Medicines & Healthcare products Regulatory Agency

NIBSC | Confidence in biological medicines

# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

**Revision date** 21-May-2024 **Revision Number** 1.01

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

### 1.1. Product identifier

**Product Code(s)** 99/540

**Product Name** Anti-PT S2 subunit Monoclonal Antibody (9G8)

**Form** Not applicable

**Pure substance/mixture** Mixture

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

**Recommended use** Laboratory use

**Uses advised against** No information available

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

**Supplier**

MHRA
Blanche Lane
South Mimms
Potters Bar
Hertfordshire
EN6 3QG
UK

For further information, please contact

**E-mail address** Standards@nibsc.org

### 1.4. Emergency telephone number

Emergency Telephone +44 (0) 1707 641467 - Mon to Fri (9.00 – 17.00 GMT) Excluding weekends and English public holiday
+44 (0) 1707 641200 - Any other time

| **Emergency Telephone - §45 - (EC)1272/2008** | |
|---|---|
| **Europe** | **112** |
| **Austria** | No information available |

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**99/540 - Anti-PT S2 subunit Monoclonal Antibody (9G8)**

| | |
|---|---|
| **Bulgaria** | |
| **Croatia** | |
| **Cyprus** | |
| **Czech Republic** | |
| **Denmark** | |
| **France** | |
| **Hungary** | |
| **Ireland** | |
| **Italy** | |
| **Lithuania** | |
| **Luxembourg** | |
| **Netherlands** | |
| **Norway** | |
| **Portugal** | |
| **Romania** | |
| **Slovakia** | |
| **Slovenia** | |
| **Spain** | |
| **Sweden** | |
| **Switzerland** | |

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

*Classification according to*
*Regulation (EC) No. 1272/2008 [CLP]*
This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

### 2.2. Label elements

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]
**Hazard statements**
This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]
EUH210 - Safety data sheet available on request

### 2.3. Other hazards

No information available.

This mixture contains no substance considered to be persistent, bioaccumulating or toxic (PBT). This mixture contains no

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substance considered to be very persistent nor very bioaccumulating (vPvB).

This product does not contain any known or suspected endocrine disruptors.

| Chemical name | EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very High Concern (SVHC) for Authorisation | EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of Substances |
|---|---|---|
| Potassium chloride | - | - |

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

Not applicable

### 3.2 Mixtures

**Chemical nature** Biological standards.

| Chemical name | Weight-% | REACH registration number | EC No (EU Index No) | Classification according to Regulation (EC) No. 1272/2008 [CLP] | Specific concentration limit (SCL) | M-Factor | M-Factor (long-term) |
|---|---|---|---|---|---|---|---|
| Potassium chloride 7447-40-7 | <0.1 | - | 231-211-8 | - | | | |

**Full text of H- and EUH-phrases: see section 16**

*Acute Toxicity Estimate*
*No information available*

| Chemical name | Oral LD50 mg/kg | Dermal LD50 mg/kg | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4 hour - vapour - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|---|---|---|---|---|---|
| Potassium chloride 7447-40-7 | 2600 | No data available | No data available | No data available | No data available |

**Additional information**
BSL1.
This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

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## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**Inhalation** Remove to fresh air.

**Eye contact** Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a doctor.

**Skin contact** Wash skin with soap and water. In the case of skin irritation or allergic reactions see a doctor.

**Ingestion** Rinse mouth.

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

**Symptoms** No information available.

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

**Note to doctors** Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

### 5.2. Special hazards arising from the substance or mixture

**Specific hazards arising from the chemical** No information available.

### 5.3. Advice for firefighters

**Special protective equipment and** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

**precautions for fire-fighters** Use personal protection equipment.

## SECTION 6: Accidental release measures

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

**Personal precautions** Ensure adequate ventilation.

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

**6.2. Environmental precautions**

**Environmental precautions** See Section 12 for additional Ecological Information.

**6.3. Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Take up mechanically, placing in appropriate containers for disposal.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

**6.4. Reference to other sections**

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling**

**Advice on safe handling** Ensure adequate ventilation.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

**7.2. Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA.

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

**Risk Management Methods (RMM)** The information required is contained in this Safety Data Sheet.

## SECTION 8: Exposure controls/personal protection

**8.1. Control parameters**

**Exposure Limits** This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

| Chemical name | European Union | Austria | Belgium | Bulgaria | Croatia |
|---|---|---|---|---|---|
| Potassium chloride 7447-40-7 | - | - | - | TWA: 5.0 mg/m³ | - |
| Chemical name | Ireland | Italy MDLPS | Italy AIDII | Latvia | Lithuania |
| Potassium chloride 7447-40-7 | - | - | - | TWA: 5 mg/m³ | TWA: 5 mg/m³ |

**Biological occupational exposure limits**
This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

**Derived No Effect Level (DNEL)** No information available.
**Predicted No Effect Concentration (PNEC)** No information available.

**8.2. Exposure controls**

**Personal protective equipment**

**Eye/face protection** Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

**Hand protection** The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective nitrile rubber gloves.

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| | |
|---|---|
| **Skin and body protection** | Wear suitable protective clothing. |
| **Respiratory protection** | No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. |
| **General hygiene considerations** | Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. |
| **Environmental exposure controls** | Do not allow into any sewer, on the ground or into any body of water. |

## SECTION 9: Physical and chemical properties

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

| | |
|---|---|
| **Physical state** | Liquid |
| **Appearance** | Liquid |
| **Colour** | colourless |
| **Odour** | No information available. |
| **Odour threshold** | No information available |

| Property | Values | Remarks • Method |
|---|---|---|
| **Melting point / freezing point** | No data available | None known |
| **Initial boiling point and boiling range** | No data available | None known |
| **Flammability** | No data available | None known |
| **Flammability Limit in Air** | | None known |
| **Upper flammability or explosive limits** | No data available | |
| **Lower flammability or explosive limits** | No data available | |
| **Flash point** | No data available | None known |
| **Autoignition temperature** | No data available | None known |
| **Decomposition temperature** | | None known |
| **pH** | No data available | None known |
| **pH (as aqueous solution)** | No data available | No information available |
| **Kinematic viscosity** | No data available | None known |
| **Dynamic viscosity** | No data available | None known |
| **Water solubility** | No data available | None known |
| **Solubility(ies)** | No data available | None known |
| **Partition coefficient** | No data available | None known |
| **Vapour pressure** | No data available | None known |
| **Relative density** | No data available | None known |

| | | |
|---|---|---|
| **Bulk density** | No data available | |
| **Liquid Density** | No data available | |
| **Relative vapour density** | No data available | None known |
| **Particle characteristics** | | |
| **Particle Size** | No information available | |
| **Particle Size Distribution** | No information available | |

**9.2. Other information**

*9.2.1. Information with regards to physical hazard classes*
Not applicable

*9.2.2. Other safety characteristics*
No information available

## SECTION 10: Stability and reactivity

**10.1. Reactivity**

**Reactivity** No information available.

**10.2. Chemical stability**

**Stability** Stable under normal conditions.

**Explosion data**
**Sensitivity to mechanical impact** None.
**Sensitivity to static discharge** None.

**10.3. Possibility of hazardous reactions**

**Possibility of hazardous reactions** None under normal processing.

**10.4. Conditions to avoid**

**Conditions to avoid** None known based on information supplied.

**10.5. Incompatible materials**

**Incompatible materials** None known based on information supplied.

**Hazardous decomposition products** None known based on information supplied.

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**Revision date** 21-May-2024 **Revision Number** 1.01

**99/540 - Anti-PT S2 subunit Monoclonal Antibody (9G8)**

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

**Information on likely routes of exposure**

**Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.

**Eye contact** Specific test data for the substance or mixture is not available.

**Ingestion** Specific test data for the substance or mixture is not available.

**Symptoms related to the physical, chemical and toxicological characteristics**

**Symptoms** No information available.

**Numerical measures of toxicity**
No information available

**Acute toxicity**

**The following values are calculated based on chapter 3.1 of the GHS document**

| | | |
|---|---|---|
| **ATEmix (oral)** | 99,999.00 | mg/kg |
| **ATEmix (dermal)** | 99,999.00 | mg/kg |
| **ATEmix (inhalation-gas)** | 99,999.00 | ppm |
| **ATEmix (inhalation-dust/mist)** | 99,999.00 | mg/l |
| **ATEmix (inhalation-vapour)** | 99,999.00 | mg/l |

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---|---|---|---|
| Potassium chloride | = 2600 mg/kg ( Rat ) | | |

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Skin corrosion/irritation** Based on available data, the classification criteria are not met.

| | |
|---|---|
| **Serious eye damage/eye irritation** | No information available. |
| **Respiratory or skin sensitisation** | No information available. |
| **Germ cell mutagenicity** | No information available. |
| **Carcinogenicity** | No information available. |
| **Reproductive toxicity** | No information available. |
| **STOT - single exposure** | No information available. |
| **STOT - repeated exposure** | No information available. |
| **Aspiration hazard** | No information available. |

**11.2. Information on other hazards**

**11.2.1. Endocrine disrupting properties**

| | |
|---|---|
| **Endocrine disrupting properties** | No information available. |

**11.2.2. Other information**

| | |
|---|---|
| **Other adverse effects** | No information available. |

## SECTION 12: Ecological information

**12.1. Toxicity**

**Ecotoxicity**

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**Unknown aquatic toxicity** Contains 0 % of components with unknown hazards to the aquatic environment.

| Chemical name | Algae/aquatic plants | Fish | Toxicity to microorganisms | Crustacea |
|---|---|---|---|---|
| Potassium chloride | EC50: =2500mg/L (72h, Desmodesmus subspicatus) | LC50: =1060mg/L (96h, Lepomis macrochirus) LC50: 750 - 1020mg/L (96h, Pimephales promelas) | - | EC50: =825mg/L (48h, Daphnia magna) EC50: =83mg/L (48h, Daphnia magna) |

**12.2. Persistence and degradability**

**Persistence and degradability** No information available.

**12.3. Bioaccumulative potential**

**Bioaccumulation** No information available.

**12.4. Mobility in soil**

**Mobility in soil** No information available.

**12.5. Results of PBT and vPvB assessment**

**PBT and vPvB assessment** No information available.

| Chemical name | PBT and vPvB assessment |
|---|---|
| Potassium chloride | The substance is not PBT / vPvB |

**12.6. Endocrine disrupting properties**

**Endocrine disrupting properties** No information available.

**12.7. Other adverse effects**
No information available.

## SECTION 13: Disposal considerations

**13.1. Waste treatment methods**

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| | |
|---|---|
| **Waste from residues/unused products** | Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation. |
| **Contaminated packaging** | Do not reuse empty containers. |

## SECTION 14: Transport information

**IATA**

| | |
|---|---|
| **14.1 UN number or ID number** | Not regulated |
| **14.2 UN proper shipping name** | Not regulated |
| **14.3 Transport hazard class(es)** | Not regulated |
| **14.4 Packing group** | Not regulated |
| **14.5 Environmental hazards** | Not applicable |
| **14.6 Special precautions for user** | |
| **Special Provisions** | None |

**IMDG**

| | |
|---|---|
| **14.1 UN number or ID number** | Not regulated |
| **14.2 UN proper shipping name** | Not regulated |
| **14.3 Transport hazard class(es)** | Not regulated |
| **14.4 Packing group** | Not regulated |
| **14.5 Marine pollutant** | Not applicable |
| **14.6 Special precautions for user** | |
| **Special Provisions** | None No information available |
| **14.7 Maritime transport in bulk according to IMO instruments** | No information available |

**RID**

| | |
|---|---|
| **14.1 UN number or ID number** | Not regulated |
| **14.2 UN proper shipping name** | Not regulated |
| **14.3 Transport hazard class(es)** | Not regulated |
| **14.4 Packing group** | Not regulated |
| **14.5 Environmental hazards** | Not applicable |
| **14.6 Special precautions for user** | |
| **Special Provisions** | None |

**ADR**

| | |
|---|---|
| **14.1 UN number or ID number** | Not regulated |
| **14.2 UN proper shipping name** | Not regulated |
| **14.3 Transport hazard class(es)** | Not regulated |
| **14.4 Packing group** | Not regulated |

**14.5 Environmental hazards** Not applicable
**14.6 Special precautions for user**
**Special Provisions** None

## SECTION 15: Regulatory information

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

| Chemical name | French RG number | Title |
|---|---|---|
| Potassium chloride<br>7447-40-7 | RG 67 | - |

**Water hazard class (WGK)** non-hazardous to water (nwg)

Poland

**SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650) . Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the**

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**International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).**

**European Union**

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

**Authorisations and/or restrictions on use:**

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

**DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors**

Not applicable

**Persistent Organic Pollutants**

Not applicable

**Ozone-depleting substances (ODS) regulation (EC) 1005/2009**

Not applicable

**International Inventories**

| | |
|---|---|
| **TSCA** | LGC has not confirmed that the chemical substances in this product are on the TSCA Inventory, and LGC is distributing this product solely for use either in applications statutorily exempt from TSCA and regulated under other laws (e.g., FFDCA, FIFRA) or in research and development activities in accordance with the TSCA Inventory R&D exemption provided at 40 CFR 720.36. It is the end-user's responsibility to understand and follow the requirements that apply to its use of this product. |
| **DSL/NDSL** | Contact supplier for inventory compliance status |
| **EINECS/ELINCS** | Contact supplier for inventory compliance status |
| **ENCS** | Contact supplier for inventory compliance status |
| **IECSC** | Contact supplier for inventory compliance status |
| **KECL** | Contact supplier for inventory compliance status |
| **PICCS** | Contact supplier for inventory compliance status |
| **AIIC** | Contact supplier for inventory compliance status |

**Legend:**

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**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
**ENCS** - Japan Existing and New Chemical Substances
**IECSC** - China Inventory of Existing Chemical Substances
**KECL** - Korean Existing and Evaluated Chemical Substances
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances
**AICS** - Australian Inventory of Chemical Substances

**15.2. Chemical safety assessment**

**Chemical Safety Report** A Chemical Safety Assessment is not required for this substance

## SECTION 16: Other information

**Key or legend to abbreviations and acronyms used in the safety data sheet**

**Legend**
SVHC: Substances of Very High Concern for Authorisation:

**Legend Section 8: Exposure controls/personal protection**

| | | | |
|---|---|---|---|
| TWA | TWA (time-weighted average) | STEL | STEL (Short Term Exposure Limit) |
| Ceiling | Maximum limit value | Sk* | Skin designation |

| Classification procedure | |
|---|---|
| Classification according to Regulation (EC) No. 1272/2008 [CLP] | Method Used |
| Acute oral toxicity | Calculation method |
| Acute dermal toxicity | Calculation method |
| Acute inhalation toxicity - gas | Calculation method |
| Acute inhalation toxicity - Vapour | Calculation method |
| Acute inhalation toxicity - dust/mist | Calculation method |
| Skin corrosion/irritation | Calculation method |
| Serious eye damage/eye irritation | Calculation method |
| Respiratory sensitisation | Calculation method |
| Skin sensitisation | Calculation method |
| Mutagenicity | Calculation method |
| Carcinogenicity | Calculation method |
| Reproductive toxicity | Calculation method |
| STOT - single exposure | Calculation method |
| STOT - repeated exposure | Calculation method |

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## 99/540 - Anti-PT S2 subunit Monoclonal Antibody (9G8)

| | |
|---|---|
| Acute aquatic toxicity | Calculation method |
| Chronic aquatic toxicity | Calculation method |
| Aspiration hazard | Calculation method |
| Ozone | Calculation method |

**Key literature references and sources for data used to compile the SDS**
Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine’s PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
World Health Organization

**Revision date** 21-May-2024

**This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**
**Disclaimer**
**The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. NIBSC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.**

**End of Safety Data Sheet**