1. Product and Company Identification

PRODUCT NAME: ELITEK® (rasburicase) for intravenous infusion
1.5 mg, 7.5 mg vial with diluent ampule

Substance name: Rasburicase

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.

2. Hazards Identification

2.1 Classification in accordance with 29 CFR 1910.1200

Classification:
Respiratory sensitization, Category 1B
Skin sensitization, Category 1B

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 information is provided for the drug product:

Signal Word: Danger

Hazard Statement(s): May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Symbol(s): Health hazard

Precautionary Statement(s):

- Prevention: Avoid breathing dust. In case of inadequate ventilation, wear respiratory protection. Wear protective gloves. Contaminated work clothing must not be allowed out of the workplace.

- Response: If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: call a doctor.
  If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.

- Storage: No phrases specified. See Section 7 for storage information.

- Disposal: Dispose of in accordance with applicable regional, national and local laws and regulations.

2.3 Hazards Not Otherwise Classified (HNOC)

Not classified.

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3. Composition/Information on Ingredients

Powder:

Chemical Name:	**Common Name:**	**CAS #:**	**Percentage or concentration range**
Oxidase, urate	Rasburicase	134774-45-1	3.5 %

Inactive ingredients: Mannitol, L-alanine, dibasic sodium phosphate.

Diluent: Water for injection, Poloxamer 188.

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4. First Aid Measures

4.1 First aid procedures

Eye contact: In case of contact with product, 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: Wash with plenty of water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.

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 breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: call a doctor.

4.2 Most important symptoms and effects, both acute and delayed

The active ingredient rasburicase is a protein (recombinant urate-oxidase). Proteins have been associated with acute allergic reactions including anaphylaxis. Those with a history of allergies and/or asthma are at most risk.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically and supportively.

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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 sulfur and nitrogen.

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 (see Section 8).

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:

Absorb spilled liquid with a suitable inert material, place in suitable container for disposal and mop area.

6.4 Methods for clean-up:

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

Product should be used in a controlled work area. Use with adequate ventilation. Avoid contact with eyes, skin and clothing. Place a disposable absorbent pad under the product preparation area. Do not eat, smoke or drink while handling product. Wash thoroughly after handling.

7.2 Conditions for Safe Storage

The lyophilized drug product and the diluent for reconstitution should be stored at 2–8°C (36–46°F). Do not freeze. Protect from light.

8. Exposure Controls/Personal Protection

8.1 Exposure Limits

Sanofi-aventis occupational exposure limit: 0.006 mg/m^3, 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 eye contact with the product.

Skin protection: Use approved chemotherapy gloves if skin contact with the product is possible; double gloves are recommended. After product preparation, the outer gloves can be removed and discarded in an approved waste container and the procedure completed. Gloves should be changed when torn, punctured or contaminated. Use of a protective or disposable gown or laboratory coat is recommended if there exists a potential for contact with the product.

Respiratory protection: None normally required for routine handling of the product. However, approved respiratory protection should be worn if there is a potential for exposure to the product. A respiratory protection program that meets OSHA 29 CFR 1910.134 and ANSI Z88.2 must be followed whenever workplace conditions warrant respirator usage.

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

Clinical Setting: Health care workers who prepare or administer hazardous drugs or who work in areas where these drugs are used should follow specific workplace handling guidelines in order to prevent exposure to these agents in the air or on work surfaces, clothing, medical equipment, or in patient urine or feces.

9. Physical and Chemical Properties

Appearance: White to off-white powder.
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: No data available.
Evaporation rate: Not applicable.
Flammability: No data available.
Upper/lower flammability or explosive limits: No data available.
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.

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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 sulfur and nitrogen.

11. Toxicological Information

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

Information on likely routes of exposure: Not expected under normal handling conditions. Unintended spills or releases could result in exposure to eyes, skin and respiratory tract.

Symptoms related to the physical, chemical and toxicological characteristics: Fever, nausea, vomiting, headache, abdominal pains, and diarrhea.

Effects of short-term (acute) exposure: Fever, nausea, vomiting, headache, abdominal pains, diarrhea. Hypotensive effect. Risk of methemoglobinemia

Effects of long-term (chronic) exposure: No treatment-related toxic effects were reported in 4 week IV animal studies with doses as high as 3 mg/kg/day.

Acute toxicity (LD50):
Oral route, rat: No data available. As a protein, not expected to be orally toxic.

Skin corrosion/irritation: Not a skin irritant.

Serious eye damage/irritation: Not an eye irritant.

Sensitization: The active ingredient rasburicase is a protein (recombinant urate-oxidase). Proteins have been associated with acute allergic reactions including anaphylaxis. Those with a history of allergies and/or asthma are at most risk. In clinical studies, anaphylaxis was reported in <1% patients receiving Elitek®.

Specific target organ toxicity – single exposure (STOT-SE): A single dose IV study in rats and mice showed no adverse clinical signs of toxicity or changes in body weight at a 15 mg/kg dose.

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

Carcinogenicity: Carcinogenicity studies in animals to evaluate tumorigenic potential of rasburicase have not been performed.

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

Reproductive toxicity and teratogenicity: Pregnant rabbits dosed daily with 10 to 100 times the human dose of rasburicase during the period of organogenesis (gestation day 6 – 19) exhibited teratogenic effects, clinical signs of maternal toxicity including weight loss and mortality, decreases in uterine weights and viable fetuses, and increased fetal resorptions, post-implantation losses and abortions. Teratogenic effects included multiple heart and great vessel malformations at all dose levels. Multiple heart and great vessel malformations were also observed in offspring of pregnant rats treated with approximately 250 times the recommended human dose of rasburicase.

Mutagenicity: Rasburicase was not mutagenic in the Ames, unscheduled DNA synthesis, chromosome analysis, mouse lymphoma, and micronucleus tests.

Aspiration hazard: No data available.

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12. Ecological Information

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

12.1. Ecotoxicity

No data available.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Other adverse effects

Rasburicase is a naturally occurring protein which is expected to readily degrade in the environment and have no significant environmental effects.

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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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