

## 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 23-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 828

**Product Name** Diclofenac impurity A

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)	239-399-3
CAS No.	15362-40-0
Pure substance/mixture	Substance
Formula	C14H9Cl2NO
Molecular weight	278.13

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

Recommended use	Laboratory use

Uses advised against No information available

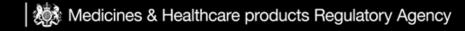
### 1.3. Details of the supplier of the safety data sheet

#### Supplier

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)

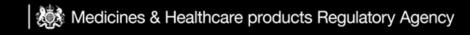
Emergency Telephone - §45 - (EC)1272/2008		
Europe	112	
Austria	No information available	
Bulgaria		
Croatia		
Cyprus		
Czech Republic		
Denmark		
France		
Hungary		
Ireland		
Italy		
Lithuania		
Luxembourg		
Netherlands		
Norway		
Portugal		
Romania		
Slovakia		
Slovenia		
Spain		
Sweden		
Switzerland		

## **SECTION 2: Hazards identification**

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

Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity - Oral	Category 4 - (H302)
Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Specific target organ toxicity — single exposure	Category 3 - (H335)
Category 3 Respiratory irritation	





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Warning

#### Hazard statements

H302 - Harmful if swallowed H315 - Causes skin irritation H319 - Causes serious eye irritation H335 - May cause respiratory irritation

### Precautionary Statements - EU (§28, 1272/2008)

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves and eye/face protection

P312 - Call a POISON CENTER or doctor if you feel unwell

P501 - Dispose of contents/ container to an approved waste disposal plant

#### 2.3. Other hazards

No information available.

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

### **Endocrine Disruptor Information** 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
1-(2,6-Dichlorophenyl)-1,3-dihydro-2H-indol-2-on	-	-
e		

## SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Chemical name Weight-% REACH registration EC No (EU Classification according Specific M-Factor M-Factor





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	number	Index No)	to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)	(long-term)
1-(2,6-Dichlorophen yl)-1,3-dihydro-2H-in dol-2-one 15362-40-0	-	239-399-3	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335)		

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

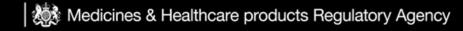
Acute Toxicity Estimate No information available

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

General advice	Show this safety data sheet to the doctor in attendance.	
Inhalation	Remove to fresh air. IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if symptoms occur.	
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.	
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.	
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.	
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).	
4.2. Most important symptoms and effects, both acute and delayed		
Symptoms	May cause redness and tearing of the eyes. Burning sensation.	
4.3. Indication of any immediate medical attention and special treatment needed		
Note to doctors	Treat symptomatically.	





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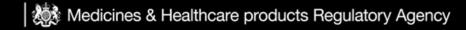
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SECTION 5: Firefighting measures		
5.1. Extinguishing media		
Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.	
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.	
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.	
5.2. Special hazards arising from the	ne substance or mixture	
Specific hazards arising from the chemical	No information available.	
5.3. Advice for firefighters		
Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.	
SECTION 6: Accidental re	lease measures	
	lease measures	
6.1. Personal precautions, protecti	ve equipment and emergency procedures Ensure adequate ventilation. Use personal protective equipment as required. Evacuate	
6.1. Personal precautions, protecti Personal precautions	ve equipment and emergency procedures Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing.	
6.1. Personal precautions, protective Personal precautions Other information	ve equipment and emergency procedures Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing. Refer to protective measures listed in Sections 7 and 8.	
6.1. Personal precautions, protective Personal precautions Other information For emergency responders	ve equipment and emergency procedures Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing. Refer to protective measures listed in Sections 7 and 8.	
6.1. Personal precautions, protective Personal precautions Other information For emergency responders 6.2. Environmental precautions	ve equipment and emergency procedures Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing. Refer to protective measures listed in Sections 7 and 8. Use personal protection recommended in Section 8. 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.





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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 handlingHandle in accordance with good industrial hygiene and safety practice. Avoid contact with<br/>skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off<br/>contaminated clothing and wash it before reuse. Ensure adequate ventilation. Avoid<br/>breathing vapours or mists. In case of insufficient ventilation, wear suitable respiratory<br/>equipment.General hygiene considerationsAvoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this<br/>product. Wash hands before breaks and after work. Wear suitable gloves and eye/face<br/>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. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

### 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

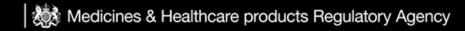
#### 8.1. Control parameters

**Exposure Limits** 

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

#### **Biological occupational exposure limits**

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





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Derived No Effect Level (DNEL) Predicted No Effect Concentration (PNEC) 8.2. Exposure controls	No information available. No information available.
Personal protective equipment	
Eye/face protection	Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields.
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 butyl rubber gloves. Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved 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.

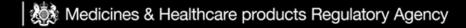
## SECTION 9: Physical and chemical properties

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

Physical state	Solid
Appearance	Solid
Colour	light yellow to brown
Odour	No information available.
Odour threshold	No information available

PropertyValuesMelting point / freezing point127 °CInitial boiling point and boiling range>200FlammabilityFlammabilityNo data availableFlammability Limit in Air

Remarks • Method None known None known None known None known





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None known None known None known

None known None known None known

None known None known None known

None known

No information available

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Upper flammability or explosive	No data available
limits	
Lower flammability or explosive	No data available
limits	
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	
рН	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Water solubility	No data available
Solubility(ies)	Methanol, Toluene
Partition coefficient	No data available
Vapour pressure	No data available
Relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Relative vapour density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
9.2. Other information	
Molecular weight	278.13
Molecular formula	C14H9Cl2NO

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

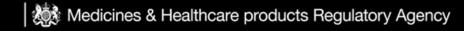
No information available.

10.2. Chemical stability

Stability

Stable under normal conditions.

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





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

10.4. Conditions to avoid

Conditions to avoid

10.5. Incompatible materials

Incompatible materials

Strong acids. Strong bases. Strong oxidising agents.

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**

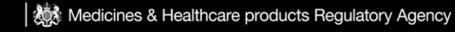
Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.	
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.	
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).	
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on components).	
Symptoms related to the physical, chemical and toxicological characteristics		
Symptoms	Redness May cause redness and tearing of the eyes	

Symptoms

Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity No information available

Acute toxicity





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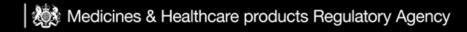
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Delayed and immediate effects as well as chronic effects from short and long-term exposure		
Skin corrosion/irritation	Classification based on data available for ingredients. Causes skin irritation. May cause skin irritation.	
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.	
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	May cause respiratory irritation.	
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.	





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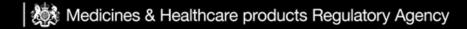
SECTION 12: Ecological information		
<u>12.1. Toxicity</u>		
Ecotoxicity	The environmental impact of this product has not been fully investigated.	
12.2. Persistence and degradability		
Persistence and degradability	No information available.	
12.3. Bioaccumulative potential		
Bioaccumulation	No information available.	
<u>12.4. Mobility in soil</u>		
12.4. Mobility III 301		
Mobility in soil	No information available.	
<u>12.5. Results of PBT and vPvB ass</u>	<u>essment</u>	
PBT and vPvB assessment	No information available.	
12.6. Endocrine disrupting properties		
Endocrine disrupting properties	No information available.	
12.7 Other adverse effects		

**12.7.** Other adverse effects 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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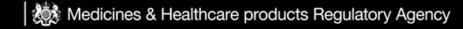
## **SECTION 14: Transport information**

14.1	UN
14.2	UN
14.3	Tra
144	Par

IATA 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
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 None
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)

slightly hazardous to water (WGK 1)

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 AIIC	Contact supplier for inventory compliance status 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

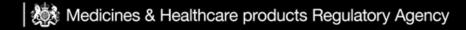
15.2. Chemical safety assessment

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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#### Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

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

TWĂ	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	On basis of test data
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	On basis of test data
Serious eye damage/eye irritation	On basis of test data
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	On basis of test data
STOT - repeated exposure	Calculation method
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))

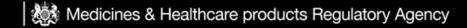
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)





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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** 23-Nov-2023

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

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