

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard

**IVIDREL 250 MCG/0.5 ML PFS**

Version	Revision Date:	SDS Number:	Date of last issue: 11/15/2023
3.1	04/11/2024	90MDGM353025	Date of first issue: 12/07/2022

SECTION 1. IDENTIFICATION

Product name : OVIDREL 250 MCG/0.5 ML PFS

Manufacturer or supplier's details

Company : EMD Serono, Inc.
One Technology Place
MA-02370 Rockland
United States of America

Responsible Department : e-mail: HealthcareSDS@emdgroun.com

Emergency telephone number : 800-424-9300 CHEMTREC (USA)
+1-703-527-3887 CHEMTREC (International)
613-996-6666 CANUTEC (Canada)
24 Hours/day; 7 Days/week

Recommended use of the chemical and restrictions on use

Recommended use : Use restricted under TSCA to research and development or as analytical reagent. Uses regulated under FDA or FIFRA are not affected.
Active pharmaceutical ingredient

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Skin irritation : Category 2

Serious eye damage : Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary statements : **Prevention:**
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON

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CENTER/ doctor.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : Mixture of inorganic and organic compounds

Components

Chemical name	CAS-No.	Concentration (% w/w)
Saccharose	57-50-1	$\geq 90 - \leq 100$
phosphoric acid	7664-38-2	$\geq 1 - < 5$

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact : Remove contaminated clothing.
Rinse with water.
If symptoms persist, call a physician.

In case of eye contact : Remove contact lenses.
Protect unharmed eye.
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.

Most important symptoms and effects, both acute and delayed : Fever
Headache
ovarian dysfunction

Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-

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- cumstances and the surrounding environment.
- Specific hazards during fire-fighting : Combustible.
- Ambient fire may liberate hazardous vapours.
- Development of hazardous combustion gases or vapours possible in the event of fire.
- Vapours are heavier than air and may spread along floors.
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.
-

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Advice for non-emergency personnel:
Do not breathe vapours, aerosols.
Evacuate the danger area, observe emergency procedures, consult an expert.
Advice for emergency responders:
Use personal protective equipment.
Dispose of promptly.
Inform the responsible authorities in case of gas leakage, or of entry into waterways, soil or drains.
Indications about waste treatment see section 13.
- Environmental precautions : If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.
-

SECTION 7. HANDLING AND STORAGE

- Technical measures : Install appropriate equipment and wear appropriate personal protective equipment (see "8. Exposure control/personal protection").
- Local/Total ventilation : Ensure adequate ventilation.
- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the ap-
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plication area.

Observe label precautions.

Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.

Keep container tightly closed in a dry and well-ventilated place.

Materials to avoid : No materials to be especially mentioned.

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Saccharose	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
		TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
phosphoric acid	7664-38-2	TWA	1 mg/m ³	ACGIH
		STEL	3 mg/m ³	ACGIH
		TWA	1 mg/m ³	NIOSH REL
		ST	3 mg/m ³	NIOSH REL

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		TWA	1 mg/m3	OSHA Z-1
		TWA	1 mg/m3	OSHA P0
		STEL	3 mg/m3	OSHA P0

Engineering measures : Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Personal protective equipment

Respiratory protection : required when vapours/aerosols are generated.

Filter type : Filter P 3 (acc. to DIN 3181) for solid and liquid particles of toxic and very toxic substances

Hand protection

Material : Nitrile rubber
Break through time : > 480 min
Glove thickness : 0.11 mm
Manufacturer : KCL 741 Dermatril® L

Eye protection : Safety glasses

Skin and body protection : Protective suit

Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures : General industrial hygiene practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Lyophilisate

Colour : white

Odour : No data available

Odour Threshold : Not applicable

pH : acidic

Melting point/range : No data available

Boiling point : No data available

Flash point : No data available

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Upper explosion limit / Upper flammability limit : Not applicable

Lower explosion limit / Lower flammability limit : Not applicable

Vapour pressure : No data available
Not applicable

Density : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not classified as explosive.

Oxidizing properties : none

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No decomposition if stored and applied as directed.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : Violent reactions possible with:
Strong oxidizing agents

Conditions to avoid : No data available

Incompatible materials : Not applicable

Hazardous decomposition products : No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Remarks: No data available

Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Saccharose:

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg
Remarks: (RTECS)

phosphoric acid:

Acute oral toxicity : LD50 (Rat, female): ca. 2,600 mg/kg
Method: OECD Test Guideline 423

Acute dermal toxicity : LD50 (Rabbit): 2,740 mg/kg
Remarks: (IUCLID)

Skin corrosion/irritation

Product:

Remarks : No data available

Remarks : Possible damages:
slight irritation

Components:

phosphoric acid:

Species : Rabbit
Method : US-EPA
Result : Causes burns.

Assessment : Causes burns.

Serious eye damage/eye irritation

Product:

Remarks : No data available

Remarks : Possible damages:
slight irritation

Components:

phosphoric acid:

Species : Rabbit
Result : Causes burns.

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Remarks : (IUCRID)
Assessment : Risk of blindness!
Remarks : Risk of serious damage to eyes.

Respiratory or skin sensitisation

Product:

Remarks : No data available

Components:

phosphoric acid:

Test Type : Patch test:
Species : human
Result : negative
Remarks : (IUCRID)

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Components:

Saccharose:

Genotoxicity in vitro : Test Type: Mutagenicity (mammal cell test):
Result: negative
Remarks: (National Toxicology Program)

phosphoric acid:

Genotoxicity in vitro : Test Type: Ames test
Test system: Escherichia coli/Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: Mouse lymphoma test
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative

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GLP: yes

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.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Repeated dose toxicity

Product:

Remarks : No data available

Further information

Product:

Remarks : Physiologically active substance.
Therapeutically used substance.

Remarks : Handle in accordance with good industrial hygiene and safety practice.

Components:

Saccharose:

Remarks : Substances which occur in nature

Remarks : Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

Remarks : Handle in accordance with good industrial hygiene and safety practice.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other :
aquatic invertebrates Remarks: No data available

Toxicity to algae/aquatic :
plants Remarks: No data available

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Toxicity to fish (Chronic toxicity) : Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : Remarks: No data available

Components:

phosphoric acid:

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 138 mg/l
Exposure time: 96 h
Remarks: (External MSDS)

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): 270 mg/l
Remarks: (IUCLID)

Persistence and degradability

Components:

phosphoric acid:

Biodegradability : Remarks: The methods for determining the biological degradability are not applicable to inorganic substances.

Bioaccumulative potential

Components:

Saccharose:

Partition coefficient: n-octanol/water : log Pow: -3.277

phosphoric acid:

Partition coefficient: n-octanol/water : log Pow: -0.77
Method: (calculated)

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Remarks: (Lit.)
Bioaccumulation is not expected.

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : Discharge into the environment must be avoided.

Components:

phosphoric acid:

Results of PBT and vPvB assessment : PBT/vPvB: Not applicable for inorganic substances

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Contaminated packaging : The hazard and precautionary statements displayed on the label also apply to any residues left in the container.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Packaging that is not properly emptied must be disposed of as the unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

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Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Skin corrosion or irritation
Serious eye damage or eye irritation

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

phosphoric acid	7664-38-2	>= 1 - < 5 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

phosphoric acid	7664-38-2	>= 1 - < 5 %
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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

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phosphoric acid 7664-38-2

Pennsylvania Right To Know

Saccharose 57-50-1
phosphoric acid 7664-38-2

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California List of Hazardous Substances

phosphoric acid 7664-38-2

California Permissible Exposure Limits for Chemical Contaminants

Saccharose 57-50-1
phosphoric acid 7664-38-2

The components of this product are reported in the following inventories:

- | | | |
|-------|---|--|
| TCSI | : | On the inventory, or in compliance with the inventory |
| TSCA | : | Product contains substance(s) not listed on TSCA inventory. |
| AIIC | : | Not in compliance with the inventory |
| DSL | : | This product contains the following components that are not on the Canadian DSL nor NDSL.

Chorionic Gonadotropin, Human Urine, Iodination Grade |
| ENCS | : | Not in compliance with the inventory |
| ISHL | : | Not in compliance with the inventory |
| KECI | : | Not in compliance with the inventory |
| PICCS | : | On the inventory, or in compliance with the inventory |
| IECSC | : | Not in compliance with the inventory |
| NZIoC | : | Not in compliance with the inventory |
| TECI | : | Not in compliance with the inventory |

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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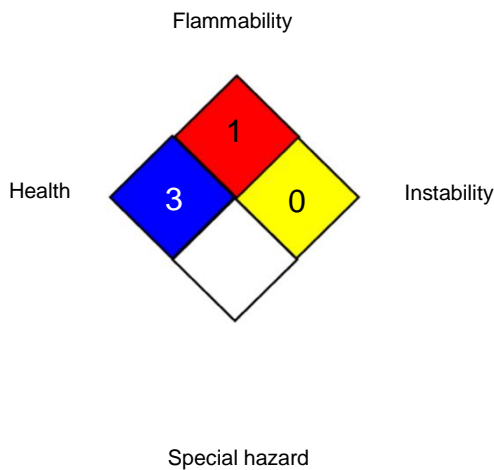
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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	/	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "/" represents a chronic hazard, while the "0" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
ACGIH / STEL	:	Short-term exposure limit
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
NIOSH REL / ST	:	STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
OSHA P0 / TWA	:	8-hour time weighted average
OSHA P0 / STEL	:	Short-term exposure limit
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil

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Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 04/11/2024

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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