*1. Identification of the substance/preparation and the company

Advantix-Spot on
Imidacloprid 10%/Permethrin 50% SO

Application:
veterinary medicine

Bayer HealthCare AG; PH-OP QA Global HSE
42096 Wuppertal, Germany, Telephone: +49 202 367738
In case of emergency: +49 214 30 99300 (Sicherheitszentrale Bayer)

*2. Composition/information on ingredients

Hazardous contents:
preparation contains

imidacloprid
weight %: < 25
CAS No.: 138261-41-3 Index No.: --
hazard symbol: Xn ELINCS No.: 428-040-8
R-phrases: 22-52

permethrin
weight % > 25
CAS No.: 52645-53-1 Index No.: 613-058-00-2
hazard symbol: Xn, N EINECS No.: 258-067-9
R-phrases: 21/22-50/53

N-methyl-2-pyrrolidone
weight % > 20
CAS No.: 872-50-4 Index No.: 606-021-00-7
hazard symbol: Xi EEC No.: 212-828-1
R-phrases: 36/38

citric acid anhydrous
weight %: < 20 hazard symbol: Xi R-phrases: 36/38
CAS-Nr. 77-92-9 EINECS No.: 201-069-1

butylated hydroxytoluene
weight %: <1 CAS No.: 128-37-0 hazard symbol: ------
EINECS No.: 204-881-4 R-phrases: ------
Index No.: ------

3. Hazards identification

Irritating to eyes.
Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

4. First-aid measures

GENERAL INFORMATION:
Take off immediately all contaminated clothing.
In case of accident or if you feel unwell, seek medical advice immediately (show safety data sheet where possible).

FOLLOWING SKIN CONTACT:
After contact with skin, wash immediately with plenty of water and soap.

FOLLOWING EYE CONTACT:
Contamination of the eyes must be treated by thorough irrigation with water, with the eyelids held open. A doctor (or eye specialist) should be consulted immediately.

UPON SWALLOWING:
If swallowed, seek medical advice immediately and show safety data sheet.

UPON INHALATION:
Supply fresh air.

INFORMATION FOR THE PHYSICIAN:
The active ingredients listed in Chapter 2 belong to the following chemical group: chloronicotinyl, syn. neonicotinoid. (imidacloprid), pyrethroid (permethrin).

5. Fire-fighting measures

Extinguishing media:
All extinguishing materials are suitable.

Combustion gases:
In case of fire hydrogen chloride, hydrogen cyanide, carbon monoxide and nitrogen oxides may develop.
Firemen have to wear self-contained breathing apparatus.

Further information:
In case of fire care must be taken to collect the quenching water.

6. Accidental release measures

If product is released it must not be allowed to enter into sewage systems, biological sewage treatment plants, surface waters and/or groundwater.

Take up with absorbent material and fill into a closable container.
Do not breathe vapour/spray.
Use the necessary personal protective equipment when handling.

To clean the floor and all objects contaminated by this material, use water and detergents.

***7. Handling and storage**

INFORMATION ON SAFE HANDLING:
During handling local official regulations must be observed in order to avert impairment of water by the product.
Only handle product with local exhaust ventilation.

INFORMATION ON FIRE AND EXPLOSION PREVENTION:
Take precautionary measures against static discharges.
Vapours can form explosive mixtures with air.

INFORMATION ON STORAGE:
For storage suitable stores with adequate product-reception volume must be used.
Store cool and dry in tightly closed original containers.
Keep away from food, drink and animal feeding stuffs.
The storage and transport temperatures (see section 14) may be restricted for specific countries for quality reasons.

VCI storage class: 3B

***8. Exposure controls/Personal protection**

When handling the product ensure adequate ventilation and provide air extraction.

Information on N-methyl-2-pyrrolidone :
MAK value: 19 ppm (80 mg/m³) (TRGS 900 (German Technical Regulations on Dangerous Substances))
Risk of cutaneous absorption.
Peak concentration limit according to Category: 4
Pregnancy group: C

Information on butylated hydroxytoluene :
MAK-value butylated hydroxytoluene: 10 mg/m³ inhalable fraction (sum of vapours and aerosols)

Personal protective clothing and equipment:
Wear garments usually required within the Pharmaceutical Industry.
Unless the product is entirely enclosed, do not handle it until you have studied the respiratory precautions issued by the appropriate authority or accident prevention association.
Recommended respiratory protection: Full mask with ABEK filter
Eye protection: goggle.
Hand protection: protective gloves for chemicals made of Baypren or PVC wear.
Information on N-methyl-2-pyrrolidone :
(Breakthrough time: > 30 min., DIN EN 374-3) (Baypren)
Recommendation: After contamination with product change the gloves immediately and remove them according to relevant national and local regulations

Occupational health:
Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!

9. Physical and chemical properties tested in accordance with

Form:	liquid	
Colour:	yellow to brown, clear	
Odour:	slightly	
Change in physical state:		
Boiling point:	199 °C	DIN 53171
Melting point:	No statements available.	
Density:	1,123 to 1,136 g/ml at 20 °C	
Vapour pressure:	No statements available.	
Miscibility with water:	Product is not miscible.	
pH value:	3,0-5,0	
Flash point:	87 °C	EN 22719
Ignition temperature:	No statements available.	

***10. Stability and reactivity**

Thermal decomposition:	No statements available.
Hazardous decomposition products:	Formation of hydrogen chloride, hydrogen cyanide, carbon monoxide and nitrogen oxides possible during thermal decomposition.
Hazardous reactions:	No statements available.
Further information:	
Spontaneous ignition according to Grewer:	No statements available.
Solid products combustibility:	not applicable
Risk of dust explosion:	not applicable
minimum ignition energy:	No statements available.

***11. Toxicological information**

Acute toxicity:
LD_{50} oral, rat: > 2000 mg/kg (Bayer)
LD_{50} dermal, rat: > 2000 mg/kg (Bayer)
LC_{50} inhalation, rat: > 3,5 mg/l, aerosol, 4 h of exposure (Bayer)
(highest technical producable concentration)., no mortality

Skin and mucous membrane compatibility:
Irritanteffects on the eyes: Irritating to eyes. (Bayer Healthcare AG)
Irritation of the skin/rabbit: non-irritant (72h) (Bayer Healthcare AG)
Irritant to the mucous membranes/rabbit: moderately irritant (Bayer)
* does not necessitate labelling

Skin sensitisation: In the guinea-pig tests the product has no skin sensitising effect. (Buehler Patch test) (Bayer)

12. Ecological information

Do not allow to enter surface waters or groundwater.

Fish toxicity:
imidacloprid:
LC_{50}: 237 mg/l (96 h); Golden orfe (Leuciscus idus melanotus) (Bayer)
LC_{50}: 211 mg/l (96 h); Rainbow trout (oncorhynchus mykiss) (Bayer)

permethrin:
LC_{50}: 0,009 mg/l (95 h); Rainbow trout (Bayer)

Toxicity for Daphnia:
imidacloprid:
EC_{50}: 0,055 mg/l (96 h); Hyalella azteca (Bayer)
EC_{50}: 85 mg/l (48 h); Water flea (Daphnia magna) (Bayer)

permethrin:
0,024 mg/l (24 h); Water flea (Daphnia magna) (Shell)

Toxicity for algae:
imidacloprid:
Growth rate:
IC_{50}: > 10 mg/l (72 h); Green algae (Desmodesmus subspicatus) (Bayer)
IC_{50}: > 100 mg/l (72 h); Green algae (Pseudokirchneriella subcapitata) (Bayer)

Toxicity to bacteria:
imidacloprid
EC_{50}: > 10000 mg/l; activated sludge (OECD 209) (Bayer)

***13. Disposal considerations**

Transport to suitable incinerator with reduced non-air emission.
Contaminated, empty containers are to be treated in the same way as the contents.

For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.

14. Transport information

GGVSE: 9 UN: 3082 PG: III
RID/ADR: 9 UN: 3082 PG: III
Warning sign: Hazard no. 90 UN No.: 3082
ADNR: 9 UN: 3082 PG: III
GGVSee/IMDG Code: 9 UN: 3082 PG: III MPO: P
ICAO-TI/IATA-DGR: 9 UN: 3082 PG: III

(to be continued)

14. Transport information (Continuation)

Declaration for land shipment: UMWELTGEFAEHRDENDER STOFF, FLUESSIG, N.A.G. (PERMETHRIN, IMIDACLOPRID, N-METHYLPYRROLIDON)

Declaration for sea shipment: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PERMETHRIN, IMIDACLOPRID, N-METHYLPYRROLIDONE)

Declaration for shipment by air: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (PERMETHRIN, IMIDACLOPRID, N-METHYLPYRROLIDONE)

Limited quantity regulations applicable in accordance with chapter 3.4 RID/ADR in compliance with threshold value

Other information:
Environmentally hazardous substance (GGVSE, RID/ADR). Irritating to the eyes. Marine pollutants. Transport temperature between +0 °C and +40 °C. Keep separated from foodstuffs.

***15. Regulatory information**

Labelling in accordance with directive 1999/45/EC (preparations) and its amendments and adaptations:

Symbols: Xi hazard descriptions: irritant
N dangerous for the environment

Contains: imidacloprid
permethrin

R 36: Irritating to eyes.
R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S 29: Do not empty into drains.
S 61: Avoid release to the environment. Refer to special instructions/Safety data sheets.

This labelling is not required for products in packages intended for end users.

Information on N-methyl-2-pyrrolidone :
There is no risk of risk of impaired fertility provided the OEL is observed.
Risk of cutaneous absorption.

Major accidents regulations: appendix I no. 9a - dangerous for the environment (R50 or R50/53)

Observe the following guidelines and information sheets issued by the Chemical Industry Employers' Insurance Association: BGV No. B1 (VBG91 "Handling hazardous substances") and BGI 660 ("Protective measures when handling hazardous substances at work").
BGI 754 ("Safe handling of hazardous materials in the pharmaceutical industry")

***15. Regulatory information** (Continuation)
Water pollution class (WGK): 3 - high impairment of water quality
WGK = Classification in accordance with the German Water Resources Act
VwVwS 27.07.2005

16. Other information
Text of all R phrases referred to in sections 2 and 3:
R 22: Harmful if swallowed.
R 21: Harmful in contact with skin.
R 36: Irritating to eyes.
R 38: Irritating to skin.
R 50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R 52: Harmful to aquatic organisms.

This safety data sheet applies to the handling of the industrial product (bulk product) in manufacturing, processing and storage establishments. The instructions given here are valid only for the product as supplied, not for derivatives resulting from its use.

The data given here is based on current knowledge and experience. The purpose of this Safety Data Sheet is to describe the products in terms of their safety requirements. The above details do not imply any guarantee concerning composition, properties or performance.

Replaces version dated: April 30, 2004