



1. Product and Company Identification

PRODUCT NAME: Xyzal® 24 HR Tablets

Substance name: Levocetirizine dihydrochloride

Supplier:

Sanofi-aventis U.S. LLC
A SANOFI COMPANY
55 Corporate Drive
Bridgewater, NJ 08807

24-Hour Transport Emergency, US (Chemtrec):	(800) 424-9300
24-Hour Transport Emergency, outside US (Chemtrec):	(703) 527-3887
US Customer Service	(800) 207-8049
24-Hour Emergency, sanofi-aventis US:	(908) 981-5550

Product use: Pharmaceutical product. Anti-histamine, an H₁ receptor antagonist indicated for allergic rhinitis.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification of the finished drug product is not required according to OSHA 29 CFR 1900.1200. The following hazard information is provided for the pure drug substance, levocetirizine dihydrochloride:

Classification:

Acute toxicity, oral, Category 4

2.2 Label elements in accordance with 29 CFR 1910.1200

Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200. The following hazard information is provided for the pure drug substance, levocetirizine dihydrochloride:

Signal Word: Warning

Hazard Statement(s): Harmful if swallowed.

Symbol(s): Exclamation mark

Precautionary Statement(s):

- ✓ Prevention: Wash hands thoroughly after handling. Do not eat, drink or smoke while using this product.
- ✓ Response: If swallowed: Call a poison center or doctor if you feel unwell. Rinse mouth.
- ✓ Storage: None.
- ✓ Disposal: Dispose of in accordance with applicable regional, national and local laws and regulations.

2.3 Hazards Not Otherwise Classified (HNOC)

Not classified.

3. Composition/Information on Ingredients

<u>Chemical Name:</u>	<u>Common Name:</u>	<u>CAS #:</u>	<u>Percentage or concentration range</u>
(R)-[2-[4-[(4-chlorophenyl)phenylmethyl]-1-piperazinyl]ethoxy] acetic acid dihydrochloride	Levocetirizine dihydrochloride	130018-87-0	4.854%

4. First Aid Measures

4.1 First aid procedures

Eye contact: In case of contact with dust from broken tablets, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention.

Skin contact: In case of contact with broken tablets, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if irritation develops and persists.

Ingestion: If swallowed, call a poison center or physician immediately. Do NOT induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person. Rinse mouth thoroughly with water.

Inhalation: If dust from broken tablets is inhaled, remove to fresh air. If breathing is difficult, trained personnel should give oxygen. Get medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Somnolence, fatigue, weakness, and urinary retention.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

5. Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media: All means: water, carbon dioxide, foam or dry chemical.

Unsuitable extinguishing media: Strong water jet.

5.2 Specific hazards arising from the chemical

Hazardous combustion products: Carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride.

5.3 Special Protective Equipment and Precautions for Fire-fighters

In case of fire, use full firefighting turnout (bunker) gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire. Move container from fire area if you can do it without risk. Do not scatter spilled material with high-pressure water streams. Dike fire-control water for later disposal.

6. Accidental Release Measures

6.1 Personal precautions and Protective Equipment:

Eye protection, respiratory protective equipment, and suitable protective clothing should be worn if significant dust emissions are generated from broken or crushed tablets.

6.2 Emergency Procedures:

Follow local workplace procedures. Prevent the product from entering the environment. Avoid discharges to sewers, drains, waterways, or onto the ground.

6.3 Methods for containment:

Vacuum or scoop up, moisten any dust with water before collection with a shovel or broom.

6.4 Methods for clean-up:

Place material in suitable container for disposal. Wash the floor with plenty of water, absorb or retain the cleaning water for disposal.

7. Handling and Storage

7.1 Precautions for Safe Handling

Use with adequate ventilation. Avoid breathing dust if tablets are crushed or spilled. Do not get dust in eyes or on skin. Wash hands thoroughly after handling.

7.2 Conditions for Safe Storage

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F). Keep container tightly closed. Protect from light.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit, levocetirizine dihydrochloride: 0.02 mg/m³, 8-hour TWA.

8.2 Appropriate Engineering Controls

Provide adequate ventilation. No other specific controls are needed under normal handling conditions.

8.3 Individual Protection Measures

Eye/face protection: Safety glasses or safety goggles should be worn if there is a potential for dust exposure from broken or crushed tablets.

Skin protection: Suitable protective gloves should be worn if handling the unfinished product or broken or crushed tablets.

Respiratory protection: None normally required. Approved respiratory protection should be worn if there is a potential for exposure to dust from handling operations or from broken or crushed tablets.

General hygiene considerations: Suitable work clothes. Wash hands before breaks and at the end of the work shift.

9. Physical and Chemical Properties

Appearance: White, film-coated, oval-shaped tablets.

Odor: No data available.

Odor threshold: No data available.

pH: No data available.

Melting point/ Freezing point: Not applicable.

Initial boiling point/boiling point range: Not applicable.

Flash point: Not applicable.

Evaporation rate: Not applicable.

Flammability: No data available.

Upper/lower flammability or explosive limits: Not applicable.

Vapor pressure: Not applicable.

Vapor density: Not applicable.

Relative density: No data available.

Solubility: No data available.

Partition coefficient: n-octanol/water: No data available.

Auto-ignition temperature: No data available.

Decomposition temperature: No data available.

Viscosity: No data available.

10. Stability and Reactivity

10.1 Reactivity

Not a reactive material under normal handling conditions.

10.2 Chemical Stability

Stable under normal handling conditions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to Avoid

Keep away from heat, sparks and flames.

10.5 Incompatible materials

Strong oxidizing and reducing agents.

10.6 Hazardous decomposition products

Carbon monoxide, carbon dioxide, oxides of nitrogen, hydrogen chloride.

11. Toxicological Information

The following information is for the active ingredient levocetirizine dihydrochloride unless otherwise noted:

Information on likely routes of exposure: Exposure to the finished product not expected under normal use. Dust from broken or crushed tablets could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: Use of XYZAL® has been associated with somnolence, fatigue, weakness, and urinary retention.

Effects of short-term (acute) exposure: No data available.

Effects of long-term (chronic) exposure: No data available.

Acute toxicity (LD50):

Oral route, rat: 365 - 865 mg/kg (racemate).

Skin corrosion/irritation: No data available.

Serious eye damage/irritation: No data available.

Sensitization: Not a dermal sensitizer based on animal tests.

Specific target organ toxicity – single exposure (STOT-SE): No data available.

Specific target organ toxicity – repeated exposure (STOT-RE): No data available.

Carcinogenicity: No carcinogenicity studies have been performed with levocetirizine. However, evaluation of cetirizine carcinogenicity studies is relevant for determination of the carcinogenic potential of levocetirizine. In a 2-year carcinogenicity study, in rats, cetirizine was not carcinogenic at dietary doses up to 20 mg/kg. In a 2-year carcinogenicity study in mice, cetirizine caused an increased incidence of benign hepatic tumors in males at a dietary dose of 16 mg/kg. No increased incidence of benign tumors was observed at a dietary dose of 4 mg/kg.

Not listed by NTP, not found to be a potential carcinogen by IARC or OSHA.

Titanium dioxide has been classified by IARC as 2B: Possibly carcinogenic to humans. Tumors were observed at high dose in animal studies by inhalation and intratracheal administration. Tumors were not observed by other routes.

Reproductive toxicity and teratogenicity: In rats and rabbits, levocetirizine was not teratogenic at oral doses up to 200 and 120 mg/kg, respectively. In a fertility and general reproductive performance study in mice, cetirizine did not impair fertility at an oral dose of 64 mg/kg.

Mutagenicity: Levocetirizine was not mutagenic in the Ames test, and not clastogenic in the human lymphocyte assay, the mouse lymphoma assay, and in vivo micronucleus test in mice.

Aspiration hazard: Not applicable.

12. Ecological Information

The following information is for the active ingredient levocetirizine dihydrochloride unless otherwise noted:

12.1. Ecotoxicity

No data available.

12.2. Persistence and degradability

Biological degradability: No data available.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

No data available.

13. Disposal Considerations

13.1 Disposal of product waste

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

13.2 Disposal of packaging waste

Dispose of in a safe manner in accordance with federal, state and local environmental regulations. Empty packages, containers or liners may contain product residue.

14. Transport Information

14.1 Basic shipping information, finished product

U.S. DOT	Not a regulated material.
ICAO/IATA	Not a regulated material.
IMDG	Not a regulated material.

15. Regulatory Information

US Regulations

CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3): Not listed.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130): Not listed.

SARA Title III:

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): Not listed.

Section 313 Toxic Release Inventory (40 CFR 372): Not listed.

State Regulations

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): Not listed.

Massachusetts Right-To-Know List: Not listed.

New Jersey Right-To-Know List: Not listed.

Pennsylvania Right-To-Know List: Not listed.

16. Other Information

Other Information: The information contained herein is based upon data considered true and accurate. Sanofi-aventis U.S. LLC. makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Abbreviations and Acronyms

CAS: Chemical Abstracts Service

DOT: U.S. Department of Transportation

EST: eastern standard time (U.S.)

IATA: International Air Transport Association

IMDG: International Maritime Dangerous Goods Code

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

OEL: Occupational Exposure Limit

PPE: Personal Protection Equipment

SDS: Safety Data Sheet

STEL: Short-term exposure limit

TWA: Time-weighted average

U.S.: United States

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First version.