

Version 4.1 Revision Date: 09.04.2020 SDS Number: 1104 Date of last issue: 10.05.2017
Date of first issue: 10.05.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

FASLODEX SOLUTION FOR INJECTION

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD Emergency Telephone
PO Box 131 +44 (0) 1235 239 670
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

ICI 182,780 long acting injection
Faslodex vials/pre-filled syringe for injection
CAS No. : Not applicable

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Treatment of advanced breast cancer in postmenopausal women previously treated with hormonal therapy.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 3
Acute toxicity (Oral) : Category 4
Reproductive toxicity : Category 1B
Effects on or via lactation
Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms : 

Signal word : Danger

Hazard statements : H226 Flammable liquid and vapour.
H302 Harmful if swallowed.
H360 May damage fertility or the unborn child.
H362 May cause harm to breast-fed children.
H410 Very toxic to aquatic life with long lasting effects.

Version 4.1 Revision Date: 09.04.2020 SDS Number: 1104 Date of last issue: 10.05.2017
Date of first issue: 10.05.2017

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.
P281 Use personal protective equipment as required.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Benzyl benzoate	120-51-4	15
Ethanol	64-17-5	10
Benzyl alcohol	100-51-6	10
Fulvestrant	129453-61-8	5

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure, keep warm and at rest. Obtain medical attention.

In case of skin contact : Remove contaminated clothing. Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.

Version 4.1 Revision Date: 09.04.2020 SDS Number: 1104 Date of last issue: 10.05.2017
Date of first issue: 10.05.2017

- In case of eye contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
- If swallowed : Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11
Harmful if swallowed.
May damage fertility or the unborn child.
May cause harm to breast-fed children.
- Notes to physician : Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.
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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : foam, CO2 or dry powder.
Water spray should be used to cool containers.
- Unsuitable extinguishing media : Do not use water jet.
- Specific hazards during firefighting : Flammable liquid and vapour.
The vapour is heavier than air and may travel a considerable distance to a source of ignition and flashback.
Combustion will evolve toxic vapours.
- Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
Prevent fire extinguishing water from contaminating surface water or the ground water system.
-

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages.
See Section 8.
Eliminate sources of ignition.
- Environmental precautions : Prevent entry into drains, sewers or watercourses.
Collect spillage.
- Methods and materials for containment and cleaning up : Absorb spillages onto sand, earth or any suitable adsorbent material.
Do not adsorb onto sawdust or other combustible materials.
Transfer to a container for disposal.
Wash the spillage area with water.
Avoid release to the environment.
See section 13.
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SECTION 7. HANDLING AND STORAGE

Version 4.1 Revision Date: 09.04.2020 SDS Number: 1104 Date of last issue: 10.05.2017
 Date of first issue: 10.05.2017

- Advice on safe handling : Avoid contact with skin and eyes.
 Avoid inhalation of vapour/mist.
 Take precautionary measures against static discharges.
- Conditions for safe storage : Keep container tightly closed, in a cool, well ventilated place.
 Keep away from sources of ignition - No Smoking.
 Protect from light.
- Recommended storage temperature : 2 - 8 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ethanol	64-17-5	TWA	1,000 ppm 1,880 mg/m ³	AU OEL
		STEL	1,000 ppm	ACGIH
Fulvestrant	129453-61-8	TWA	0.001 mg/m ³	COM; HYG

- Engineering measures** : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.
 See Section 6 for environmental precautions.

Personal protective equipment

- Respiratory protection : Use an air fed hood if the risk assessment does not support the selection of other protection.
- Eye protection : Use safety glasses to protect against direct contact with the liquid if the risk assessment does not support the selection of other protection.
- Skin and body protection : Use impervious clothing to protect against direct contact with the liquid or for repeated, excessive handling use full chemical protective suit if the risk assessment does not support the selection of other protection. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.
- Protective measures : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for

Version	Revision Date:	SDS Number:	Date of last issue: 10.05.2017
4.1	09.04.2020	1104	Date of first issue: 10.05.2017

selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	No data available
Odour	:	ethereal
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	29 °C
Evaporation rate	:	No data available
Upper explosion limit / Upper flammability limit	:	3.5 %(V)
Lower explosion limit / Lower flammability limit	:	19 %(V)
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies) Water solubility	:	No data available

SAFETY DATA SHEET



Version 4.1 Revision Date: 09.04.2020 SDS Number: 1104 Date of last issue: 10.05.2017
Date of first issue: 10.05.2017

Solubility in other solvents : No data available

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

Auto-ignition temperature : 365 °C

Decomposition temperature : No data available

Viscosity

 Viscosity, dynamic : No data available

 Viscosity, kinematic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No known reactivity hazard under normal conditions.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : None known.

Conditions to avoid : No conditions producing hazardous situations known.

Incompatible materials : None known.

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 2,000 mg/kg
Method: Calculation method

Remarks: May cause effects as described under single exposure.(STOT)

Acute inhalation toxicity : Remarks: May cause effects as described under single exposure.(STOT)

Acute toxicity estimate: > 20 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method

Acute dermal toxicity : Remarks: May cause effects as described under repeated

Version	Revision Date:	SDS Number:	Date of last issue: 10.05.2017
4.1	09.04.2020	1104	Date of first issue: 10.05.2017

exposure.(STOT)

Components:

Ethanol:

Acute oral toxicity : Remarks: May cause effects as described under single exposure.(STOT)

Acute inhalation toxicity : Remarks: May cause effects as described under single exposure.(STOT)

Acute dermal toxicity : Remarks: Unlikely to be hazardous by skin absorption.

Fulvestrant:

Acute oral toxicity : Remarks: Low acute oral toxicity.

Acute inhalation toxicity : Remarks: May cause effects as described under repeated exposure.(STOT)

Acute dermal toxicity : Remarks: No information available.

11.2 Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : May cause skin irritation.

Components:

Benzyl benzoate:

Remarks : May cause skin irritation.

Ethanol:

Remarks : Slight/mild irritant.
Repeated or prolonged contact may cause defatting of the skin resulting in dryness, cracking and dermatitis.

Fulvestrant:

Result : Mild skin irritation

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks : The vapour and liquid are irritant.
May cause strong stinging and burning sensation.
Permanent damage is unlikely.

Version 4.1 Revision Date: 09.04.2020 SDS Number: 1104 Date of last issue: 10.05.2017
Date of first issue: 10.05.2017

Components:**Benzyl benzoate:**

Remarks : May cause eye irritation.

Ethanol:

Remarks : The vapour and liquid are irritant.
May cause strong stinging and burning sensation.

Benzyl alcohol:

Remarks : The vapour and liquid are irritant.

Fulvestrant:

Remarks : May cause eye irritation.
Unlikely to be a severe irritant to the eye.

11.4 Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

Remarks : Rare cases of skin sensitisation have been reported.

Components:**Benzyl benzoate:**

Remarks : Repeated and/or prolonged contact may cause skin sensitisation.

Ethanol:

Remarks : No information available.

Fulvestrant:

Remarks : Unlikely to cause skin sensitisation.

Chronic toxicity**11.5 Germ cell mutagenicity**

Not classified based on available information.

Components:**Ethanol:**

Germ cell mutagenicity - Assessment : No information available.

Fulvestrant:

Version	Revision Date:	SDS Number:	Date of last issue: 10.05.2017
4.1	09.04.2020	1104	Date of first issue: 10.05.2017

Germ cell mutagenicity - Assessment : The substance is not considered to be genotoxic.

11.6 Carcinogenicity

Not classified based on available information.

Components:

Ethanol:

Carcinogenicity - Assessment : No information available.

Fulvestrant:

Carcinogenicity - Assessment : A lifetime study in animals has shown that repeated doses produce benign tumours of the ovaries and testes in rats., These effects are related to the compound's hormonal activity.

11.7 Reproductive toxicity

May damage fertility or the unborn child.
May cause harm to breast-fed children.

Components:

Ethanol:

Reproductive toxicity - Assessment : No information available.

Fulvestrant:

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Repeated exposure may produce adverse effects on the reproductive systems of men and women., Studies in animals have shown that low doses produce embryo/foetotoxic effects in the absence of maternal toxicity., (including embryoletality).
Effects on or via lactation

11.8 STOT - single exposure

Not classified based on available information.

Components:

Ethanol:

Exposure routes : Inhalation, Ingestion
Remarks : The vapour has anaesthetic properties and when inhaled at high concentrations, it may cause respiratory irritation, headache, fatigue, dizziness and incoordination.
Minute amounts aspirated into the lungs during ingestion may cause pulmonary injury.

Benzyl alcohol:

Remarks : May cause irritation to the upper respiratory tract.

SAFETY DATA SHEET



Version 4.1 Revision Date: 09.04.2020 SDS Number: 1104 Date of last issue: 10.05.2017
Date of first issue: 10.05.2017

Ingestion may cause irritation of the gastrointestinal tract.
The vapour has anaesthetic properties and when inhaled at concentrations above the occupational exposure limit it may cause headache, fatigue, dizziness, incoordination and loss of consciousness.

Fulvestrant:

Remarks : No specific effects reported.

11.9 STOT - repeated exposure

Not classified based on available information.

Components:

Ethanol:

Exposure routes : Inhalation
Target Organs : Liver
Remarks : Repeated exposure to high levels may produce adverse effects on the liver.

Benzyl alcohol:

Remarks : Repeated and/or prolonged contact with the skin may have a degreasing action and cause dermatitis.

Fulvestrant:

Exposure routes : Oral
Remarks : An ingestion study in animals has shown that high doses produce adverse effects on the heart.

11.10 Aspiration toxicity

Not classified based on available information.

Components:

Ethanol:

No information available.

Fulvestrant:

No information available.

Further information

Product:

Remarks : This health hazard assessment is based on a consideration of the composition of this product.

Version	Revision Date:	SDS Number:	Date of last issue: 10.05.2017
4.1	09.04.2020	1104	Date of first issue: 10.05.2017

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:****Ecotoxicology Assessment**

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.
 Remarks: This environmental hazard assessment is based on information available on the components of the formulation.
 Information refers to Fulvestrant

Components:**Benzyl benzoate:**

Toxicity to fish : (Lepomis macrochirus (Bluegill sunfish)): 10 mg/l
 Exposure time: 96 h
 Test Type: LC50

Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 13,500 - 14,900 mg/l
 Exposure time: 96 h

LC50 (Danio rerio (zebra fish)): 14,200 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 9,268 - 14,221 mg/l
 Exposure time: 48 h
 Test Type: static test

Fulvestrant:

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 0.047 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.0000057 mg/l
 Exposure time: 42 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.01 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211
 Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity) : 10,000

Toxicity to microorganisms : IC50 (Sewage sludge organisms): > 100 mg/l
 Exposure time: 3 h
 Method: OECD Test Guideline 209

Version 4.1 Revision Date: 09.04.2020 SDS Number: 1104 Date of last issue: 10.05.2017
Date of first issue: 10.05.2017

Ecotoxicology Assessment

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Persistence and degradability**Components:****Ethanol:**

Biodegradability : Remarks: The substance is substantially biodegradable in water.
There is evidence of photodegradation in air.

BOD/COD : BOD/COD: 0.57 %

Fulvestrant:

Biodegradability : aerobic
Inoculum: activated sludge
Concentration: 100 mg/l
Biodegradation: < 5 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Not rapidly degradable.

Bioaccumulative potential**Components:****Ethanol:**

Bioaccumulation : Remarks: The substance has low potential for bioaccumulation.

Fulvestrant:

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 355
Concentration: 0.0001 mg/l
Method: OECD Test Guideline 305

Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 357
Concentration: 0.001 mg/l
Method: OECD Test Guideline 305

Remarks: The substance has low potential for bioaccumulation.

Mobility in soil**Components:****Ethanol:**

Mobility : Remarks: Water solubility \geq 1 mg/l.
Liquid with high volatility.

SAFETY DATA SHEET



Version 4.1 Revision Date: 09.04.2020 SDS Number: 1104 Date of last issue: 10.05.2017
Date of first issue: 10.05.2017

Distribution among environmental compartments : Remarks: No information available.

Fulvestrant:

Mobility : Remarks: The substance is essentially insoluble in water.

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Disposal should be in accordance with local, state or national legislation.
Solvent residues must not be allowed to enter drains, sewers or watercourses or to contaminate the ground.
Dispose of contents/ container to an approved incineration plant.
Large volumes may be suitable for redistillation by solvent contractors.

Contaminated packaging : Empty container will retain residue. Observe all hazard precautions.

SECTION 14. TRANSPORT INFORMATION

ICAO/IATA

UN No. : 1993
Proper Shipping Name : Flammable liquid, n.o.s. (ETHANOL, FULVESTRANT)
Class : 3
Packing Group : III

IMO/IMDG

UN No. : 1993
Proper Shipping Name : FLAMMABLE LIQUID, N.O.S. (ETHANOL, FULVESTRANT)
Class : 3
Packing Group : III
Marine pollutant : Marine pollutant

SAFETY DATA SHEET



Version 4.1 Revision Date: 09.04.2020 SDS Number: 1104 Date of last issue: 10.05.2017
Date of first issue: 10.05.2017

ADR

UN No. : 1993
Proper Shipping Name : FLAMMABLE LIQUID, N.O.S. (ETHANOL, FULVESTRANT)
Class : 3
Label(s) : 3
Packing Group : III
Environmental hazards : Environmentally hazardous

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

TCSI : Not listed
TSCA : Substance(s) not listed on TSCA inventory
AICS : Not listed
DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
Fulvestrant
ENCS : Not listed
ISHL : Not listed
KECI : Not listed
IECSC : Not listed
CHINV : Not in compliance with the inventory
REACH : Not in compliance with the inventory
TRINV : Not in compliance with the inventory

Version	Revision Date:	SDS Number:	Date of last issue: 10.05.2017
4.1	09.04.2020	1104	Date of first issue: 10.05.2017

SECTION 16. OTHER INFORMATION**Further information**

Revision Date : 09.04.2020

Other information : Minor changes:
3
11
12
15

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / STEL : Short-term exposure limit
AU OEL / TWA : Exposure standard - time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CHINV - China Inventory; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM - In-house occupational exposure limit; CPR - Controlled Products Regulations; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; HYG - Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IC50 - Half maximal inhibitory concentration; ICAO - International Civil 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; Sen - Capable of causing respiratory sensitization; Sk - Can be absorbed through skin, thus contributing to systemic effects; STEL - Short-term exposure limit 15-minutes time-weighted average; TLV - Threshold Limit Value (ACGIH); TLV-C - Threshold Limit Value Ceiling limit (ACGIH); TRINV - Turkey Inventory; TSCA - Toxic Substances Control Act (United States); TWA - Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

SAFETY DATA SHEET



Version	Revision Date:	SDS Number:	Date of last issue: 10.05.2017
4.1	09.04.2020	1104	Date of first issue: 10.05.2017

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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