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 NICOTINE PATCH
Registration number -
Synonyms PROJECT NRT PATCH * NICOTINE TRANSDERMAL SYSTEM * NICOTINE, FORMULATED PRODUCT
Issue date 15-April-2013
Version number 03
Revision date 15-April-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
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
US: +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.

SECTION 3: Composition/information on ingredients

3.2. Mixtures
SECTION 4: First aid measures

General information Not available.

4.1. Description of first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed The possible consequences of overexposure include: increased heart rate; increased blood pressure; salivation; abdominal pain; headache; depression; dizziness; respiratory depression.

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

SECTION 5: Firefighting measures

General fire hazards Expected to be non-combustible.

5.1. Extinguishing media Suitable extinguishing media Water, Foam. Dry chemical powder.

Unsuitable extinguishing media Carbon dioxide (CO2).

5.2. Special hazards arising from the substance or mixture Not available.

5.3. Advice for firefighters Special protective equipment for firefighters Wear suitable protective equipment.

Special fire fighting procedures In the event of fire, cool tanks with water spray. Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures For non-emergency personnel Keep unnecessary personnel away.

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

6.2. Environmental precautions No special environmental precautions required.

6.3. Methods and material for containment and cleaning up Stop the flow of material, if this is without risk. Dike far ahead of spill for later disposal. Following product recovery, flush area with water. Never return spills in original containers for re-use.

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 prolonged exposure. Use care in handling/storage.

7.2. Conditions for safe storage, including any incompatibilities Store in original tightly closed container. Use care in handling/storage. Store in accordance with local/regional/national/international regulation.

7.3. Specific end use(s) Medicinal Product
SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

<table>
<thead>
<tr>
<th>GSK Components</th>
<th>Type</th>
<th>Value</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICOTINE (CAS 54-11-5)</td>
<td>15 MIN STEL</td>
<td>200 mcg/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>8 HR TWA</td>
<td>70 mcg/m3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OHC</td>
<td>3</td>
<td>Reproductive hazard</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
<td>Skin</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UK. EH40 Workplace Exposure Limits (WELs) Components</th>
<th>Type</th>
<th>Value</th>
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</thead>
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<tr>
<td>NICOTINE (CAS 54-11-5)</td>
<td>STEL</td>
<td>1.5 mg/m3</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>0.5 mg/m3</td>
</tr>
</tbody>
</table>

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

No special ventilation requirements.

Individual protection measures, such as personal protective equipment

Eye/face protection

Not normally needed.

Skin protection

- Hand protection

Not normally needed.

- Other

Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Respiratory protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. No personal respiratory protective equipment normally required.

Thermal hazards

Not available.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practices.

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

Patch.

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.
### 9.2. Other information

No relevant additional information available.

### SECTION 10: Stability and reactivity

10.1. Reactivity

Not available.

10.2. Chemical stability

Material is stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid

None under normal conditions.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Nitrogen oxides (NOx).

### SECTION 11: Toxicological information

**General information**

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

**Information on likely routes of exposure**

- **Ingestion**: May be harmful if swallowed.
- **Inhalation**: Not available.
- **Skin contact**: Health injuries are not known or expected under normal use.
- **Eye contact**: Health injuries are not known or expected under normal use. May be irritating to eyes.

**Symptoms**

The possible symptoms of overexposure include: increased heart rate; increased blood pressure; salivation; abdominal pain; headache; depression; dizziness; respiratory depression.

**NICOTINE nervous system**

### 11.1. Information on toxicological effects

#### Acute toxicity

May be harmful if swallowed.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICOTINE (CAS 54-11-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dermal</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>140 mg/kg</td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
<td>188 mg/kg</td>
</tr>
</tbody>
</table>

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

**Skin corrosion/irritation**

Health injuries are not known or expected under normal use.

**Serious eye damage/eye irritation**

Health injuries are not known or expected under normal use.

**Respiratory sensitisation**

Not available.

**Skin sensitisation**

Health injuries are not known or expected under normal use.

**Germ cell mutagenicity**

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Germ cell mutagenicity**

- **Mutagenicity**
  - NICOTINE
    - Ames
    - Result: negative
Mutagenicity

NICOTINE

In vitro cytogenetics assay
Result: negative
Mouse micronucleus test
Result: negative
in vitro micronucleus assay
Result: positive
Organ: gingivum
sister chromatid exchange
Result: positive

Carcinogenicity

NICOTINE

TiO2 produced carcinogenic effects in a lifetime study in mice. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

Reproductive toxicity

Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Developmental effects

NICOTINE

Reduced bodyweight
Result: positive
Species: Rabbit
Reduced bodyweight
Result: positive
Species: Rat
Sensitive species
Result: positive
Species: Mouse
Organ: Cleft palate

Specific target organ toxicity - single exposure

NICOTINE

Nervous system.

Specific target organ toxicity - repeated exposure

NICOTINE

Circulatory system.

Aspiration hazard
Not available.

Mixture versus substance information
Not available.

Other information
None known.

SECTION 12: Ecological information

12.1. Toxicity

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICOTINE (CAS 54-11-5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aquatic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea</td>
<td>EC50</td>
<td>Water flea (Daphnia pulex)</td>
</tr>
<tr>
<td>Fish</td>
<td>EC50</td>
<td>Rainbow trout (Adult Oncorhyncus mykiss)</td>
</tr>
</tbody>
</table>

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

12.2. Persistence and degradability
No data is available on the degradability of this product.

12.3. Bioaccumulative potential
Not available.

Partition coefficient
n-octanol/water (log Kow)

| NICOTINE | 1.17 |

Material name: NICOTINE PATCH

SDS UK

5 / 7
Bioconcentration factor (BCF)  
NICOTINE 5

12.4. Mobility in soil  
Adsorption  
Soil/sediment sorption - log Koc  
NICOTINE Estimated

Mobility in general  
Volatility  
Henry's law  
NICOTINE Estimated

12.5. Results of PBT and vPvB assessment  
Not available.

12.6. Other adverse effects  
Not available.

12.7. Additional information  
None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods  
Residual waste  
Not available.

Contaminated packaging  
Empty containers should be taken to an approved waste handling site for recycling or disposal.

EU waste code  
Not available.

Disposal methods/information  
Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR  
Not regulated as dangerous goods.

IATA  
Not regulated as dangerous goods.

IMDG  
Not regulated as dangerous goods.

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.

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.

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended NICOTINE (CAS 54-11-5)  
Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended NICOTINE (CAS 54-11-5)  
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  
Not available.
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 breast feeding
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.

NICOTINE (CAS 54-11-5)

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

NICOTINE (CAS 54-11-5)

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

Not available.

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

Not available.

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

R25 Toxic if swallowed.
R27 Very toxic in contact with skin.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R63 Possible risk of harm to the unborn child.
H301 Toxic if swallowed.
H310 Fatal in contact with skin.
H361 Suspected of damaging fertility or the unborn child.
H411 Toxic to aquatic life with long lasting effects.

Revision information

Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Transport Information: Agency Name and Packaging Type/Transport Mode Selection

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.