SAFETY DATA SHEETS

This SDS packet was issued with item:

078944527

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

078944516



Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Date of Issue: 08/11/2021

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier Product Form: Mixture

Product Name: Ciprofloxacin Tablets USP, 750 mg, 500 mg and 250 mg

Synonyms: -250 mg white, round, film-coated tablets imprinted with "WW927" on one side, 500 mg white medium capsule shape, film-coated tablet, engraved with "WW928" from one side and plain from the other side, and 750 mg white, large capsule-shaped, film-coated tablets imprinted with "WW929" on one side.

1.2. Intended Use of the Product

Use of the Substance/Mixture: Prescription medication. See Package Insert for more information.

1.3. Name, Address, and Telephone of the Responsible Party

Hikma Pharmaceuticals USA Inc.

Hikma Pharmaceuticals

Bayadar Wadi Seer

Columbus, Ohio 43228

(614) 276-4000

Amman, Jordan

t: +962 6 580 2900

f: +962 6 581 7102

1.4. Emergency Telephone Number

Emergency Number : For Chemical Emergency Call CHEMTREC day or night

Within USA and Canada: 1.800.424.9300

SECTION 2: HAZARDS IDENTIFICATION

This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

2.1. Classification of the Substance or Mixture

Skin Sens. 1A H317 STOT RE 1 H372 Aquatic Acute 2 H401

Full text of hazard classes and H-statements: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



GHSOR

Signal Word (GHS-US) : Danger

Hazard Statements (GHS-US) : H317 - May cause an allergic skin reaction.

H372 - Causes damage to organs (Oral) through prolonged or repeated exposure

(Tendons).

H401 - Toxic to aquatic life.

Precautionary Statements (GHS-US): P260 - Do not breathe vapors, mist, or spray.

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P272 - Contaminated work clothing must not be allowed out of the workplace.

P273 - Avoid release to the environment.

P280 - Wear protective gloves, protective clothing, and eye protection.

P302+P352 - If on skin: Wash with plenty of water. P314 - Get medical advice/attention if you feel unwell. P321 - Specific treatment (see section 4 on this SDS).

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P363 - Wash contaminated clothing before reuse.

P501 - Dispose of contents/container in accordance with local, regional, national,

and international regulations.

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2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions. Product is in pill form, but contains substances that are combustible dusts. If these substances in their powder form are allowed to accumulate, dispersed in sufficient quantities in air, and in the presence of an ignition source, it may cause a dust explosion.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
Ciprofloxacin hydrochloride	3-Quinolinecarboxylic acid, 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-, hydrochloride (1:1) / 1-Cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid monohydrochloride / Ciprofloxacin monohydrochloride anhydrous / 1-Cyclopropyl-6-fluoro-1,4-dihydro-4-oxo(piperazinyl)-3-quinolinecarboxylic acid hydrochloride hydrate / 1,4-Dihydro-4-oxo-6-fluoro-1-cyclopropyl(piperazin-1-yl)quinoline-3-carbonic acid hydrochloride monohydrate	(CAS-No.) 93107-08-5	65 - 85	Skin Sens. 1A, H317 STOT RE 1, H372 Aquatic Acute 2, H401
Cellulose	Microcrystalline cellulose / CELLULOSE / Cellulose, microcrystalline	(CAS-No.) 9004-34-6	7 - 13	Comb. Dust
Starch	Starch, potato / Tapioca starch / Starches (cornstarch, potato starch, tapioca starch, wheat starch) / Pregelatinized potato starch / Starches / AVENA SATIVA STARCH / Corn starch / Wheat starch / High amylose cornstarch / Starch, edible / ORYZA SATIVA (RICE) STARCH / Avena sativa (oat) starch / Solanum tuberosum starch / Starch (High-polymeric carbohydrate material usually derived from cereal grains such as corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca. Includes starch which has been pregelatinized by heating in the presence of water.) / High amylose maize resistant starch / Zea mays (corn) starch / Topical starch / ORYZA SATIVA STARCH / SOLANUM TUBEROSUM STARCH / TAPIOCA STARCH / ZEA MAYS STARCH	(CAS-No.) 9005-25-8	3 - 7	Comb. Dust

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Starch, carboxymethyl ether, sodium salt	Starch carboxymethyl ether sodium salt / Starch, carboxymethyl, sodium salt / Sodium starch glycolate / Sodium carboxymethylstarch / SODIUM CARBOXYMETHYL STARCH / Sodium carboxymethyl starch / Sodium starch glycolate, unspecified	(CAS-No.) 9063-38-1	1 - 5	Comb. Dust
Magnesium stearate	Octadecanoic acid, magnesium salt / Stearate, magnesium / Stearic acid, magnesium salt / Octadecanoic acid, magnesium salt (2:1) / Magnesium distearate / MAGNESIUM STEARATE / Salts of stearic acids with magnesium bases / Dioctadecanoate magnesium / Magnesium octadecanoate / Bis(octadecanoic acid)magnesium salt / Salt of stearic acid with magnesium base / magnesium stearate	(CAS-No.) 557-04-0	1-5	Comb. Dust
Silica, amorphous	Amorphous silica / Silica / Silica, amorphous, fumed / Silica, colloidal / Silicon dioxide / Silicon dioxide, amorphous / Silicon dioxide, amorphous / SILICA / Silicon(IV) oxide / Un-crystalline silica / Pigment White 27 / Silicon dioxide (amorphous) / Silicon dioxide amorphous / Silicon dioxide - Silicon dioxide containing crystalline and amorphous / Fumed silica / SOLUM DIATOMEAE / silicon dioxide	(CAS-No.) 7631-86-9	<1	Not classified
Oils, vegetable, hydrogenated	Fats and Glyceridic oils, vegetable, hydrogenated / Hydrogenated mixed vegetable oils / Hydrogenated wegetable oil / Mixed vegetable oil, hydrogenated / Mixed vegetable oils, hydrogenated / Mixed vegetable oils, hydrogenated / Hydrogenated Vegetable Oil Hydrolyzed Actin / Hydrogenated animal or vegetable oil or fat / Fats and oils, hydrogenated, from vegetable food sources / Fats and glyceridic oils, vegetable, hydrogenated / HYDROGENATED VEGETABLE OIL / Hydrogenated vegetable oil and fat / Hydrogenated vegetable fats and glyceridic oils	(CAS-No.) 68334-28-1	<1	Not classified

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with soap and water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

First-aid Measures After Eye Contact: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for at least 15 minutes. Obtain medical attention.

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^{*}The exact percentage of the composition have been withheld as a trade secret [29 CFR 1910.1200].

^{**}See Package Insert for further information.

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First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Skin sensitization. Causes damage to organs (Oral) through prolonged or repeated exposure (Tendons).

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Causes damage to organs (Oral) through prolonged or repeated exposure (Tendons). Repeated or prolonged contact with skin may cause dermatitis.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive. For particulates and dust: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides.

Other Information: Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe dust. Do not get in eyes, on skin, or on clothing. Avoid generating dust.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Product is in tablet form, but contains substances that are combustible dusts. If these substances in their powder form are allowed to accumulate, dispersed in sufficient quantities in air, and in the presence of an ignition source, it may cause a dust explosion.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not breathe dust. Avoid contact with eyes, skin and clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

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Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Oxidizers.

Storage Temperature: 20 – 25 °C (68 °F - 77 °F)

7.3. Specific End Use(s)

Prescription medication. See Package Insert for more information.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Silica, amorphous (7631-86-9)		
USA NIOSH	NIOSH REL (TWA)	6 mg/m³
USA IDLH	IDLH	3000 mg/m ³
USA OSHA	OSHA PEL (TWA) [1]	6 mg/m ³
USA OSHA	OSHA PEL (TWA) [2]	20 mppcf (80mg/m³/%SiO ₂)
Starch (9005-	-25-8)	
USA ACGIH	ACGIH OEL TWA	10 mg/m ³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA)	10 mg/m³ (total dust)
		5 mg/m³ (respirable dust)
USA OSHA	OSHA PEL (TWA) [1]	15 mg/m³ (total dust)
		5 mg/m³ (respirable fraction)
Magnesium	stearate (557-04-0)	
USA ACGIH	ACGIH OEL TWA	10 mg/m³ (inhalable particulate matter (Stearates)
		3 mg/m³ (respirable particulate matter (Stearates)
Cellulose (90	04-34-6)	
USA ACGIH	ACGIH OEL TWA	10 mg/m³
USA NIOSH	NIOSH REL (TWA)	10 mg/m³ (total dust)
		5 mg/m³ (respirable dust)
USA OSHA	OSHA PEL (TWA) [1]	15 mg/m³ (total dust)
		5 mg/m³ (respirable fraction)

8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Safety glasses.







Materials for Protective Clothing

Hand Protection

Eye and Face Protection

Skin and Body Protection

Respiratory Protection

Other Information

: Chemically resistant materials and fabrics.

: Wear protective gloves.

: Chemical safety glasses.

: Wear suitable protective clothing.

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory

protection.When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Solid

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Appearance	: 250 mg white, round, film-coated tablets imprinted with "WW927" on one side
	500 mg white medium capsule shape, film-coated tablet, engraved with "WW928" from one side and plain from the other side
	750 mg white, large capsule-shaped, film-coated tablets imprinted with "WW929" on one side.
Odor	: No data available
Odor Threshold	: No data available
рН	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity: Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).
- **10.3.** Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
- **10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials. Avoid formation of concentrated dusts suspended in air. If dust is generated: Potential dust explosion hazard.
- 10.5. Incompatible Materials: Oxidizers.
- 10.6. Hazardous Decomposition Products: Not expected to decompose under ambient conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Not classified
Acute Toxicity (Dermal): Not classified
Acute Toxicity (Inhalation): Not classified

Ciprofloxacin hydrochloride (93107-08-5)		
LD50 Oral Rat	> 5 g/kg	
Silica, amorphous (7631-86-9)		
LD50 Oral Rat	7900 mg/kg	
LD50 Dermal Rabbit	> 2000 mg/kg (No deaths)	
Magnesium stearate (557-04-0)		
LD50 Oral Rat	> 2000 mg/kg	
Cellulose (9004-34-6)		
LD50 Oral Rat	> 5000 mg/kg	
LD50 Dermal Rabbit	> 2000 mg/kg	
LC50 Inhalation Rat	> 5800 mg/m³ (Exposure time: 4 h)	

Skin Corrosion/Irritation: Not classified
Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

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Silica, amorphous (7631-86-9)	
IARC group	3

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Causes damage to organs through prolonged or repeated exposure.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation. Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction. Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Causes damage to organs (Oral) through prolonged or repeated exposure (Tendons). Repeated or prolonged

contact with skin may cause dermatitis.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Toxic to aquatic life.

Silica, amorphous (7631-86-9)	
LC50 Fish 1	5000 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
EC50 - Crustacea [1]	7600 mg/l (Exposure time: 48 h - Species: Ceriodaphnia dubia)

12.2. Persistence and Degradability

Ciprofloxacin Tablets USP, 750 mg, 500 mg and 250 mg	
Persistence and Degradability Not established.	

12.3. Bioaccumulative Potential

Ciprofloxacin Tablets USP, 750 mg, 500 mg and 250 mg	
Bioaccumulative Potential Not established.	
Silica, amorphous (7631-86-9)	
BCF Fish 1 (no bioaccumulation expected)	

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Ciprofloxacin Tablets USP, 750 mg, 500 mg and 29	50 mg
SARA Section 311/312 Hazard Classes	Health hazard - Specific target organ toxicity (single or repeated exposure)
	Health hazard - Respiratory or skin sensitization
Silica, amorphous (7631-86-9)	
Listed on the United States TSCA (Toxic Substance	s Control Act) inventory
Starch (9005-25-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

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EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the	
	Chemical Data Reporting Rule, (40 CFR 711).	
Oils, vegetable, hydrogenated (68334-28-1)		
Listed on the United States TSCA (Toxic Substances Contro	ol Act) inventory	
Magnesium stearate (557-04-0)		
Listed on the United States TSCA (Toxic Substances Contro	ol Act) inventory	
Cellulose (9004-34-6)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory		
EPA TSCA Regulatory Flag XU - XU - indicates a substance exempt from reporting under th		
	Chemical Data Reporting Rule, (40 CFR 711).	
Starch, carboxymethyl ether, sodium salt (9063-38-1)		
Listed on the United States TSCA (Toxic Substances Control Act) inventory		
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the	
	Chemical Data Reporting Rule, (40 CFR 711).	

15.2. US State Regulations		
Silica, amorphous (7631-86-9)		
U.S Pennsylvania - RTK (Right to Know) List		
U.S Massachusetts - Right To Know List		
Starch (9005-25-8)		
U.S Pennsylvania - RTK (Right to Know) List		
U.S Massachusetts - Right To Know List		
Oils, vegetable, hydrogenated (68334-28-1)		
U.S Pennsylvania - RTK (Right to Know) List		
Cellulose (9004-34-6)		
U.S New Jersey - Right to Know Hazardous Substance List		
U.S Pennsylvania - RTK (Right to Know) List		

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision

U.S. - Massachusetts - Right To Know List

: 08/11/2021

Other Information: This document has been prepared in accordance with the SDSrequirements of the OSHA Hazard Communication Standard 29 CFR

1910.1200

Drug products in final form, packaged according to the US Food,

Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) ready for

administration to the patient, are considered exempt from the US

2012 Hazard Communication Standard

FDA: Ciprofloxacin Tablets USP, 750 mg, 500 mg and 250 mg is an

approved prescription medication

GHS Full Text Phrases:

Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Comb. Dust	Combustible Dust
Skin Sens. 1	Skin sensitization, Category 1
Skin Sens. 1A	Skin sensitization, category 1A
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
H317	May cause an allergic skin reaction
H372	Causes damage to organs through prolonged or repeated exposure
H401	Toxic to aquatic life

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)

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