SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006



SKYCIS 100 PREMIX

Version 1.4

Revision Date 07.06.2012

Print Date 30.04.2013

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

Trade name

SKYCIS 100 PREMIX

Substance Number

: 000004269870

Common Name

: Monteban Premix

Item Code

: AF0615, AH0615, AF0611, AF0506, AF0507, MS8260, AF0515, AF0511, AF0512,

AF1510, AF0510, MS8261, AF0505, AF1542

Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture

: Veterinary Pharmaceutical

Details of the supplier of the safety data sheet

Elanco Animal Health Division of Eli Lilly and Company 2500 Innovation Way Greenfield, IN 46140 1-800-428-4441 lilly msds@lilly.com

Emergency telephone number

CHEMTREC: 1-800-424-9300

(Outside U.S. 1-703-527-3887)

SECTION 2. HAZARDS IDENTIFICATION

Classification of the substance or mixture Classification (REGULATION (EC) No 1272/2008)

Classification according to EC Directives

Harmful if swallowed. (Xn, R22) Risk of serious damage to eyes. (Xi, R41) Irritating to respiratory system and skin. (Xi, R37/38)

Label elements

Labelling according to EC Directives 1999/45/EC



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R-phrase(s)

Harmful if swallowed.

Risk of serious damage to eyes.

Irritating to respiratory system and skin.

S-phrase(s)

Do not breathe dust.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

After contact with skin, wash immediately with plenty of water. This material and its container must be disposed of in a safe way. Wear suitable protective clothing, gloves and eye/face protection.

In case of accident or if you feel unwell, seek medical advice immediately (show the label

where possible).

Hazardous components which must be listed on the label:

• 55134-13-9

Narasin

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	EC and/or Registration number	Classification REGULATION (EC) No 1272/2008	Classification 67/548/EEC	Concentration [%]
Narasin	55134-13-9	NA	Acute Tox. 2; H300, H330 Eye Dam. 1; H318 STOT RE 1; H372 Aquatic Chronic 2; H411	T+; R26 T; R25 Xi; R41 N; R51/53	5 ± 11
Excipients	NA	NA		1	88
Anti-dusting Oil	NA	NA		Xi; R36/37/38	2
Microtracer FS	NA	NA			0 - 0,5

Excipients may include: rice hulls. corn cob grits. soy bean mill run.

For the full text of the R-phrases mentioned in this Section, see Section 16. For the full text of the H-phrases mentioned in this Section, see Section 16.



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NA = Not applicable, Not assigned, or Not available.

SECTION 4. FIRST AID MEASURES

Description of first aid measures

Inhalation

This formulation is not considered to be an inhalation hazard due to its coarse granular nature and its low potential for aerosolization. If inhaled, remove to fresh air. If breathing is irregular or stopped, administer artificial respiration. Call a physician

immediately.

Skin contact

Wash off immediately with soap and plenty of water. Take off all contaminated clothing immediately. Get medical attention if irritation develops and persists. Wash contaminated clothing before re-use.

Eye contact

: In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

Ingestion

: Call a physician or poison control center. Drink promptly a large quantity of milk, egg white, gelatin solution, or if these are not available, large quantities of water. Avoid alcohol. Induce vomiting by giving syrup of ipecac. Do not induce vomiting or give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Symptoms

Irritating to skin. Irritating to respiratory system.

Hazards

Causes eye burns.

Indication of any immediate medical attention and special treatment needed

Treatment

: Immediate rinsing may prevent permanent damage.

SECTION 5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable extinguishing media

: Water Carbon dioxide (CO2) Dry chemical

Special hazards arising from the substance or mixture

Dust may form explosive mixture in air. Hazardous decomposition products formed under fire conditions.

Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Environmental precautions



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Try to prevent the material from entering drains or water courses. Refer to Sections 11 and 12 for health and environmental hazard information.

Methods and materials for containment and cleaning up

Vacuum material with appropriate dust collection filter in place. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Be aware of potential for dust explosion when using electrical equipment. Use absorbent/adsorbent material to solidify liquids. Large spills due to traffic accidents, etc., should be reported immediately to CHEMTREC and Elanco Animal Health for assistance.

Reference to other sections

Refer to Sections 8, 11, 12 and 13 for more information.

SECTION 7. HANDLING AND STORAGE

Precautions for safe handling

Caution! Do not allow adult turkeys, horses or other equines access to formulations containing Narasin. Ingestion of narasin by equines and adult turkeys has been fatal. Do not feed to laying chickens. Avoid contact with skin, eyes and clothing. Wash hands thoroughly after handling. For personal protection see section 8.

Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep container tightly closed in a dry and well-ventilated place.

Specific end uses

Not applicable.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Components	Exposure Limit Values	
Narasin	LEG: 12 hour TWA 11 μg/m3	
Excipients	Spain: VLA-ED 4 mg/m3 dust (grain dust) United Kingdom: TWA 10 mg/m3 inhalable fraction (grain dust) United Kingdom: STEL 30 mg/m3 inhalable fraction (grain dust) Ireland: TWA 10 mg/m3 (grain dust) ACGIH: TWA 4 mg/m3 (grain dust)	

In a manufacturing setting, wear chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Exposure controls

Engineering measures

Laboratory fume hood or local exhaust ventilation.



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Personal protective equipment

Respiratory protection Respirator selection must be based on known or anticipated exposure levels, the

hazards of the product and the safe working limits of the respirator. Use respirators and components tested and approved under appropriate government standards such

as NIOSH (US) or CEN (EU).

Eye protection Safety glasses with side-shields conforming to EN166

Skin and body protection When mixing and handling, use protective clothing, impervious gloves, and dust

respirator. Operators should wash thoroughly with soap and water after handling.

If accidental eye contact occurs, immediately rinse with plenty of water.

Skin and body protection Chemical-resistant gloves and impermeable body covering to minimize skin

contact. Protective gloves complying with EN 374.

Hygiene measures The anti-dusting oil reduces potential exposure under normal conditions of use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form : granules
Physical state : solid

Colour : tan to brown

Odour : No information available.

pH

no data available

Melting point

no data available

Boiling point

no data available

Flash point

no data available

Flammability (solid, gas)

No test data available.

Autoignition temperature

no data available

Oxidizing properties

The substance or mixture is not classified as oxidizing.

Lower explosion limit Upper explosion limit no data available no data available

Vapour pressure

no data available

Specific Gravity : no data available
Water solubility : no data available
Viscosity, dynamic : no data available
Explosive properties : Not explosive

Relative vapour density : no data available
Evaporation rate : no data available
Odor Threshold : no data available

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Other information

No information available.

SECTION 10. STABILITY AND REACTIVITY

Reactivity

Reaction with water

Not water reactive.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

Hazardous polymerisation does not occur.

Conditions to avoid

None known.

Incompatible materials

Strong oxidizing agents

Hazardous decomposition products

Hazardous decomposition products formed under fire conditions.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute oral toxicity:

LD50 (rat) 331 mg/kg

Acute inhalation toxicity:

This formulation is not considered to be an inhalation hazard due to its coarse granular

nature and its low potential for aerosolization.

Acute dermal toxicity:

LD50 (rabbit) 5 000 mg/kg

No mortality. No toxicity.

Skin corrosion/irritation:

rabbit, Severe skin irritation

Serious eye damage/eye

rabbit, Corrosive

irritation:

Immediate rinsing may prevent permanent damage.

Respiratory or skin sensitization

Narasin:

Did not cause sensitization on laboratory animals.

STOT - single exposure

No effects identified in animal studies. (Active ingredient)

STOT - repeated exposure

Narasin:

Animal studies have reported the following effects: Central nervous system effects. Tremors. Convulsions. Heart effects. Change in heart rate or rhythm. Skeletal muscle

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effects.

Animal testing did not show any carcinogenic effects.

Carcinogenicity

Reproductive toxicity

Narasin:

No effects identified in animal studies.

Germ cell mutagenicity

Narasin:

Result in genetic toxicity assays (in vitro and in vivo): Negative.

Aspiration hazard:

No aspiration toxicity classification

SECTION 12. ECOLOGICAL INFORMATION

Toxicity

Narasin LC50 / 96 h / Oncorhynchus mykiss (rainbow trout): > 1,4 - < 2,0 mg/l

LC50 / 96 h / Lepomis macrochirus (Bluegill sunfish): 3,27 mg/l

EC50 / 72 h / Selenastrum capricornutum: 0,77 mg/l

(biomass)

EC50 / 72 h / Selenastrum capricornutum: 2,92 mg/l

(average specific growth rate)

EC50 / 48 h / Daphnia magna (Water flea): 7,72 mg/l

LC50 / 14 d / Colinus virginianus (Bobwhite quail): 73,96 mg/kg

male

LC50 / 14 d / Colinus virginianus (Bobwhite quail): > 70 - < 100 mg/kg

female

LC50 / 5 d / Colinus virginianus (Bobwhite quail): 630 ppm(m)

Dietary (mycelial)

LC50 / 5 d / Anas platyrhynchos (Mallard duck): 3 800 ppm(m)

Dietary (mycelial)

LC50 / 14 d / Eisenia fetida (earthworms): 46,4 mg/kg

Excipients

no data available

Lilly Aquatic Exposure Guideline

Narasin Drinking Water: 30 µg/l

Chronic Exposure of Aquatic Organisms: 15,5 µg/l Acute Exposure of Aquatic Organisms: 139 µg/l



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Persistence and degradability

Biodegradability

Narasin

Soil Microflora

Carbon transformation: no significant effects at 17.43 mg/kg Nitrogen transformation: no significant effects at 17.43 mg/kg

Photolysis half-life (days): 1.5 (pH 7)

Hydrolysis half-life (days): 3.5, none, none, (pH 5, 7, 9)

Soil degradation half-life (days): 8.8

Soil adsorption coefficient (log koc): > 5.63 at pH 4.5 and 6

Soil biodegradation half-life (days): 21, 49, 29 (sandy loam, loam, clay loam) no data

available

Bioaccumulative potential

Narasin

Kow < 4

Mobility in soil

Soil adsorption coefficient (log koc): > 5.63 at pH 4.5 and 6

Results of PBT and vPvB assessment

A Chemical Safety Assessment is not required for this substance.

Other adverse effects

German Water Hazard Classification: WGK 3 (severe hazard to waters)

SECTION 13. DISPOSAL CONSIDERATIONS

Waste treatment methods

In accordance with local and national regulations.

SECTION 14. TRANSPORT INFORMATION

Special precautions for user

Not dangerous goods in the meaning of ADR, IMO/IMDG, ICAO/IATA

SECTION 15. REGULATORY INFORMATION

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

EINECS

n (Negative listing)

TSCA

n (Negative listing)

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AICS : n (Negative listing)
DSL : n (Negative listing)
ENCS (JP) : n (Negative listing)
KECI (KR) : n (Negative listing)
PICCS (PH) : n (Negative listing)
INV (CN) : n (Negative listing)

Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance.

SECTION 16. OTHER INFORMATION

Lilly Lab Labeling Code

Health: 3
Fire:1
Reactivity:0

Full text of R-phrases referred to under sections 2 and 3

R22 Harmful if swallowed.
R25 Toxic if swallowed.
R26 Very toxic by inhalation.

R36/37/38 Irritating to eyes, respiratory system and skin.
R37/38 Irritating to respiratory system and skin.

R41 Risk of serious damage to eyes.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic

environment.

Full text of H-Statements referred to under sections 2 and 3.

H300 Fatal if swallowed.
H318 Causes serious eye damage.
H330 Fatal if inhaled.

H372 Causes damage to organs through prolonged or repeated exposure.

H411 Toxic to aquatic life with long lasting effects.

Further information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health

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