# SAFETY DATA SHEET

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

**1.1. Product identifier**

| | |
|---|---|
| **Trade name or designation of the mixture** | PANADOL ACTIFAST |
| **Registration number** | - |
| **Synonyms** | PANADOL ACTIFAST TABLETS 500 MG * PANADOL RAPID (AUSTRALIA) * PANADOL ZAPP * DOLEX ULTRARAPIDO * FORMULA NUMBER FCN 0201 * PARACETAMOL, FORMULATED PRODUCT |
| **Issue date** | 23-July-2002 |
| **Version number** | 07 |
| **Revision date** | 02-September-2012 |
| **Supersedes date** | 08-December-2006 |

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Identified uses** Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Uses advised against** No other uses are advised.

**1.3. Details of the supplier of the safety data sheet**

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

**1.4. Emergency telephone number**

TRANSPORT EMERGENCIES (by country / geographic region):

| | |
|---|---|
| Africa / EU / Israel / Middle East (English / European languages): | +44 (0) 1235 239 670 |
| Asia Pacific (except China): | +65 3158 1074 |
| China: | +86 10 5100 3039 |
| Middle East / Africa (Arabic-speaking countries): | +44 (0) 1235 239 671 |
| United States: | +1 703 527 3887 |

available 24 hrs/7 days; multi-language response

## SECTION 2: Hazards identification

**2.1. Classification of the substance or mixture**

**Classification according to Directive 67/548/EEC or 1999/45/EC as amended**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Classification according to Regulation (EC) No 1272/2008 as amended**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**2.2. Label elements**

**Label according to Regulation (EC) No. 1272/2008 as amended**

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

**Supplemental label information** Not applicable.

**2.3. Other hazards**

Expected to be non-combustible.
Caution - Pharmaceutical agent.
Handling this product in its final form presents minimal risk from occupational exposure.
Health effects information is based on hazards of components.
No information is available about the potential of this product to produce adverse environmental effects. This product contains an ingredient(s) that is harmful to aquatic organisms; and may cause long-term adverse effects in the aquatic environment. Environmental information on components is listed in Section 12.

## SECTION 3: Composition/information on ingredients

**3.1. Mixtures**

**General information**

| Chemical name | % | CAS-No. / EC No. | REACH Registration No. | INDEX No. | Notes |
|---|---|---|---|---|---|
| SODIUM BICARBONATE | 40 - < 50 | 144-55-8<br>205-633-8 | - | - | |
| **Classification:** **DSD:** - | | | | | |
| **CLP:** - | | | | | |
| PARACETAMOL | 37.9 | 103-90-2<br>203-157-5 | - | - | |
| **Classification:** **DSD:** Xn;R22, N;R51/53 | | | | | |
| **CLP:** Acute Tox. 4;H302, Aquatic Chronic 3;H412 | | | | | |
| MICROCRYSTALLINE CELLULOSE | 5 - < 10 | 9004-34-6<br>232-674-9 | - | - | |
| **Classification:** **DSD:** - | | | | | |
| **CLP:** - | | | | | |
| Starch | 3 - < 5 | 9005-25-8<br>232-679-6 | - | - | |
| **Classification:** **DSD:** - | | | | | |
| **CLP:** - | | | | | |
| MAGNESIUM STEARATE | < 1 | 557-04-0<br>209-150-3 | - | - | |
| **Classification:** **DSD:** Xi;R36/37/38 | | | | | |
| **CLP:** Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335 | | | | | |

Other components below reportable levels 1 - < 3

## SECTION 4: First aid measures

**General information**

Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

**4.1. Description of first aid measures**

**Inhalation**

Physical form suggests that risk of inhalation exposure is negligible.

**Skin contact**

Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

**Eye contact**

Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

**Ingestion**

Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

**4.2. Most important symptoms and effects, both acute and delayed**

Not established.

**4.3. Indication of any immediate medical attention and special treatment needed**

No specific antidotes are recommended. Medical treatment in cases of overexposure should be treated as an overdose of acetaminophen/paracetamol. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

## SECTION 5: Firefighting measures

**General fire hazards** This product is non-combustible, although the packaging is combustible.

**5.1. Extinguishing media**

**Suitable extinguishing media** Water or foam extinguishers are recommended.

**Unsuitable extinguishing media** Carbon dioxide or dry powder extinguishers may be ineffective.

**5.2. Special hazards arising from the substance or mixture** Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

**5.3. Advice for firefighters**

**Special protective equipment for firefighters** Since toxic, corrosive or flammable vapours might be evolved from fires involving this material, self contained breathing apparatus and full protective equipment are recommended for firefighters.

**Special fire fighting procedures** For single units (packages): No special requirements needed.
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters.
If possible, contain and collect firefighting water for later disposal.

## SECTION 6: Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

**For non-emergency personnel** Wear protective clothing and equipment consistent with the degree of hazard.

**For emergency responders** Use personal protection recommended in Section 8 of the MSDS.

**6.2. Environmental precautions** For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

**6.3. Methods and material for containment and cleaning up** Collect and place it in a suitable, properly labelled container for recovery or disposal. No specific decontamination or detoxification procedures have been identified for this product.

**6.4. Reference to other sections** For personal protection, see section 8. For waste disposal, see section 13.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling** Avoid breaking or crushing tablets.

**7.2. Conditions for safe storage, including any incompatibilities** No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

**7.3. Specific end use(s)** Medicinal Product

## SECTION 8: Exposure controls/personal protection

**8.1. Control parameters**

**Occupational exposure limits**

**GSK**

| Components | Type | Value |
|---|---|---|
| MAGNESIUM STEARATE (557-04-0) | OHC | 1 |
| MICROCRYSTALLINE CELLULOSE (9004-34-6) | OHC | 1 |
| PARACETAMOL (103-90-2) | 8 HR TWA | 4000 mcg/m3 |
| | OHC | 1 |
| SODIUM BICARBONATE (144-55-8) | 8 HR TWA | 5000 mcg/m3 |
| | OHC | 1 |

**UK. EH40 Workplace Exposure Limits (WELs)**

| Components | Type | Value | Form |
|---|---|---|---|
| MICROCRYSTALLINE CELLULOSE (9004-34-6) | STEL | 20 mg/m3 | Inhalable dust. |
| | TWA | 4 mg/m3 | Respirable dust. |
| | | 10 mg/m3 | Inhalable dust. |
| PARACETAMOL (103-90-2) | TWA | 10 mg/m3 | Inhalable dust. |
| Starch (9005-25-8) | TWA | 4 mg/m3 | Respirable. |
| | | 10 mg/m3 | Inhalable |

**Biological limit values**

**EU**
No biological exposure limits noted for the ingredient(s).

**United Kingdom**
No biological exposure limits noted for the ingredient(s).

| | |
|---|---|
| **Recommended monitoring procedures** | Not available. |
| **Derived No Effect Level (DNEL)** | Not available. |
| **Predicted no effect concentrations (PNECs)** | Not available. |

**8.2. Exposure controls**

| | |
|---|---|
| **Appropriate engineering controls** | Not available. |

**Individual protection measures, such as personal protective equipment**

| | |
|---|---|
| **General information** | An eye wash station should be available. |
| **Eye/face protection** | Wear approved safety glasses with side shields if eye contact is possible. |
| **Skin protection** | |
| **- Hand protection** | None required for the normal handling of this material. |
| **- Other** | Not available. |
| **Respiratory protection** | No personal respiratory protective equipment normally required. |
| **Thermal hazards** | Not available. |
| **Hygiene measures** | None required for normal handling. Wash hands and arms thoroughly after handling. |

**Environmental exposure controls**

| | |
|---|---|
| **Hazard guidance and control recommendations** | Not available. |

## SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

**Appearance**

| | |
|---|---|
| **Physical state** | Solid. |
| **Form** | Tablet. |
| **Colour** | Not available. |
| **Odour** | Not available. |
| **Odour threshold** | Not available. |
| **pH** | Not applicable. |
| **Melting point/freezing point** | Not available. |
| **Initial boiling point and boiling range** | Not available. |
| **Flash point** | Not applicable. |
| **Evaporation rate** | Not applicable. |
| **Flammability (solid, gas)** | Not applicable. |

**Upper/lower flammability or explosive limits**

| | |
|---|---|
| **Flammability limit - lower (%)** | Not available. |
| **Flammability limit - upper (%)** | Not available. |
| **Explosive limit - lower (%)** | Not available. |
| **Explosive limit – upper (%)** | Not available. |
| **Vapour pressure** | Not applicable. |
| **Vapour density** | Not applicable. |
| **Relative density** | Not available. |
| **Solubility(ies)** | Not available. |
| **Partition coefficient (n-octanol/water)** | Not available. |
| **Decomposition temperature** | Not available. |
| **Viscosity** | Not applicable. |

**Explosive properties** Not available.

**Oxidizing properties** Not available.

**9.2. Other information** No relevant additional information available.

## SECTION 10: Stability and reactivity

**10.1. Reactivity** Not available.

**10.2. Chemical stability** This product is expected to be stable.

**10.3. Possibility of hazardous reactions** Not available.

**10.4. Conditions to avoid** None for normal handling of this product.

**10.5. Incompatible materials** Not available.

**10.6. Hazardous decomposition products** Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

## SECTION 11: Toxicological information

**General information** Not available.

**Information on likely routes of exposure**

**Ingestion** Exposure from ingestion may occur. Adverse effects might occur following ingestion.

**Inhalation** Not expected to occur during normal handling of this product.

**Skin contact** Direct contact may occur. Irritation is not expected following direct contact.

**Eye contact** Direct contact may occur. Minor irritation might occur following direct contact with eyes.

**Symptoms** Adverse effects might occur in the following organ(s) following overexposure: liver

**11.1. Information on toxicological effects**

**Acute toxicity** Adverse effects might occur following ingestion. Assessment based upon effects of individual components.

| Components | Species | Test results |
|---|---|---|
| MAGNESIUM STEARATE (557-04-0) | | |
| **Acute** | | |
| *Oral* | | |
| LD50 | Rat | > 2000 mg/kg |
| MICROCRYSTALLINE CELLULOSE (9004-34-6) | | |
| **Acute** | | |
| *Dermal* | | |
| LD50 | Rabbit | > 2000 mg/kg |
| *Oral* | | |
| LD50 | Rat | > 2000 mg/kg |
| PARACETAMOL (103-90-2) | | |
| **Acute** | | |
| *Oral* | | |
| LD50 | Rat | 1944 mg/kg |
| SODIUM BICARBONATE (144-55-8) | | |
| **Acute** | | |
| *Oral* | | |
| LD50 | Rat | 4220 mg/kg |

**Skin corrosion/irritation** Irritation is not expected following direct contact. Assessment based upon effects of individual components.

**Irritation Corrosion - Skin: P.I.I. value**

| | |
|---|---|
| MAGNESIUM STEARATE | 0 |
| PARACETAMOL | 0.3 |

**Serious eye damage/eye irritation** Minor irritation might occur following direct contact with eyes. Assessment based upon effects of individual components.

**Eye / Kay and Calandra class - Intact**

| | |
|---|---|
| PARACETAMOL | 4 |
| MAGNESIUM STEARATE | 4 |
| | Recovery Period: 2 days |

**Respiratory sensitisation** No studies have been conducted.

**Skin sensitisation** Sensitisation (allergic skin reaction) is not expected. Assessment based upon effects of individual components.

**Germ cell mutagenicity** Contains paracetamol which produced evidence of DNA damage in the following assay(s): in vitro cytogenetics assay. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect. No evidence of DNA damage occurred in the following assay(s): mouse micronucleus test; bacterial mutation assay (Ames); bacterial mutation test (SOS/umu); mammalian cell mutation assay (CHO/HGPRT forward mutation assay).

**Carcinogenicity** Positive results occurred in some studies that are not considered to be relevant to occupational exposure conditions. Paracetamol produced carcinogenic effects in a lifetime study in rats. Assessment based on equivocal lab results. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect. A lifetime study with mice demonstrated no evidence of carcinogenicity.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

PARACETAMOL (CAS 103-90-2) 3 Not classifiable as to carcinogenicity to humans.

**Reproductive toxicity** No adverse effects have been reported following extensive use or exposure in humans.

**Specific target organ toxicity - single exposure** See effects of repeat exposure.

**Specific target organ toxicity - repeated exposure** Adverse effects might occur in the following organ(s) following overexposure: liver; kidney.

**Aspiration hazard** No studies have been conducted.

**Mixture versus substance information** No studies have been conducted.

**Other information** None known for this material in humans.

## SECTION 12: Ecological information

**12.1. Toxicity** No information is available about the potential of this product to produce adverse environmental effects. This product contains an active ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of each ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

| Components | | Species | Test results |
|---|---|---|---|
| MAGNESIUM STEARATE (557-04-0) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Fish | EC50 | Orange-red killfish (Adult Oryzias latipes) | 130 mg/l, 96 hours |
| Microtox | EC50 | Microtox | 12.5 mg/l, 15 minutes |
| PARACETAMOL (103-90-2) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Algae | EC50 | Green algae (Scenedesmus subspicatus) | 134 mg/l, 72 hours |
| Crustacea | EC50 | Water flea (Daphnia magna) | 50 mg/l, 48 hours, Static test |
| Fish | EC50 | Fathead minnow (Juvenile Pimephales promelas) | 814 mg/l, 96 hours, Flow-through test |
| Microtox | EC50 | Microtox | 1000 mg/l, 30 minutes |
| SODIUM BICARBONATE (144-55-8) | | | |
| **Aquatic** | | | |
| *Acute* | | | |
| Algae | EC50 | Algae (Nitscheria linearis) | 650 mg/l, 5 days |
| Crustacea | EC50 | Water flea (Daphnia magna) | 2350 mg/l, 48 hours, Static test |
| Fish | EC50 | Bluegill sunfish (Adult Lepomis macrochirus) | 8250 - 9000 mg/l, 96 hours, Static test |
| | | Mosquito fish (Adult Gambusia affinis) | 7550 mg/l, 96 hours, Static test |

**12.2. Persistence and degradability** This material contains an active ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.

**Photolysis**

**Half-life (Photolysis-atmospheric)**

| | |
|---|---|
| MAGNESIUM STEARATE | 17 Hours Estimated |

**UV/visible spectrum wavelength**

| | |
|---|---|
| MAGNESIUM STEARATE | 210 nm |

**Biodegradability**

**Percent degradation (Aerobic biodegradation-inherent)**

| | |
|---|---|
| MAGNESIUM STEARATE | 77 %, 28 days BOD |
| PARACETAMOL | 99 %, 5 days Modified Zahn-Wellens, Activated sludge |

**Percent degradation (Aerobic biodegradation-ready)**

| | |
|---|---|
| MAGNESIUM STEARATE | 95 %, 22 days Sturm test |

**Percent degradation (Aerobic biodegradation-soil)**

| | |
|---|---|
| MAGNESIUM STEARATE | 50 %, 13 days |

**12.3. Bioaccumulative potential** Not available.

**Partition coefficient n-octanol/water (log Kow)**

| | |
|---|---|
| PARACETAMOL | 0.36 |

**Bioconcentration factor (BCF)**

| | |
|---|---|
| MAGNESIUM STEARATE | > 9999 Estimated |

**12.4. Mobility in soil**

**Adsorption**

**Soil/sediment sorption - log Koc**

| | |
|---|---|
| MAGNESIUM STEARATE | 5.86 Estimated |

**Mobility in general**

**Volatility**

**Henry's law**

| | |
|---|---|
| PARACETAMOL | 0 atm m^3/mol Estimated |

**12.5. Results of PBT and vPvB assessment** Not available.

**12.6. Other adverse effects** Not available.

## SECTION 13: Disposal considerations

**13.1. Waste treatment methods**

**Residual waste** Not available.

**Contaminated packaging** Not available.

**EU waste code** Not available.

**Disposal methods/information** Observe all local and national regulations when disposing of this product. Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

## SECTION 14: Transport information

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

**ADR**

Not regulated as dangerous goods.

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

## SECTION 15: Regulatory information

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**EU regulations**

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I**

Not listed.

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II**

Not listed.

**Regulation (EC) No. 850/2004 on persistent organic pollutants, Annex I as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**

Not listed.

**Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended**

Not listed.

**Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry**

Not listed.

**Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA**

Not listed.

**Authorisations**

**Regulation (EC) No. 143/2011 Annex XIV Substances Subject to Authorisation**

Not listed.

**Restrictions on use**

**Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**

Not listed.

**Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work**

Not listed.

**Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding**

Not listed.

**Other EU regulations**

**Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances**

Not listed.

| | |
|---|---|
| **National regulations** | Not available. |
| **15.2. Chemical safety assessment** | Not available. |

## SECTION 16: Other information

| | |
|---|---|
| **List of abbreviations** | Not available. |
| **References** | GSK Hazard Determination |
| **Information on evaluation method leading to the classification of mixture** | Not available. |
| **Full text of any statements or R-phrases and H-statements under Sections 2 to 15** | R22 Harmful if swallowed.<br>R36/37/38 Irritating to eyes, respiratory system and skin.<br>R51/53 Toxic to aquatic organisms, May cause long-term adverse effects in the aquatic environment.<br>H302 - Harmful if swallowed.<br>H315 - Causes skin irritation.<br>H319 - Causes serious eye irritation.<br>H335 - May cause respiratory irritation.<br>H412 - Harmful to aquatic life with long lasting effects. |
| **Revision information** | IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING: Synonyms<br>Composition/Information on Ingredients: Ingredients<br>Physical & Chemical Properties:<br>TRANSPORT INFORMATION: Material Transportation Information<br>REGULATORY INFORMATION: Risk Phrases - Class. |
| **Training information** | Not available. |
| **Disclaimer** | The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose. |
| **Issue date** | 23-July-2002 |
| **Revision date** | 02-September-2012 |