for containment and cleaning up**
Absorb spillage with suitable absorbent material. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

**Precautions for safe handling**
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

**Occupational exposure limits**
No exposure limits noted for ingredient(s).
Biological exposure limits

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, handle solutions outside of containment or without local exhaust ventilation only during procedures with no potential for aerosolization. Handle solutions where aerosolization may occur (e.g., vortexing, pipetting, pumping) in a chemical fume hood, biological safety cabinet or ventilated balance enclosure. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper donning and doffing practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Liquid.

Form

Liquid.

Color


Odor

Not available.

Odor threshold

Not available.

pH

6.2

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility(ies)

Solubility (water)

Not available.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.
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
Contact with incompatible materials.

Incompatible materials
Strong oxidizing agents.

Hazardous decomposition products
Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

**Inhalation**
Knowledge about health hazard is incomplete.

**Skin contact**
Knowledge about health hazard is incomplete.

**Eye contact**
Knowledge about health hazard is incomplete.

**Ingestion**
Knowledge about health hazard is incomplete.

**Symptoms related to the physical, chemical, and toxicological characteristics**
Not available.

Information on toxicological effects

**Acute toxicity**

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute</strong> Dibasic Sodium Phosphate (CAS 7558-79-4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>Rabbit</td>
<td>&gt; 300 mg/kg, 24 Hours</td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dust</td>
<td>Rat</td>
<td>&gt; 0.83 mg/l, 4 Hours</td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 500 mg/kg</td>
</tr>
</tbody>
</table>

**MONOBASIC SODIUM PHOSPHATE (MONOHYDRATE) (CAS 7558-80-7)**

**Acute**

<table>
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<tr>
<th>Components</th>
<th>Species</th>
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<td>Rat</td>
<td>&gt; 0.83 mg/l, 4 Hours</td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>&gt; 500 mg/kg</td>
</tr>
</tbody>
</table>

**Polysorbate 20 (CAS 9005-64-5)**

**Oral**

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>&gt; 33 g/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>36700 µliters/kg</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**
Knowledge about health hazard is incomplete.

**Serious eye damage/eye irritation**
Knowledge about health hazard is incomplete.
Local effects
Polysorbate 20 15 ml Irritation test
Result: Irritant.
Species: Human
Organ: Skin.
Test Duration: 3 days
Severity: Mild.

Dibasic Sodium Phosphate
Eye irritation test: (Draize)
Result: Mild irritation
Species: Rabbit
Skin irritation test: (Draize)
Result: Mild irritation
Species: Rabbit

Respiratory or skin sensitization
Respiratory sensitization Knowledge about health hazard is incomplete.
Skin sensitization Knowledge about health hazard is incomplete.
Polysorbate 20 Maximisation Assay (Magnusson and Kligman)
Result: Moderate.
Species: Guinea pig
Maximisation Assay (Magnusson and Kligman)
Result: Severe.
Species: Guinea pig

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.
Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity
Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens
Not listed.

Reproductive toxicity Suspected of damaging fertility or the unborn child.
A component of this material caused adverse fetal effects in animal studies.

Reproductivity
Polysorbate 20 0 - 5000 mg/kg/day Reproductivity
Result: No developmental toxicity was observed.
Species: Mouse

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.
Aspiration hazard Knowledge about health hazard is incomplete.

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>MONOBASIC SODIUM PHOSPHATE (MONOHYDRATE) (CAS 7558-80-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish</td>
<td>LC50</td>
<td>Western mosquitofish (Gambusia affinis) 186 mg/l, 96 hours</td>
</tr>
</tbody>
</table>

Persistence and degradability
No data is available on the degradability of any ingredients in the mixture.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
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).

Contaminated packaging
Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

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

General information
It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

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

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Dibasic Sodium Phosphate (CAS 7558-79-4) Listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
Yes

Classified hazard categories
Reproductive toxicity

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 2016 (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.

International Inventories

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

*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: 10-29-2019

Version #: 01

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