

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

### 1.1. Product identifier

|  |   |
|--|---|
| Trade name or designation of the mixture | WELLBUTRIN SR TABLETS   |
| Registration number                      | -   |
| Synonyms                                 | WELLBUTRIN SR (SUSTAINED RELEASE) TABLETS * WELLBUTRIN SR TABLETS 100 MG * WELLBUTRIN SR TABLETS 150 MG * WELLBUTRIN SR TABLETS 200 MG * WELLBUTRIN SR CONTROLLED RELEASE TABLETS * WELLBUTRIN SR COMPRIMIDOS * WELLBUTRIN SR COMPRIMIDOS RECUBIERTOS * WELLBUTRIN SR POTAHOVANE TABLETY * WELLBUTRIN SR TABLETAS * WELLBUTRIN SR TABLETY * WELLBUTRIN SR * NDC NO 0173-0947-55 * NDC NO 0173-0135-55 * NDC NO 0173-0722-00 * BUPROPION HYDROCHLORIDE, FORMULATED PRODUCT |
| Issue date                               | 16-October-2013   |
| Version number                           | 14  |
| Revision date                            | 16-October-2013   |

### 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](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://www.gsk.com)

### 1.4. Emergency telephone number

TRANSPORT EMERGENCIES::  
UK In-country toll call: + (44)-870-8200418  
International toll call: +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

#### 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** Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

## General information

| Chemical name                     | %  | CAS-No. / EC No.        | REACH Registration No. | INDEX No. | Notes |
|-----------------------------------|--|-------------------------|------------------------|-----------|-------|
| BUPROPION HYDROCHLORIDE           | 26 - < 36.1  | 31677-93-7<br>250-759-9 | -                      | -         |       |
| <b>Classification:</b>            | <b>DSD:</b> Xn;R22, Xi;R36, N;R50-53   |                         |                        |           |       |
|                                   | <b>CLP:</b> Acute Tox. 4;H302, Eye Irrit. 2;H319, Aquatic Acute 1;H400, Aquatic Chronic 1;H410 |                         |                        |           |       |
| MICROCRYSTALLINE CELLULOSE        | 20 - < 30  | 9004-34-6<br>232-674-9  | -                      | -         |       |
| <b>Classification:</b>            | <b>DSD:</b> -  |                         |                        |           |       |
|                                   | <b>CLP:</b> -  |                         |                        |           |       |
| HYDROXYPROPYL METHYL<br>CELLULOSE | 10 - < 20  | 9004-65-3<br>-          | -                      | -         |       |
| <b>Classification:</b>            | <b>DSD:</b> -  |                         |                        |           |       |
|                                   | <b>CLP:</b> -  |                         |                        |           |       |
| MAGNESIUM STEARATE                | < 1  | 557-04-0<br>209-150-3   | -                      | -         |       |
| <b>Classification:</b>            | <b>DSD:</b> Xi;R36/37/38   |                         |                        |           |       |
|                                   | <b>CLP:</b> Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335                              |                         |                        |           |       |

Other components below reportable levels 30 - < 40

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

**Composition comments** The full text for all R- and H-phrases is displayed in section 16.

## SECTION 4: First aid measures

**General information** Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. 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

|                     |  |
|---------------------|--|
| <b>Inhalation</b>   | In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur. |
| <b>Skin contact</b> | Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.  |
| <b>Eye contact</b>  | Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.  |
| <b>Ingestion</b>    | If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately.   |

**4.2. Most important symptoms and effects, both acute and delayed** Irritation of eyes and mucous membranes. The following adverse effects have been noted with therapeutic use of this material: insomnia; agitation; anxiety; headache; tremor; visual disturbances; dry mouth; nausea; vomiting; rash; depression; constipation; convulsions.

**4.3. Indication of any immediate medical attention and special treatment needed** No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

## SECTION 5: Firefighting measures

**General fire hazards** No unusual fire or explosion hazards noted.

### 5.1. Extinguishing media

|                                       |  |
|---------------------------------------|--|
| <b>Suitable extinguishing media</b>   | Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ). |
| <b>Unsuitable extinguishing media</b> | None known.  |

**5.2. Special hazards arising from the substance or mixture** During fire, gases hazardous to health may be formed.

**5.3. Advice for firefighters**

**Special protective equipment for firefighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

**Special fire fighting procedures** In the event of fire, cool tanks with water spray.

**SECTION 6: Accidental release measures**

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

**For non-emergency personnel** Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

**For emergency responders** Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.

**6.2. Environmental precautions** Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.

**6.3. Methods and material for containment and cleaning up** Stop the flow of material, if this is without risk. Collect spillage. Prevent product from entering drains. Following product recovery, flush area with water.

**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** Do not taste or swallow. Avoid contact with eyes. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.

**7.2. Conditions for safe storage, including any incompatibilities** Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

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

**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

**Occupational exposure limits**

| <b>GSK Components</b>                            | <b>Type</b> | <b>Value</b>        |                                     |
|--|-------------|---------------------|-------------------------------------|
| BUPROPION HYDROCHLORIDE (CAS 31677-93-7)         | 8 HR TWA    | 1000 mcg/m3         |                                     |
|  | OHC         | 2                   |                                     |
| HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)   | OHC         | 1                   |                                     |
| MAGNESIUM STEARATE (CAS 557-04-0)                | OHC         | 1                   |                                     |
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)       | OHC         | 1                   |                                     |
| <b>UK. EH40 Workplace Exposure Limits (WELs)</b> |             |                     |                                     |
| <b>Components</b>                                | <b>Type</b> | <b>Value</b>        | <b>Form</b>                         |
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)       | STEL        | 20 mg/m3            | Inhalable dust.                     |
|  | TWA         | 4 mg/m3<br>10 mg/m3 | Respirable dust.<br>Inhalable dust. |

**Recommended monitoring procedures** Follow standard monitoring procedures.

**Derived No Effect Level (DNEL)** Not available.

**Predicted no effect concentrations (PNECs)** Not available.

**8.2. Exposure controls**

**Appropriate engineering controls** An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

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

**General information** Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Eye wash fountain is recommended.

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

#### **Skin protection**

**- Hand protection** The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

**- Other** Not normally needed.

**Respiratory protection** No personal respiratory protective equipment normally required.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**Hygiene measures** An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. When using, do not eat, drink or smoke.

#### **Environmental exposure controls**

**Hazard guidance and control recommendations** Environmental manager must be informed of all major releases.

## **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 available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

#### **Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Vapour pressure** Not available.

**Vapour density** Not available.

**Relative density** Not available.

**Solubility(ies)** Not available.

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

|                               |   |
|-------------------------------|---|
| <b>Viscosity</b>              | Not available.                                |
| <b>Explosive properties</b>   | Not available.                                |
| <b>Oxidizing properties</b>   | Not available.                                |
| <b>9.2. Other information</b> | No relevant additional information available. |

## SECTION 10: Stability and reactivity

|   |   |
|---|---|
| <b>10.1. Reactivity</b>                         | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| <b>10.2. Chemical stability</b>                 | Material is stable under normal conditions.   |
| <b>10.3. Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.                                   |
| <b>10.4. Conditions to avoid</b>                | Contact with incompatible materials.  |
| <b>10.5. Incompatible materials</b>             | Strong oxidising agents. Fluorine.  |
| <b>10.6. Hazardous decomposition products</b>   | Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.       |

## SECTION 11: Toxicological information

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

### Information on likely routes of exposure

|                     |   |
|---------------------|---|
| <b>Ingestion</b>    | Health injuries are not known or expected under normal use. May be harmful if swallowed.                          |
| <b>Inhalation</b>   | Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation. |
| <b>Skin contact</b> | Health injuries are not known or expected under normal use. Dust or powder may irritate the skin.                 |
| <b>Eye contact</b>  | Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.               |

**Symptoms** The following adverse effects have been noted with therapeutic use of this material: insomnia; agitation; anxiety; headache; tremor; visual disturbances; dry mouth; nausea; vomiting; rash; depression; constipation; convulsions.

### 11.1. Information on toxicological effects

**Acute toxicity** Health injuries are not known or expected under normal use. Adverse effects might occur with repeated ingestion.

| Components                                     | Species | Test results             |
|--|---------|--------------------------|
| BUPROPION HYDROCHLORIDE (CAS 31677-93-7)       |         |                          |
| <b>Acute</b>                                   |         |                          |
| <i>Oral</i>                                    |         |                          |
| LD50   | Mouse   | 544 - 636 mg/kg          |
|  | Rat     | 482 - 607 mg/kg          |
| <b>Chronic</b>                                 |         |                          |
| <i>Oral</i>                                    |         |                          |
| LOEL   | Dog     | 40 mg/kg/day, 52 weeks   |
|  | Rat     | 100 mg/kg/day, 104 weeks |
|  |         | 25 mg/kg/day, 55 weeks   |
| NOAEL  | Dog     | 40 mg/kg/day, 52 weeks   |
|  | Rat     | 100, 104 weeks           |
|  |         | 100 mg/kg/day, 55 weeks  |
| <b>Subacute</b>                                |         |                          |
| <i>Oral</i>                                    |         |                          |
| NOAEL  | Dog     | 150 mg/kg/day, 47 Day    |
| <b>Subchronic</b>                              |         |                          |
| <i>Oral</i>                                    |         |                          |
| NOAEL  | Rat     | 450 mg/kg/day, 90 Day    |
| HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3) |         |                          |
| <b>Acute</b>                                   |         |                          |
| <i>Oral</i>                                    |         |                          |
| LD50   | Rat     | > 2000 mg/kg             |

| Components   | Species   | Test results                            |
|--|---|---|
| MAGNESIUM STEARATE (CAS 557-04-0)  |   |   |
| <b>Acute</b>   |   |   |
| <i>Oral</i>  |   |   |
| LD50   | Rat   | > 2000 mg/kg                            |
| MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)                                   |   |   |
| <b>Acute</b>   |   |   |
| <i>Dermal</i>  |   |   |
| LD50   | Rabbit  | > 2000 mg/kg                            |
| <i>Oral</i>  |   |   |
| LD50   | Rat   | > 2000 mg/kg                            |
| * Estimates for product may be based on additional component data not shown. |   |   |
| <b>Skin corrosion/irritation</b>   | Health injuries are not known or expected under normal use.   |   |
| <b>Corrosivity</b>   |   |   |
| BUPROPION HYDROCHLORIDE  | OECD 404  | Result: Non-irritant<br>Species: Rabbit |
| <b>Irritation Corrosion - Skin: P.I.I. value</b>                             |   |   |
| MAGNESIUM STEARATE   | 0   |   |
| BUPROPION HYDROCHLORIDE  | 0.5   |   |
| <b>Serious eye damage/eye irritation</b>                                     | Health injuries are not known or expected under normal use. Dust or powder may irritate eye tissue.   |   |
| <b>Eye</b>   |   |   |
| BUPROPION HYDROCHLORIDE  | Result: Irritant<br>Species: Rabbit   |   |
| <b>Respiratory sensitisation</b>   | Not available.  |   |
| <b>Skin sensitisation</b>  | Health injuries are not known or expected under normal use.   |   |
| <b>Maximisation assay (Magnusson and Kligman)</b>                            |   |   |
| HYDROXYPROPYL METHYL CELLULOSE   | Result: negative<br>Species: Guinea pig   |   |
| <b>Germ cell mutagenicity</b>  | No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.  |   |
| <b>Germ cell mutagenicity</b>  |   |   |
| <b>Mutagenicity</b>  |   |   |
| BUPROPION HYDROCHLORIDE  | Ames<br>Result: negative<br>L5178Y mouse lymphoma thymidine kinase locus assay<br>Result: negative<br>in vivo cytogenetics assay<br>Result: positive<br>Species: Rat  |   |
| <b>Carcinogenicity</b>   | Health injuries are not known or expected under normal use.   |   |
| BUPROPION HYDROCHLORIDE  | Result: negative<br>Species: Mouse<br>Result: negative<br>Species: Rat  |   |
| <b>Reproductive toxicity</b>   | This product is not expected to cause reproductive or developmental effects.  |   |
| <b>Reproductive toxicity</b>   |   |   |
| <b>Reproductivity</b>  |   |   |
| BUPROPION HYDROCHLORIDE  | Embryo-foetal development- Oral<br>Result: Maternal toxicity; adverse foetal effects<br>Species: Rabbit<br>Embryo-foetal development- Oral<br>Result: maternal toxicity<br>Species: Rat<br>Fertility<br>Result: No effect |   |
| <b>Specific target organ toxicity - single exposure</b>                      | None known.   |   |
| <b>Specific target organ toxicity - repeated exposure</b>                    | None known.   |   |
| <b>Aspiration hazard</b>   | Not available.  |   |

**Mixture versus substance information** No information available.

**Other information** Not available.

## SECTION 12: Ecological information

**12.1. Toxicity** No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment.

| Components  |                     | Species   | Test results                                       |
|---|---------------------|---|--|
| <b>BUPROPION HYDROCHLORIDE (CAS 31677-93-7)</b>       |                     |   |  |
| <b>Aquatic</b>  |                     |   |  |
| <i>Acute</i>  |                     |   |  |
| Activated Sludge Respiration                          | IC50                | Residential sludge                                    | > 100 mg/l, 3 hours, Nominal                       |
|   | NOEC                | Residential sludge                                    | 100 mg/l, 3 hours, Nominal                         |
| Algae   | EC50                | Green algae ( <i>Scenedesmus subspicatus</i> )        | 0.95 mg/l, 72 hours                                |
|   | NOEC                | Green algae ( <i>Scenedesmus subspicatus</i> )        | 0.62 mg/l, 72 hours                                |
| Crustacea   | EC50                | Water flea ( <i>Daphnia magna</i> )                   | 3.8 mg/l, 48 hours, Static test, OECD 202          |
|   | NOEC                | Water flea ( <i>Daphnia magna</i> )                   | 1 mg/l, 48 hours, Static test                      |
| Fish  | EC50                | Rainbow trout (Juvenile <i>Oncorhynchus mykiss</i> )  | 33 mg/l, 96 hours, Static renewal test, OECD 203   |
|   | NOEC                | Rainbow trout (Juvenile <i>Oncorhynchus mykiss</i> )  | 16 mg/l, 96 hours, Static renewal test             |
| Microtox  | MIC                 | <i>Aspergillus flavus</i>                             | 1000 mg/l  |
|   |                     | <i>Azotobacter chroococcum</i>                        | > 1000 mg/l  |
|   |                     | <i>Chaetomium globosum</i>                            | 1000 mg/l  |
|   |                     | <i>Nostoc</i> sp.                                     | 1000 mg/l  |
|   |                     | <i>Pseudomonas fluorescens</i>                        | > 1000 mg/l  |
| <i>Chronic</i>  |                     |   |  |
| Crustacea   | LOEC                | Water flea ( <i>Ceriodaphnia dubia</i> )              | > 0.4 mg/l, 7 days, 7 day static renewal, EPA 1002 |
|   | NOEC                | Water flea ( <i>Ceriodaphnia dubia</i> )              | 0.4 mg/l, 7 days                                   |
| Fish  | Growth test<br>NOEC | Fathead minnow (Juvenile <i>Pimephales promelas</i> ) | 0.1 mg/l, 32 days, Static renewal test             |
| <b>HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)</b> |                     |   |  |
| <b>Aquatic</b>  |                     |   |  |
| <i>Acute</i>  |                     |   |  |
| Fish  | EC50                | Fish  | > 100 mg/l, 96 hours                               |
| <b>MAGNESIUM STEARATE (CAS 557-04-0)</b>              |                     |   |  |
| <b>Aquatic</b>  |                     |   |  |
| <i>Acute</i>  |                     |   |  |
| Fish  | EC50                | Orange-red killfish (Adult <i>Oryzias latipes</i> )   | 130 mg/l, 96 hours                                 |
| Microtox  | EC50                | Microtox  | 12.5 mg/l, 15 minutes                              |

\* Estimates for product may be based on additional component data not shown.

## 12.2. Persistence and degradability

### Persistence and degradability

#### Photolysis

##### Half-life (Photolysis-aqueous)

BUPROPION HYDROCHLORIDE 54 Hours

##### Half-life (Photolysis-atmospheric)

MAGNESIUM STEARATE 17 Hours Estimated

##### UV/visible spectrum wavelength

BUPROPION HYDROCHLORIDE 251 nm

MAGNESIUM STEARATE 210 nm

## Hydrolysis

### Half-life (Hydrolysis-neutral)

BUPROPION HYDROCHLORIDE 16.7 Days

## Biodegradability

### Percent degradation (Aerobic biodegradation-inherent)

BUPROPION HYDROCHLORIDE 96 %, 14 days Modified Zahn-Wellens, Activated sludge  
MAGNESIUM STEARATE 77 %, 28 days BOD

### Percent degradation (Aerobic biodegradation-ready)

BUPROPION HYDROCHLORIDE 1.21 %, 14 days  
MAGNESIUM STEARATE 95 %, 22 days Sturm test

### Percent degradation (Aerobic biodegradation-soil)

MAGNESIUM STEARATE 50 %, 13 days

## 12.3. Bioaccumulative potential

### Partition coefficient

#### n-octanol/water (log Kow)

BUPROPION HYDROCHLORIDE 1.54  
HYDROXYPROPYL METHYL CELLULOSE -5

### Bioconcentration factor (BCF)

HYDROXYPROPYL METHYL CELLULOSE 3.2 Estimated  
MAGNESIUM STEARATE > 9999 Estimated

## 12.4. Mobility in soil

### Adsorption

#### Sludge/biomass distribution coefficient - log Kd

BUPROPION HYDROCHLORIDE 1.79 Measured, pH 7

#### Soil/sediment sorption - log Koc

BUPROPION HYDROCHLORIDE 2.93 Calculated  
MAGNESIUM STEARATE 5.86 Estimated

### Mobility in general

#### Volatility

##### Henry's law

BUPROPION HYDROCHLORIDE 0 atm m<sup>3</sup>/mol, 25 C Estimated  
HYDROXYPROPYL METHYL CELLULOSE 0 atm m<sup>3</sup>/mol Estimated

#### Distribution

##### Octanol/water distribution coefficient log DOW

BUPROPION HYDROCHLORIDE -0.6, pH 1.2  
-0.91, pH 6  
1.54, pH 7.4

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

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

#### Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

#### EU waste code

The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

#### Disposal methods/information

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Special precautions

Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

### ADR

14.1. UN number UN3077

14.2. UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (BUPROPION HYDROCHLORIDE, FORMULATED PRODUCT)

|   |   |
|---|---|
| <b>14.3. Transport hazard class(es)</b> | 9   |
| <b>Subsidiary class(es)</b>             | -   |
| <b>14.4. Packing group</b>              | III   |
| <b>14.5. Environmental hazards</b>      | Yes   |
| <b>Tunnel code</b>                      | Not available.                                  |
| <b>Labels required</b>                  | 9   |
| <b>Additional information:</b>          |   |
| <b>Special Provisions</b>               | 8, 146, 335, A112, B54, IB8, IP3, N20, T1, TP33 |

#### IATA

|   |  |
|---|--|
| <b>14.1. UN number</b>                  | UN3077   |
| <b>14.2. UN proper shipping name</b>    | Environmentally hazardous substance, solid, n.o.s. (BUPROPION HYDROCHLORIDE, FORMULATED PRODUCT) |
| <b>14.3. Transport hazard class(es)</b> | 9  |
| <b>Subsidiary class(es)</b>             | -  |
| <b>14.4. Packing group</b>              | III  |
| <b>Labels required</b>                  | Not available.   |
| <b>Additional Information:</b>          |  |
| <b>Passenger &amp; cargo</b>            | Allowed.   |
| <b>Packaging Instruction</b>            | 956  |
| <b>Pkg Inst cargo only</b>              | 956  |
| <b>Pkg Inst pasenger &amp; cargo</b>    | Y956   |
| <b>LQ</b>                               |  |
| <b>SP See 44</b>                        | A97,A158,A179  |
| <b>Max net qty pkg</b>                  | 400 kg   |
| <b>Max net qty pkg cargo only</b>       | 400 kg   |
| <b>Max net qty pkg LQ</b>               | 30 kg G  |

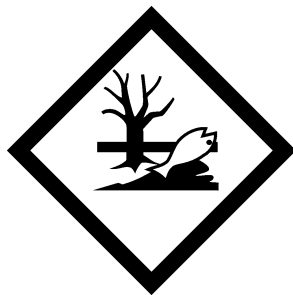
#### IMDG

|   |  |
|---|--|
| <b>14.1. UN number</b>                    | UN3077   |
| <b>14.2. UN proper shipping name</b>      | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (BUPROPION HYDROCHLORIDE, FORMULATED PRODUCT) |
| <b>14.3. Transport hazard class(es)</b>   | 9  |
| <b>Subsidiary class(es)</b>               | -  |
| <b>14.4. Packing group</b>                | III  |
| <b>14.5. Environmental hazards</b>        |  |
| <b>Marine pollutant</b>                   | Yes  |
| <b>Labels required</b>                    | Not available.   |
| <b>EmS</b>                                | F-A, S-F   |
| <b>14.6. Special precautions for user</b> | Not available.   |

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**      MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

**ADR; IATA; IMDG**





## 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. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**

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.

**Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**

Not listed.

**Directive 94/33/EC on the protection of young people at work**

Not listed.

#### Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

#### National regulations

Follow national regulation for work with chemical agents.

#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

## SECTION 16: Other information

#### List of abbreviations

Not available.

#### References

GSK Hazard Determination

**Information on evaluation method leading to the classification of mixture**

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

**Full text of any statements or R-phrases and H-statements under Sections 2 to 15**

R22 Harmful if swallowed.  
R36 Irritating to eyes.  
R36/37/38 Irritating to eyes, respiratory system and skin.  
R50 Very toxic to aquatic organisms.  
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
R53 May cause long term adverse effects in the aquatic environment.  
H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

**Revision information**

Product and Company Identification: Business Units  
Composition / Information on Ingredients: Ingredients  
Physical & Chemical Properties:  
TOXICOLOGICAL INFORMATION:  
Ecological Information: Reports  
Transport Information: Product Shipping Name/Packing Group  
GHS: Classification

**Training information**

Follow training instructions when handling this material.

**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.