

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-Apr-2024 Revision Number 1

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

1.1. Product identifier

Product Code(s) CAT 880

Product Name Ibuprofen impurity B

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

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

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				

EGHS / EN Page 1/20



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-Apr-2024

Revision Number 1

CAT 880 - Ibuprofen impurity B

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]

regulation (20) No. 1272/2000 [OZI]	
Acute toxicity - Oral	Category 4 - (H302)
Acute toxicity - Dermal	Category 4 - (H312)
Acute toxicity - Inhalation (Vapours)	Category 4 - (H332)
Serious eye damage/eye irritation	Category 2 - (H319)
Flammable liquids	Category 2 - (H225)

2.2. Label elements

Contains Acetonitrile

EGHS / EN Page 2/20



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-Apr-2024

Revision Number 1

CAT 880 - Ibuprofen impurity B



Signal word Danger

Hazard statements

H302 - Harmful if swallowed

H312 - Harmful in contact with skin

H319 - Causes serious eve irritation

H332 - Harmful if inhaled

H225 - Highly flammable liquid and vapour

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

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

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

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P321 - Specific treatment (see supplemental first aid instructions on this label)

P370 + P378 - In case of fire: Use dry chemical, CO2, water spray or alcohol-resistant foam to extinguish

P403 + P235 - Store in a well-ventilated place. Keep cool

2.3. Other hazards

This mixture contains no substance considered to be persistent, bioaccumulating or toxic (PBT). This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

Endocrine Disruptor Information 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	Disruptor Assessment List of
Acetonitrile	-	-
(2RS)-2-(4-Butylphenyl)propanoic Acid	-	-

SECTION 3: Composition/information on ingredients

EGHS / EN Page 3/20



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-Apr-2024 Revision Number 1

CAT 880 - Ibuprofen impurity B

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	Weight-%	ĕ	,	Classification according	•	M-Factor	M-Factor
		number	index No)	to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)		(long-term)
Acetonitrile	80 - 100	-	200-835-2	Acute Tox. 4 (H302)	-		
75-05-8				Acute Tox. 4 (H312)			
				Acute Tox. 4 (H332)			
				Eye Irrit. 2 (H319)			
				Flam. Liq. 2 (H225)			
(2RS)-2-(4-Butylphe	<0.1	-	641-468-1	Acute Tox. 4 (H302)			
nyl)propanoic Acid							
3585-49-7							

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

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapour - mg/L	hour - gas - ppm
Acetonitrile 75-05-8	No data available	2000	26.8	No data available	No data 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 symptoms persist, call a doctor. If breathing has stopped, give

EGHS / EN Page 4/20



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-Apr-2024

Revision Number 1

CAT 880 - Ibuprofen impurity B

artificial respiration. Get medical attention immediately.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep

eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Skin contactWash off immediately with soap and plenty of water while removing all contaminated clothes

and shoes. If symptoms persist, call a doctor.

Ingestion Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious

person. Get medical attention.

Self-protection of the first aider Remove all sources of ignition. Ensure that medical personnel are aware of the material(s)

involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid

contact with skin, eyes or clothing. Avoid breathing vapours or mists.

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

Symptoms May cause redness and tearing of the eyes. Burning sensation. Coughing and/ or wheezing.

Difficulty in breathing.

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 Dry chemical. Carbon dioxide (CO2). Water spray. Alcohol resistant foam.

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

Risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

5.3. Advice for firefighters

EGHS / EN Page 5/20



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-Apr-2024

CAT 880 - Ibuprofen impurity B

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Revision Number 1

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Evacuate personnel to safe areas. Use personal protective equipment as required. See

section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material. Avoid breathing

vapours or mists.

Other information Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

6.2. Environmental precautions

Environmental precautions Refer to protective measures listed in Sections 7 and 8. Prevent further leakage or spillage if

safe to do so. Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Do not touch or walk through spilled material. A

vapour suppressing foam may be used to reduce vapours. Dyke far ahead of spill to collect run-off water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand

or other non-combustible material and transfer to containers for later disposal.

Methods for cleaning up Take precautionary measures against static discharges. Dam up. Soak up with inert

absorbent material. Pick up and transfer to properly labelled containers.

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.

EGHS / EN Page 6/20



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-Apr-2024

Revision Number 1

CAT 880 - Ibuprofen impurity B

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Use personal protection equipment. Avoid breathing vapours or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use with local exhaust ventilation. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. In case of insufficient ventilation, wear suitable respiratory equipment.

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. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

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 away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labelled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations. Keep out of the reach of children. Store locked up.

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

EGHS / EN Page 7/20



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-Apr-2024

Revision Number 1

CAT 880 - Ibuprofen impurity B

Chemical name	Euro	pean Union	Austria	Belgium	Bu	ılgaria	Croatia
Acetonitrile		/A: 40 ppm	TWA: 40 ppm	TWA: 20 ppm		: 40 ppm	TWA: 40 ppm
75-05-8		A: 70 mg/m ³	TWA: 70 mg/m ³	TWA: 34 mg/m ³		70 mg/m ³	TWA: 70 mg/m ³
		*	STEL 160 ppm	Sk*	,	Sk*	Sk*
			STEL 280 mg/m ³				
			Sk*				
Chemical name		Cyprus	Czech Republic	Denmark		stonia	Finland
Acetonitrile		/A: 40 ppm	TWA: 70 mg/m ³	TWA: 40 ppm		: 40 ppm	TWA: 20 ppm
75-05-8	TW	4: 70 mg/m³	Sk*	TWA: 70 mg/m ³		70 mg/m ³	TWA: 34 mg/m ³
			Ceiling: 100 mg/m ³	STEL: 80 ppm		Sk*	STEL: 40 ppm
				STEL: 140 mg/m ³			STEL: 68 mg/m ³
				Sk*			Sk*
Chemical name		France	Germany TRGS	Germany DFG		reece	Hungary
Acetonitrile		/A: 40 ppm	TWA: 10 ppm	TWA: 10 ppm		: 40 ppm	TWA: 40 ppm
75-05-8	1 1 1 1 1 1	4: 70 mg/m ³	TWA: 17 mg/m ³	TWA: 17 mg/m ³		70 mg/m ³	TWA: 70 mg/m ³
		Sk*	Sk*	Peak: 20 ppm		: 60 ppm	STEL: 5 mg/m³ Sk*
				Peak: 34 mg/m ³ Sk*		105 mg/m³ Sk*	SK
Chemical name		Ireland	Italy MDLPS	Italy AIDII		atvia	Lithuania
Acetonitrile	Τ\Λ	/A: 40 ppm	TWA: 20 ppm	TWA: 20 ppm		: 40 ppm	TWA: 40 ppm
75-05-8		4: 70 mg/m ³	TWA: 35 mg/m ³	TWA: 34 mg/m ³		70 mg/m ³	TWA: 70 mg/m ³
75 55 5		L: 120 ppm	Sk*	Sk*		Sk*	Sk*
		_: 310 mg/m ³				O.K	
	• • • •	Sk*					
Chemical name	Lu	xembourg	Malta	Netherlands	No	orway	Poland
Acetonitrile	TV	/A: 40 ppm	TWA: 40 ppm	TWA: 20 ppm		: 30 ppm	TWA: 70 mg/m ³
75-05-8	TW	4: 70 mg/m³	TWA: 70 mg/m ³	TWA: 34 mg/m ³		50 mg/m ³	STEL: 140 mg/m ³
		Sk*	Sk*	STEL: 4.5 ppm		: 45 ppm	Sk*
				STEL: 5 mg/m ³		75 mg/m ³	
				Sk*		Sk*	
Chemical name		Portugal	Romania	Slovakia		ovenia	Spain
Acetonitrile		/A: 40 ppm	TWA: 40 ppm	TWA: 40 ppm		: 40 ppm	TWA: 40 ppm
75-05-8	I IVV	4: 70 mg/m ³	TWA: 70 mg/m ³	TWA: 70 mg/m ³		70 mg/m ³	TWA: 68 mg/m ³
		Sk*	STEL: 1 mg/m³ Sk*	Sk*		140 mg/m ³	Sk*
			J SK	Ceiling: 5 mg/m ³		: 80 ppm Sk*	
Chemical name		Sweden		Switzerland		_	ted Kingdom
Acetonitrile		NGV: 30 ppm		TWA: 20 ppm			VA: 40 ppm
75-05-8			50 mg/m ³	TWA: 34 mg/m		TW	'A: 68 mg/m ³
			e KGV: 60 ppm	STEL: 40 ppm			EL: 60 ppm
		Vägledande	KGV: 100 mg/m ³	STEL: 68 mg/m ³		STEL: 102 mg/m ³	
			Sk*	Sk*			Sk*

EGHS / EN Page 8/20



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-Apr-2024 Revision Number 1

CAT 880 - Ibuprofen impurity B

Biological occupational exposure limits

Chemical name	European Union	Austria	Bulgaria	Croatia	Czech Republic
Acetonitrile	-	-	-	6.5 mg/24 hours -	-
75-05-8				urine (Thiocyanates)	
				- urine collected over	
				24 hours	
				<3 mg - urine and	
				blood (Thiocyanate	
				ratio in urine (mg/g	
				Creatinine) and	
				Carboxyhemoglobin	
				in blood (%)) - urine	
				and blood collected	
				at the end of the	
				work shift	

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). Tight sealing

safety 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 butyl rubber gloves. Wear

suitable gloves. Impervious gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

Antistatic boots.

Respiratory protectionNo protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

EGHS / EN Page 9/20



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-Apr-2024

Revision Number 1

CAT 880 - Ibuprofen impurity B

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. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks

and immediately after handling the product.

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 sweet. Aromatic. **Odour threshold** No information available

Remarks • Method Property Values

-45.72 °C Melting point / freezing point None known Initial boiling point and boiling range81.61 °C None known None known **Flammability** No data available Flammability Limit in Air None known

Upper flammability or explosive 17 Vol%

limits

Lower flammability or explosive 3 Vol% - 50 g/m3

limits

Flash point 2°C None known 524 °C **Autoignition temperature** None known

Decomposition temperature

None known pН No data available None known

pH (as aqueous solution) No data available No information available No data available None known Kinematic viscosity

Dynamic viscosity 0.35 mPas @ 25°C Water solubility No data available None known Solubility(ies) No data available None known **Partition coefficient** -0.34None known Vapour pressure 94.51 - 98.64 hPa @ 20°C None known

Relative density 0.7857

Bulk density No data available **Liquid Density** No data available

Relative vapour density 1.42 None known

EGHS / EN Page 10/20



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-Apr-2024 Revision Number 1

CAT 880 - Ibuprofen impurity B

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 Yes.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid Heat, flames and sparks. Excessive heat.

10.5. Incompatible materials

Incompatible materialsNone known based on information supplied.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

EGHS / EN Page 11/20



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-Apr-2024 Revision Number 1

CAT 880 - Ibuprofen impurity B

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. Harmful by inhalation. (based on components).

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. May cause irritation.

Prolonged contact may cause redness and irritation. May be absorbed through the skin in

harmful amounts. Harmful in contact with skin. (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 May cause redness and tearing of the eyes. Coughing and/ or wheezing.

Numerical measures of toxicity

Acute toxicity

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

ATEmix (oral) 500.30 mg/kg
ATEmix (dermal) 1,100.70 mg/kg
ATEmix (inhalation-gas) 99,999.00 ppm
ATEmix (inhalation-dust/mist) 99,999.00 mg/l
ATEmix (inhalation-vapour) 11.00 mg/l

Component Information

	Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Ī	Acetonitrile	= 2460 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	= 26.8 mg/L (Rat) 4 h

EGHS / EN Page 12/20



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 Number 1

Revision date 23-Apr-2024

CAT 880 - Ibuprofen impurity B

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

Skin corrosion/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 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

EGHS / EN Page 13/20



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-Apr-2024 Revision Number 1

CAT 880 - Ibuprofen impurity B

12.1. Toxicity

Ecotoxicity

Unknown aquatic toxicity

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

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Acetonitrile	-	LC50: 1600 - 1690mg/L (96h, Pimephales promelas) LC50: =1000mg/L (96h, Pimephales promelas) LC50: =1850mg/L (96h, Lepomis macrochirus) LC50: =1650mg/L (96h, Poecilia reticulata)	<u>-</u>	EC50: 3,600 mg/l (48h, daphnia)

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

Chemical name	Partition coefficient
Acetonitrile	-0.34

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	
Acetonitrile	The substance is not PBT / vPvB	

12.6. Endocrine disrupting properties

EGHS / EN Page 14/20



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-Apr-2024 Revision Number 1

CAT 880 - Ibuprofen impurity B

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused

products

Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld

containers.

SECTION 14: Transport information

<u>IATA</u>

14.1 UN number or ID number UN1648

14.2 UN proper shipping name Acetonitrile mixture

14.3 Transport hazard class(es)14.4 Packing group

Description UN1648, Acetonitrile mixture, 3, II

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions ERG CodeNone
3L

MDG

14.1 UN number or ID number UN1648

14.2 UN proper shipping name Acetonitrile mixture

14.3 Transport hazard class(es)14.4 Packing group

Description UN1648, Acetonitrile mixture, 3, II, (2°C c.c.)

14.5 Marine pollutant NP

14.6 Special precautions for user

Special Provisions None

EmS-No. F-E, S-D No information available

EGHS / EN Page 15/20



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-Apr-2024

Revision Number 1

CAT 880 - Ibuprofen impurity B

14.7 Maritime transport in bulk according to IMO instruments

No information available

RID

14.1 UN number or ID number UN1648

14.2 UN proper shipping name Acetonitrile mixture

14.3 Transport hazard class(es) 3

14.4 Packing group

Description UN1648, Acetonitrile mixture, 3, II

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions None **Classification code** F1

ADR

14.1 UN number or ID number UN1648

14.2 UN proper shipping name Acetonitrile mixture

14.3 Transport hazard class(es)

14.4 Packing group

Description UN1648, Acetonitrile mixture, 3, II, (D/E)

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions None
Classification code F1
Tunnel restriction code (D/E)

SECTION 15: Regulatory information

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

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Acetonitrile	RG 84	-
75-05-8		

Germany

Water hazard class (WGK) obviously hazardous to water (WGK 2)

EGHS / EN Page 16/20



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-Apr-2024

Revision Number 1

CAT 880 - Ibuprofen impurity B

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 contains one or more substance(s) 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

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorisation per REACH Annex XIV
Acetonitrile - 75-05-8	75.	

EGHS / EN Page 17/20



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-Apr-2024 Revision Number 1

CAT 880 - Ibuprofen impurity B

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

P5a - FLAMMABLE LIQUIDS P5b - FLAMMABLE LIQUIDS P5c - FLAMMABLE LIQUIDS

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
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
Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
AllC
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

EGHS / EN Page 18/20



SAFETY DATA SHEET

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Revision Number 1

Revision date 23-Apr-2024

CAT 880 - Ibuprofen impurity B

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

Full text of H-Statements referred to under section 3

H225 - Highly flammable liquid and vapour

H302 - Harmful if swallowed

H312 - Harmful in contact with skin

H319 - Causes serious eye irritation

H332 - Harmful if inhaled

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 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
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method

EGHS / EN Page 19/20



SAFETY DATA SHEET

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Revision date 23-Apr-2024

Revision Number 1

CAT 880 - Ibuprofen impurity B

Ozone	Calculation method
Flammable liquids	On basis of test data

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

23-Apr-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. 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

EGHS / EN Page 20/20