



SAFETY DATA SHEET

1. Identification

Product identifier	Cross-Reacting Material 197 (CRM197)		
Other means of identification			
Catalog number	1150800		
Recommended use	For analytical laboratory 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 United States		
Telephone	Customer Service	301-881-0666	
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	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.

Label elements

Hazard symbol	None.
Signal word	None.
Hazard statement	Not available.
Precautionary statement	
Prevention	Not available.
Response	Not available.
Storage	Not available.
Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixture

Chemical name	Common name and synonyms	CAS number	%
Sucrose	Sugar	57-50-1	90.46
Dibasic Sodium Phosphate	Disodium hydrogenorthophosphate	7558-79-4	5.43
CRM197		945275-85-4	3.62
MONOBASIC SODIUM PHOSPHATE (MONOHYDRATE)		7558-80-7	0.4
Polysorbate 80	Polyoxyethylene 20 sorbitan monooleate	9005-65-6	0.1

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
Indication of immediate medical attention and special treatment needed	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	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. 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 dust from the spilled material. 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	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. 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 materials, 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. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. OSHA Table Z-1 Permissible Exposure Limits (PEL) for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value
Sucrose (CAS 57-50-1)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards Recommended Exposure Limits (REL)

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	For laboratory operations, use good technique and limit open handling. 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	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. 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 USP materials.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Solid.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
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 available.
Upper/lower flammability or explosive limits	
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.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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	Avoid temperatures exceeding the flash point. 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.
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Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Dibasic Sodium Phosphate (CAS 7558-79-4)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 300 mg/kg, 24 Hours
Inhalation		
<i>Dust</i>		
LC50	Rat	> 0.83 mg/l, 4 Hours
Oral		
LD50	Rat	> 500 mg/kg
MONOBASIC SODIUM PHOSPHATE (MONOHYDRATE) (CAS 7558-80-7)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 300 mg/kg, 24 Hours
Inhalation		
<i>Dust</i>		
LC50	Rat	> 0.83 mg/l, 4 Hours
Oral		
LD50	Rat	> 500 mg/kg

Components	Species	Test Results
Polysorbate 80 (CAS 9005-65-6)		
Oral		
LD50	Mouse	25 g/kg
	Rat	> 5000 mg/kg
Sucrose (CAS 57-50-1)		
Oral		
LD50	Rat	29700 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
Local effects		
Polysorbate 80		150 mg Eye irritation Result: Irritant. Species: Rabbit Severity: Mild.
Dibasic Sodium Phosphate		Eye irritation test: (Draize) Result: Mild irritation Species: Rabbit
Polysorbate 80		Eye irritation Result: Negative. Species: Rabbit
Dibasic Sodium Phosphate		Skin irritation test: (Draize) Result: Mild irritation Species: Rabbit
Polysorbate 80		Skin irritation Result: Irritant. Species: Rabbit Severity: Mild. Skin irritation Result: Negative. Species: Human
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about health hazard is incomplete.	
Polysorbate 80		Maximisation Assay (Magnusson and Kligman) Result: Negative. Species: Guinea pig Organ: Skin
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity		
Polysorbate 80		Ames test (Salmonella typhimurium), with and without activation Result: Negative. Chromosome aberration Result: Positive.
Sucrose		Mutagenicity, Chromosomal aberrations in CHO-WBL cells Result: Positive: (+/- activation)
Polysorbate 80		Mutagenicity, DNA inhibition test in human lymphocytes and mouse cells Result: Positive. Mutagenicity, Human lymphocytes mutagenicity test Result: Inconclusive.
Sucrose		Mutagenicity, Mouse lymphoma test Result: Negative (+/- activation)
Polysorbate 80		Mutagenicity, Sister chromatid exchange assay Result: Negative.
Carcinogenicity	Knowledge about carcinogenicity is incomplete.	

Carcinogenicity
Polysorbate 80

50000 ppm Carcinogenicity, No evidence of carcinogenicity in female mice. Forestomach ulcers and increased incidence of squamous hyperplasia and inflammation of the forestomach in female mice.
Species: Mouse
Test Duration: 103 weeks
50000 ppm Carcinogenicity, No evidence of carcinogenicity in female rats. Equivocal evidence of pheochromocytomas of the adrenal medulla in male rats.
Species: Rat
Test Duration: 103 weeks

IARC Monographs. Overall Evaluation of Carcinogenicity
Not listed.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)
Not listed.
US. National Toxicology Program (NTP) Report on Carcinogens
Not listed.

Reproductive toxicity Knowledge about health hazard is incomplete.

Reproductivity
Polysorbate 80

10 mg/kg/day Reproductivity, No evidence of fetal toxicity or increased incidence of developmental defects with intravenous doses.
Species: Rabbit
16 ml/kg Reproductivity, Lower body weight in postnatal offspring but no adverse effects on neurodevelopment with administration in drinking water.
Species: Rat
7000 mg/kg/day Reproductivity, No evidence of fetal toxicity or increased birth defects with oral doses.
Species: Rat
Reproductivity, No evidence of birth defects with injection in chick eggs.
Species: Chick

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 Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

Components	Species	Test Results
MONOBASIC SODIUM PHOSPHATE (MONOHYDRATE) (CAS 7558-80-7)		
Aquatic		
Acute		
Fish	LC50	Western mosquitofish (Gambusia affinis) 186 mg/l, 96 hours
Persistence and degradability	No data is available on the degradability of any ingredients in the mixture.	
Bioaccumulative potential		
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.

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 applicable.

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 not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)**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 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)**SARA 302 Extremely hazardous substance**

Not listed.

SARA 311/312 Hazardous chemical No

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 1986 (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

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*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	04-03-2024
Version #	01
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