



## SAFETY DATA SHEET

Product code: JANFLUB5%

Revision date: 01/30/2004

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

**Supplier:**

Janssen Animal Health BVBA  
Turnhoutseweg 30  
2340 Beerse  
Belgium

**Emergency telephone number:** +32 14 602444  
**Product name:** FLUBENOL 5% powder  
**Product code:** JANFLUB5%  
**Synonyms:** None.  
**Flexeril** Flubenol 5% powder.

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

| Components   | CAS Number | Weight % | EINECS-No. | Classification |
|--------------|------------|----------|------------|----------------|
| Flubendazole | 31430-15-6 | 5        | 2506244    | -              |

### 3. HAZARDS IDENTIFICATION

**General hazard information:** No specific danger known.

**Indication of danger:**  
Not dangerous goods

**Most important hazards**  
No specific dangers known.

**Carcinogenicity rating:**  
J & J:

EC:

Active ingredient flubendazole: Did not show carcinogenic effects in animal experiments.  
Active ingredient flubendazole: Did not show carcinogenic effects in animal experiments

### 4. FIRST AID MEASURES

**Company:** Johnson & Johnson  
**Product name:** FLUBENOL 5% powder

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**Eye contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

**Ingestion:** Rinse mouth. Consult a physician if necessary.

**Inhalation:** Remove from exposure to fresh air. Contact a physician.

**Skin contact:** After contact with skin, wash immediately with plenty of water. Immediately remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Seek medical attention if symptoms appear.

**Protection of first-aiders:** No information available.

**Notes to physician:** Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

**Suitable extinguishing media:** Water fog or mist.  
Carbon dioxide (CO<sub>2</sub>).  
Dry powder.  
Foam.  
Dry sand.

**Extinguishing media which must not be used for safety reasons:** None.

**Specific hazards:** None known.

**Special protective equipment for firefighters:** Wear a self-contained breathing apparatus and full protective gear.

**Combustion products or resulting gases:** Nitrogen oxides  
Carbon monoxide  
Carbon dioxide (CO<sub>2</sub>)  
Sulphur oxides  
Fluorine  
Hydrogen fluoride

## 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions:** Wear appropriate eye, skin, respiratory protection, disposable dust impervious suit and shoe covers.  
Avoid dust formation.

**Environmental precautions:** Do not wash down sewers or waterways.  
Do not allow material to contaminate ground water system.

**Methods for cleaning up:**

**Powder Spills:**

Evacuate area.

Next, use disposable towels moistened with an appropriate cleaning agent (i.e. solvent, detergent and water, etc.) to complete cleaning process. A designated HEPA vacuum can be used as an alternative cleaning method for large spills. All waste must be placed in a sealable, properly labeled waste disposal bag. Over bag into a sealable, properly labeled waste disposal bag. Material must be disposed of as hazardous drug waste.

**Liquid Spills:**

Evacuate area.

Next, use disposable towels moistened with an appropriate cleaning agent (i.e. solvent, detergent and water, etc.) to complete cleaning process. All waste must be placed in a sealable, properly labeled waste disposal bag. Over bag into a sealable, properly labeled waste disposal bag. Material must be disposed of as hazardous drug waste.

**7. HANDLING AND STORAGE**

**Handling:**

**Technical measures/precautions:**

Use only in area provided with appropriate exhaust ventilation. Handle and store per labeled instructions

**Safe handling advice:**

Wear safety glasses with side-shields and nitrile gloves when handling powders or chemically resistant gloves when handling solutions (be sure to wear appropriate chemically resistant glove depending on type of solvents used). Clean work surfaces at the end of each day.

**Storage:**

**Technical measures/storage conditions:**

Store and transport in sealed bags contained within rigid drums or appropriate closed containers in a manner that minimizes the potential for spillage or container damage.

**Incompatible products:**

No special restrictions on storage with other products.

**Specific use(s):**

None under normal use

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**Exposure limits:**

| Components   | CAS Number | Weight % | J&J - OEL Data (TWA - 8 hr) | J&J - OEL Data (STEL): | J&J - OEL Data (Ceiling Limit Value): | J&J - PBOEL |
|--------------|------------|----------|-----------------------------|------------------------|---------------------------------------|-------------|
| Flubendazole | 31430-15-6 | 5        | 0.5 mg/m <sup>3</sup>       |                        |                                       | Category 1  |

**Exposure controls / personal protection**

**Engineering controls:**

Ensure adequate ventilation.

Use vented enclosures or fume hoods when weighing, handling, or transferring small quantities (<500mg) of powders. For large scale activities (greater than 500 mg), use glove boxes or contained processes supplemented with local exhaust at contaminant release points.

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**Product name:** FLUBENOL 5% powder

|                                 |   |
|---------------------------------|---|
| <b>Respiratory protection:</b>  | Respiratory protection dependent on airborne exposures.<br>When handling small quantities (between 200mg and 500mg), use a respirator equipped with filters approved for dusts, mists, fumes and radionuclides (HEPA/N100 or in EU: ABEK-P3).<br>When handling large quantities, use powered air-purifying respirators equipped with HEPA filters or air-supplied hood, helmet or hardcap.<br>Supplied air respirators with HEPA filters may be required in the absence of effective local exhaust ventilation for control of airborne dusts. |
| <b>Hand protection:</b>         | Wear nitrile gloves when handling as a solid or liquid formulation. When handling solutions, wear chemical-resistant gloves appropriate for the solvent(s) making up the solution.  |
| <b>Eye protection:</b>          | Wear eye and face protection.<br>Safety glasses with side-shields recommended.<br>Goggles recommended if potential exists for direct exposure to dust or splashes.  |
| <b>Skin and body protection</b> | Wear disposable dust impervious protective suit and shoe covers.  |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### General Information

**Physical state:** Fine powder.

### Important Health Safety and Environmental Information

**Appearance:** White to off-white  
**Bulk density:** 1.53  
**Dust cloud ignition temperature:** 360 °C  
**Risk of dust explosion:** Dust explosion class 1

### Other information

**Color:** White to off-white.

## 10. STABILITY AND REACTIVITY

|  |  |
|--|--|
| <b>Chemical stability:</b>               | Stable under recommended storage conditions.   |
| <b>Hazardous polymerization:</b>         | Hazardous polymerization does not occur.   |
| <b>Hazardous decomposition products:</b> | Unknown on investigational drug substance.   |
| <b>Materials to avoid:</b>               | Oxidizing agents.<br>Strong acids and strong bases.                                  |
| <b>Conditions to avoid:</b>              | Heat, flames and sparks<br>Stable for 5 years at a temperature between 15 and 30 °C. |

## 11. TOXICOLOGICAL INFORMATION

### Acute toxicity

**LD50/oral/rat (mg/kg) =** 5000 (flubendazole)

### Local effects

**Oral:** Non-toxic  
**Eye irritation** 0.1 ml of a 50% suspension of 5% flubendazole premix caused no irritation in rabbits.

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**Skin irritation:** Unknown on product.  
**Inhalation:** No mortality at a concentration of 1.2 g/m<sup>3</sup> (maximum attainable concentration).

**Chronic toxicity**

**Oral:** Unknown on product.  
**Inhalation:** Unknown on product.  
**Dermal:** Unknown on product.

**Subchronic toxicity**

**Oral:** Unknown on product.  
**Dermal:** Unknown on product.

**Specific effects**

**Corrosive effects:** Unknown on product.  
**Sensitization:** Unknown on product.  
**Target organ effects:** Flubendazole has no significant organ toxicity.  
**Mutagenic effects:** Flubendazole is not mutagenic in several mutagenic tests.

**Reproductive effects:** Flubendazole is not a reproductive effector in animals.  
**Developmental effects:** Unknown on product.

**Carcinogenic effects:** Flubendazole did not show carcinogenic effects in animal experiments.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity:**

**Ecotoxicity effects:** No data available  
**Aquatic toxicity effects:** No data available.

**Mobility:** No data available  
**Persistence / degradability:** No data available.  
**Bioaccumulation:** No data available  
**Degradation:** No data available.

**13. DISPOSAL CONSIDERATIONS**

**Waste from residues / unused products:** In accordance with local and national regulations.  
Do not dispose of waste into sewer.

**Contaminated packaging:** Empty packing materials should be handled according to local current procedures or according to local bye-laws or national laws.

**Methods for cleaning up:**

**Powder Spills:**

Evacuate area.

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**Liquid Spills:**

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**14. TRANSPORT INFORMATION**

**IMO/IMDG:**

|                       |                |
|-----------------------|----------------|
| Proper shipping name: | Not regulated  |
| UN/Id No.:            | Not regulated  |
| Hazard class:         | Not regulated  |
| IMDG-labels:          | Not regulated  |
| Packing group:        | Not regulated  |
| Marine pollutant:     | Not regulated. |

**ADR/RID:**

|                             |                |
|-----------------------------|----------------|
| TREM-card:                  | Not regulated. |
| Hazard class/packing group: | Not regulated. |
| ADR/RID-labels:             | Not regulated. |
| UN/Id No.:                  | Not regulated. |
| Proper shipping name:       | Not regulated. |

**IATA/ICAO:**

|                       |                |
|-----------------------|----------------|
| Hazard class:         | Not regulated  |
| Packing group:        | Not regulated. |
| Proper shipping name: | Not regulated  |
| ID/UN No.:            | Not regulated  |
| IATA - label:         | Not regulated. |

**15. REGULATORY INFORMATION**

**Indication of danger:** Not dangerous goods

**Contains:**

**Company:** Johnson & Johnson  
**Product name:** FLUBENOL 5% powder

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**R -phrase(s)**

No specific dangers known.

**S -phrase(s)**

**16. OTHER INFORMATION**

**This data sheet contains changes from the previous version in section(s):**

None

**Additional advice**

Consult your supplier if the material is to be used for special applications such as in the food industry or for hygiene, medical or surgical end-use

**Text of R phrases mentioned in Section 2**

**Literary Reference:**

1. Safety Test Lab reports
2. Toxicology department reports
3. Medical Department advice
4. EC guidelines for labeling
5. IMDG (regulations of dangerous goods transported by boat)
6. IATA (regulations dangerous goods transported by air)
7. ADR 2003-2005

**MSDS Format:**

European Format

This Material Safety Data Sheet was prepared in accordance with 93/112/EEC.

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**End of Safety Data Sheet**