

Loxapine succinate salt Apollo Scientific

Part Number: BIL2251 Version No: 1.1

Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Chemwatch Hazard Alert Code: 2

Issue Date: 10/08/2023 Print Date: 10/08/2023 S.REACH.GB-NIR.EN

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

1.1. Product Identifier

Product name	Loxapine succinate salt			
Chemical Name	loxapine succinate			
Synonyms	Not Available			
Chemical formula	C18-H18-CI-N3-O .C4-H6-O4			
Other means of identification	Not Available			
CAS number	27833-64-3*			
EC number	248-682-0			

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

Relevant identified uses	Use according to manufacturer's directions.
Uses advised against	No specific uses advised against are identified.

1.3. Details of the manufacturer or supplier of the safety data sheet

Registered company name	Apollo Scientific		
Address	hitefield Road, Bredbury SK62QR United Kingdom		
Telephone	01614060505		
Fax	0161 406 0506		
Website	http://www.apolloscientific.co.uk/		
Email	sales@apolloscientific.co.uk		

1.4. Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	Not Available
Other emergency telephone numbers	Not Available

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classification according to
regulation (EC) No 1272/2008
[CLP] and amendments [1]

H302 - Acute Toxicity (Oral) Category 4, H312 - Acute Toxicity (Dermal) Category 4, H315 - Skin Corrosion/Irritation Category 2, H319 - Serious Eye Damage/Eye Irritation Category 2, H332 - Acute Toxicity (Inhalation) Category 4, H335 - Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3

Legend: 1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

2.2. Label elements

Hazard pictogram(s)



Signal word

Warning

Part Number: BIL2251
Version No: 1.1

Page 2 of 12

Loxapine succinate salt

Issue Date: **10/08/2023**Print Date: **10/08/2023**

Hazard statement(s)

H302	Harmful if swallowed.		
H312	Harmful in contact with skin.		
H315	Causes skin irritation.		
H319	Causes serious eye irritation.		
H332	Harmful if inhaled.		
H335	May cause respiratory irritation.		

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P271	Use only outdoors or in a well-ventilated area.		
P261	Avoid breathing dust/fumes.		
P264	Wash all exposed external body areas thoroughly after handling.		
P270	Do not eat, drink or smoke when using this product.		
P280	Wear protective gloves, protective clothing, eye protection and face protection.		

Precautionary statement(s) Response

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.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P330	Rinse mouth.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

Precautionary statement(s) Storage

P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

Precautionary statement(s) Disposal

Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

2.3. Other hazards

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients

P501

3.1.Substances

1. CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
1. 27833-64-3* 2.248-682-0 3.Not Available 4.Not Available	100	Loxapine succinate salt	Acute Toxicity (Oral) Category 4, Acute Toxicity (Dermal) Category 4, Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Acute Toxicity (Inhalation) Category 4, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H302, H312, H315, H319, H332, H335 [1]	0	Not Available

Legend:

1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

3.2.Mixtures

See 'Information on ingredients' in section 3.1

SECTION 4 First aid measures

4.1. Description of first aid measures

If this product comes in contact with the eyes:

Eye Contact

- Wash out immediately with fresh running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

Part Number: BIL2251 Page 3 of 12 Issue Date: 10/08/2023 Version No: 1.1 Print Date: 10/08/2023 Loxapine succinate salt

Skin Contact	If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Inhalation	 If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. Transport to hospital, or doctor, without delay.
Ingestion	 IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY. For advice, contact a Poisons Information Centre or a doctor. Urgent hospital treatment is likely to be needed. In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist. If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS. Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise: INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. NOTE: Wear a protective glove when inducing vomiting by mechanical means.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

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

As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination).

For poisons (where specific treatment regime is absent):

BASIC TREATMENT

- ▶ Establish a patent airway with suction where necessary.
- ▶ Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- Monitor and treat, where necessary, for pulmonary oedema.
- Monitor and treat, where necessary, for shock.
- Anticipate seizures.
- DO NOT use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

ADVANCED TREATMENT

- F Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- Positive-pressure ventilation using a bag-valve mask might be of use
- Monitor and treat, where necessary, for arrhythmias.
- Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

SECTION 5 Firefighting measures

5.1. Extinguishing media

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility None known. 5.3. Advice for firefighters Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area. Fire Fighting DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.

Part Number: BIL2251 Page 4 of 12

Loxapine succinate salt

Issue Date: 10/08/2023 Print Date: 10/08/2023

Fire/Explosion Hazard

- Non combustible
- Not considered a significant fire risk, however containers may burn.

May emit poisonous fumes

May emit corrosive fumes

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

Version No: 1.1

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

► Remove all ignition sources. Clean up all spills immediately. Avoid contact with skin and eyes. **Minor Spills** Control personal contact with the substance, by using protective equipment. Use dry clean up procedures and avoid generating dust. Place in a suitable, labelled container for waste disposal. Moderate hazard. ► CAUTION: Advise personnel in area. Alert Emergency Services and tell them location and nature of hazard. Control personal contact by wearing protective clothing. Prevent, by any means available, spillage from entering drains or water courses. **Major Spills** Recover product wherever possible. FIF DRY: Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. IF WET: Vacuum/shovel up and place in labelled containers for disposal. ALWAYS: Wash area down with large amounts of water and prevent runoff into drains. ▶ If contamination of drains or waterways occurs, advise Emergency Services

6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

7.1. Precautions for safe handling

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- ► DO NOT enter confined spaces until atmosphere has been checked
- ▶ DO NOT allow material to contact humans, exposed food or food utensils.
- Avoid contact with incompatible materials. Safe handling
 - ► When handling, **DO NOT** eat, drink or smoke.
 - Keep containers securely sealed when not in use.
 - Avoid physical damage to containers.
 - Always wash hands with soap and water after handling.
 - ▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.
 - Use good occupational work practice.
 - Observe manufacturer's storage and handling recommendations contained within this SDS.
 - Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

Fire and explosion protection

See section 5

- ► Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry area protected from environmental extremes.
- Store away from incompatible materials and foodstuff containers
- Protect containers against physical damage and check regularly for leaks.
- ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.

Other information

- Consider storage in bunded areas ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams)
- Figure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	 Polyethylene or polypropylene container. Check all containers are clearly labelled and free from leaks. 			
Storage incompatibility	None known			
Hazard categories in accordance with Regulation (EC) No 1272/2008	Not Available			

Loxapine succinate salt

Issue Date: 10/08/2023 Print Date: 10/08/2023

Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of

Not Available

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
Not Available	Not Available	Not Available

^{*} Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not Available						

Not Applicable

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
Loxapine succinate salt	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
Loxapine succinate salt	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit	
Loxapine succinate salt	E	≤ 0.01 mg/m³	
Notes:	Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.		

8.2. Exposure controls

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.

Employers may need to use multiple types of controls to prevent employee overexposure.

Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection. An approved self contained breathing apparatus (SCBA) may be required in some situations.

Provide adequate ventilation in warehouse or closed storage area. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

8.2.1. Appropriate engineering controls

Type of Contaminant:	Air Speed:
solvent, vapours, degreasing etc., evaporating from tank (in still air).	0.25-0.5 m/s (50-100 f/min.)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of

 Part Number: BIL2251
 Page 6 of 12
 Issue Date: 10/08/2023

 Version No: 1.1
 Print Date: 10/08/2023

Loxapine succinate salt

1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

8.2.2. Individual protection measures, such as personal protective equipment











Eye and face protection

Safety glasses with side shields.

► Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]

Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

Skin protection

See Hand protection below

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

- · frequency and duration of contact,
- · chemical resistance of glove material,
- · glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).

- · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
- · Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.
- \cdot Contaminated gloves should be replaced.

As defined in ASTM F-739-96 in any application, gloves are rated as:

- · Excellent when breakthrough time > 480 min
- · Good when breakthrough time > 20 min
 - · Fair when breakthrough time < 20 min
 - · Poor when glove material degrades

For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.

It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.

Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.

Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:

- · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.
- · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene.
- nitrile rubber.
- butyl rubber.
- fluorocaoutchouc
- polyvinyl chloride

Gloves should be examined for wear and/ or degradation constantly.

Body protection

Hands/feet protection

See Other protection below

Other protection

- Overalls.P.V.C apron.
- Barrier cream.
- Skin cleansing cream.
- Eve wash unit.

Respiratory protection

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	-	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3	-
		Air-line*	-

Part Number: BIL2251 Page 7 of 12
Version No: 1.1

Loxapine succinate salt

Issue Date: **10/08/2023** Print Date: **10/08/2023**

100+ x ES - Air-line** PAPR-P3

* - Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- · Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- · Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- · Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
- · Use approved positive flow mask if significant quantities of dust becomes airborne.
- \cdot Try to avoid creating dust conditions.

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Not Available		
Physical state	Solid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Available
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	 Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2

Loxapine succinate salt

Issue Date: **10/08/2023**Print Date: **10/08/2023**

10.6. Hazardous decomposition products

See section 5.3

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Inhaled	Inhalation of dusts, generated by the material, during the course of normal handling, may be harmful. The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.
Ingestion	Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.
Skin Contact	Skin contact with the material may be harmful; systemic effects may result following absorption. This material can cause inflammation of the skin on contact in some persons. The material may accentuate any pre-existing dermatitis condition Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye	This material can cause eye irritation and damage in some persons.
Chronic	Long-term exposure to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

Legend:

1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

Loxapine succinate salt

Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.

Acute Toxicity	✓	Carcinogenicity	×
Skin Irritation/Corrosion	✓	Reproductivity	×
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✓
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	×
Mutagenicity	x	Aspiration Hazard	x

Legend:

★ - Data either not available or does not fill the criteria for classification

— Data available to make classification

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

Legend:

Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation	
	No Data available for all ingredients	

12.4. Mobility in soil

Page 9 of 12

Issue Date: 10/08/2023 Version No: 1.1 Print Date: 10/08/2023 Loxapine succinate salt

Ingredient	Mobility	
	No Data available for all ingredients	

12.5. Results of PBT and vPvB assessment

	Р	В	Т	
Relevant available data	Not Available	Not Available	Not Available	
PBT	×	×	×	
vPvB	×	×	×	
PBT Criteria fulfilled?	PBT Criteria fulfilled?			
vPvB			No	

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

- ▶ Containers may still present a chemical hazard/ danger when empty.
- ▶ Return to supplier for reuse/ recycling if possible.

Product / Packaging disposal

- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.
- ▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.
- ▶ Recycle wherever possible or consult manufacturer for recycling options.
- ► Consult State Land Waste Management Authority for disposal.
- ▶ Bury residue in an authorised landfill.
- ▶ Recycle containers if possible, or dispose of in an authorised landfill.

Waste treatment options Not Available Sewage disposal options Not Available

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Land transport (ADK): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS			
14.1. UN number or ID number	Not Applicable		
14.2. UN proper shipping name	Not Applicable		
14.3. Transport hazard	Class Not Applic	cable	
class(es)	Subsidiary risk Not Applic	cable	
14.4. Packing group	Not Applicable		
14.5. Environmental hazard	Not Applicable		
	Hazard identification (Kemler	Not Applicable	
	Classification code	Not Applicable	
14.6. Special precautions for user	Hazard Label	Not Applicable	
	Special provisions	Not Applicable	
	Limited quantity	Not Applicable	
	Tunnel Restriction Code	Not Applicable	

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable		
14.2. UN proper shipping name	Not Applicable		
14.3. Transport hazard class(es)	ICAO/IATA Class Not Applicable ICAO / IATA Subrisk Not Applicable ERG Code Not Applicable		

Version No: 1.1

Loxapine succinate salt

Issue Date: 10/08/2023 Print Date: 10/08/2023

14.4. Packing group	Not Applicable		
14.5. Environmental hazard	Not Applicable		
	Special provisions	Not Applicable	
	Cargo Only Packing Instructions	Not Applicable	
	Cargo Only Maximum Qty / Pack	Not Applicable	
14.6. Special precautions for user	Passenger and Cargo Packing Instructions	Not Applicable	
usu	Passenger and Cargo Maximum Qty / Pack	Not Applicable	
	Passenger and Cargo Limited Quantity Packing Instructions	Not Applicable	
	Passenger and Cargo Limited Maximum Qty / Pack	Not Applicable	

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable		
14.2. UN proper shipping name	Not Applicable		
14.3. Transport hazard class(es)	IMDG Class Not Applicable IMDG Subrisk Not Applicable		
14.4. Packing group	Not Applicable		
14.5. Environmental hazard	Not Applicable		
14.6. Special precautions for user	EMS Number Not Applicable Special provisions Not Applicable Limited Quantities Not Applicable		

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable		
14.2. UN proper shipping name	Not Applicable		
14.3. Transport hazard class(es)	Not Applicable Not Applicable		
14.4. Packing group	Not Applicable		
14.5. Environmental hazard	Not Applicable		
14.6. Special precautions for user	Classification code Special provisions	Not Applicable Not Applicable	
	Limited quantity	Not Applicable	
	Equipment required	Not Applicable	
	Fire cones number	Not Applicable	

14.7. Maritime transport in bulk according to IMO instruments

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
Loxapine succinate salt	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
Loxapine succinate salt	Not Available

SECTION 15 Regulatory information

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

Loxapine succinate salt is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable -: Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, -2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Information according to 2012/18/EU (Seveso III):

Seveso Category Not Available

Part Number: BIL2251 Page 11 of 12 Issue Date: 10/08/2023

Version No: 1.1 Print Date: 10/08/2023 Loxapine succinate salt

15.2. Chemical safety assessment

For further information please look at the Chemical Safety Assessment and Exposure Scenarios prepared by your Supply Chain if available.

ECHA SUMMARY

Ingredient	CAS number	Index No	ECHA Dossier
Loxapine succinate salt	27833-64-3*	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 3; Eye Irrit. 2	GHS06; Dgr	H301; H319
2	Acute Tox. 3; Eye Irrit. 2	GHS06; Dgr	H301; H319

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

National Inventory Status

National inventory diates		
National Inventory	Status	
Australia - AIIC / Australia Non-Industrial Use	No (Loxapine succinate salt)	
Canada - DSL	No (Loxapine succinate salt)	
Canada - NDSL	No (Loxapine succinate salt)	
China - IECSC	No (Loxapine succinate salt)	
Europe - EINEC / ELINCS / NLP	Yes	
Japan - ENCS	No (Loxapine succinate salt)	
Korea - KECI	No (Loxapine succinate salt)	
New Zealand - NZIoC	No (Loxapine succinate salt)	
Philippines - PICCS	No (Loxapine succinate salt)	
USA - TSCA	No (Loxapine succinate salt)	
Taiwan - TCSI	Yes	
Mexico - INSQ	No (Loxapine succinate salt)	
Vietnam - NCI	No (Loxapine succinate salt)	
Russia - FBEPH	No (Loxapine succinate salt)	
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.	

SECTION 16 Other information

Revision Date	10/08/2023
Initial Date	10/08/2023

Full text Risk and Hazard codes

H301 Toxic if swallowed

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered. For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

Definitions and abbreviations

PC - TWA: Permissible Concentration-Time Weighted Average

PC - STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit₀ IDLH: Immediately Dangerous to Life or Health Concentrations

ES: Exposure Standard

OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit Of Detection

OTV: Odour Threshold Value BCF: BioConcentration Factors

BEI: Biological Exposure Index

AIIC: Australian Inventory of Industrial Chemicals

DSL: Domestic Substances List

Part Number: BIL2251 Page 12 of 12 Issue Date: 10/08/2023 Version No: 1.1 Print Date: 10/08/2023

Loxapine succinate salt

NDSL: Non-Domestic Substances List

IECSC: Inventory of Existing Chemical Substance in China

EINECS: European INventory of Existing Commercial chemical Substances

ELINCS: European List of Notified Chemical Substances

NLP: No-Longer Polymers

ENCS: Existing and New Chemical Substances Inventory

KECI: Korea Existing Chemicals Inventory

NZIoC: New Zealand Inventory of Chemicals

PICCS: Philippine Inventory of Chemicals and Chemical Substances

TSCA: Toxic Substances Control Act TCSI: Taiwan Chemical Substance Inventory INSQ: Inventario Nacional de Sustancias Químicas

NCI: National Chemical Inventory

FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

olucomountum una procedure a	additional of the product of the title disconnection for mixtures about any to regulation (25) 12.22.000 [02.1]	
Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	Classification Procedure	
Acute Toxicity (Oral) Category 4, H302	Expert judgement	
Acute Toxicity (Dermal) Category 4, H312	Expert judgement	
Skin Corrosion/Irritation Category 2, H315	Expert judgement	
Serious Eye Damage/Eye Irritation Category 2, H319	Expert judgement	
Acute Toxicity (Inhalation) Category 4, H332	Expert judgement	
Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3 , H335	Expert judgement	

Powered by AuthorITe, from Chemwatch.