1. IDENTIFICATION OF MATERIAL AND SUPPLIER

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Malvern, PA 19355
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24-Hour Transport Emergency: (800) 424-9300 (CHEMTREC) in US
(703) 527-3887 (CHEMTREC) outside US

Product: Aflibercept Formulation: 25 mg/mL
Synonyms: AVE0005, VEGF Trap
Intended Use: Treatment of cancer

2. HAZARDS IDENTIFICATION

Only Authorized and Trained Personnel should handle this material.

Sanofi-aventis Occupational Exposure Band for active ingredient: OEB 3 (10 – 100 mcg/m3)

Hazard Summary
This is a substance from an experimental program, and there is insufficient information available to assess the hazards fully.

Signs and Symptoms of Overexposure
The effects of overexposure are not known. No cases of overdose have been reported to date.

Potential Health Effects
See Section 11 for more information.

Potential Developmental Toxicity Effects
No information is known on possible hazards to fetus or pregnant subjects. Based on a compound with similar mechanism of action, embryoletality and teratogenicity could be expected.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: AVE 0005
CAS Number: 862111-31-8

Inactive Ingredients	CAS Number
Sucrose	57-50-1
Sodium chloride	7647-14-5
Sodium citrate dihydrate	6132-04-3
Polysorbate 20	9005-64-5
Sodium phosphate dibasic heptahydrate	7782-85-6
Sodium phosphate monobasic monohydrate	10049-21-5
Water for injection	7732-18-5

4. FIRST AID MEASURES

Eye Contact
In case of contact with the product solution, flush eyes with water for at least 15 minutes. Seek medical attention immediately.

Skin Contact
If the formulation comes in contact with skin and clothing, remove contaminated clothing and wash thoroughly with running water for at least 15 minutes. Use soap if available. Seek medical attention if irritation develops.

Ingestion
Seek medical attention immediately. Never give anything by mouth to an unconscious person.

Inhalation
The formulation could be inhaled if liquid is aerosolized. If inhaled, remove to fresh air. Seek medical attention immediately.

Note To Physicians
The effects of overexposure are not known. Provide supportive treatment.

5. FIRE FIGHTING MEASURES

This product is mainly composed of water and therefore presents no fire or explosion hazard.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions
Necessary personal protective equipment should be worn when cleaning up a spill (see Section 8).

Small Spills
Wipe up spill with absorbent material and place in an impervious container. Wash the contaminated area with an undiluted household or commercial sodium hypochlorite (bleach) solution. Carefully place the waste in a labeled receptacle for safe disposal as a contaminated waste. Wash skin thoroughly after handling.

7. HANDLING AND STORAGE

Handling
To minimize hazards from accidental breakage or spills of containers and to simplify clean-up, store and transport within secondary containers, pans or trays or apply site-specific precautions. Use disposable protective coatings and/or barrier sheeting in use areas where possibility of spillage exists to simplify cleanup.

Storage
Label all containers with hazard information (see section 15). Keep containers tightly closed. Store at 2^0 to 8^0 C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

GENERAL CONTROLS AND PROTECTION FOR LABORATORY AND PRODUCTION

A workplace risk assessment must be carried out in order to determine the correct engineering control measures and personal protective equipment.

Exposure Limit Values
Sanofi-aventis Exposure Limit Band: OEB 3: 10 – 100 mcg/m^3

Respiratory Protection
Respiratory protective equipment can only be used in place of engineering controls as a temporary measure in emergency situations or when control by other means is not feasible. Respiratory protection must be used when there is risk of airborne exposure above recommended exposure levels. All respiratory protection should be in compliance with the regulations applicable to the country of use.

Hand protection
All vials should be handled wearing impervious gloves.

Eye Protection
Avoid eye contact. Use safety goggles for eye protection if there is risk of eye contact.

Skin Protection
If there is a risk of skin contamination, impervious clothing should be worn to protect exposed skin.
All personnel should wash thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
AVE0005 formulation is supplied as a colorless to pale yellow liquid in glass vials.

Unless otherwise stated, data relate to the active drug substance AVE 0005:

Basic Physical Properties
Molecular Formula: Recombinant human protein.
Molecular Weight: 115 kDa
Melting Point: Not applicable.
Solubility in water at 25 °C: > 100 mg/mL.
Density (formulation): 1.081 g/cm3.
pH (formulation): 6.0

10. STABILITY AND REACTIVITY

Stability
Stable. For storage conditions, see Section 7.

Conditions to Avoid
Freezing due to risk of cracked vials.

Incompatible Materials
Incompatibility of this material has not been investigated.

Hazardous Decomposition Products
May emit irritating fumes when heated to decomposition: carbon monoxide, carbon dioxide, urea and ammonia.

Possibility of Hazardous Reactions
Will not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY: Acute toxicity by single intravenous infusion: NOAEL considered to be 150 mg/kg in rats.

EFFECTS OF REPEATED EXPOSURE: Repeat dose studies in animals by the SC and/or IV routes have shown the kidney, growth plates and ovary to be the primary target organs.

POTENTIAL ADVERSE EVENTS IN THE CLINIC: Hypersensitivity, hypertension, proteinuria, nausea, vomiting, dehydration, headache, epistaxis, renal dysfunction, and hoarseness.

DEVELOPMENTAL TOXICITY: No information is known on possible hazards to fetus or pregnant subjects. Based on a compound with similar mechanism of action, embryoletality and teratogenicity could be expected.

12. ECOLOGICAL INFORMATION

Not determined.

13. DISPOSAL CONSIDERATIONS

Dispose of in accordance with local, state and federal regulations. Wastes should be double contained (e.g. double sealed bags) and labeled indicating contents to ensure safe handling and disposal. Incineration of waste product is recommended.

14. TRANSPORT INFORMATION

ADR, ICAO/IATA and US DOT: Not regulated for transport.

US DOT Reportable Quantity: Not Assigned.

15. REGULATORY INFORMATION

OSHA hazards according to 29 CFR 1910.1200: Not determined.

This product does not contain any ingredients which are regulated on the US EPA List of Toxic Chemicals (40 CFR Part 372) and is therefore not subject to release reporting under section 313 of EPCRA.

EU Labeling: The product is classified and labeled in accordance with EC Directives.

Hazard symbols: none.

R Phrases: none.

S Phrases:
S7: Keep container tightly closed.
S23: Do not breathe gas/fumes/vapor/spray.
S24/25: Avoid contact with skin and eyes.

16. OTHER INFORMATION

Hazard label for this substance should state: "sanofi-aventis OEB 3 for research and development purposes only by trained personnel".

This material safety data sheet is intended for personnel handling of this material in research, development and clinical manufacturing. It does not address the therapeutic use of this product. Therapeutic agents are intended for use under direction of a physician. As a general precaution, personnel who handle drug product should avoid contact (ingestion, inhalation, skin and eye) with this substance.

Report any unexpected adverse events immediately.

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