



# MATERIAL SAFETY DATA SHEET

Revision date: 26-Dec-2005

Version: 1.0

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

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ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Paracetamol, Codeine Phosphate and Buclizine Hydrochloride Tablets**

**Trade Name:** Migralve Pink  
**Synonyms:** None  
**Chemical Family:** Mixture  
**Intended Use:** Consumer healthcare product for the treatment of migraine headache

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Codeine phosphate	52-28-8	200-137-8	8 mg ***
Stearic acid	57-11-4	200-313-4	*
Buclizine Hydrochloride	129-74-8	204-962-4	6.25 mg ***
Aluminum Oxide	1344-28-1	215-691-6	*
Magnesium stearate	557-04-0	209-150-3	*
Acetaminophen (paracetamol)	103-90-2	203-157-5	500 mg ***
Titanium dioxide	13463-67-7	236-675-5	*
Colloidal silicon dioxide	7631-86-9	231-545-4	*

Ingredient	CAS Number	EU EINECS List	%
Starch, pregelatinized	9005-25-8	232-679-6	*
Macrogol 400	Not assigned	Not listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not listed	*
Erythrosine (CI 45430)	16423-68-0	240-474-8	*

### Additional Information:

\* Proprietary  
\*\*\* per tablet/capsule/lozenge/suppository  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Pink tablets  
**Signal Word:** WARNING

**Statement of Hazard:** May cause liver and kidney effects  
May be harmful if swallowed.  
May cause gastrointestinal and central nervous systems effects

**Additional Hazard Information:**

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<b>Short Term:</b>	No data available however, direct contact may cause eye irritation. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
<b>Long Term:</b>	Acute overdosage of acetaminophen can cause liver damage. Chronic abuse may result in kidney effects. Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus.
<b>Known Clinical Effects:</b>	Adverse effects associated with the therapeutic use of acetaminophen include skin rash and gastrointestinal disturbances. The most frequently observed adverse reactions to codeine include lightheadedness, dizziness, drowsiness, nausea, vomiting, constipation, and depression of respiration. Clinical use of this drug has caused liver effects, kidney effects, addiction, symptoms of dependence/withdrawal.
<b>EU Indication of danger:</b>	Not classified
<b>Note:</b>	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 4. FIRST AID MEASURES

<b>Eye Contact:</b>	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin Contact:</b>	Wash skin with soap and water. If irritation occurs or persists, get medical attention.
<b>Ingestion:</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
<b>Inhalation:</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### 5. FIRE FIGHTING MEASURES

<b>Extinguishing Media:</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous Combustion Products:</b>	Formation of toxic gases is possible during heating or fire.
<b>Fire Fighting Procedures:</b>	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	Spills should be handled by vacuuming or wet mopping. Avoid generating airborne dust. Transfer all waste to a labeled container and move it to a secure holding area.

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### 7. HANDLING AND STORAGE

**General Handling:** If tablets or capsules are crushed and/or broken, avoid breathing dust. Avoid contact with eyes, skin and clothing. Avoid generating airborne dust. Use adequate ventilation.

**Storage Conditions:** Store as directed by product packaging.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Codeine phosphate

Pfizer OEL TWA-8 Hr: 0.07 mg/m<sup>3</sup>

#### Starch, pregelatinized

OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup> total dust  
5 mg/m<sup>3</sup> respirable fraction

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup> TWA

#### Aluminum Oxide

OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup> total dust  
5 mg/m<sup>3</sup> respirable fraction

ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup> TWA

#### Acetaminophen (paracetamol)

Pfizer OEL TWA-8 Hr: 3 mg/m<sup>3</sup>

#### Titanium dioxide

OSHA - Final PELs - TWAs: 15 mg/m<sup>3</sup> total dust  
ACGIH Threshold Limit Value (TWA) 10 mg/m<sup>3</sup> TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

**Analytical Method:** Acetaminophen (paracetamol): SAM# 189.0 (HPLC); SAM# 186.0 (CE); STP P 58.14 Codeine phosphate: SAM #094.0 (Contact Pfizer for additional details)

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

#### Personal Protective Equipment:

**Hands:** Not required for the normal use of this product. Wear protective gloves when working with large quantities.

**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

**Respiratory protection:** Not required for the normal use of this product. 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Tablet	<b>Color:</b>	Pink
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

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### 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** None known  
**Incompatible Materials:** None known  
**Polymerization:** Will not occur

### 11. TOXICOLOGICAL INFORMATION

**General Information:** There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Codeine phosphate**

Rat Oral LD50 266 mg/kg  
Rat Subcutaneous LD50 229mg/kg  
Rat Intravenous LD50 75mg/kg  
Mouse Oral LD50 250mg/kg

##### **Stearic acid**

Rat Oral LD50 > 4640 mg/kg  
Rabbit Dermal LD50 > 5000mg/kg

##### **Magnesium stearate**

Rat Oral LD50 > 2000 mg/kg  
Rat Inhalation LC50 > 2000 mg/m<sup>3</sup>

##### **Titanium dioxide**

Rat Oral LD50 > 7500 mg/kg

##### **Hydroxypropyl methylcellulose**

Rat Oral LD50 > 10,000 mg/kg

##### **Acetaminophen (paracetamol)**

Rat Oral LD50 2404 mg/kg  
Mouse Oral LD50 338mg/kg

##### **Buclizine Hydrochloride**

Mouse Oral LD50 2100 mg/kg  
Mouse Intraperitoneal LD50 430mg/kg

##### **Erythrosine (CI 45430)**

Rat Oral LD50 1840 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Stearic acid**

Skin Irritation Rabbit Mild

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

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### Codeine phosphate

14 Day(s) Rat Oral 125 mg/kg NOEL Thymus, Male reproductive system  
13 Week(s) Rat Oral 100 mg/kg NOEL None identified  
13 Week(s) Mouse Oral 260 mg/kg NOEL None identified

### Acetaminophen (paracetamol)

60 Day(s) Rat Oral 600 mg/kg/day LOEL Kidney  
13 Week(s) Mouse Oral 3200 ppm NOEL Liver  
13 Week(s) Rat Oral 6200 ppm NOEL Liver, Kidney, Reproductive system, Lymphoid tissue, Thymus  
200 Day(s) Rat Oral 200 mg/kg/day NOEL None identified

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Codeine phosphate

Embryo / Fetal Development Mouse Subcutaneous 110-120 mg/kg/day LOEL Embryotoxicity  
Embryo / Fetal Development Rabbit Oral 30 mg/kg/day NOEL No effects at maximum dose  
Embryo / Fetal Development Rat Oral 30 mg/kg/day NOEL Maternal Toxicity, Embryotoxicity  
Embryo / Fetal Development Hamster Oral 20 mg/kg/day NOEL Developmental toxicity

#### Acetaminophen (paracetamol)

2 Generation Reproductive Toxicity Mouse Oral 0.25 % NOEL Neonatal toxicity  
Reproductive & Fertility Mouse Oral 0.1 % LOEL Not Teratogenic, Fertility, Neonatal mortality  
Embryo / Fetal Development Rat Oral 250 mg/kg NOEL Not Teratogenic

#### Buclizine Hydrochloride

Embryo / Fetal Development Rat Oral 360 mg/kg LOEL Teratogenic

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Codeine phosphate

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vitro* Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative  
*In Vivo* Micronucleus Mouse Bone Marrow Negative  
Sex-Linked Recessive Lethal Test *Drosophila* Negative

#### Acetaminophen (paracetamol)

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
Chromosome Aberration Chinese Hamster Ovary (CHO) cells Positive  
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Codeine phosphate

2 Year(s) Rat Oral, in feed 70 mg/kg NOEL Not carcinogenic  
2 Year(s) Mouse Oral, in feed 400 mg/kg NOEL Not carcinogenic

#### Acetaminophen (paracetamol)

104 Week(s) Rat Female Oral, in feed 600 ppm LOEL Malignant tumors, Blood  
104 Week(s) Rat Male Oral, in feed 6000 ppm NOEL Not carcinogenic  
104 Week(s) Mouse Oral, in feed 6000 ppm NOEL Not carcinogenic

#### Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.  
See below

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Colloidal silicon dioxide

IARC: Group 3

Titanium dioxide

IARC: Group 3

Acetaminophen (paracetamol)

IARC: Group 3

### 12. ECOLOGICAL INFORMATION

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

### 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

### 14. TRANSPORT INFORMATION

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

### 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

**OSHA Label:**

WARNING

May cause liver and kidney effects

May be harmful if swallowed.

May cause gastrointestinal and central nervous systems effects

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

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<b>Codeine phosphate</b>	
California Proposition 65	developmental toxicity, initial date 5/15/98
EU EINECS List	200-137-8
<b>Stearic acid</b>	
EU EINECS List	200-313-4
Inventory - United States TSCA - Sect. 8(b)	Listed
<b>Starch, pregelatinized</b>	
EU EINECS List	232-679-6
Inventory - United States TSCA - Sect. 8(b)	Listed
<b>Buclizine Hydrochloride</b>	
EU EINECS List	204-962-4
Inventory - United States TSCA - Sect. 8(b)	Listed
<b>Aluminum Oxide</b>	
CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration fibrous form only
EU EINECS List	215-691-6
Inventory - United States TSCA - Sect. 8(b)	Listed
<b>Magnesium stearate</b>	
EU EINECS List	209-150-3
Inventory - United States TSCA - Sect. 8(b)	Listed
<b>Acetaminophen (paracetamol)</b>	
EU EINECS List	203-157-5
Inventory - United States TSCA - Sect. 8(b)	Listed
<b>Titanium dioxide</b>	
EU EINECS List	236-675-5
Inventory - United States TSCA - Sect. 8(b)	Listed
<b>Colloidal silicon dioxide</b>	
EU EINECS List	231-545-4
Inventory - United States TSCA - Sect. 8(b)	Listed
<b>Hydroxypropyl methylcellulose</b>	
Inventory - United States TSCA - Sect. 8(b)	Listed
<b>Erythrosine (CI 45430)</b>	
EU EINECS List	240-474-8
Inventory - United States TSCA - Sect. 8(b)	Listed

## 16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.

End of Safety Data Sheet