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# Medicines & Healthcare products Regulatory Agency

British Pharmacopoeia

**Quality standards** 

# 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-Nov-2023

**Revision Number** 1

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

1.1. Product identifier	
Product Code(s)	CAT 851
Product Name	Nabumetone impurity D
Form	Not applicable

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No (EU Index No)	-
CAS No.	127053-22-9
Pure substance/mixture	Substance
Formula	C15H14O2
Molecular weight	226.27

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

Uses advised against No information available

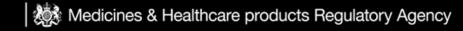
## 1.3. Details of the supplier of the safety data sheet

#### Supplier

British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom

Tel: +44 (0)20 3080 6561 eMail: bpcrs@mhra.gov.uk

For further information, please contact





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E-mail address

bpcrs@mhra.gov.uk

#### 1.4. Emergency telephone number

**Emergency Telephone** 

+44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

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

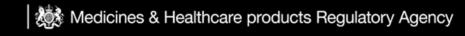
#### 2.1. Classification of the substance or mixture

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

#### 2.2. Label elements

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP] Hazard statements

This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]





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#### 2.3. Other hazards

No information available.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information This pro	This product does not contain any known or suspected endocrine disruptors.		
Chemical name	EU - REACH (1907/2006) - Article 59(1)	EU - REACH (1907/2006) - Endocrine	
	- Candidate List of Substances of Very	Disruptor Assessment List of	
	High Concern (SVHC) for Authorisation	Substances	
(E)-4-(6-Methoxynaphthalen-2-yl)but-3-en-2-one	-	-	

# SECTION 3: Composition/information on ingredients

## 3.1 Substances

Chemical name	Weight-%	REACH registration number		Classification according to Regulation (EC) No. 1272/2008 [CLP]	M-Factor	M-Factor (long-term)
(E)-4-(6-Methoxyna phthalen-2-yl)but-3- en-2-one 127053-22-9		-	-	-		

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

Acute Toxicity Estimate No information available

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

# SECTION 4: First aid measures

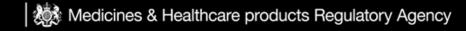
## 4.1. Description of first aid measures

Inhalation

Remove to fresh air.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.





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a doctor.		
in with soap and water. In the case of skin irritation or allergic reactions see a		
outh.		
4.2. Most important symptoms and effects, both acute and delayed		
nation available.		
4.3. Indication of any immediate medical attention and special treatment needed		
mptomatically.		

# SECTION 5: Firefighting measures 5.1. 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 chemical No information available.

5.3. Advice for firefighters

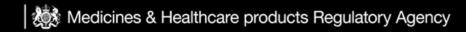
Special protective equipment and	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.
precautions for fire-fighters	Use personal protection equipment.

## 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.





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#### 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)		

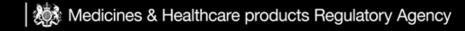
Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

# 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.





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**Biological occupational exposure limits** 

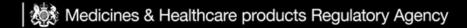
This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL) Predicted No Effect Concentration (PNEC)	No information available. 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.
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	Solid
Appearance	Solid
Colour	off-white to yellow
Odour	No information available.
Odour threshold	No information available





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<b>D</b>	N/ I	
Property National Advantage	<u>Values</u> No data available	Remarks • Method
Melting point / freezing point		None known
Initial boiling point and boiling rang		None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Flash point	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
рН	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	Soluble in water	None known
Solubility(ies)	Chloroform, Ethyl acetate, slightly	
	soluble	
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		
Molecular weight	226.27	
Molecular formula	C15H14O2	

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

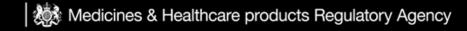
# SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Reactivity

No information available.

10.2. Chemical stability





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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.

## **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** 

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





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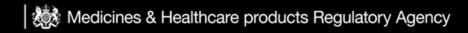
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Delayed and immediate effects as	well as chronic effects from short and long-term exposure
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	No information available.
Respiratory 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 hazard	<u>S</u>
11.2.1. Endocrine disrupting prop	erties
Endocrine disrupting properties	No information available.
11.2.2. Other information	
Other adverse effects	No information available.





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SECTION 12: Ecological information

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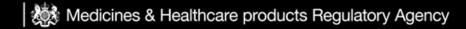
	normation
12.1. Toxicity	
Ecotoxicity	The environmental impact of this product has not been fully investigated.
12.2. Persistence and degradability	
Persistence and degradability	No information available.
12.3. Bioaccumulative potential	
Bioaccumulation	No information available.
12.4. Mobility in soil	
Mobility in soil	No information available.
12.5. Results of PBT and vPvB ass	<u>essment</u>
PBT and vPvB assessment	No information available.
12.6. Endocrine disrupting proper	<u>ties</u>
Endocrine disrupting properties	No information available.
12.7. Other adverse effects	

**<u>12.7. Other adverse effects</u>** No information available.

# **SECTION 13: Disposal considerations**

#### 13.1. Waste treatment methods

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.





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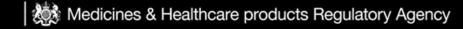
## **SECTION 14: Transport information**

## <u>IATA</u>

<ul> <li>14.1 UN number or ID number</li> <li>14.2 UN proper shipping name</li> <li>14.3 Transport hazard class(es)</li> <li>14.4 Packing group</li> <li>14.5 Environmental hazards</li> <li>14.6 Special precautions for user Special Provisions</li> </ul>	Not regulated Not regulated Not regulated Not applicable None
IMDG14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Marine pollutant14.6Special precautions for user Special Provisions14.7Maritime transport in bulk according to IMO instruments	Not regulated Not regulated Not regulated Not regulated Not applicable None No information available No information available
RID14.1UN number or ID number14.2UN proper shipping name14.3Transport hazard class(es)14.4Packing group14.5Environmental hazards14.6Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable
ADR 14.1 UN number or ID number 14.2 UN proper shipping name 14.3 Transport hazard class(es) 14.4 Packing group 14.5 Environmental hazards 14.6 Special precautions for user Special Provisions	Not regulated Not regulated Not regulated Not regulated Not applicable None

# **SECTION 15: Regulatory information**

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





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#### National regulations

Germany 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 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).

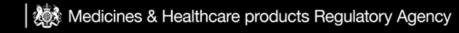
#### **European Union**

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





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Persistent Organic Pollutants Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories TSCA	Complies under research and development exemption or is regulated by a different government agency.
DSL/NDSL EINECS/ELINCS ENCS IECSC KECL PICCS	Contact supplier for inventory compliance status Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status

Legend:

**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

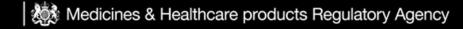
15.2. Chemical safety assessment

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





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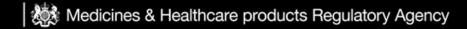
#### Legend

SVHC: Substances of Very High Concern for Authorisation:

TWA	ction 8: Exposure controls/personal protec 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 to:	xicity		Calculation method
Acute dermal	2		Calculation method
Acute inhalat	ion toxicity - gas		Calculation method
Acute inhalat	ion toxicity - Vapour		Calculation method
Acute inhalat	ion toxicity - dust/mist		Calculation method
Skin corrosio	n/irritation		Calculation method
Serious eye o	damage/eye irritation		Calculation method
Respiratory s	ensitisation		Calculation method
Skin sensitisa	ation		Calculation method
Mutagenicity			Calculation method
Carcinogenic	ity		Calculation method
Reproductive	toxicity		Calculation method
STOT - single	e exposure		Calculation method
STOT - repea	ated exposure		Calculation method
Acute aquation	c toxicity		Calculation method
Chronic aqua	tic toxicity		Calculation method
Aspiration ha	zard		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)





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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

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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. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be heldresponsible 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