LANSOPRAZOLE

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Reference number: 75060
Issue date: 12/2/2004 Revision date: 12/21/2022 Supersedes version of: 5/9/2019 Version: 8.0

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

1.1. Product identifier

Product form	:	Substance
Trade name	:	LANSOPRAZOLE
Chemical name	:	2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl]methylsulfinyl]-1H-benzoimidazole
IUPAC name	:	2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl]methylsulfinyl]-1H-benzoimidazole
CAS-No.	:	103577-45-3
Product code	:	75060
Type of product	:	Active Ingredient for Medicinal / Pharmaceutical Use
Formula	:	C16H14F3N3O2S
Synonyms	:	1H-Benzimidazole, 2-[[[3-methyl-4-(2,2,2- trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]; 2-[[3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl]methylsulfinyl]-1H-benzoimidazole; Lansoprazole Powder
Other means of identification	:	SMILES: CC1=C(OCC(F)(F)F)C=CN=C1CS(=O)C1=NC2=CC=CC=C2N1

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

1.2.1. Relevant identified uses

Main use category	:	API,Industrial use,Professional use
Industrial/Professional use spec	:	Active Ingredient for Medicinal / Pharmaceutical Use Industrial For professional use only
Use of the substance/mixture	:	Anti-ulcer agents. Anti-Infective agents. Enzyme Inhibitors. Proton-pump Inhibitors.
Function or use category	:	Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier
MOEHS IBÉRICA, S.L.
Roma, 8 - P.I. Cova Solera
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

Manufacturer
MOEHS CATALANA, S.L.
Cesar Martinell i Brunet, 12 A P.I. Rubi Sud
08191 Rubi
Spain
T +34 93 586 05 20 - F +34 93 699 8350
hse@moehs.es - www.moehs.com

1.4. Emergency telephone number

Emergency number	:	+34 93 586 05 20 (9:00 - 17:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Skin sensitisation, Category 1	H317
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335

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

Adverse physicochemical, human health and environmental effects

Causes skin and eye irritation. May cause sensitisation of susceptible persons.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.

Precautionary statements (CLP) : P261 - Avoid breathing spray, dust.
P264 - Wash hands, forearms and face thoroughly after handling.
P271 - Use only outdoors or in a well-ventilated area.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P280 - Wear eye protection, protective gloves, protective clothing, face protection.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P314 - Get medical advice/attention if you feel unwell.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P405 - Store locked up.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Other hazards which do not result in classification : Dust could form explosive mixtures with air

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
LANSOPRAZOLE	CAS-No.: 103577-45-3	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

First-aid measures after skin contact : Wash with plenty of water/…. Wash contaminated clothing before reuse. If skin irritation occurs: Wash with plenty of water/…, Get medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects : If you feel unwell, seek medical advice.

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : Causes skin irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Causes serious eye irritation.

Symptoms/effects after ingestion : May cause sensitisation of susceptible persons by skin contact.

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

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust/fume/gas/mist/vapours/spray. Use only outdoors or in a well-ventilated area.

Hygiene measures : Wash hands, forearms and face thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Store at room temperature. Keep away from ignition sources.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 3 (0.01 - 0.1 mg/m3)

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:
Local exhaust or breathing protection. Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

8.2.2. Personal protection equipment

Personal protective equipment:
Avoid all unnecessary exposure.

Personal protective equipment symbol(s):

8.2.2.1. Eye and face protection

Eye protection:
Chemical goggles or safety glasses

8.2.2.2. Skin protection

Skin and body protection:
Wear suitable protective clothing

Hand protection:
Wear protective gloves.

Hand protection				
Type	**Material**	**Permeation**	**Penetration**	**Standard**
Disposable gloves	Polyvinylalcohol (PVA), Polyvinylchloride (PVC), Fluoroelastomer (FKM), Neoprene rubber (HNBR), Latex	2 (> 30 minutes)	2 (< 1.5)	EN ISO 374

Other skin protection Materials for protective clothing		
Condition	**Material**	**Standard**
Good resistance:	Tyvek®, Polyethylene, Polyethylene/ethylenevinylalcohol, Synthetic material, Latex	EN 13034, EN 1149-1, EN 14126, , EN ISO 13982-1

8.2.2.3. Respiratory protection

Respiratory protection:
Wear appropriate mask

Respiratory protection			
Device	**Filter type**	**Condition**	**Standard**
Dust mask, Full face mask, Powered hoods/helmets, Powered Air-Purifying Respirator (PAPR)	Type P3	High dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

Other information:
Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	white.
Appearance	:	Local powder.
Molecular mass	:	369.36 g/mol
Odour	:	characteristic.
Odour threshold	:	Not available
Melting point	:	178 – 182 °C ºC
Freezing point	:	Not available
Boiling point	:	≈ 555.8 °C
Flammability	:	Dust could form explosive mixtures with air
Explosive properties	:	Could form explosive mixtures with air.
Explosive limits	:	Not applicable
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable

Flash point	:	≈ 289.9 °C
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Moderately soluble in water. Water: ≈ 0.97 mg/l [Experimental] Ethanol: Soluble
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Partition coefficient n-octanol/water (Log Pow)	:	≈ 2.76 [Predicted, calculated using ALOGPS]
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	≈ 1.5 g/cm³
Relative density	:	Not available
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not available
Particle size distribution	:	Not available
Particle shape	:	Not available
Particle aspect ratio	:	Not available
Particle aggregation state	:	Not available
Particle agglomeration state	:	Not available
Particle specific surface area	:	Not available
Particle dustiness	:	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Minimum ignition energy	:	4 mJ
Additional information	:	Layer Minimum flammability Temperature : Melt. Dust Cloud minimum Flammability Temperature : 630ºC. Explosion Severity Factor Kmax (bar.m/s) : 299. Explosion Class : 2

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide. Nitrogen oxides. Sulphur oxides.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified
Additional information : Based on available data, the classification criteria are not met

LANSOPRAZOLE (103577-45-3)	
LD50 oral rat	> 5000 mg/kg
LD50, acute, intraperitoneal, rat	5000 mg/kg

Skin corrosion/irritation : Causes skin irritation.
Serious eye damage/irritation : Causes serious eye irritation.
Respiratory or skin sensitisation : May cause sensitisation of susceptible persons by skin contact
Additional information : Based on available data, the classification criteria are not met
Germ cell mutagenicity : Not classified
Additional information : Based on available data, the classification criteria are not met
Carcinogenicity : Not Listed on IARC (International Agency for Research on Cancer)
Additional information : Based on available data, the classification criteria are not met
Reproductive toxicity : Not classified
Additional information : Based on available data, the classification criteria are not met
STOT-single exposure : May cause respiratory irritation.
STOT-repeated exposure : Not classified
Additional information : Based on available data, the classification criteria are not met
Aspiration hazard : Not classified
Additional information : Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

11.2.2. Other information

Potential adverse human health effects and symptoms : Irritation: may cause irritation to the respiratory system,Severely irritant to skin,May cause sensitisation of susceptible persons
Other information : Likely routes of exposure: inhalation, skin and eye.

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute) : Not classified
Hazardous to the aquatic environment, long–term (chronic) : Not classified

12.2. Persistence and degradability

LANSOPRAZOLE (103577-45-3)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

LANSOPRAZOLE (103577-45-3)	
BCF - Fish [1]	≈ 135 [Predicted by BCFWIN v2.17]

LANSOPRAZOLE (103577-45-3)	
Partition coefficient n-octanol/water (Log Pow)	≈ 2.76 [Predicted, calculated using ALOGPS]

12.4. Mobility in soil

LANSOPRAZOLE (103577-45-3)	
Organic Carbon Normalized Adsorption Coefficient (Log Koc)	≈ 4.407 [Predicted by PCKOCWIN v1.66]

12.5. Results of PBT and vPvB assessment

LANSOPRAZOLE (103577-45-3)
vPvB: not relevant – no registration required

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.
Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
Additional information : Industrial waste.
Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

In accordance with / ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

UN-No. (ADR) : Not applicable
UN-No. (IMDG) : Not applicable
UN-No. (IATA) : Not applicable
UN-No. (ADN) : Not applicable
UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA
Transport hazard class(es) (IATA) : Not applicable

ADN
Transport hazard class(es) (ADN) : Not applicable

RID
Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable
Packing group (IMDG) : Not applicable
Packing group (IATA) : Not applicable
Packing group (ADN) : Not applicable
Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No
Marine pollutant : No
Other information : No supplementary information available

14.6. Special precautions for user

Overland transport
No data available

Transport by sea
No data available

Air transport
No data available

Inland waterway transport
No data available

Rail transport
No data available

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

Germany

Water hazard class (WGK)	:	Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).
Hazardous Incident Ordinance (12. BImSchV)	:	Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen	:	The substance is not listed
SZW-lijst van mutagene stoffen	:	The substance is not listed
SZW-lijst van reprotoxische stoffen – Borstvoeding	:	The substance is not listed
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid	:	The substance is not listed
SZW-lijst van reprotoxische stoffen – Ontwikkeling	:	The substance is not listed

Denmark

Classification remarks	:	Emergency management guidelines for the storage of flammable liquids must be followed
Danish National Regulations	:	Young people below the age of 18 years are not allowed to use the product

Switzerland

Storage class (LK)	:	LK 11/13 - Solids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
IARC	International Agency for Research on Cancer
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
IATA	International Air Transport Association
EC50	Median effective concentration
LC50	Median lethal concentration
LD50	Median lethal dose
IMDG	International Maritime Dangerous Goods
vPvB	Very Persistent and Very Bioaccumulative
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of H- and EUH-statements:	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.