SDS: AK-FLUOR® (fluorescein injection, USP) 10%
AK-FLUOR® (fluorescein injection, USP) 25%

SAFETY DATA SHEET

1. Identification

Product Identifier: AK-FLUOR® (fluorescein injection, USP) 10%
AK-FLUOR® (fluorescein injection, USP) 25%

Synonyms: AK-FLUOR®; Fluorescein Injection; Fluorescein Sodium; Acid Yellow 73; Uranine; FD&C yellow 8; CI acid yellow 73; Spiro[isobenzofuran-1(3H), 9'-[9H]xanthen]-3-one, 3',6'-dihydroxy-, disodium salt; C.I. 45350.

National Drug Code (NDC): 17478-253-10
17478-250-20

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product. Persons developing hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Spiro[isobenzofuran-1(3H), 9'-[9H]xanthen]-3-one, 3',6'-dihydroxy-, disodium saltmonohydrochloride (1:1)	518-47-8	Fluorescein Sodium; Acid Yellow 73; Uranine; FD&C Yellow 8; CI Acid Yellow 73; C.I. 45350	$C_{20}H_{10}O_5 \cdot Na_2$	376.27	10% and 25%

*The formula also contains Water for Injection. Sodium Hydroxide and/or Hydrochloric Acid mat be used to adjust pH (8.3 – 9.8).

4. First Aid Measures

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: No data available.

Medical Conditions Aggravated by Exposure: May aggravate allergies and bronchial asthma.

Notes to Physician: Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides and sodium oxides.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment/ Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Fluorescein Sodium	No data available.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color: Liquid/Red-orange.
Odor: No data available.
Odor Threshold: No data available.
pH: 8.3 – 9.8.
Melting Point: No data available.
Freezing Point: No data available.
Boiling Point: No data available.
Flash Point: No data available.
Evaporation Rate: No data available.
Flammability (solid, gas): No data available.
Flammability Limit - Lower: No data available.
Flammability Limit - Upper: No data available.
Vapor Pressure: No data available.
Vapor Density: No data available.
Relative Density: No data available.
Solubility(ies): Miscible in water.
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

Reactivity: No data available.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.

Incompatible Materials: Oxidizers, acids, bases.

Hazardous Decomposition Products: No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion: May be harmful if swallowed.

Skin Contact: May be harmful if absorbed through the skin. May cause yellowish discoloration. May cause irritation.

Eye Contact: May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: Hives, itching, bronchospasm, and anaphylaxis have been reported. Syncope and hypotension may occur. Cardiac arrest, basilar artery ischemia, severe shock and death may occur rarely.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Fluorescein Sodium	Rat	Oral	LD_{50}	6,721 mg/kg

Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.
Dermal Irritation: No data available.
Eye Irritation: No data available.
Sensitization: No data available.

Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	Based on clinical use, possible target organs include the central and peripheral nervous systems and the cardiovascular system.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
Mutagenicity:	No data available.
Aspiration Hazard:	No data available.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Not listed.
Pennsylvania:	Not listed.
California Proposition 65:	Not listed.

16. Other Information

Not made with natural rubber latex.

NFPA Rating:		**HMIS Classification:**	
Health:	0	Health:	0
Flammability:	0	Flammability:	0
Reactivity:	0	Physical Hazard:	0

Revision Date: 06/15/2015

Revision Number: 2

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.

SDS: Akten®
(lidocaine hydrochloride ophthalmic gel) 3.5%

SAFETY DATA SHEET

1. Identification

Product Identifier: Akten® (lidocaine hydrochloride ophthalmic gel) 3.5%

Synonyms: Akten®; Lidocaine Hydrochloride Ophthalmic Gel; Lidocaine Hydrochloride; Lidocaine; Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxylidide, 2-(diethylamino)-hydrochloride; 2-Diethylamino-N-(2,6-dimethylphenyl) acetamide hydrochloride; Lignocaine; Xylocaine.

National Drug Code (NDC): 17478-792-01

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.

Health Hazards: Specific target organ toxicity – single exposure (narcotic effects) Category 3

Symbol(s):

Signal Word: Warning.

Hazard Statement(s):

H336 May cause drowsiness or dizziness.

Precautionary Statement(s):

P261 Do not breathe mist/vapours/spray.

P271 Use in a well ventilated area.

P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P312 Call a POISON CENTER or doctor/physician if you feel unwell.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/provincial/federal regulations.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: May be harmful if swallowed, in contact with the skin or inhaled. Lidocaine is well absorbed through mucous membranes, the gastrointestinal tract and damaged skin. Abdominal discomfort may occur after ingestion. Because Akten® is a local anesthetic, contact with the eyes or skin may cause temporary loss of feeling or sensation. May cause general hypotension, bradycardia, central nervous system depression, dizziness, blurred vision, tremors, drowsiness, convulsions, and/or unconsciousness See product label and/or product insert for additional information.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxylidide, 2-(diethylamino)-, hydrochloride	73-78-9	Lidocaine Hydrochloride; 2-Diethylamino-N-(2,6-dimethylphenyl)acetamide hydrochloride; Lidocaine; Lignocaine; Xylocaine	$C_{14}H_{22}N_2O$• HCl	270.8	3.5%

*The formula also contains Hypromellose, Sodium Chloride, and Purified Water. The pH may be adjusted to 5.5 to 7.5 with Sodium Hydroxide and/or Hydrochloric Acid.

4. First Aid Measures

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If

	irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Abdominal discomfort if ingested; eye irritation, skin irritation, loss of feeling/sensation; respiratory irritation if inhaled. May cause hypersensitivity.
Medical Conditions Aggravated by Exposure:	Pre-existing hypersensitivity to lidocaine or related amide-type anesthetics. Pre-existing nervous system, Cardiovascular or hepatic ailments.
Notes to Physician:	None.

5. Firefighting Measures

Suitable Extinguishing Media:	Use extinguishing media for type of surrounding fire.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:	These products include carbon oxides, nitrogen oxides and hydrogen chloride.
Other Specific Hazards:	Closed containers may explode from the heat of fire.
Special Protective Equipment/ Precautions for Firefighters:	Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from oxidizers, acids, bases and water reactive materials.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Lidocaine Hydrochloride	Not established.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Semi-solid/Clear.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	5.5 to 7.5.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Miscible in water.
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

Reactivity:	Reactive with water reactive materials.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Oxidizers, acids, bases and water reactive materials.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May be harmful if absorbed through the skin. May cause skin irritation.
Eye Contact:	May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Lidocaine Hydrochloride	Mouse	Oral	LD_{50}	220 – 292 mg/kg
Lidocaine Hydrochloride	Rat	Oral	LD_{50}	317 mg/kg

Acute Toxicity – Dermal: No data available.
Acute Toxicity – Inhalation: No data available.
Corrosivity: No data available.
Dermal Irritation: No data available.
Eye Irritation: No data available.
Sensitization: No data available.
Toxicokinetics/Metabolism: No data available.
Target Organ Effects: No data available.
Reproductive Effects: No data available.
Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.
Aspiration Hazard: No data available.

12. Ecological Information

Ecotoxicity

Aquatic: No data available.
Terrestrial: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Lidocaine hydrochloride.
Pennsylvania:	Lidocaine hydrochloride.
California Proposition 65:	Not listed.

16. Other Information

Not made with natural rubber latex.

NFPA Rating:

Health:	2
Flammability:	0
Reactivity:	0

Revision Date: 06/15/2015

Revision Number: 1

Disclaimer: This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.

Safety Data Sheet

AVASTIN® Vials 400 mg/16 ml

according to Regulation (EU) nr. 1907/2006

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

1.1. Product identifier

Product name	AVASTIN® Vials 400 mg/16 ml
Product code	SAP-10062575

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

Use	- formulated pharmaceutical active substance (antineoplastic)

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: F. Hoffmann-La Roche AG Postfach CH-4070 Basel Switzerland Phone +41-61/688 54 80 Fax +41-61/681 72 76 E-Mail info.sds@roche.com	Local representation:

1.4. Emergency telephone number

Emergency telephone number	Phone	+41-61/688 54 80

SECTION 2: Hazards identification

2.1. / 2.2. Classification of the substance or mixture / Label elements

GHS Classification	no classification and labelling according to CLP (EC Regulation 1272/2008)

2.3. Other hazards

Note	- no information available

SECTION 3: Composition/information on ingredients

Characterization	bevacizumab and other inactive ingredients

Ingredient	Concentration	GHS-Classification (pure ingredient)
Bevacizumab 216974-75-3	25 mg/ml	
Trehalose dihydrate 6138-23-4	60 mg/ml	
Disodium hydrogen phosphate 7558-79-4	1.2 mg/ml	
Polysorbate 20 9005-64-5 01-2119971749-17	0.4 mg/ml	
Sodium dihydrogen phosphate 10049-21-5 01-2119489796-13	5.8 mg/ml	
water solution suitable for injection		

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse immediately with tap water for at least 20 minutes - open eyelids forcibly
Skin contact	- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	- remove the casualty to fresh air and keep him/her calm - in the event of symptoms get medical treatment

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

Note	- no information available

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

Note to physician	- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide - adapt extinguishing media to surrounding fire conditions

5.2. Special hazards arising from the substance or mixture

Specific hazards	-	no particular hazards known

5.3. Advice for firefighters

Protection of fire-fighters	-	precipitate gases/vapours/mists with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	-	no special precautions required

6.2. Environmental precautions

Environmental protection	-	no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	-	collect spilled solutions with inert adsorbent and hand over to waste removal

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials	-	aluminium, glass, enamel, stainless steel
Note	-	do not shake solution

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	-	2 - 8 °C - do not freeze - protected from light
Validity	-	2 to 8 °C, in the unopened original container, see "best use before" date stated on the label
Packaging materials	-	vials

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air	-	IOEL (Internal Occupational Exposure Limit): 0.05 mg/m3	*1

8.2. Exposure controls

Respiratory protection	-	respiratory protection not necessary during normal operations
Hand protection	-	protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection	-	safety glasses

1 referring to: Bevacizumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Colour	clear to slightly opalescent colourless to pale brown
Form	aqueous solution sterile liquid
Density	1.031 g/ml
pH value	5.9 to 6.3
Boiling temperature	~ 100 °C

9.2. Other information

Note	-	no information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Note	-	no information available

10.2. Chemical stability

Stability	-	does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution

10.3. Possibility of hazardous reactions

Note	-	no information available

10.4. Conditions to avoid

Note	-	no information available

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- not bioavailable by oral administration	*1
	- NOEL 50 mg/kg (i.v., cynomolgus monkey)	*1
Chronic toxicity	- LOAEL 2 mg/kg/w (i.v., cynomolgus monkey; 26 weeks)	*1
Local effects	- no information available	
Sensitization	- no information available	
Mutagenicity	- no information available	
Carcinogenicity	- no information available	
Reproductive toxicity	- teratogenic and embryotoxic (i.v., rabbit)	*1
	- critical exposure in human after parenteral administration only	*1
	- parenteral administration to pregnant women can cause fetal harm	*1
STOT-single exposure	- no information available	
STOT-repeated exposure	- no information available	
Aspiration hazard	- no information available	
Note	- humanised monoclonal antibody which binds to and inactivates the vascular endothelial growth factor (VEGF)	*1
	- therapeutic dose: 5 mg/kg/2w	*1
	- elimination half-life: 20 d	*1
	- side effect(s) during therapy: tendency to bleeding, thrombophlebitis, proteinuria	*1

1 referring to: Bevacizumab

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

- no adverse influence on substrate biodegradation (activated sludge)
  concentration (14 d) 100 mg active substance/l
  (Manometric Respirometry Test, OECD No. 301 F)
- barely toxic for algae (nominal concentration = 100 mg/l), growth inhibition possibly due to turbidity caused by test substance (Scenedesmus (=Desmodesmus) subspicatus)
  ErC_{50} (72 h) > 100 mg active substance/l
  EbC_{50} (72 h) ~ 100 mg active substance/l
  NOEC (72 h) < 100 mg active substance/l
  (OECD No. 201)
- barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l) (Daphnia magna)
  EC_{50} (48 h) > 100 mg active substance/l
  NOEC (48 h) 100 mg active substance/l
  (OECD No. 202)

12.2. Persistence and degradability

Ready biodegradability

- readily biodegradable
  78 % BOD/ThOD, 28 d
  96 % DOC, 28 d
  (Manometric Respirometry Test, OECD No. 301 F)

12.3. Bioaccumulative potential

Note

- no information available

12.4. Mobility in soil

Note

- no information available

12.5. Results of PBT and vPvB assessment

Note

- no information available

12.6. Other adverse effects

Note

- no information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues

- observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note	-	not classified as Dangerous Good according to the Dangerous Goods Regulations

SECTION 15: Regulatory information

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

Water hazard class (Germany)	not hazardous for water (own classification according to directive VwVwS of 17.05.1999)

SECTION 16: Other information

Edition documentation	-	changes from previous version in sections 1, 3

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.

Safety Data Sheet
acc. to OSHA HCS (29 CFR 1910.1200)

Printing date 05/20/2015 Reviewed on 05/20/2015

1 Identification

· **Product identifier**

· **Trade name: BETADINE® 5% Sterile Ophthalmic Prep Solution**

· **Article number:**

· **Recommended use and restriction on use**
· **Recommended use:** Surgical Product
· **Restrictions on use:** Contact manufacturer.

· **Details of the supplier of the Safety Data Sheet**
· **Manufacturer/Supplier:**
Alcon Laboratories, Inc.
6201 S. Freeway
Fort Worth, Texas 76134 USA
Tel 1-817-551-4444
E-mail: safety.datasheets@alcon.com

2 Hazard(s) identification

· **Classification of the substance or mixture**

GHS07

Eye Irrit. 2A H319 Causes serious eye irritation.
· **Additional information:**
0 percent of the mixture consists of ingredient(s) of unknown toxicity.
There are no other hazards not otherwise classified that have been identified.

· **Label elements**
· **GHS label elements**
The product is not classified as hazardous according to OSHA GHS regulations within the United States.
The product is classified and labeled according to the Globally Harmonized System (GHS).
· **Hazard pictograms**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**
povidone-iodine
· **Hazard statements**
H319 Causes serious eye irritation.
· **Precautionary statements**

P264	Wash thoroughly after handling.
P280	Wear eye protection / face protection.
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.

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Safety Data Sheet
acc. to OSHA HCS (29 CFR 1910.1200)

Printing date 05/20/2015 Reviewed on 05/20/2015

Trade name: BETADINE® 5% Sterile Ophthalmic Prep Solution

(Contd. of page 1)

· **Hazard description:**
· **WHMIS-symbols:** Not hazardous under WHMIS.
· **Classification system:**
· **NFPA ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

25655-41-8	povidone-iodine	Eye Dam. 1, H318 Skin Irrit. 2, H315	5.0%

· **Additional information:**
For the listed ingredients, the identity and exact percentages are being withheld as a trade secret.

4 First-aid measures

· **Description of first aid measures**
· **General information:** No special measures required.
· **After inhalation:** Supply fresh air; consult doctor in case of complaints.
· **After skin contact:**
Generally the product does not irritate the skin.
Wash with soap and water.
If skin irritation is experienced, consult a doctor.
· **After eye contact:**
Product is indiciated for ocular usage. In case of persistent or severe irritation after usage, discontinue use and seek medical advice.
· **After swallowing:**
Rinse out mouth and then drink plenty of water.
Do not induce vomiting; immediately call for medical help.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed** Irritant to eyes.
· **Danger** No further relevant information available.

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Safety Data Sheet
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Printing date 05/20/2015 Reviewed on 05/20/2015

Trade name: BETADINE® 5% Sterile Ophthalmic Prep Solution

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· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
· **For safety reasons unsuitable extinguishing agents:** None.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:**
Wear self-contained respiratory protective device.
Wear fully protective suit.
· **Additional information** No further relevant information available.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation.
For large spills, wear protective clothing.
· **Environmental precautions:** No special measures required.
· **Methods and material for containment and cleaning up:**
Absorb liquid components with liquid-binding material.
Dispose contaminated material as waste according to item 13.
· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling:**
· **Precautions for safe handling** No special measures required.
· **Information about protection against explosions and fires:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
Avoid storage near extreme heat, ignition sources or open flame.
· **Information about storage in one common storage facility:** Store away from foodstuffs.
· **Further information about storage conditions:** Keep receptacle tightly sealed.
· **Specific end use(s)** No further relevant information available.

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Safety Data Sheet
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Printing date 05/20/2015 Reviewed on 05/20/2015

Trade name: BETADINE® 5% Sterile Ophthalmic Prep Solution

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8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**
· **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
Keep away from foodstuffs, beverages and feed.
· **Engineering controls:** No further relevant information available.
· **Breathing equipment:** Not required under normal conditions of use.
· **Protection of hands:**
Gloves not required under normal conditions of use.
Wear protective gloves to handle contents of damaged or leaking units.
· **Material of gloves** Rubber gloves
· **Eye protection:**
Not required for normal handling. Wear protective eyewear while handling damaged or leaking product.
· **Body protection:** Not required under normal conditions of use.
· **Limitation and supervision of exposure into the environment** No special requirements.
· **Risk management measures** No special requirements.

9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**

Form:	Liquid
Color:	Dark brown
· **Odor:**	Odorless
· **Odor threshold:**	Not determined.
· **pH-value at 20 °C (68 °F):**	5.0 - 6.0
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· **Flash point:**	The product is not flammable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Auto-ignition temperature:**	Not determined.
· **Decomposition temperature:**	Not determined.
· **Auto igniting:**	Product is not self-igniting.

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· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**
Lower: Not determined.
Upper: Not determined.

· **Vapor pressure:** Not determined.

· **Density:** Not determined.
· **Relative density** Not determined.
· **Vapour density** Not determined.
· **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**
Water: Fully miscible.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**
Dynamic: Not determined.
Kinematic: Not determined.

· **Solvent content:**
Organic solvents: Not determined.
Water: Not determined.
· **Other information** No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** Possible in traces.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **LD/LC50 values that are relevant for classification:** None.
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Subacute to chronic toxicity:** No further relevant information available.

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· **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Probable Routes of Exposure**
Inhalation.
Ingestion.
Eye contact.
Skin contact.
· **Acute effects (acute toxicity, irritation and corrosivity):** Irritating to eyes.
· **Repeated Dose Toxicity:** No further relevant information available.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behavior in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation:**
The user of this material has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state and federal laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes. Residual materials should be treated as hazardous.

· **Uncleaned packagings:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agent:** Water, if necessary with cleansing agents.

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Trade name: BETADINE® 5% Sterile Ophthalmic Prep Solution

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14 Transport information

· **UN-Number**
· **DOT, ADR, ADN, IMDG, IATA** Not Regulated
· **UN proper shipping name**
· **DOT, ADR, ADN, IMDG, IATA** Not Regulated
· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**
· **Class** Not Regulated
· **Packing group**
· **DOT, ADR, IMDG, IATA** Not Regulated
· **Environmental hazards:**
· **Marine pollutant:** No
· **Special precautions for user** Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
· **UN "Model Regulation":** -

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **United States (USA)**
· **SARA**

· **Section 355 (extremely hazardous substances):**
None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**
None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**
All ingredients are listed.

· **Proposition 65 (California)**

· **Chemicals known to cause cancer:**
None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**
None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**
None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**
None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

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Trade name: BETADINE® 5% Sterile Ophthalmic Prep Solution

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· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**
None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **State Right to Know Listings**
None of the ingredients is listed.

· **Canadian substance listings:**

· **Canadian Domestic Substances List (DSL)**
All ingredients are listed.

· **Canadian Ingredient Disclosure list (limit 0.1%)**
None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 1%)**
None of the ingredients is listed.

· **Other regulations, limitations and prohibitive regulations**
This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 05/20/2015 / -

· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
ACGIH: American Conference of Governmental Industrial Hygienists
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

· **Sources**
SDS Prepared by:
ChemTel Inc.
1305 North Florida Avenue

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Safety Data Sheet
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Printing date 05/20/2015 Reviewed on 05/20/2015

Trade name: BETADINE® 5% Sterile Ophthalmic Prep Solution

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Tampa, Florida USA 33602-2902
Toll Free North America 1-888-255-3924 Intl. +01 813-248-0573
Website: www.chemtelinc.com

1. IDENTIFICATION OF MATERIAL AND SUPPLIER

Sanofi-aventis US Inc.
Scientific & Medical Affairs,
9 Great Valley Parkway, P.O. Box 3026
Malvern, PA 19355
Emergency Telephone: (610) 889-8911
For Technical Information call (908) 231-4829

Sanofi-aventis US Inc.
Scientific & Medical Affairs,
1041 Route 202-206, PO Box 6800
Bridgewater, NJ 08807-0800
Emergency Telephone: (908) 231-2666
For Technical Information call (908) 231-4829

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.

Disclaimer of Expressed and Implied Warranties
This information is furnished without warranty, representation or license of any kind, except that it is accurate to the best of sanofi-aventis Inc.'s knowledge or obtained from sources believed to be accurate. Sanofi-aventis Inc. does not assume any legal responsibility for use or reliance upon same.

SAFETY DATA SHEET

1. Identification

Product identifier **Indocyanine Green**

Other means of identification

Catalog number 1340009

Chemical name 1H-Benz[e]indolium, 2-[7-[1,3-dihydro-1,1-dimethyl-3-(4-sulfobutyl)-2H-benz[e]indol-2-ylidene]-1,3,5- heptatrienyl]-1,1-dimethyl-3-(4-sulfobutyl)-, hydroxide, inner salt, sodium salt

Synonym(s) ICG

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
US

Telephone RS Technical Services 301-816-8129

Website www.usp.org

E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & Canada 1-800-424-9300
CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity, single exposure	Category 3 respiratory tract irritation

OSHA hazard(s) Not classified.

Label elements

Signal word Warning

Hazard statement Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.

Precautionary statement

Prevention Use only outdoors or in a well-ventilated area. Wash thoroughly after handling. Wear protective gloves. Wear eye/face protection.

Response If inhaled: Remove person to fresh air and keep comfortable for breathing. Call a poison center/doctor if you feel unwell. If in eyes: 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. If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse.

Storage Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Indocyanine Green	ICG	3599-32-4	100

4. First-aid measures

Inhalation Move to fresh air. Call a POISON CENTER or doctor/physician if you feel unwell.

Skin contact Remove contaminated clothing. Wash off with soap and plenty of water. If skin irritation occurs: Get medical advice/attention.

Eye contact Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.

Most important symptoms/effects, acute and delayed Irritation of eyes, skin, and mucous membranes.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically.

General information Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire-fighting equipment/instructions Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines No exposure standards allocated.

Appropriate engineering controls Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Olive-brown, dark-green, blue-green, dark-blue, or black powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless or slight odor.
Odor threshold	Not available.
pH	6 0.5% solution
Melting point/freezing point	469.4 - 473 °F (243 - 245 °C) (decomposes >200 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C Negligible.
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Soluble.
Partition coefficient (n-octanol/water)	-0.29 at pH 7.4
Auto-ignition temperature	Not available.
Decomposition temperature	> 392 °F (> 200 °C)
Viscosity	Not available.
Other information	
Chemical family	Benzindole.
Molecular formula	C43-H48-N2-O6-S2.Na
Molecular weight	774.98 g/mol
Solubility (other)	Soluble in methanol; practically insoluble in most other organic solvents.
Specific gravity	> 1

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.

Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx. NaOx.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Due to lack of data the classification is not possible.
Inhalation	May cause irritation to the respiratory system.
Skin contact	Causes skin irritation.
Eye contact	Causes serious eye irritation.
Symptoms related to the physical, chemical, and toxicological characteristics	Irritant effects. Nausea.
Cross sensitivity	Persons sensitive to iodide or iodide-containing products may be sensitive to this material also.

Acute toxicity

Product	Species	Test Results
Indocyanine Green (CAS 3599-32-4)		
Acute		
Other		
LD50	Rabbit	50 mg/kg, intravenous
	Rat	50 mg/kg, intravenous

Skin corrosion/irritation	Causes skin irritation.
Serious eye damage/eye irritation	Causes serious eye irritation.
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Data from germ cell mutagenicity tests were not found. Due to lack of data the classification is not possible.
Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Reproductive toxicity	Due to lack of data the classification is not possible.
Specific target organ toxicity - single exposure	Respiratory tract irritation.
Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.
Aspiration hazard	Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Not available.
Hazardous waste code	Not available.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.

15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable. All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No

Other federal regulations

Safe Drinking Water Act (SDWA)	Not regulated.
Food and Drug Administration (FDA)	Not regulated.
US state regulations	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date	08-20-2008
Revision date	08-07-2014
Version #	02
Further information	Not available.

Disclaimer

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Revision Information

This document has undergone significant changes and should be reviewed in its entirety.

MATERIAL SAFETY DATA SHEET

Product Name: **Lidocaine Hydrochloride Injection, USP, 1% & 2%**

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone **Hospira, Inc.**	CHEMTREC: 800-424-9300 224 212-2055
Product Name	**Lidocaine Hydrochloride Injection, USP, 1% & 2%**
Synonyms	Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-monohydrochloride; 2',6'-Acetoxylidide, 2-(diethylamino)-, hydrochloride

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Lidocaine Hydrochloride
Chemical Formula $C_{14}H_{22}N_2O \bullet HCl$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Lidocaine Hydrochloride	≤ 2.0%	73-78-9	AN7600000

Non-hazardous ingredients include water and/or sodium chloride. Hazardous ingredients present at less than 1% may include sodium hydroxide and/or hydrochloric acid (used to adjust the pH).

3. HAZARD INFORMATION

Emergency Overview

Lidocaine Hydrochloride Injection, USP, 1% or 2%, contains lidocaine hydrochloride, an amide-type local anesthetic used as a local anesthetic for pain management. In the workplace, this product should be considered possibly irritating to the skin, eyes and respiratory tract. Possible target organs include the nervous system and cardiovascular system.

Occupational Exposure Potential

Information on the absorption of this product via inhalation or skin contact is not available. Published reports have indicated that similar local anesthetics have some potential to be absorbed through intact skin. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms

Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected. In normal clinical use, adverse effects may include fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anemia, back pain, post-operative pain and fetal distress. Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur. Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal

3. HAZARD INFORMATION: continued

Signs and Symptoms: continued	edema), tachycardia, sneezing nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.
Medical Conditions Aggravated by Exposure	Pre-existing hypersensitivity to lidocaine or related amide-type anesthetics. Pre-existing nervous system or cardiovascular ailments.
Carcinogen Lists:	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed

4. FIRST AID MEASURES

Eye Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability	Non-flammable
Fire & Explosion Hazard	None
Extinguishing Media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb any liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling	No special handling required under conditions of normal product use.
Storage	No special storage required for hazard control. For product protection, store at 20 to 25°C (68 to 77°F). See USP Controlled Room Temperature. Protect from light.
Special Precautions	No special precautions are required for hazard controls.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits		
Component	**OSHA-PEL**	**ACGIH-TLV**	**Hospira EEL**
Lidocaine Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 500 mcg/m3 STEL: 5 mg/m3

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

Respiratory Protection	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely and engineering controls are not adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (P100) is recommended. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Skin Protection	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Eye Protection	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Engineering Controls	Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear, colorless liquid.
Odor	Not determined.
Odor Threshold:	NA
pH:	Between 5.0 and 7.0
Melting point/Freezing point:	Approximately that of water (0 °C, 32 °F).
Initial Boiling Point/Boiling Point Range	Approximately that of water (100 °C, 212 °F).
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure	Approximately that of water (17.5 mm Hg at 20 °C).
Vapor Density (Air =1)	NA
Evaporation Rate	NA
Specific Gravity	Approximately that of water (1.0).
Solubility	Very soluble in water and in alcohol; soluble in chloroform; insoluble in ether.
Log Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature	NA
Decomposition temperature	NA

10. STABILITY AND REACTIVITY

Reactivity Not determined.

Chemical Stability Stable under standard use and storage conditions.

Hazardous Reactions Not determined

Conditions to avoid Not determined

Incompatibilities Strongly alkaline conditions. Methyl vinyl ether; zinc.

Hazardous Decomposition Products Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides and nitrogen oxides (NOx), and hydrogen chloride.

Hazardous Polymerization Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION:

Acute Toxicity:

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Lidocaine Hydrochloride	100	LD50	Oral	220 292	mg/kg mg/kg	Mouse Mouse
Lidocaine Hydrochloride	100	LD50	Intraperitoneal	122 63	mg/kg mg/kg	Rat Mouse
Lidocaine Hydrochloride	100	LD50	Intravenous	21 15 25.6 24.5	mg/kg mg/kg mg/kg mg/kg	Rat Mouse Rabbit Guinea Pig
Lidocaine Hydrochloride	100	LD50	Intratracheal	28	mg/kg	Rabbit

LD 50: Dosage that produces 50% mortality.

Aspiration Hazard None anticipated from normal handling of this product.

Dermal Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to broken skin and mucous membranes, and may produce numbness.

Ocular Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation, numbness, and blurred vision.

Dermal or Respiratory Sensitization None anticipated from normal handling of this product. However, inadvertent contact of this product with the respiratory system may produce irritation and numbness. Rarely, allergic-type reactions have been reported during the clinical use of lidocaine.

11. TOXICOLOGICAL INFORMATION: continued

Reproductive Effects

In a fertility study in rats, lidocaine given subcutaneously at a dosage of 30 mg/kg (180 mg/m2) to mating pairs did not produce alterations in fertility or general reproductive performance of rats. Subcutaneous administration of lidocaine to pregnant rats at a dosage of to 50 mg/kg did not produce evidence of harm to the fetus. In rabbits, there was no evidence of harm to the fetus at a subcutaneous dosage of 5 mg/kg. Treatment of rabbits with a subcutaneous dosage of 25 mg/kg produced evidence of maternal toxicity and evidence of delayed fetal development, including a non-significant decrease in fetal weight and an increase in minor skeletal anomalies. The effect of lidocaine on post-natal development was evaluated in rats by treating pregnant female rats daily subcutaneously at dosages of 2, 10, and 50 mg/kg from day 15 of pregnancy and up to 20 days post partum. No signs of adverse effects were seen either in dams or in the pups up to and including the dose of 10 mg/kg; however, the number of surviving pups was reduced at 50 mg/kg, both at birth and the duration of lactation period; this effect is most likely secondary to maternal toxicity. A second study evaluated the effects of lidocaine on post-natal development in the rat that included assessment of the pups from weaning to sexual maturity. Rats were treated subcutaneously for 8 months with 10 or 30 mg/kg lidocaine, a treatment duration that included 3 mating periods. There was no evidence of altered post-natal development in any offspring; however, both doses of lidocaine significantly reduced the average number of pups per litter surviving until weaning of offspring from the first 2 mating periods.

Mutagenicity

The mutagenic potential of lidocaine was evaluated in the Ames Salmonella reverse mutation assay, an *in vitro* chromosome aberrations assay in human lymphocytes and in an *in vivo* mouse micronucleus assay. There was no indication of any mutagenic effect in these studies.

Carcinogenicity

Long-term studies in animals to evaluate the carcinogenic potential of most local anesthetics, including lidocaine, have not been conducted.

Target Organ Effects

Based on clinical use, possible target organs include the nervous system and the cardiovascular system.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity Not determined for product.

Persistence/Biodegradability Not determined for product.

Bioaccumulation Not determined for product.

Mobility in Soil Not determined for product.

13. DISPOSAL CONSIDERATIONS:

Waste Disposal	If discarded as produced, this product is not a RCRA "listed" or "characteristic" hazardous waste. However, uses resulting in a chemical or physical change of the product or contamination of the product with other materials may subject it to regulation as a hazardous waste. All waste materials must be properly characterized by the waste generator. Further, disposal of all pharmaceuticals should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

DOT STATUS:	Not Regulated
Proper Shipping Name:	NA
Hazard class:	NA
Un number:	NA
Packing group:	NA
Reportable quantity:	NA
ICAO/IATA STATUS	Not regulated
Proper shipping name:	NA
Hazard class:	NA
Un number:	NA
Packing group:	NA
Reportable quantity:	NA
IMDG STATUS	Not regulated
Proper shipping name:	NA
Hazard class:	NA
Un number:	NA
Packing group:	NA
Reportable quantity:	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status	This product is exempt. However, lidocaine hydrochloride is listed on the TSCA inventory.
CERCLA Status	Not listed
SARA 302 Status	Not listed
SARA 313 Status	Not listed
RCRA Status	Not listed
PROP 65 (Calif.)	Not listed

Notes:
TSCA, Toxic Substance Control Act;
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act;
SARA, Superfund Amendments and Reauthorization Act;
RCRA, US EPA, Resource Conservation and Recovery Act;
Prop 65, California Proposition 65

15. REGULATORY INFORMATION: continued

U.S. OSHA Classification Possible Irritant
Target Organ Toxin

GHS Classification

Hazard Class	Acute Oral Toxicity	Eye Irritation	Target Organ Toxicity
Hazard Category	Unclassified	2B	2
Symbol			
Signal Word		Warning	Warning
Hazard Statement		Causes eye irritation	May cause damage to the nervous system and cardiovascular system through prolonged or repeated exposure.

Prevention: Do not breathe vapor or spray.

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classifications*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance lidocaine hydrochloride.

Classification(s):	Harmful	Irritant
Symbol:		
Indication of Danger	Xn	Xi

Risk Phrases: R22 – Harmful if swallowed
R36/37 - Irritating to eyes and respiratory system

Safety Phrases: S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with eyes
S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Global Occupational Toxicology
Date Prepared: February 22, 2008

Disclaimer:
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Safety Data Sheet

LUCENTIS(R) Vials (0.5 mg/0.05 ml)

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

1.1. Product identifier

Product name		LUCENTIS(R) Vials (0.5 mg/0.05 ml)
Product code		SAP-10138289
Synonyms	-	LUCENTIS(R) Vials (10 mg/ml)

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

Use	-	pharmaceutical active substance	*1
	-	to treat the "wet" type of age-related macular degeneration (ARMD)	*1

1.3. Details of the supplier of the safety data sheet

Company information	Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America Phone 001-(650) 225-1000 E-Mail info.sds@roche.com US Chemtrec phone: (800)-424-9300	Local representation:

1.4. Emergency telephone number

Emergency telephone number	US Chemtrec phone: (800)-424-9300

1 referring to: Ranibizumab

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification: no classification and labelling according to GHS

Other hazards

Note: - no information available

SECTION 3: Composition/information on ingredients

Characterization	recombinant humanised monoclonal antibody (Ranibizumab) with excipients

Ingredients	Concentration	GHS-Classification (pure ingredient)
Ranibizumab 347396-82-1	1 %	

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse immediately with tap water for at least 20 minutes - open eyelids forcibly
Skin contact	- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	- remove the casualty to fresh air and keep him/her calm - in the event of symptoms get medical treatment

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

Note	- no information available

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

Note to physician	- treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide, adapt extinguishing media to surrounding fire conditions
Flash point (liquid)	not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards	- no particular hazards known

5.3. Advice for firefighters

Protection of fire-fighters	- precipitate gases/vapours/mists with water spray

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	-	no special precautions required

6.2. Environmental precautions

Environmental protection	-	no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	-	collect spilled solutions with inert adsorbent and hand over to waste removal

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials	-	glass

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	-	2 - 8 °C
	-	do not freeze
	-	protected from heat and light
Validity	-	2 to 8 °C, in the unopened original container, see "best use before" date stated on the label, after opening the content should be used within a short period
Packaging materials	-	vials
	-	keep it in the outer carton in order to protect from light

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air	-	IOEL (Internal Occupational Exposure Limit): 0.2 mg/m3	*1

8.2. Exposure controls

Respiratory protection	-	Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
	-	respiratory protection not necessary during normal operations
	-	breathing apparatus in case of aerosol mist formation
Hand protection	-	protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection	-	safety glasses
1 referring to:		Ranibizumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	colorless to slightly yellow
Form	sterile liquid
pH value	5.5

9.2. Other information

Note	-	no information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Note	-	no information available

10.2. Chemical stability

Stability	-	as for all other proteins, monoclonal antibodies are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created
	-	does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution

10.3. Possibility of hazardous reactions

Note	-	no information available

10.4. Conditions to avoid

Conditions to avoid	-	warming

10.5. Incompatible materials

Note	-	no information available

10.6. Hazardous decomposition products

Note	-	no information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- no information available	
Local effects	- no information available	
Sensitization	anaphylactic reactions may occur following the parenteral application of proteins; rare cases of hypersensitivity have been described	*1
Mutagenicity	- no information available	
Carcinogenicity	- no information available	
Reproductive toxicity	- should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus	*1
	- the systemic exposure to ranibizumab is low after ocular administration, but due to its mechanism of action, ranibizumab must be regarded as potentially teratogenic and embryo-/foetotoxic	*1
STOT-single exposure	- no information available	
STOT-repeated exposure	- no information available	
Aspiration hazard	- no information available	
Note	- elimination half-life (after a single dose): ~ 2.9 d	*1
	- due to its human tissue specificity, any standard toxikological program is inadequate for the preclinical safety evaluation of ranibizumab.	*1
	- therapeutic dose (intravitreal): 300 µg	*1
	- no significant toxicities were observed with treatment	*1
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact	
	- Carcinogenicity: not listed by NTP, IARC or OSHA	

1 referring to: Ranibizumab

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected	*1

12.2. Persistence and degradability

Ready biodegradability	- globular proteins are generally well biodegradable	*1

12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

1 referring to: Ranibizumab

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues
- observe local/national regulations regarding waste disposal
- drain very small quantities into wastewater treatment plant

SECTION 14: Transport information

Note - not classified as Dangerous Good according to the Dangerous Goods Regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements
- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Note	-	Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.
Edition documentation	-	first edition

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.

SAFETY DATA SHEET
Triamcinolone acetonide

Revision: 07/14/2015

according to Regulation (EC) No. 1907/2006 as amended by (EC) No. 1272/2008

Section 1. Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Code: 18026

Product Name: Triamcinolone acetonide

Synonyms: 9-fluoro-11.beta.,21-dihydroxy-16a,17-[(1-methylethylidene)bis(oxy)]-pregna-1,4-diene-3,20-dione; NSC 21916;

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

Relevant identified uses: For research use only, not for human or veterinary use.

1.3 Details of the Supplier of the Safety Data Sheet:

Company Name: Cayman Chemical Company
1180 E. Ellsworth Rd.
Ann Arbor, MI 48108

Web site address: www.caymanchem.com

Information: Cayman Chemical Company +1 (734)971-3335

1.4 Emergency telephone number:

Emergency Contact: CHEMTREC Within USA and Canada: +1 (800)424-9300
CHEMTREC Outside USA and Canada: +1 (703)527-3887

Section 2. Hazards Identification

2.1 Classification of the Substance or Mixture:

Toxic To Reproduction, Category 1B

2.2 Label Elements:

GHS Signal Word: **Danger**

GHS Hazard Phrases:

H360: May damage fertility or the unborn child.

GHS Precaution Phrases:

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P280: Wear {protective gloves/protective clothing/eye protection/face protection}.

GHS Response Phrases:

P308+313: IF exposed or concerned: Get medical attention/advice.

GHS Storage and Disposal Phrases:

Please refer to Section 7 for Storage and Section 13 for Disposal information.

2.3 Adverse Human Health Effects and Symptoms: Material may be irritating to the mucous membranes and upper respiratory tract.
May be harmful by inhalation, ingestion, or skin absorption.
May cause eye, skin, or respiratory system irritation.
May damage fertility or the unborn child.
To the best of our knowledge, the toxicological properties have not been thoroughly investigated.

Section 3. Composition/Information on Ingredients

CAS # / RTECS #	Hazardous Components (Chemical Name)/ REACH Registration No.	Concentration	EC No./ EC Index No.	GHS Classification
76-25-5 TU3920000	Pregna-1,4-diene-3,20-dione,9-fluoro-11,21-dihydroxy-16,17-(1-methylethylidene)bis(oxy)-, (11.beta.	100.0 %	200-948-7 NA	Toxic Repro. 1B: H360

Section 4. First Aid Measures

4.1 Description of First Aid Measures:

In Case of Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

In Case of Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

In Case of Eye Contact: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

In Case of Ingestion: Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Section 5. Fire Fighting Measures

5.1 Suitable Extinguishing Media: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray.
Use water spray to cool fire-exposed containers.

Unsuitable Extinguishing Media: A solid water stream may be inefficient.

5.2 Flammable Properties and Hazards: No data available.

No data available.

Flash Pt: No data.

Explosive Limits: LEL: No data. UEL: No data.

Autoignition Pt: No data.

5.3 Fire Fighting Instructions: As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental Release Measures

6.1 Protective Precautions, Protective Equipment and Emergency Procedures: Avoid raising and breathing dust, and provide adequate ventilation.
As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

6.2 Environmental Precautions: Take steps to avoid release into the environment, if safe to do so.

6.3 Methods and Material For Containment and Cleaning Up: Contain spill and collect, as appropriate.
Transfer to a chemical waste container for disposal in accordance with local regulations.

Section 7. Handling and Storage

7.1 Precautions To Be Taken in Handling: Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid prolonged or repeated exposure.

7.2 Precautions To Be Taken in Storing: Keep container tightly closed.
Store in accordance with information listed on the product insert.

Section 8. Exposure Controls/Personal Protection

8.1 Exposure Parameters:

CAS #	Partial Chemical Name	Britain EH40	France VL	Europe
76-25-5	Pregna-1,4-diene-3,20-dione,9-fluoro-11,21-dihydroxy-16,17-(1-methylethylidene)bis(oxy)-, (11.beta.	No data.	No data.	No data.

CAS #	Partial Chemical Name	OSHA TWA	ACGIH TWA	Other Limits
76-25-5	Pregna-1,4-diene-3,20-dione,9-fluoro-11,21-dihydroxy-16,17-(1-methylethylidene)bis(oxy)-, (11.beta.	No data.	No data.	No data.

8.2 Exposure Controls:

8.2.1 Engineering Controls (Ventilation etc.): Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

8.2.2 Personal protection equipment:

Eye Protection: Safety glasses

Protective Gloves: Compatible chemical-resistant gloves

Other Protective Clothing: Lab coat

Respiratory Equipment (Specify Type): NIOSH approved respirator, as conditions warrant.

Work/Hygienic/Maintenance Practices: Do not take internally.
Facilities storing or utilizing this material should be equipped with an eyewash and a safety shower.
Wash thoroughly after handling.

No data available.

Section 9. Physical and Chemical Properties

9.1 Information on Basic Physical and Chemical Properties

Physical States: [ ] Gas [ ] Liquid [X] Solid

Appearance and Odor: A crystalline solid

Melting Point: No data.

Boiling Point: No data.

Flash Pt: No data.

Evaporation Rate: No data.

Flammability (solid, gas): No data available.

Explosive Limits: LEL: No data. UEL: No data.

Vapor Pressure (vs. Air or mm Hg): No data.

Vapor Density (vs. Air = 1): No data.

	Specific Gravity (Water = 1):	No data.
	Solubility in Water:	No data.
	Solubility Notes:	~0.5 mg/ml in a 1:1 solution of DMSO:PBS (pH 7.2); ~5 mg/ml in EtOH; ~20 mg/ml in DMSO & DMF;
	Autoignition Pt:	No data.
9.2	**Other Information**	
	Percent Volatile:	No data.
	Molecular Formula & Weight:	C24H31FO6 434.5

Section 10. Stability and Reactivity

10.1	**Reactivity:**	No data available.
10.2	**Stability:**	Unstable [ ] Stable [X]
10.3	**Stability Note(s):**	Stable if stored in accordance with information listed on the product insert.
	Polymerization:	Will occur [ ] Will not occur [X]
10.4	**Conditions To Avoid:**	No data available.
10.5	**Incompatibility - Materials To Avoid:**	No data available.
10.6	**Hazardous Decomposition or Byproducts:**	No data available.

Section 11. Toxicological Information

11.1	**Information on Toxicological Effects:**	The toxicological effects of this product have not been thoroughly studied. Triamcinolone acetonide - Toxicity Data: Oral Rodent - mouse 2168 mg/kg; Oral Rodent - rat 1451 mg/kg;
	Chronic Toxicological Effects:	Triamcinolone acetonide - Investigated as a hormone, mutagen, reproductive effector. Only select Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information. Triamcinolone acetonide RTECS Number: TU3920000

CAS #	Hazardous Components (Chemical Name)	NTP	IARC	ACGIH	OSHA
76-25-5	Pregna-1,4-diene-3,20-dione,9-fluoro-11,21-dihydroxy-16,17-(1-methylethylidene)bis(oxy)-, (11.beta.	n.a.	n.a.	n.a.	n.a.

Section 12. Ecological Information

12.1	**Toxicity:**	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.
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	**Results of PBT and vPvB assessment:**	No data available.
12.6	**Other adverse effects:**	No data available.

Section 13. Disposal Considerations

13.1 Waste Disposal Method: Dispose in accordance with local, state, and federal regulations.

Section 14. Transport Information

14.1 LAND TRANSPORT (US DOT):

DOT Proper Shipping Name: Not dangerous goods.

DOT Hazard Class:

UN/NA Number:

14.1 LAND TRANSPORT (European ADR/RID):

ADR/RID Shipping Name: Not dangerous goods.

UN Number:

Hazard Class:

14.3 AIR TRANSPORT (ICAO/IATA):

ICAO/IATA Shipping Name: Not dangerous goods.

Additional Transport Information: Transport in accordance with local, state, and federal regulations.

Section 15. Regulatory Information

EPA SARA (Superfund Amendments and Reauthorization Act of 1986) Lists

CAS #	Hazardous Components (Chemical Name)	S. 302 (EHS)	S. 304 RQ	S. 313 (TRI)
76-25-5	Pregna-1,4-diene-3,20-dione,9-fluoro-11,21-dihydroxy-16,17-(1-methylethylidene)bis(oxy)-, (11.beta.	No	No	No

CAS #	Hazardous Components (Chemical Name)	Other US EPA or State Lists
76-25-5	Pregna-1,4-diene-3,20-dione,9-fluoro-11,21-dihydroxy-16,17-(1-methylethylidene)bis(oxy)-, (11.beta.	CAA HAP,ODC: No; CWA NPDES: No; TSCA: Yes - Inventory; CA PROP.65: No

Regulatory Information Statement: This SDS was prepared in accordance with 29 CFR 1910.1200 and Regulation (EC) No.1272/2008.

Section 16. Other Information

Revision Date: 07/14/2015

Additional Information About This Product: No data available.

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