

# SAFETY DATA SHEET

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## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

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### Contact information

#### General



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<b>Product identifier</b>	Mirtazapine Transdermal Ointment
<b>Synonyms</b>	2-methyl-1,2,3,4,10,14b-hexahydropyrazino[2,1-a]pyrido[2,3-c][2]benzazepine
<b>Trade names</b>	Mirataz™
<b>Chemical family</b>	Mixture - contains mirtazapine
<b>Relevant identified uses of the substance or mixture and uses advised against</b>	Bulk formulated pharmaceutical mixture.
<b>Note</b>	This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture. Workers manufacturing this product/mixture should consult the SDS of each hazardous ingredient for hazard information and handling recommendations.

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## SECTION 2 - HAZARDS IDENTIFICATION

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<b>Classification of the substance or mixture</b>	<b>Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada. Consult prescribing/packaging information. The classification and labeling listed below is for bulk drug product.</b>
<b>Globally Harmonized System [GHS]</b>	Irritant (eye) - Category 2.

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**SECTION 2 - HAZARDS IDENTIFICATION ...continued**

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**Label elements****GHS hazard pictogram****GHS signal word**

Warning

**GHS hazard statements**

H319 - Causes serious eye irritation.

**GHS precautionary statements**

P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/eye protection/face protection. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice/attention.

**Other hazards**

No data were available for the mixture.

**Note**

This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

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**SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS**

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<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Polyethylene oxide/ polyethylene glycol	25322-68-3	500-038-2	50-75%	Not classified
2-(2-ethoxy- ethoxy)ethanol	111-90-0	203-919-7	10-25%	Eye Irrit 2: H319
Mirtazapine	85650-52-8	288-060-6	1-10%	ATO4: H302; STOT-SE3: H336
Polydimethylsiloxanes	63148-62-9	618-493-1	1-10%	CA 2: H411
Starch	9005-25-8	232-679-6	1-10%	Not classified

**Note**

The substances listed above are considered hazardous. The remaining components are not hazardous and/or present at amounts below reportable limits.

Starch and polyethylene glycol are included because they have OELs and are present at or above 1%.

Amounts are listed as ranges; the exact percentage of composition is withheld as a trade secret. See Section 16 for full text of GHS classifications.

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## SECTION 4 - FIRST AID MEASURES

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### Description of first aid measures

<b>Immediate Medical Attention Needed</b>	Yes
<b>Eye Contact</b>	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
<b>Ingestion</b>	Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11.
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.

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## SECTION 5 - FIREFIGHTING MEASURES

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<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, and nitrogen-containing compounds.
<b>Flammability/Explosivity</b>	No explosivity or flammability data identified.
<b>Advice for firefighters</b>	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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<b>Personal precautions, protective equipment and emergency procedures</b>	If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment (see section 8). Area should be adequately ventilated. Do not breathe dust/mist/vapors/spray.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up</b>	For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.

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## SECTION 7 - HANDLING AND STORAGE

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<b>Precautions for safe handling</b>	Follow recommendations for handling bulk formulated/packaged pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling.
<b>Conditions for safe storage including any incompatibilities</b>	Store at < 25°C (77°F)
<b>Specific end use(s)</b>	No information identified.

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## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

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<b>Note</b>	Wash hands, face and other potentially exposed areas immediately in the event of physical contact.
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### Control Parameters/ Occupational Exposure Limit Values

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Polyethylene oxide/ polyethylene glycol	ECHA	DNEL	500 µg/m <sup>3</sup>
	AIHA	8-hour TWA	10 mg/m <sup>3</sup> (Polyethylene glycols MW >200)
2-(2-ethoxy-ethoxy)ethanol	AIHA	TWA-8 HR	25 ppm
	Estonia	TWA-8 HR	10 ppm (skin)
	Germany	Ceiling	100 mg/m <sup>3</sup> (inhalable fraction)
	Germany	TWA-8 HR	50 mg/m <sup>3</sup> (inhalable fraction)
	Germany	TWA-8 HR	6 ppm
	Sweden	STEL	30 ppm

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION...continued**


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**Control Parameters/  
Occupational Exposure  
Limit Values ...continued**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
	Sweden	TWA-8 HR	15 ppm
Mirtazapine	--	--	--
Polydimethylsiloxanes	--	--	--
Starch	ACGIH, Belgium, Bulgaria, Portugal, Spain, Singapore	TWA-8 HR	10 mg/m <sup>3</sup>
	Czech Republic, Slovak Republic	TWA-8 HR	4 mg/m <sup>3</sup>
	Greece, NIOSH	TWA-8 HR	10 mg/m <sup>3</sup> (inhalable fraction); 5 mg/m <sup>3</sup> (respirable fraction)
	Ireland, United Kingdom	TWA-8 HR	10 mg/m <sup>3</sup> (inhalable fraction); 4 mg/m <sup>3</sup> (respirable fraction)
	OSHA	TWA-8 HR	15 mg/m <sup>3</sup> (total dust); 5 mg/m <sup>3</sup> (respirable fraction)
	United Kingdom	STEL	30 mg/m <sup>3</sup> (inhalable fraction); 12 mg/m <sup>3</sup> (respirable fraction)
	NIOSH	TWA-10 HR	10 mg/m <sup>3</sup> (total dust); 5 mg/m <sup>3</sup> (respirable fraction)

**Exposure/Engineering  
controls**

None required for normal handling of packaged product. If handling bulk product and/or containers are open/crushed/broken: Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points. Use engineered local exhaust ventilation (LEV) and/or enclosure for procedures where aerosolization may occur such as opened transfers, pumping, and spraying. Solutions can be handled outside a containment system or without LEV during procedures with no potential for aerosolization. All containers for solutions and slurries must be covered while being transferred.

**Respiratory  
protection**

None required for normal handling of packaged product. If handling bulk product and/or containers are open/crushed/broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. At a minimum, a tight-fitting full-face respirator with HEPA filters is required when performing aerosol generating operations. A powered air-purifying respirator (PAPR) with HEPA filters and head cover is required for spill cleanup.

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION...continued**

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<b>Hand protection</b>	None required for the normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact is possible.
<b>Skin protection</b>	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.
<b>Eye/face protection</b>	None required for normal handling of packaged product. Wear safety glasses with side shields if eye contact is likely, e.g., during clean up of large spill. Base the choice of protection on the job activity and potential for contact with eyes and face.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**Information on basic physical and chemical properties**

<b>Appearance</b>	Ointment
<b>Color</b>	White
<b>Odor</b>	Waxy
<b>Odor threshold</b>	No information identified.
<b>pH</b>	Not applicable
<b>Melting point/ freezing point</b>	No information identified.
<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	Not applicable.
<b>Vapor pressure</b>	No information identified

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued**

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<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	No information identified.
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (<i>n</i>-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular formula</b>	Not applicable (Mixture)
<b>Molecular weight</b>	Not applicable (Mixture)

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**SECTION 10 - STABILITY AND REACTIVITY**

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<b>Reactivity</b>	Stable under normal conditions.
<b>Chemical stability</b>	Stable under normal handling and storage conditions.
<b>Possibility of hazardous reactions</b>	Not expected to occur.
<b>Conditions to avoid</b>	No information identified.
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition products</b>	See Section 5 - Hazardous combustion products.

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**SECTION 11 - TOXICOLOGICAL INFORMATION**

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<b>Note</b>	<b>No data on product formulation. The following information is for mirtazapine and other ingredients, where applicable.</b>
<b>Information on toxicological effects</b>	
<b>Route of entry</b>	May be absorbed by inhalation, skin contact and ingestion.

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**SECTION 11 - TOXICOLOGICAL INFORMATION ...continued**


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**Acute toxicity**

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Polyethylene oxide/ polyethylene glycol	LD <sub>50</sub>	Oral	Rat	>30,000 mg/day
	LD <sub>50</sub>	Dermal	Rabbit	>20,000 mg/kg
2-(2-ethoxy-ethoxy)ethanol	LD <sub>50</sub>	Oral	Rat	1920 - >5000 mg/kg
	LD <sub>50</sub>	Oral	Mouse/ Rabbit	>2000 mg/kg
	LD <sub>50</sub>	Dermal	Rabbit	>2000 mg/kg
	LC <sub>50</sub>	Inhalation	Rat	>5240 mg/m <sup>3</sup>
Mirtazapine	LD <sub>50</sub>	Oral	Rat (female)	320 mg/kg
	LD <sub>50</sub>	Oral	Rat (male)	490 mg/kg
Polydimethylsiloxanes	--	--	--	--
Starch	--	--	--	--

**Irritation/Corrosion** No studies identified.

**Sensitization** No studies identified.

**STOT-single exposure** No studies identified.

**STOT-repeated exposure/Repeat-dose toxicity** No studies identified.

**Reproductive toxicity** No studies identified.

**Developmental toxicity** No studies identified.

**Genotoxicity** No studies identified.

**Carcinogenicity** No studies identified. None of the components of this mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

**Aspiration hazard** No data available.

**Human health data** See "Section 2 - Other Hazards"

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**SECTION 12 - ECOLOGICAL INFORMATION**


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**Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Polyethylene oxide/ polyethylene glycol	EC <sub>50</sub> (24 h)	<i>Daphnia magna</i> (daphnid)	>1000 mg/L
	LC <sub>50</sub> (96 h)	<i>Poecilia reticulata</i> (freshwater fish)	>100 mg/L
2-(2-ethoxy-ethoxy)ethanol	LC <sub>50</sub> (96 h)	Fish (various species)	>1000 mg/L
	EC <sub>50</sub> (48 h)	Freshwater invertebrates	>1000 mg/L
Mirtazapine	--	--	--
Polydimethylsiloxanes	LC <sub>50</sub> (96 h)	Fish	3.16 mg/L
	EC <sub>50</sub> (48 h)	Crustacean (Daphnia)	44.50 mg/L



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**SECTION 12 - ECOLOGICAL INFORMATION ...continued**

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**Toxicity ...continued**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Starch	--	--	--
<b>Persistence and Degradability</b>	No data available.		
<b>Bioaccumulative potential</b>	No data available.		
<b>Mobility in soil</b>	No data available.		
<b>Results of PBT and vPvB assessment</b>	Not performed.		
<b>Other adverse effects</b>	No data available.		
<b>Note</b>	The ecological characteristics of this mixture have not been fully investigated. Releases to the environment should be avoided.		

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**SECTION 13 - DISPOSAL CONSIDERATIONS**

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<b>Waste treatment methods</b>	Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. 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.
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**SECTION 14 - TRANSPORT INFORMATION**

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<b>Transport</b>	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
<b>UN number</b>	None assigned.
<b>UN proper shipping name</b>	None assigned.
<b>Transport hazard classes and packing group</b>	None assigned.
<b>Environmental hazards</b>	This product/mixture is not regulated as an environmental hazard or a marine pollutant.
<b>Special precautions for users</b>	Due to lack of data, avoid release to the environment.

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**SECTION 14 - TRANSPORT INFORMATION ...continued**

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**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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**SECTION 15 - REGULATORY INFORMATION**

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**Safety, health and environmental regulations/legislation specific for the substance or mixture** This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.

**Chemical safety assessment** Not conducted.

**TSCA status** Drugs are exempt from TSCA.

**SARA section 313** Not listed.

**California proposition 65** Not listed.

**Additional information** No other information identified.

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**SECTION 16 - OTHER INFORMATION**

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**Full text of H phrases and GHS classifications** E12A - Eye irritant Category 2A. H319 - Causes serious eye irritation. ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. STOT-SE3 - Specific Target Organ Toxicity Following Single Exposure Category 3. H336 - May cause drowsiness or dizziness. CA2 - Chronic Aquatic Toxicity Category 2. H411 - Toxic to aquatic life with long lasting effects.

**Sources of data** Information from published literature and internal company data.

**Abbreviations** ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT -

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**SECTION 16 - OTHER INFORMATION ...continued**

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**Abbreviations  
...continued**

Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

**Issue Date**

20 March 2020

**Revisions**

This is the first version of this SDS.

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