SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Doxorubicin Hydrochloride Injection, USP**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	January 08, 2009
SDS Revision Date:	February 19, 2024

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. category 1.
Carcinogenicity. Category 1A.
Germ cell mutagenicity. Category 2.
Reproductive toxicity. Category 2.
Skin Sensitization. category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause cancer.
Suspected of causing genetic defects.
Suspected of damaging fertility or the unborn child.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Store locked up.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Potential adverse reactions from prescribed doses are described in the package insert and include: acute and delayed cardiotoxicity, myelosuppression, secondary leukemia, hepatic impairment, nausea, vomiting, mucositis, ulceration and necrosis of the colon, hypersensitivity, peripheral neurotoxicity, alopecia, hyperpigmentation of nail beds and dermal creases, rash, itching and photosensitivity. The symptoms and signs of overdosage include enhanced toxic effects of mucositis, leukopenia, and thrombocytopenia. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with hypersensitivity to doxorubicin, any of its excipients, or other anthracyclines or anthracenediones. Also, individuals with cardiovascular disease, hepatic, renal, and bone marrow impairment.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.

Doxorubicin Hydrochloride	25316-40-9	2 mg/mL
Sodium Chloride	7647-14-5	9 mg/mL
Water for Injection	7732-18-5	Quantity Sufficient

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at refrigerated temperatures 2 to 8°C (36 to 46°F). Protect from light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.

Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Red orange.
Boiling Point:	100°C
Melting Point:	205°C (raw material)
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	2.5 - 4.5
Molecular Formula:	Mixture
Molecular Weight:	579.99
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from light and excessive heat.

SECTION 11 : TOXICOLOGICAL INFORMATION

Doxorubicin Hydrochloride :

Acute Toxicity:	Acute Toxicity: LD50 IV Mouse: 21.1 mg/kg

Doxorubicin Hydrochloride :

NTP:	NTP: Reasonably anticipated to be a human carcinogen.
Chronic Effects:	Cardiotoxicity, myelosuppression, hypersensitivity, and skin or nail hyperpigmentation.
Teratogenicity:	Pregnancy Category D:Doxorubicin can cause fetal harm when administered to a pregnant woman. Doxorubicin is teratogenic and embryotoxic in rats.

Doxorubicin Hydrochloride :

RTECS Number:	QI9295900
Ingestion:	Oral - Mouse LD50: 698 mg/kg [Sense Organs and Special Senses (Eye) - Lacrimation Behavioral - Muscle weakness Gastrointestinal - Hypermotility, diarrhea] Oral - Mouse LD50: 570 mg/kg [Blood - Other changes]
Other Toxicological Information:	Intravenous. - Rat LD50: 12510 ug/kg [Gastrointestinal - hypermotility, diarrhea Skin and Appendages - dermatitis, allergic (after topical exposure) Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intravenous. - Mouse LD50: 1245 ug/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LD50: 5980 ug/kg [Behavioral - food intake (animal) Behavioral - muscle weakness] Intravenous. - Mouse LD50: 12.5 mg/kg [Blood - other changes] Intravenous. - Rat TDLo: 2 mg/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intravenous. - Rat TDLo: 6 mg/kg [Blood - changes in erythrocyte (RBC) count Reproductive - Paternal Effects - testes, epididymis, sperm duct Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intravenous. - Human TDLo: 0.5 mg/kg [Immunological Including Allergic - anaphylaxis]

Intravenous. - Rat TDLo: 7.5 mg/kg [Liver - other changes Kidney/Ureter/Bladder - other changes Biochemical - Metabolism (Intermediary) - lipids including transport]
Intravenous. - Rat TDLo: 7.5 mg/kg [Cardiac - cardiomyopathy including infarction Kidney/Ureter/Bladder - other changes Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation]
Intravenous. - Rat TDLo: 5 mg/kg [Cardiac - pulse rate Kidney/Ureter/Bladder - changes in tubules (including acute renal failure, acute tubular necrosis) Kidney/Ureter/Bladder - renal function tests depressed]
Intravenous. - Rat TDLo: 12480 ug/kg/13W (intermittent) [Cardiac - changes in heart weight Blood - leukopenia Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - phosphatases]
Intravenous. - Rat TDLo: 15 mg/kg/5W (intermittent) [Cardiac - other changes Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intravenous. - Rat TDLo: 9 mg/kg/3W (intermittent) [Cardiac - EKG changes not diagnostic of specified effects Nutritional and Gross Metabolic - weight loss or decreased weight gain Related to Chronic Data - death]
Intravenous. - Rat TDLo: 22400 ug/kg/4W (intermittent) [Kidney/Ureter/Bladder - proteinuria Blood - normocytic anemia Blood - changes in leukocyte (WBC) count]
Intravenous. - Rat TDLo: 12 mg/kg/6W (intermittent) [Cardiac - other changes Related to Chronic Data - death]
Intravenous. - Mouse TDLo: 40 mg/kg/7W (intermittent) [Cardiac - other changes Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intravenous. - Rabbit TDLo: 18 mg/kg/30D (continuous) [Endocrine - changes in thymus weight Blood - normocytic anemia Related to Chronic Data - death]
Intravenous. - Rat TDLo: 20 mg/kg/4D (intermittent) [Related to Chronic Data - death]
Intravenous. - Rat TDLo: 18.75 mg/kg/5D (intermittent) [Related to Chronic Data - death]
Intravenous. - Rat TDLo: 18.75 mg/kg/5D (intermittent) [Kidney/Ureter/Bladder - changes in tubules (including acute renal failure, acute tubular necrosis) Blood - leukopenia Blood - thrombocytopenia]
Intravenous. - Rat TDLo: 6.25 mg/kg/5D (intermittent) [Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intravenous. - Rat TDLo: 7.5 mg/kg/3D (intermittent) [Endocrine - changes in spleen weight Endocrine - changes in thymus weight Blood - changes in cell count (unspecified)]
Intravenous. - Rat TDLo: 2 mg/kg/2W (intermittent) [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)]
Intravenous. - Rat TDLo: 4 mg/kg/4W (intermittent) [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count) Nutritional and Gross Metabolic - weight loss or decreased weight gain Related to Chronic Data - changes in testicular weight]
Intravenous. - Mouse TDLo: 16 mg/kg/2W (intermittent) [Endocrine - tumors Tumorigenic - protects against induction of experimental tumors]
Intravenous. - Human TDLo: 1 mg/kg/29D (intermittent) [Gastrointestinal - hypermotility, diarrhea Gastrointestinal - nausea or vomiting Blood - normocytic anemia]
Intravenous. - Human TDLo: 1 mg/kg/29D (intermittent) [Blood - leukopenia Blood - thrombocytopenia Skin and Appendages - hair]
Intravenous. - Rabbit TDLo: 18 mg/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct]
Intravenous. - Rabbit TDLo: 600 ug/kg [Reproductive - Maternal Effects - ovaries, fallopian tubes]
Intravenous. - Rat DNA damage: 20 mg/kg
Subcutaneous - Rat LD50: 21840 ug/kg [Gastrointestinal - hypermotility, diarrhea Skin and Appendages - dermatitis, allergic (after topical exposure) Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Subcutaneous - Mouse LD50: 7678 ug/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: 13.5 mg/kg [Blood - other changes]
Subcutaneous - Rat TDLo: 26 mg/kg/13W (intermittent) [Cardiac - other changes Kidney/Ureter/Bladder - changes in both tubules and glomeruli Blood - other changes]
Subcutaneous - Rat TDLo: 1500 ug/kg [Reproductive - Paternal Effects - prostate, seminal vesicle, Cowper's gland, accessory glands]
Subcutaneous - Mouse TDLo: 4500 ug/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count) Reproductive - Paternal Effects - testes, epididymis, sperm duct]
Intraperitoneal. - Rat LD50: 16030 ug/kg [Gastrointestinal - hypermotility, diarrhea Skin and Appendages - dermatitis, allergic (after topical exposure) Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intraperitoneal. - Mouse LD50: 11160 ug/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 4.6 mg/kg [Blood - other changes]
Intraperitoneal. - Mouse TDLo: 15 mg/kg [Cardiac - cardiomyopathy including infarction Cardiac - other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - cytochrome oxidases (including oxidative phosphorylation)]
Intraperitoneal. - Rat TDLo: 60 mg/kg/30D (continuous) [Liver - changes in liver weight Endocrine - changes in spleen weight Blood - normocytic anemia]
Intraperitoneal. - Rat TDLo: 18900 ug/kg/21D (intermittent) [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - transaminases]
Intraperitoneal. - Rat TDLo: 6300 ug/kg/3D (intermittent) [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - transaminases]
Intraperitoneal. - Rat TDLo: 38 mg/kg/14W (intermittent) [Cardiac - EKG changes not diagnostic of specified effects Kidney/Ureter/Bladder - other changes in urine composition Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol)]
Intraperitoneal. - Mouse : 18 mg/kg/5W (intermittent) [Tumorigenic - protects against induction of experimental tumors]
Intraperitoneal. - Rat TDLo: 16 mg/kg/4W (intermittent) [Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intraperitoneal. - Rat TDLo: 20 mg/kg/4W (intermittent) [Cardiac - cardiomyopathy including infarction Cardiac - EKG changes not diagnostic of specified effects Cardiac - change in force of contraction]
Intraperitoneal. - Rat TDLo: 6.25 mg/kg/8D (intermittent) [Related to Chronic Data - death]
Intraperitoneal. - Rat TDLo: 20 mg/kg/4W (intermittent) [Cardiac - cardiomyopathy including infarction Nutritional and Gross Metabolic - weight loss or decreased weight gain Related to Chronic Data - death]
Intraperitoneal. - Rat TDLo: 6 mg/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count) Reproductive - Paternal Effects - testes, epididymis, sperm duct Reproductive - Paternal Effects - prostate, seminal vesicle, Cowper's gland, accessory glands]
Intraperitoneal. - Mouse TDLo: 1 mg/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count) Reproductive - Paternal Effects - testes, epididymis, sperm duct]
Intraperitoneal. - Mouse TDLo: 7 mg/kg [Reproductive - Fertility - female fertility index (e.g.numberfemales pregnant pernumbersperm positive females;numberfemales pregnant pernumberfemales mated) Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea)]
Intraperitoneal. - Rabbit TDLo: 30 mg/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct]
Intraperitoneal. - Rabbit TDLo: 60 mg/kg [Reproductive - Maternal Effects - ovaries, fallopian tubes]
Intraperitoneal. - Mouse DNA inhibition: 15 mg/kg
Intraperitoneal. - Mouse Mutation test systems : 15 mg/kg
Intraperitoneal. - Mouse Cytogenetic analysis: 12 mg/kg
Intraperitoneal. - Rat DNA adduct: 4 mg/kg
Intraperitoneal. - Rat DNA damage: 16 mg/kg/4W

Sodium Chloride :

RTECS Number: VZ4725000

Eye: Eye - Rabbit Standard Draize test.: 10 mg [Moderate]

Skin:	Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild] Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Inhalation:	Inhalation - Rat LC50: >42 gm/m3/1H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LDLo: 1100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle contraction or spasticity Cardiac - other changes] Intravenous. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse TDLo: 2.1 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)] Intravenous. - Rabbit LDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)] Subcutaneous - Rat LDLo: 3500 mg/kg [Behavioral - irritability] Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Skin and Appendages - dermatitis, irritative (after systemic exposure)] Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death] Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Subcutaneous - Mouse TDLo: 2500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)] Subcutaneous - Mouse TDLo: 13440 mg/kg [Reproductive - Fertility - abortion] Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LDLo: 3.72 gm/kg [Behavioral - tremor Behavioral - convulsions or effect on seizure threshold] Intraperitoneal. - Rat TDLo: 1710 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Effects on Newborn - behavioral] Intraperitoneal. - Rat Cytogenetic analysis: 2338 mg/kg

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

EINECS Number:	246-818-3
Sodium Chloride :	
TSCA Inventory Status:	Listed
EINECS Number:	231-598-3
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	3*
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

SDS Creation Date:	January 08, 2009
SDS Revision Date:	February 19, 2024
SDS Revision Notes:	Overall SDS review - no changes to formulation. Revised the HMIS ratings for Health, Flammability, Reactivity, and Personal Protective Equipment (PPE).

Disclaimer:

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