

1. Product and company identification

Product Identifiers

Product Name	Rap/Tac/CsA Control	
Synonym	Rap/Tac/CsA Control Level 1	Rap/Tac/CsA Control Level 2
	Rap/Tac/CsA Control Level 3	Rap/Tac/CsA Control Level Q
Catalog Number	280-Q, 280-1, 280-2, 280-3	
Trade Name	ISD Whole Blood Control	
Chemical Family	Liquid/Mixture	
Application of the substance/ mixture	In-vitro laboratory reagent or component.	
Manufacturer	More Diagnostics Inc. 2020 11th street Los Osos, CA 93402	Telephone (805) 528-6005 Fax (805) 528-3532 www.morediagnostics.com
Supplier	Thermo Fisher Scientific 46500 Kato Road Fremont, CA 94538	Telephone (510) 979-5000 Fax (510) 979-5002

Emergency telephone number (805) 528-6005

Note The pharmacological, toxicological, and ecological properties of this product/mixture have not been fully characterized. This data sheet will be updated as more data become available.

2. Hazards identification

**Classification of substance or
mixture** The product is not classified according to the Globally Harmonized System (GHS).

**Regulation (EC)
1272/2008 [GHS]** Mixture not yet fully tested.

**Directive 67/548/EEC or
1999/45/EC** Mixture not yet fully tested.

Label Elements:

GHS hazard pictogram None required.

GHS signal word None required.

GHS hazard statement(s) None required.

GHS precautionary statements None required.

**EU symbol/indication of
danger** None required.

Risk (R) Phrase(s) None required.

Signal word None required.

Emergency Overview:

Routes of exposure Inhalation, Ingestion, Skin

Classification system:

NFPA ratings (scale 0-4) Health =0 Fire = 0 Reactivity = 0

Special hazards

Contains human sourced material and should be treated/handled as potentially infectious. All such human sourced material has been derived from donors tested individually and shown by FDA

methods to be free from antibodies to HIV, Hepatitis B and C. No test method can offer complete assurance that these or other infectious agents are not present, this product should be handled using standard biosafety precautions.

Other hazards:**Results of PBT and vPvB assessment**

PBT: Not applicable.

vPvB: Not applicable.

3. Composition/Information on ingredients

Chemical characterization: Mixtures**Description** Mixture of substances listed below with non-hazardous components.

Listing of dangerous and non-hazardous components Human Whole Blood 50-100%

Additional information Human source material is listed because it is a potential biohazard. The remaining components are non-hazardous and/or present at amounts below reportable limits.

4. First aid measures

Description of first aid measures

Immediate medical action needed No. If exposed or concerned: Get medical advice/attention.

Eye contact Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting and lowering eyelids. Get medical attention if symptoms occur.

Skin contact Immediately wash skin with soap and water for at least 15 minutes. Remove contaminated clothing/shoes. Wash clothing before reuse. Clean shoes thoroughly before reuse. Get medical attention if symptoms occur or persist.

Inhalation Immediately move exposed person to fresh air. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Loosen tight clothing such as a collar, tie, belt or waistband. Immediately notify medical personnel and supervisor. Get medical attention if symptoms occur.

Ingestion Wash out mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Immediately notify medical personnel and supervisor.

Most important symptoms and effects, both acute and delayed No further relevant information available.

Indication of any immediate medical attention and special treatment needed No further relevant information available.

5. Fire-fighting measures

Extinguishing media CO₂, extinguishing powder or water spray, as appropriate for surrounding fire and materials.

Special hazards arising from the substance or mixture No further relevant information available.

Flammability/Explosivity No explosivity or flammability data identified.

Advice for firefighters Wear self-contained breathing apparatus for firefighting if necessary. Material may be potentially infectious. Decontaminate all equipment after use.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Handle as potentially infectious. Avoid breathing vapors, mist or gas. For personal protection see section 8.

Environmental precautions Do not empty into drains. Avoid release into the environment.

Methods and materials for containment and cleaning up Absorb liquid components with liquid-binding material. Pick up mechanically. Clean the affected area carefully with a suitable cleaner such as 5% chlorine bleach solution. Place spill materials in suitable, closed containers for disposal.

Reference to other sections See section 13 for disposal information.

7. Handling and storage

Precautions for safe handling Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing vapor and mist.

Conditions for safe storage, including any incompatibles Store at $\leq -14^{\circ}\text{C}$ away from incompatibles. See Package Insert for additional storage information.

Specific end use(s) No further relevant information available.

8. Exposure controls/personal protection

Control parameters

Components with workplace control parameters Contains no substances with occupational exposure limits.

Exposure/Engineering controls Follow the usual biosafety practices for handling potentially infectious materials. The usual precautionary measures for handling chemicals should be followed.

Eye/face protection Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Hand protection Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching the gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Skin protection Wear appropriate gloves, lab coat, or other protective over garment if skin contact is possible. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection	Respiratory protection not required. For nuisance exposures use type OV/AG (US) or type ABEK (EU EN 14387) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Control of environmental exposure	No special environmental precautions required.
Other protective measures	Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area.

9. Physical and chemical properties

Information on basic physical and chemical properties.

Appearance	Liquid
Color	Red
Odor	No information identified.
Odor threshold	No information identified.
pH	6.5-8.0
Melting point	Undetermined.
Freezing point	Undetermined.
Initial boiling point and boiling range	Undetermined.
Flash point	Not applicable.
Evaporation rate	Undetermined.
Flammability	Not applicable.
Upper/lower flammability or explosive limits.	Product does not present an explosion hazard.
Vapor pressure	Undetermined.
Vapor density	Undetermined.
Relative density	Undetermined
Water solubility	Miscible in water.
Solvent solubility	Undetermined.
Partition coefficient	Undetermined.
Auto-ignition temperature	Undetermined.
Decomposition temperature	Undetermined.
Viscosity	Undetermined.
Explosive properties	Product does not present an explosion hazard.
Oxidizing properties	Undetermined.
Molecular weight	Not applicable (Mixture).
Molecular formula	Not applicable (Mixture).

10. Stability and reactivity

Reactivity	No information identified.
Chemical stability	Stable when stored as recommended.

Possibility of hazardous reactions	Not expected to occur.
Conditions to avoid	Avoid temperatures $\geq 37^{\circ}\text{C}$.
Incompatible materials	None reported/determined.
Hazardous decomposition products	No information identified.

11. Toxicological information

Information on toxicological effects

Acute toxicity	No data available.
Inhalation:	No data available.
Dermal:	No data available.
Skin irritation	No data available.
Eye irritation	No data available.
Sensitization	No data available.
Germ cell mutagenicity	No data available.
Carcinogenicity	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
	ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by ACGIH.
	NTP: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by NTP.
	OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by OSHA.
Reproductive toxicity	No data available.
Specific target organ toxicity - single exposure	No data available.
Specific target organ toxicity - repeated exposure	No data available.
Aspiration hazard	No data available.
Additional information	To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. Ecological information

Toxicity No data available.

Persistence and degradability No data available.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Results of PBT and vPvB assessment PBT: Not applicable.
vPvB: Not applicable.

Other adverse effects No data available.

13. Disposal considerations

Waste treatment methods

Recommendation Dispose of waste in accordance to national, regional, or local regulations. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner. e.g. appropriately permitted municipal or on-site wastewater treatment facility.

14. Transport information

Transport Based on the available data, this product/mixture is not regulated as hazardous material/dangerous under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

UN Number None assigned

UN proper shipping name None assigned

Transport hazard classes and packing group None assigned

Environmental hazards Based on the available data, this product/mixture is not regulated as an environmental hazard or a marine pollutant.

Special precautions for users Mixture not fully tested - avoid exposure.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code Not applicable

15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture This SDS complies with the requirements under US, EU and GHS (EU CLP - Regulation EC No 1272/2008) guidelines. Consult your local or regional authorities for more information.

Chemical safety assessment	Not conducted
OSHA hazardous	Caution. Mixture not fully tested. This product contains human source material and should be treated/handled as a potential biohazard.
WHMIS classification	This product/mixture has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.
TSCA	60-00-4 ethylenediaminetetraacetic acid
SARA section 313	Not listed
California proposition 65	Warning : This product contains less than 0.1% of a chemical known to the state of California to cause cancer or reproductive toxicity.
Chemical name	Cyclosporine A 59865-13-3
California Proposition 65	Carcinogen Revision Date: 01/01/1992

16. Other information

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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