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MERCK

Merck Animal Health
One Merck Dr
Whitehouse Station, NJ 08889

MATERIAL SAFETY DATA SHEET

Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

MSDS NAME: **Zeranol Bulk Product Formulation**

SYNONYM(S):
Bagopell Cattle Unlabelled
Ralgro Beef Strip
Ralgro Cattle
Ralgro Cattle Red
Ralgro Cattle Unlabelled
Ralgro Lamb
Ralgro Magnum
Ralgro Sheep Red
Ralgro Single Wheel
Ralgro UNL 24DS
Ralgro with Metal Marker

MSDS NUMBER: SP000742

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

Transportation Emergencies - CHEMTREC
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

Rocky Mountain Poison Center (For Human Exposure)
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Powder
Yellow
Odorless
Toxic if swallowed.
Irritating to eyes, skin, or respiratory system.
May be irritating to digestive tract.
May be harmful with prolonged or repeated exposure.
May cause impaired fertility.
May cause effects to:
endocrine system
nervous system
reproductive system
fetus
liver

POTENTIAL HEALTH EFFECTS:

Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) are presented.

Zeranol is a nonsteroidal, estrogen (female hormone) with anabolic activity (promoting metabolic reactions to build up complex chemical compounds such as proteins in the body). It is the active ingredient in several animal health products and is administered to domestic livestock in order to produce an increase in weight gain. Zeranol is an animal health product and has not been tested, approved, or marketed for human use.

The effect of occupational exposure to zeranol at a manufacturing plant that formulates, pelletizes and packages zeranol pellets was investigated by NIOSH health scientists. The original study was based on a report of breast symptoms among plant workers and reports of gynecomastia in two young male children of workers at the facility (two separate households). Zeranol dust carried home on workclothes was suspected in causing the children's symptoms. A follow-up study was conducted after plant expansion and improved industrial hygiene practices were in place. In the follow-up study a questionnaire showed a non-statistically significant increase in breast symptoms in workers compared with control subjects. No cases of gynecomastia (male breast tissue enlargement) in male workers were identified and blood samples failed to show measurable quantities of zeranol, zearalenone or main metabolites. NIOSH scientists conducting this follow-up study concluded that it was generally negative or equivocal in documenting estrogenic effects in exposed workers.

In animals, zeranol produces adverse effects directly related to its estrogenic pharmacology. In laboratory animals, repeated exposure to zeranol produces weight gain depression, increased liver weights, and changes in reproductive organ weights and function. As predicted by its endocrine mechanism of action, changes in estrogen-sensitive tissues are the most consistent adverse effect following repeated oral exposure to zeranol across species.

Reproductive studies in animals provide evidence that zeranol administration can reduce the fertility of male and female laboratory animals. In addition, zeranol exposure during pregnancy can lead to reduced fetal viability. No evidence of zeranol-induced birth defects has been found.

In long-term feeding studies in several animal species, zeranol caused treatment-related increases in mortality and signs of endocrine activity. No treatment-related changes in tumor incidence were found in rats or dogs, but male mice had a statistically significant increase in pituitary tumors.

Lactose is not expected to produce significant toxicity with workplace exposure. Lactose may cause irritation to the eyes, skin, and mucous membranes from mechanical action. Lactose may cause abdominal pain, bloating and diarrhea if ingested in large amounts or in lactose-intolerant individuals. Lactose may cause allergic reactions in sensitive individuals.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

PRODUCT USE: Veterinary product

CHEMICAL FORMULA: Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed.

CHEMICAL COMPOSITION

INGREDIENT	CAS NUMBER	PERCENT
Zeranol	26538-44-3	71
Boric Acid	10043-35-3	< 10
Magnesium Stearate	557-04-0	< 10
Lactose Monohydrate	64044-51-5	20-30

ADDITIONAL INFORMATION: This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

SECTION 4. FIRST AID MEASURES

INHALATION: Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

SKIN CONTACT: In case of skin contact, while wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

EYE CONTACT: In case of eye contact, immediately rinse eyes thoroughly with plenty of water. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

INGESTION: Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. IMMEDIATELY consult a physician. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth and drink a glass of water.

SECTION 5. FIRE FIGHTING MEASURES

FLAMMABILITY DATA:

Flash Point: Not determined (liquids) or not applicable (solids).

DUST EXPLOSIVITY DATA:

The information presented below is for the active ingredient in this product.

Deflagration Index (Kst):	180 bar m/s
Maximum Explosion Pressure (PMAX):	7.6 bar
Minimum Ignition Energy (MIE):	5-10 mJ
Hazard Classification:	Based on dust explosivity testing, this material is considered a weak/moderate explosion hazard.

EXPLOSION HAZARDS:
Under normal conditions of use, this material does not present a significant fire or explosion hazard. However, like most organic compounds, this material may present a dust deflagration hazard if sufficient quantities are suspended in air. This material has been shown by standard laboratory testing to present a weak dust deflagration hazard.

This material has been shown to be sensitive to ignition by electrostatic discharges. All conductive plant items and operations personnel handling this material should be suitably grounded. Consideration should also be given to the possibility of ignition due to electrostatic discharges from accumulating powder.

SPECIAL FIRE FIGHTING PROCEDURES:
Wear full protective clothing and self-contained breathing apparatus (SCBA).

SUITABLE EXTINGUISHING MEDIA:
Carbon dioxide (CO_2), extinguishing powder or water spray.

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:
Avoid generation of dust during clean-up. Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

SPILL RESPONSE / CLEANUP:
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

SECTION 7. HANDLING AND STORAGE

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

STORAGE:
Store in a cool, dry, well ventilated area.

See Section 8 for exposure controls and additional safe handling information.

SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

OCCUPATIONAL EXPOSURE BAND (OEB):
OEB 4: 1-10 mcg/m^3. Materials in an OEB 4 category are considered high health hazards. The OEB is range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

OCCUPATIONAL EXPOSURE GUIDELINE (OEG):
An Occupational Exposure Guideline of 1 mcg/m^3 (8-hr TWA) has been established for zeranol. Consult your site safety and industrial hygiene professional(s) for additional guidance.

EXPOSURE CONTROLS
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

Respiratory Protection:	Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.
Skin Protection:	Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.
Eye Protection:	Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection:

In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

EXPOSURE LIMIT VALUES

INGREDIENT	CAS NUMBER	ACGIH TLV (TWA)	OSHA PEL (TWA)
Boric Acid	10043-35-3	2 mg/m^3	
Magnesium Stearate	557-04-0	10 mg/m^3	

INGREDIENT	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Boric Acid	10043-35-3	6 mg/m^3			

No exposure limits are available for the active ingredient(s) or any other hazardous ingredient in this formulation.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

FORM: Powder
COLOR: Yellow
ODOR: Odorless
SPECIFIC GRAVITY: 1.3
SOLUBILITY:
Water: Insoluble

See Section 5 for flammability/explosivity information.

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under normal conditions.

INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition is expected if used according to manufacturer's specifications.

SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the following individual ingredients, and not to the mixture(s).

ACUTE TOXICITY DATA

ORAL:
Zeranol has been shown to be practically non-toxic in single dose studies in a variety of animal species. Rodent oral LD50s are greater than 40 g/kg.

Lactose: Oral LD50: > 10g/kg (rat)

REPEAT DOSE TOXICITY DATA

SUBCHRONIC / CHRONIC TOXICITY:
In repeated dose studies zeranol produces adverse effects directly related to its estrogenic pharmacology. The majority of available data is by the oral route of exposure and studies from 4 days to 10 years have been conducted in mice, rats, dogs and monkeys. In laboratory animals repeated exposure to zeranol produces weight gain depression, increased liver weights, and changes in reproductive organ weights and function. Changes in estrogen-sensitive tissues are the most consistent adverse effect found following repeated oral exposure to zeranol across species. NOEL values from repeated-dose studies using rats and dogs ranged from 0.025 to 0.25 mg/kg/day. In other studies using dogs and monkeys, a NOEL could not be established. In these studies, LOEL values ranged from 1.25 to 15 mg/kg/day.

Male and female rats administered zeranol by the oral route at a dose of 200 mg/kg for 4 days showed a decrease in male reproductive organ weights and an increase in female uterine and adrenal weights. Clinical chemistry showed a decrease in total cholesterol and blood glucose levels.

Dietary administration of zeranol to rats at dosages as high as 8.6 mg/kg/day for 13-weeks produced slight growth suppression, a slight increase in relative liver and kidney weights, and histopathological changes in the liver. In a 14-week oral capsule study in dogs at dosages as high as 6.25 mg/kg/day, treated males showed a non-statistical trend toward decrease in testes and prostate weights and treated females showed a trend toward increased uterine weight. High dose dogs had arrested spermatogenesis and one animal showed prostatic epithelial atrophy.

In longer studies, rats were exposed for twenty-six weeks to dietary zeranol as high as 6.4 mg/kg/day. A slight reduction in food consumption and body weight gain and mild liver histopathology in both sexes were reported. In another experiment where dogs received 29 weeks of dietary exposure to zeranol at dosages as high as 25 mg/kg/day, hematological changes, testicular atrophy, squamous metaplasia in the prostate, endometrial hyperplasia, ovarian atrophy, squamous metaplasia in the bladder, hypercellularity of the bone marrow and hair loss was observed in the high dose group. Males across the exposure groups showed a trend toward body weight loss. Females in the mid and high dose groups showed estrogenic effects including edematous vulvas and cornification of the vaginal epithelium.

In other studies, dogs and monkeys were exposed to zeranol for seven and ten years at dosages as high as 37.5 and 75 mg/kg/day, respectively. In both dogs and monkeys, body weights of treated animals were consistently lower than controls and showed a treatment-related pattern. In dogs, high dose animals had slight, but consistent reductions in hemoglobin, hematocrit, erythrocyte count, cholesterol, and triglyceride values. Histopathological evaluation showed a strong uterotropic effect at both high and low dose levels. Findings included cystic endometrial hyperplasia, endometriosis interna and pyometritis (killed 2 high dose dogs and 4 low dose dogs). In monkeys, organ weights revealed a consistent elevation in liver weights in treated animals. Relative uterus weights were also elevated in the low and high-dose groups. Pathological changes in treated monkeys were confined to tissues normally responsive to estrogenic chemicals. The uterine changes included, cystic endometrial hyperplasia, myometrial hypertrophy and endometriosis externa. Other reported findings in female reproductive tissues included, absence of corpora luteal development, ovarian atrophy, marked ductal and acinar hyperplasia of the mammary glands (high-dose group), and proliferative changes of the cervical glands. No NOEL could be established in either of these studies.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
Reproductive and developmental toxicity endpoints have been extensively evaluated for zeranol in a wide range of study designs. Standard Reproduction studies have been conducted with young adult rats and mice. Two and three generation studies have also been conducted with rats. Teratology testing with zeranol has also been performed using mouse, rat and rabbit animal models. These tests provide evidence that zeranol administration can reduce the fertility of male and female laboratory animals. Zeranol exposure during pregnancy can lead to reduced fetal viability. No evidence of teratological effects have been reported. Zearanol's potential to exert adverse effects on reproductive and developmental outcomes is directly related to its weak estrogenic activity. Reproductive studies in male and female rats treated orally with zeranol at doses of 0.3125, 1.25 and 5.0 mg/kg/day for 60 days prior to mating with untreated opposite sex animals. Males and females given zeranol at 1.25 and 5 mg/kg/day experienced reduced fertility [NOEL 0.3125 mg/kg/day]. Pups born to females mated with zeranol-treated males appeared normal. Mid and high doses of zeranol produced decreased fertility, decreased liter size at birth, an increased number of stillborn animals, and reduced neonatal survival. No malformations were observed.

Rat teratogenicity studies with zeranol were conducted at 2 and 6 mg/kg/day. A dose of 6 mg/kg/day produced a high incidence of resorptions with few living fetuses [NOEL 2 mg/kg/day]. In another study pregnant rats were administered zeranol at doses of 0, 2, and 6 mg/kg/day from days 6 through 15 of gestation. Both treated groups had reduced numbers of live fetuses and increased numbers of resorptions when examined on day 20 of gestation [LOEL for fetotoxicity 2 mg/kg/day]. No evidence of malformations were found.

Rabbit teratogenicity studies were conducted with zeranol at doses of 0, 1, and 5 mg/kg/day from day 6 through day 18 of gestation. No significant developmental or teratological effects were found [Developmental NOEL was greater than or equal to 5 mg/kg/day].

Reproductive effects of oral zeranol were also assessed in a three-generation rat study. Dietary exposure up to 200 ppb zeranol over three generations had no observable effect on fertility, gestational survival of fetuses or 21 day survival of pups. No teratological effects were observed. Zeranol has also been studied in a two-generation, two litter reproduction dietary study in rats at higher exposure levels (300, 3,000 and 30,000 ppb). Females exposed to 30,000 ppb zeranol had reduced body weight gain throughout the treatment period and delivered fewer pups. High dose F(1b) pups showed lower reproductive indices for both litter intervals. No malformations were observed in any of the pups examined. [Reproductive NOEL 3,000 ppb or approximately 0.3 mg/kg/day].

MUTAGENICITY / GENOTOXICITY:
Zeranol was negative in a bacterial mutagenicity assay (AMES) with or without metabolic activation. Zeranol was also negative in vitro in a mouse lymphoma forward mutation assay and negative in vivo in a mouse bone marrow cytogenetics assay. DNA repair and binding studies in primary rat hepatocyte cultures were also negative.

CARCINOGENICITY:
Long term feeding studies in mice, rats, and dogs have been completed to evaluate the chronic toxicity and carcinogenic potential of zeranol. In these studies zeranol was administered in feed to male and female animals for two years using standard bioassay study designs. Zeranol caused treatment related increases in mortality and clear signs of estrogenic activity. In male mice zeranol produced an increase in pituitary tumors. No treatment related changes in tumor incidence were found in rats or dogs. Male and female mice (50 per sex, per group) were fed zeranol mixed with their diet at concentrations of 0, 0.15, 1.5 or 15.0 ppm for 2 years. This high dose converts to a daily dose of approximately 1.5 mg/kg/day. Male mice in the mid- and high-dose groups showed moderate reduction in body weight gain. Overall mortality in zeranol treated males and females was higher than in controls (all dose groups). Male mice consuming the high dose of zeranol had an increase in the incidence of pituitary anterior lobe adenomas compared with control animals. The NOEL for tumor formation was 1.5 ppm or approximately 0.15 mg/kg/day. No toxicity NOEL was established in this study due to the elevated mortality across all zeranol treatment groups. The LOEL for toxicity was 0.15 ppm zeranol or approximately 0.015 mg/kg/day.

There have been two rat bioassays completed with zeranol. In the first, male and female rats (25-35 per sex, per group) were exposed by diet to 0.8, 6.4 and 20 mg zeranol/kg/day for two years. After two years, body weight gain was depressed for all groups of male rats and exposed females at 6.4 and 20 mg/kg/day. Cataracts formed in one animal at the mid-dose and four animals at the high dose. Organ weight data showed treatment related decreases in ovaries, prostate gland, seminal vesicles and testes. Treatmant-related histopathological changes were observed in liver, ovaries, uterus, prostate, seminal vesicles and testes in all groups of exposed rats. Uterine changes included endometrial squamous metaplasia with occasional instances of cytic hyperplasia and endometritis.

No treatment related changes in tumor incidence were observed following lifetime exposures to dietary zeranol. Lifetime exposures to zeranol over a lower dose range has also been conducted in rats. In this study groups of male and female rats (50 per sex, per group) were fed diets containing zeranol at dose levels of 0.0, 0.25, 2.5 and 25 ppm. This converts to approximate 2 year dose rates of 0.0, 0.0125, 0.125 and 1.25 mg/kg/day for control, low-, medium- and high-dose groups, respectively. At these dose levels of zeranol there were small changes in weight vs control, limited evidence of toxicity, and no change in mortality. Estrogenic effects of zeranol exposure were seen at the high- and mid- dose levels. The NOEL for the study was 0.25 ppm or approximately 0.0125 mg/kg/day. No evidence of neoplastic changes was found.

In another chronic study male and female dogs (4 per sex, per group) were exposed by diet to 0.025, 2.5 and 25 mg zeranol/kg/day for two years. Animals in the low- and mid-dose groups experienced slightly greater body weight gain and enlarged vulvas. At 25 mg/kg/day, testes and ovaries were atrophied and vaginal epithelial cornification was observed. Squamous metaplasia and inflammatory changes in the uterus and prostrate were also noted. One male dog developed a cystadenoma. No other tumors were identified.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

There are no ecototoxicity data available for this product or its components.

ENVIRONMENTAL DATA

There are no environmental data available for this product or its components.

SECTION 13. DISPOSAL CONSIDERATIONS

MATERIAL WASTE:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

PACKAGING AND CONTAINERS:
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15. REGULATORY INFORMATION

TSCA LISTING

INGREDIENT	TSCA
Zeranol	X
Boric Acid	X
Magnesium Stearate	X
Lactose Monohydrate	X

U.S. STATE REGULATIONS

INGREDIENT	PARTK	MNRTK	MIRTK	RIRTK
Magnesium Stearate		X		

Check state requirements for ingredient listing.

SECTION 16. OTHER INFORMATION

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

DEPARTMENT ISSUING MSDS:

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