

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

General information

| Chemical name | % | CAS-No. / EC No. | REACH Registration No. | INDEX No. | Notes |
|------------------------|-------------|--|------------------------|--------------|-------|
| NICOTINE | 10.0 - 40.0 | 54-11-5 200-193-3 | - | 614-001-00-4 | # |
| Classification: | DSD: | Repr. Cat. 3;R63, T+;R27, T;R25, N;R51/53 | | | |
| | CLP: | Acute Tox. 3;H301, Acute Tox. 1;H310, STOT SE 3;H335, Repr. 2;H361, STOT SE 1;H370, Aquatic Acute 1;H400, Aquatic Chronic 2;H411 | | | |
| 60.0 - 90.0 | | | | | |

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 (CO ₂). |

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

| GSK Components | Type | Value | Note |
|------------------------|-------------|------------|---------------------|
| NICOTINE (CAS 54-11-5) | 15 MIN STEL | 200 mcg/m3 | |
| | 8 HR TWA | 70 mcg/m3 | |
| | OHC | 3 | Reproductive hazard |
| | | 3 | Skin |

| UK. EH40 Workplace Exposure Limits (WELs) Components | Type | Value |
|--|------|-----------|
| NICOTINE (CAS 54-11-5) | STEL | 1.5 mg/m3 |
| | TWA | 0.5 mg/m3 |

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.

| | |
|---|---|
| Vapour pressure | Not applicable. |
| Vapour density | Not applicable. |
| Relative density | Not available. |
| Solubility(ies) | Not available. |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | 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 | 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.

| Components | Species | Test results |
|------------------------|---------|--------------|
| NICOTINE (CAS 54-11-5) | | |
| Acute | | |
| <i>Dermal</i> | | |
| LD50 | Rat | 140 mg/kg |
| <i>Oral</i> | | |
| LD50 | Rat | 188 mg/kg |

* 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.
Inhalation
Result: negative
Species: Rat
oral
Result: negative
Species: Rat
tumour promotor
Species: Mouse

Reproductive toxicity

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

Reproductive toxicity

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.

nervous system

Specific target organ toxicity - repeated exposure
NICOTINE

Circulatory system.

Cardiovascular system

Aspiration hazard

Not available.

Mixture versus substance information

Not available.

Other information

None known.

SECTION 12: Ecological information

12.1. Toxicity

| Components | | Species | Test results |
|------------------------|------|---|---|
| NICOTINE (CAS 54-11-5) | | | |
| Aquatic | | | |
| <i>Acute</i> | | | |
| Crustacea | EC50 | Water flea (<i>Daphnia pulex</i>) | 0.242 mg/l, 48 hours, Static renewal test |
| Fish | EC50 | Rainbow trout (Adult <i>Oncorhynchus mykiss</i>) | 4 mg/l, 96 hours |

* 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

Bioconcentration factor (BCF)

NICOTINE 5

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

NICOTINE 2 Estimated

Mobility in general**Volatility****Henry's law**NICOTINE 0 atm m³/mol Estimated**12.5. Results of PBT** Not available.**and vPvB assessment****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.

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

NICOTINE (CAS 54-11-5)

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

NICOTINE (CAS 54-11-5)

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

Material name: NICOTINE PATCH

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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.

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

Product and Company Identification: Product and Company Identification
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.