SAFETY DATA SHEETS

This SDS packet was issued with item:

078949193

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078928557 078934105 078938303

teva

SAFETY DATA SHEET

Issuing Date 27-May-2021 Revision date 03-Jun-2021 Revision Number 1

1. Identification

Product identifier

Product Name Cyclosporine Capsules

Other means of identification

Product Code(s) FG00383

UN/ID no. UN3175

Synonyms None

Recommended use of the chemical and restrictions on use

Uses/ Identified uses Pharmaceutical

Restrictions on use No information available

Details of the supplier of the safety data sheet

Manufacturer

400 Interpace Parkway Teva Corporate Headquarters Parsippany, NJ. 07054 Teva Corporate Headquarters 5 Bazel Street PO Box 3190

USA Petah Tikva, Israel

Emergency telephone number

Emergency Telephone United States/Canada/Puerto Rico: 1-800-424-9300 (Chemtrec) [24-hrs]

International: +1-703-741-5970 (Chemtrec) [24-hours]

E-mail SDS.TevalL@teva.co.il

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Carcinogenicity	Category 1A
Reproductive toxicity	Category 2
Effects on or via lactation	Yes
Flammable solids	Category 1

Hazards not otherwise classified (HNOC)

Label elements

Danger		

Flammable solid May cause harm to breast-fed children Suspected of damaging fertility or the unborn child



Proprietary

12.5

Weight-%

Precautionary Statements - Prevention

Wear protective gloves/protective clothing/eye protection/face protection

Cyclosporine Ethyl Alcohol

Chemical Name

3. Composition/information on ingredients

Dispose of contents/container to an approved waste disposal plant

In case of fire: Use CO2, dry chemical, or foam to extinguish IF exposed or concerned: Get medical advice/attention

Mixture

Not applicable.

Unknown acute toxicity

May be harmful if swallowed Other information

Harmful to aquatic life

Store locked up

Substance

Do not breathe dusts or mists

Wash face, hands and any exposed skin thoroughly after handling

Ground/bond container and receiving equipment

Do not eat, drink or smoke when using this product

Harmful to aquatic life with long lasting effects

Precautionary Statements - Disposal

Precautionary Statements - Storage

Precautionary Statements - Response

Avoid contact during pregnancy/while nursing

Do not handle until all safety precautions have been read and understood

Obtain special instructions before use

Physical state Solid

Appearance No information available

Trade secret

Page 2/11

£-£1-99869

9-11-49

CAS No

100 % of the mixture consists of ingredient(s) of unknown toxicity

S7.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist) 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor) 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas) 90.8 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity 69.1 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

Odor No information available

Revision date 03-Jun-2021

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

General advice IF exposed or concerned: Get medical advice/attention. Show this safety data sheet to the

doctor in attendance.

Inhalation Remove to fresh air.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open

while rinsing. Do not rub affected area.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated

clothes and shoes.

Ingestion Clean mouth with water and drink afterwards plenty of water.

Self-protection of the first aider Remove all sources of ignition. Ensure that medical personnel are aware of the material(s)

involved, take precautions to protect themselves and prevent spread of contamination.

Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

5. Fire-fighting measures

Suitable Extinguishing Media Dry chemical. Carbon dioxide (CO2). Water spray. Alcohol resistant foam.

Unsuitable extinguishing media CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the

chemical

Risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire

extinguishing water must be disposed of in accordance with local regulations.

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge Yes.

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Evacuate personnel to safe areas. Use personal protective equipment as required. See

section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the

product must be grounded. Do not touch or walk through spilled material.

Other information Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

For emergency responders

Use personal protection recommended in Section 8.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor

suppressing foam may be used to reduce vapors. Keep out of drains, sewers, ditches and

waterways.

Methods for cleaning up

Take precautionary measures against static discharges. Pick up and transfer to properly

labeled containers.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections See section 8 for more information. See section 13 for more information.

7. Handling and storage

Precautions for safe handling

Advice on safe handling

Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use with local exhaust ventilation. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations.

8. Exposure controls/personal protection

Control parameters

Exposure Limits

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethyl Alcohol	STEL: 1000 ppm	TWA: 1000 ppm	IDLH: 3300 ppm
64-17-5		TWA: 1900 mg/m ³	TWA: 1000 ppm
		(vacated) TWA: 1000 ppm	TWA: 1900 mg/m ³
		(vacated) TWA: 1900 mg/m ³	-

Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Tight sealing safety goggles.

Hand protection Wear suitable gloves. Impervious gloves.

Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron. Skin and body protection

Antistatic boots.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

Environmental exposure controls No information available.

General hygiene considerations Do not eat, drink or smoke when using this product. Contaminated work clothing should not

be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties

Information on basic physical and chemical properties

Solid Physical state

Appearance No information available No information available Color Odor No information available **Odor threshold** No information available

Property Values Remarks • Method

No data available pН None known Melting point / freezing point No data available None known No data available Boiling point / boiling range None known Flash point No data available None known **Evaporation rate** No data available None known Flammability (solid, gas) No data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressure No data available Vapor density No data available

None known No data available None known Relative density No data available Water solubility None known

Solubility in other solvents No data available No data available **Partition coefficient** None known None known **Autoignition temperature** No data available **Decomposition temperature** No data available None known Kinematic viscosity No data available None known No data available Dynamic viscosity None known

Other information

Explosive properties No information available **Oxidizing properties** No information available No information available Softening point No information available K st (bar.m/s) Minimum Ignition Energy (mJ) No information available Molecular weight No information available **VOC Content (%)** No information available **Liquid Density** No information available **Bulk density** No information available

10. Stability and reactivity

Reactivity No information available.

Stable under normal conditions. Chemical stability

Possibility of hazardous reactions Hazardous polymerization does not occur.

Conditions to avoid Heat, flames and sparks.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document .

 ATEmix (oral)
 3,658.20 mg/kg

 ATEmix (dermal)
 20,800.00 mg/kg

 ATEmix (inhalation-dust/mist)
 124.70 mg/l

Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity

69.1 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

90.8 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

87.5 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

Carcinogenicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ethyl Alcohol	= 7060 mg/kg (Rat)	-	= 124.7 mg/L (Rat) 4 h
64-17-5			
Cyclosporine	1480 mg/kg (Rat)	-	-
59865-13-3			

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation

Respiratory or skin sensitization

No information available.

No information available.

No information available.

Classification based on data available for ingredients.

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
Ethyl Alcohol 64-17-5	A3	Group 1	Known	Х
Cyclosporine 59865-13-3	-	Group 1	Known	Х

Legend

ACGIH (American Conference of Governmental Industrial Hygienists)

A3 - Animal Carcinogen

IARC (International Agency for Research on Cancer)

Group 1 - Carcinogenic to Humans

NTP (National Toxicology Program)

Known - Known Carcinogen

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

Reproductive toxicity Classification based on data available for ingredients. May cause harm to breastfed babies.

STOT - single exposure No information available.

STOT - repeated exposureNo information available.

Target organ effects liver, Respiratory system, Eyes, Skin, Central nervous system, blood, Reproductive System.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity

Harmful to aquatic life with long lasting effects.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethyl Alcohol 64-17-5	-	95 Hr LC50 Fathead minnow: 14200 - 15100 mg/L	-	48 Hr LC50 Daphnia magna: 9268 - 14221 mg/L; 24 Hr EC50 Daphnia magna: 10800 mg/L; 48 Hr EC50 Daphnia magna: 2 mg/L [Static]

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Component Information

1	Chemical Name	Partition coefficient	
	Ethyl Alcohol	-0.32	
	64-17-5		

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused

products

Should not be released into the environment. Dispose of in accordance with local

regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture of weld

containers.

California Hazardous Waste Status This product contains one or more substances that are listed with the State of California as

a hazardous waste.

Chemical Name	California Hazardous Waste Status	
Ethyl Alcohol	Toxic	
64-17-5	Ignitable	

14. Transport information

DOT

UN/ID no. UN3175

Proper shipping name SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

Hazard class 4.1 Packing group

Special Provisions 47, IB6, IP2, T3, TP33

Description UN3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Ethyl Alcohol), 4.1, II

Emergency Response Guide 133

Number

.00

<u>TDG</u>

UN/ID no. UN3175

Proper shipping name SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

Hazard class 4.1 Packing group

Description UN3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Ethyl Alcohol), 4.1, II

<u>MEX</u>

UN/ID no. UN3175

Proper shipping name SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

Hazard class 4.1 Special Provisions 216, 274 Packing group II

Description UN3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Ethyl Alcohol), 4.1, II

ICAO (air)

UN/ID no. UN3175

Proper shipping name SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

Hazard class 4.1
Packing group II
Special Provisions A46

Description UN3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Ethyl Alcohol), 4.1, II

<u>IATA</u>

UN number UN3175

UN proper shipping name SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

Transport hazard class(es) 4.1
Packing group

Description UN3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Ethyl Alcohol), 4.1, II

IMDG

UN number UN3175

UN proper shipping name SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

Transport hazard class(es) 4.1
Packing group II
EmS-No. F-A, S-I
Special Provisions 216, 274
Marine pollutant NP.

Description UN3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Ethyl Alcohol), 4.1, II

RID

UN number UN3175

UN proper shipping name SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

Transport hazard class(es) 4.1
Packing group II
Classification code F1

Description UN3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Ethyl Alcohol), 4.1, II

Labels 4.1

ADR

UN number UN3175

UN proper shipping name SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.

Hazard class 4.1
Packing group III
Classification code F1
Tunnel restriction code (E)

Special Provisions 216, 274, 601

Description UN3175, SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (Ethyl Alcohol), 4.1, II

Labels 4.1

ADN

UN proper shipping name SOLIDS CONTAINING FLAMMABLE LIQUID, MOLTEN

Transport hazard class(es) 4.1
Packing group II
Classification code F1

Special Provisions 216, 274, 601, 800

Description UN3175, SOLIDS CONTAINING FLAMMABLE LIQUID, MOLTEN (Ethyl Alcohol), 4.1, II

Hazard label(s) 4.1 Limited quantity (LQ) 1 kg Ventilation VE01, VE03

15. Regulatory information

International Inventories

Contact supplier for inventory compliance status. **TSCA** Contact supplier for inventory compliance status. **DSL/NDSL** Contact supplier for inventory compliance status. **EINECS/ELINCS** Contact supplier for inventory compliance status. **ENCS IECSC** Contact supplier for inventory compliance status. **KECL** Contact supplier for inventory compliance status. **PICCS** Contact supplier for inventory compliance status. Contact supplier for inventory compliance status. **AICS**

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

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

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

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). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product contains the following Proposition 65 chemicals:.

Chemical Name	California Proposition 65
Ethyl Alcohol - 64-17-5	Carcinogen
	Developmental
Cyclosporine - 59865-13-3	Carcinogen

U.S. State Right-to-Know Regulations

US State Regulations

This product does not contain any substances regulated by state right-to-know regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Ethyl Alcohol 64-17-5	X	X	Х
Propylene glycol 57-55-6	X	-	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA Health hazards 1 Flammability 0 Instability 0 Physical and chemical properties 0

HMIS Health hazards 1* Flammability 0 Physical hazards 0 Personal protection X

______ Chronic Hazard Star Legend *= Chronic Health Hazard

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

RTECS (Registry of Toxic Effects of Chemical Substances)

World Health Organization

Issuing Date 27-May-2021

Revision date 03-Jun-2021

Revision NoteNo information available.

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.

End of Safety Data Sheet