

Fenbendazole (0.5%) Pellets Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.0	14.04.2025	7987910-00010	Date of first issue: 22.03.2021

SECTION 1. IDENTIFICATION

Product identifier : Fenbendazole (0.5%) Pellets Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification in accordance with ABNT NBR 14725 Standard**

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**
P273 Avoid release to the environment.
Response:
P391 Collect spillage.

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Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
White mineral oil (petroleum)	8042-47-5		≥ 1 -< 5
fenbendazole	43210-67-9	Repr., 2 STOT RE, (Oral)(Liver, Stomach, Nervous system, Lymph nodes) , 2 Aquatic Acute, 1 Aquatic Chronic, 1	$\geq 0,25$ -< 1

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

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- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Silicon 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
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SECTION 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.
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
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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SECTION 7. HANDLING AND STORAGE

- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.
 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
 Minimize dust generation and accumulation.
 Keep container closed when not in use.
 Keep away from heat and sources of ignition.
 Take precautionary measures against static discharges.
 Take care to prevent spills, waste and minimize release to the environment.
- 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.
- Conditions for safe storage : Keep in properly labeled containers.
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
 Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum)	8042-47-5	TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
fenbendazole	43210-67-9	TWA	100 µg/m ³ (OEB 2)	Internal

- Engineering measures** : Use feasible engineering controls to minimize exposure to compound.
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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 vapor type

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Hand protection	
Material	: Chemical-resistant gloves
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	: pellets
Color	: tan to light brown
Odor	: characteristic
Odor Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: Not applicable
Evaporation rate	: Not applicable
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	: Not applicable
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapor pressure	: Not applicable
Relative vapor density	: Not applicable
Relative density	: No data available
Density	: No data available

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Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Autoignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: Not applicable
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available
Particle characteristics	
Particle size	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Acute oral toxicity	: LD50 (Rat): > 5.000 mg/kg
Acute inhalation toxicity	: LC50 (Rat): > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist

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	Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity	: LD50 (Rabbit): > 2.000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity

fenbendazole:

Acute oral toxicity	: LD50 (Rat): > 10.000 mg/kg LD50 (Mouse): > 10.000 mg/kg
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Skin corrosion/irritation

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Species	: Rabbit
Result	: No skin irritation

fenbendazole:

Species	: Rabbit
Result	: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Species	: Rabbit
Result	: No eye irritation

fenbendazole:

Species	: Rabbit
Result	: No eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Test Type	: Buehler Test
Routes of exposure	: Skin contact
Species	: Guinea pig

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Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Method: OECD Test Guideline 474 Result: negative Remarks: Based on data from similar materials

fenbendazole:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: DNA Repair Result: negative Test Type: Chromosomal aberration Result: negative Test Type: in vitro test Test system: mouse lymphoma cells Metabolic activation: Metabolic activation Result: equivocal
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Carcinogenicity

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Species	: Rat
Application Route	: Ingestion
Exposure time	: 24 Months
Result	: negative

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Species	: Mouse
Application Route	: oral (feed)
Exposure time	: 2 Years
NOAEL	: 405 mg/kg body weight
Result	: negative

Species : Rat

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Application Route	: Oral
Exposure time	: 2 Years
NOAEL	: 5 mg/kg body weight
Result	: negative
Target Organs	: Lymph nodes, Liver

Reproductive toxicity

Not classified based on available information.

Components:**White mineral oil (petroleum):**

Effects on fertility	: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Skin contact Result: negative
Effects on fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative

fenbendazole:

Effects on fertility	: Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: oral (feed) General Toxicity Parent: NOAEL: 15 mg/kg body weight Fertility: LOAEL: 45 mg/kg body weight Result: Effects on fertility.
Effects on fetal development	: Test Type: Development Species: Dog, female Application Route: Oral Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-spring were detected., No teratogenic effects. Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 25 mg/kg body weight Result: Fetotoxicity. Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 63 mg/kg body weight Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 120 mg/kg body weight Result: No effects on fetal development.

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Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:**fenbendazole:**

Routes of exposure : Ingestion
Target Organs : Liver, Stomach, Nervous system, Lymph nodes
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****White mineral oil (petroleum):**

Species : Rat
LOAEL : 160 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat
LOAEL : ≥ 1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Method : OECD Test Guideline 412

fenbendazole:

Species : Rat
LOAEL : 500 mg/kg
Application Route : Oral
Exposure time : 2 Weeks
Target Organs : Kidney, Liver

Species : Rat
NOAEL : > 2.500 mg/kg
Application Route : Oral
Exposure time : 30 Days
Remarks : No significant adverse effects were reported

Species : Rat
LOAEL : 1.600 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Central nervous system
Symptoms : Tremors

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Species	: Dog
NOAEL	: 4 mg/kg
LOAEL	: 8 mg/kg
Exposure time	: 6 Months
Target Organs	: Stomach, Nervous system, Lymph nodes

Aspiration toxicity

Not classified based on available information.

Components:**fenbendazole:**

|| No aspiration toxicity classification

Experience with human exposure**Components:****fenbendazole:**

|| Ingestion : Symptoms: Rapid respiration, Salivation, anorexia, Diarrhea

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****White mineral oil (petroleum):**

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: NOEC (Oncorhynchus mykiss (rainbow trout)): 1.000 mg/l Exposure time: 28 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 1.000 mg/l Exposure time: 21 d

fenbendazole:

Toxicity to fish	: LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,009 mg/l Exposure time: 21 d
Toxicity to daphnia and other	: EC50 (Daphnia magna (Water flea)): 0,0088 mg/l

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aquatic invertebrates	Exposure time: 48 h
	Method: OECD Test Guideline 202
M-Factor (Acute aquatic toxicity)	: 100
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0,00113 mg/l
	Exposure time: 21 Days
	Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	: 10

Persistence and degradability**Components:****White mineral oil (petroleum):**

Biodegradability	: Result: Not readily biodegradable.
	Biodegradation: 31 %
	Exposure time: 28 d

Bioaccumulative potential**Components:****fenbendazole:**

Partition coefficient: n-octanol/water	: log Pow: 3,32
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Mobility in soil**Components:****fenbendazole:**

Distribution among environmental compartments	: log Koc: 3,8 - 4,7
	Method: FDA 3.08

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	: Do not dispose of waste into sewer.
	Dispose of in accordance with local regulations.
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.

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

UN number	: UN 3077
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Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(fenbendazole)
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(fenbendazole)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(fenbendazole)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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

Not applicable for product as supplied.

Domestic regulation**ANTT**

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(fenbendazole)
Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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

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National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025
Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material 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.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

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 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; 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, Bioaccumu-

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lative 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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