

## Ampicillin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/28
6.0	2025/04/14	10082471-00009	Date of first issue: 2021/10/27

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## 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Ampicillin Formulation

**Supplier's company name, address and phone number**

Company name of supplier : MSD

Address : 1-13-12, Kudan-kita, Chiyoda-ku, Tokyo, Japan

Telephone : 03-6272-1099

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product

Restrictions on use : Not applicable

## 2. HAZARDS IDENTIFICATION

**GHS classification of chemical product**

Respiratory sensitisation : Category 1

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 3

**GHS label elements**

Hazard pictograms :



Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H401 Toxic to aquatic life.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P261 Avoid breathing mist or vapours.  
P273 Avoid release to the environment.

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P284 Wear respiratory protection.

**Response:**

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

**Disposal:**

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

**Other hazards which do not result in classification**

None known.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
ampicillin	69-53-4	>= 10 - < 20	-

**4. FIRST AID MEASURES**

- |   |  |
|---|--|
| General advice  | : In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.   |
| If inhaled  | : If inhaled, remove to fresh air.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention.  |
| In case of skin contact                                     | : Wash with water and soap as a precaution.<br>Get medical attention if symptoms occur.  |
| In case of eye contact                                      | : Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.   |
| If swallowed  | : If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>Rinse mouth thoroughly with water.  |
| Most important symptoms and effects, both acute and delayed | : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Protection of first-aiders                                  | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).  |
| Notes to physician  | : Treat symptomatically and supportively.  |

**5. FIREFIGHTING MEASURES**

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- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Nitrogen oxides (NO<sub>x</sub>)  
Carbon oxides  
Sulphur oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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**6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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**7. HANDLING AND STORAGE****Handling**

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
Take care to prevent spills, waste and minimize release to the environment.
- Avoidance of contact : Oxidizing agents
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**Storage**

- Conditions for safe storage : Keep in properly labelled containers.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents
- Packaging material : Unsuitable material: None known.

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**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Threshold limit value and permissible exposure limits for each component in the work environment**

Components	CAS-No.	Value type (Form of	Control parameters / Concentra-	Basis
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		exposure)	tion standard / Permissible con- centration	
ampicillin	69-53-4	TWA	0.6 mg/m <sup>3</sup> (OEB 2)	Internal
Further information: RSEN				

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Laboratory operations do not require special containment.

**Personal protective equipment**

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Hand protection : Chemical-resistant gloves

Material

Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state : suspension

Colour : white to off-white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit  
Upper explosion limit / Up- : No data available

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per flammability limit

Lower explosion limit /  
Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity  
Viscosity, kinematic : No data availableSolubility(ies)  
Water solubility : No data availablePartition coefficient: n-  
octanol/water : Not applicable

Vapour pressure : No data available

Density and / or relative density  
Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics  
Particle size : Not applicable

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**10. STABILITY AND REACTIVITY**

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Can react with strong oxidizing agents.
Conditions to avoid	: None known.
Incompatible materials	: Oxidizing agents

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Hazardous decomposition products : No hazardous decomposition products are known.

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**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Not classified based on available information.

**Components:****ampicillin:**

Acute oral toxicity	: LD50 (Rat): 10,000 mg/kg
	LD50 (Mouse): 15,200 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Rat): 6,200 mg/kg
	Application Route: Intravenous
	LD50 (Mouse): 4,600 mg/kg
	Application Route: Intravenous

**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:****ampicillin:**

Exposure routes	: Inhalation
Result	: Sensitiser

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****ampicillin:**

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Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
		Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Result: negative
		Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: negative
		Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative
		Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Rat Application Route: Oral Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****ampicillin:**

Species	:	Rat
Application Route	:	Oral
Exposure time	:	2 Years
	:	750 mg/kg body weight
Tumor Type	:	adrenal, Leukaemia, breast tumors

Species	:	Mouse
Application Route	:	Oral
Exposure time	:	2 Years
	:	3,000 mg/kg body weight
Tumor Type	:	Lungs
Remarks	:	Benign tumor(s)

Carcinogenicity - Assessment	:	Weight of evidence does not support classification as a carcinogen
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**Reproductive toxicity**

Not classified based on available information.

**Components:****ampicillin:**



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Effects on fertility	: Test Type: Fertility Species: Guinea pig Target Organs: Uterus (including cervix)
Effects on foetal development	: Test Type: Development Species: Rat Developmental Toxicity: NOAEL: 250 mg/kg body weight Result: No effects on foetal development

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****ampicillin:**

Species	: Rat
LOAEL	: 3,000 mg/kg
Application Route	: Oral
Exposure time	: 13 Weeks
Symptoms	: Diarrhoea

Species	: Mouse
LOAEL	: 2,000 mg/kg
Application Route	: Oral
Exposure time	: 13 Weeks
Symptoms	: Diarrhoea

Species	: Rat
LOAEL	: 750 mg/kg
Application Route	: Oral
Exposure time	: 2 yr
Target Organs	: Thyroid, forestomach
Symptoms	: Diarrhoea, Salivation, decreased activity

Species	: Mouse
LOAEL	: 2,000 mg/kg
Application Route	: Oral
Exposure time	: 2 yr
Target Organs	: forestomach
Symptoms	: Ulceration, Inflammation, fungal infections

**Aspiration toxicity**

Not classified based on available information.

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## Experience with human exposure

Components:

## ampicillin:

- |            |   |  |
|------------|---|--|
| Inhalation | : | Symptoms: Asthma, Hay fever<br>Remarks: May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Ingestion  | : | Symptoms: skin rash, Nausea, Diarrhoea, Vomiting, colitis, urticaria   |

## 12. ECOLOGICAL INFORMATION

## Ecotoxicity

Components:

## ampicillin:

- |   |   |   |
|---|---|---|
| Toxicity to fish                                    | : | LC50 ( <i>Oryzias latipes</i> (Japanese medaka)): > 1,000 mg/l<br>Exposure time: 96 h<br><br>LC50 ( <i>Oncorhynchus mykiss</i> (rainbow trout)): > 100 mg/l<br>Exposure time: 96 h  |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 ( <i>Daphnia magna</i> (Water flea)): > 100 mg/l<br>Exposure time: 48 h  |
| Toxicity to algae/aquatic plants                    | : | EC50 ( <i>Anabaena flos-aquae</i> ): 190 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC ( <i>Anabaena flos-aquae</i> ): 13 µg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>EC50 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 100 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC ( <i>Pseudokirchneriella subcapitata</i> (green algae)): 100 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| M-Factor (Acute aquatic toxicity)                   | : | 1   |
| Toxicity to microorganisms                          | : | EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition   |

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Method: OECD Test Guideline 209

NOEC: 9 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Persistence and degradability****Components:****ampicillin:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 35 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Bioaccumulative potential****Components:****ampicillin:**

Partition coefficient: n-octanol/water : log Pow: -2.0  
pH: 7

**Mobility in soil**

No data available

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable

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Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

**IATA-DGR**

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

**National Regulations**

Refer to section 15 for specific national regulation.

**Special precautions for user**

Not applicable

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**15. REGULATORY INFORMATION****Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law****Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

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**Substances Prevented From Impairment of Health**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Not applicable

**Substances Subject to be Indicated Names**

Not applicable

**Skin and Eye Damage Substances (ISHL MO Art. 594-2)**

Not applicable

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Not regulated as a dangerous good

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**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION****Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; 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; 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 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 Or-

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ganisation 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; 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; 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; 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; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; 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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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