

MATERIAL SAFETY DATA SHEET

005778

SECTION 1 - IDENTIFICATION OF PRODUCT AND COMPANY

Phibro Animal Health 65 Challenger Road Ridgefield Park, NJ 07660 Emergency telephone: Hours of operation 1-800-345-4735 24 Hours

Product Information: Hours of operation 1-888-475-7355

M-F 9 a.m. - 5 p.m. Bastern Time

Trade names

MECADOX®

Product Name

Carbadox Medicated Premix-10

Therapeutic use

Antibacterial/Growth promoter

Description

Uniform yellow meal with a cereal odor

SECTION 2 - COMPOSITION

Ingredient

Carbadox Inert Material CAS Number

6804-07-5

Amount <5%

Proprietary

SECTION 3 - HAZARDS IDENTIFICATION

Signal word

CAUTION

Statements of hezard

MAY CAUSE LIVER EFFECTS (BASED ON ANIMAL STUDIES).

Eye effects

None known

Skin effects

None known

Inhalation effects

None known

Ingestion effects

See Known clinical effects and 'Other potential health effects', below.

Known clinical effects

Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal initiation, vomiting,

transient diamhea, nausea, and abdominal pain.

Other potential health

effects

Individuals sensitive to this material or other materials in its chemical

class may develop allergic reactions.

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Skin Wash skin with soap and water. Remove contaminated clothing and shoes.

Wash clothing and thoroughly clean shoes before reuse. If irritation occurs

or persists, get medical attention.

Eyes Immediately flush eyes with water for at least 15 minutes. If irritation

occurs or persists, get medical attention

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get

medical attention immediately.

Ingestion If swallowed, get medical attention. Do not induce vomiting unless

directed by medical personnel. Never give anything by mouth to an

unconscious person.

SECTION 5 - FIRE FIGHTING MEASURES

Fire fighting instructions Wear approved positive pressure, self-contained breathing apparatus and

full protective turn out gear. Evacuate area and fight fire from a safe

distance.

Extinguishing media Use carbon dioxide, dry chemical, or water spray.

Flash point Not applicable

Hazardous combustion Emits toxic fumes of carbon monoxide, carbon dioxide and oxides of

nitrogen

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General Review Sections 3, 8 and 12 before proceeding with clean up.

Small spill Sweep material into appropriate recovery container. Clean spill area

thoroughly. Avoid creating airborne dust.

Large spill Sweep material into appropriate recovery container. Close container and

move it to a secure holding area. Avoid creating airborne dust.

SECTION 7 - HANDLING AND STORAGE

General handling Minimize dust generation and accumulation. Use with adequate

ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing

dust,

Storage conditions Store out of direct sunlight in a well ventilated area at room temperature.

Keep container tightly closed when not in use.

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SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits

Compound

Issuer ACGIH Type

OEL

Light mineral oil

TWA-8 HR

STEL (15 min) 10 mg/m³ (mist) 5 mg/m³ (mist)

ACGIH OSHA

TWA-8 HR

5 mg/m³ (mist)

Enterance has the component (s) listed above. OEL Data for

Ventilation

General room ventilation is adequate unless the process generates dust or

fumes.

Respiratory protection

In dusty conditions use an approved dust mask or more protection as needed. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control

exposures to below the OEL.

Eye protection

Wear safety glasses with sideshields if airborne dust is present.

Skin protection

If dust is created wear long sleeves and pants to proteot akin.

Hand protection

Rubber gloves

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form

Uniform meal

Color

Yellow

Odor

Cereal odor

Molecular weight

Mixture

Molecular formula

Mixture

 \mathbf{H} q

Not applicable

Boiling point

Not applicable

Melting point

No data available

Density

No data available

Vapor pressure

Not applicable

Water solubility

No data available

Solvent solubility

No data available

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SECTION 10 - STABILITY AND REACTIVITY

Reactivity

Stable

Conditions to avoid

Heat, sparks, flame, and electrostatic discharge

Oral

Incompatibilities

Oxidizers

Hazardous decomposition

See Section 5 - under Hazardous combustion products.

products

Hazardous

polymerization

Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Toxicology summary

The information included in this section describes the potential hazards of the active ingredient.

Acute toxicity

Compound Carbadox

Type Ronte Oral LD_{50}

Species Mouse Rat

Dosage 2810 mg/kg 850 mg/kg

Eye

No data available

LDso

Skin

No data available

Inhalation

No date available

Ingestion

See table above

Mutagenicity

Evidence of carbadox mutagenicity was observed in the following in vitro assays with or without metabolic activation; the Ames test in S. typhimurium TA98 and TA100, the DNA repair test in B. subtilis (rec assay) and S. typhimurium (uvr assay) and in the sister chromatid exchange assay in Chinese hamster V79 cells. It was also positive in the following in vivo assays: the micronucleus test in rats, the mouse chromosomal aberration test, and in the mouse transplacental

micronucleus test.

Subchronic effects

Short-term toxicity studies of carbadox were performed in rats and dogs. Oral doses of carbadox at 25 and 50 mg/kg/day for three weeks, produced vomiting in dogs. Clinical chemistry changes indicative of liver toxicity were seen at the 50 mg/kg/day dose level. There were no gross or histopathologic changes attributed to carbadox. In rats, oral doses of carbadox at 50 or 100 mg/kg/day for one month produced pronounced inhibition of body weight gain and food consumption; no gross or

histopathologic changes were seen.

Chronic toxicity

See Chronic effects/Carchogenicity below.

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SECTION 11 - TOXICOLOGY INFORMATION ... continued

Chronic effects/ carcinogenicity

Long-term oral toxicity studies of carbadox were conducted in rats and monkeys. In rats, carbadox was given in the diet at dose levels of 5, 10, 25, 50 or 100 mg/kg/day for 2 years. At the 50 and 100 mg/kg/day carbadox, all animals died within the first three months of the study. The pathologic alterations found in these animals were similar at both dose levels and indicated damage to the lung (pulmonary edema and hemorrhage), adrenal gland (adrenocortical degeneration or hemorrhage), spleen (deposition of splenic hemosiderin), failure of accessory sex organs secretory function (males) and severe suppression of body and organ weights (seminal vesicle, prostate gland and testicular fat body). Drugrelated liver toxicity was seen in 92% of the animals at dose level of 25 mg/kg/day (hepatic parenchymatous degeneration, necrosis and nodular hyperplasia with areas of anaplasia; additionally, 21% exhibited hepatic carcinoma with metastatic invasion of the pulmonary parenchyma, kidney or abdominal lymphoid tissue). At the 10 mg/kg/day, drug-related liver toxicity (hepatic nodular hyperplasia) was observed. No drug-related changes occurred at the 5 mg/kg/day dose level. In a two-year toxicity study in monkeys, carbadox was given orally at dose levels of 5, 10, or 20 mg/kg/day. Monkeys showed no clinical evidence of liver toxicity at doses up to 20 mg/kg/day after 18 months.

Carcinogen status

None of the components of this formulation is listed as a carcinogen by IARC. NTP or OSHA.

Reproductive effects

Rats from the second long-term toxicity study were used in a threegeneration study to investigate the effects of carbadox on fertility and reproduction. No adverse effects were seen in the mature litters of the second generation.

Teratogenicity

No data available

Target organs

Liver

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview

The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

SECTION 13 - DISPOSAL INFORMATION

Disposal procedure

Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this mixture.

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SECTION 14 - TRANSPORTATION INFORMATION

General shipping instructions

Not regulated for transport under USDOT, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

TSCA status

Not listed

SARA section 302

No

SARA section 313

Νo

California Proposition 65

Not listed

SECTION 16 - OTHER

Disclaimer

Phibro Animal Health believes that the information contained in this Material Safety Data Sheet is accurate. While Phibro provides this information in good faith, it does not expressly or impliedly warrant its accuracy.

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