abbvie
SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: Oritavancin Glycopeptide Nucleus

Synonyms: Oritavancin Glycopeptide; Oritavancin NFB

Trade name: Oritavancin

Drug Code Number: 40216; 20033863

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

Recommended use: Industrial use
Process Intermediate
Scientific research and development

1.3 Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900

Customer Service Telephone: 1-800-255-5162 (US and Canada only)
+1-847-937-7433

E-mail Address: AbbVie.SDS@abbvie.com

1.4 Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008
General Note AbbVie

Skin corrosion/irritation	Category 2
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Specific target organ systemic toxicity (repeated exposure)	Category 1
Chronic aquatic toxicity	Chronic toxicity 2

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Indication of danger:
Xi - Irritant
T - Toxic
N - Dangerous for the environment

Risk Phrases:
R38 - Irritating to skin
R42 - May cause sensitization by inhalation
R43 - May cause sensitization by skin contact
R48 - Danger of serious damage to health by prolonged exposure
R51 - Toxic to aquatic organisms
R53 - May cause long-term adverse effects in the aquatic environment

2.2 Label elements

Signal Word: Danger

Hazard Statements:
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H372 - Causes damage to organs through prolonged or repeated exposure
H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements
P272 - Contaminated work clothing should not be allowed out of the workplace
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P273 - Avoid release to the environment

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Oritavancin Glycopeptide 118395-73-6	100	NA	Xi; R38 R42/43 T;R48 N; R51/53	STOT RE 1 (H372) Skin Irrit. 2 (H315) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) Aquatic Chronic 2 (H411)	No data available

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of 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.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: Analogy suggests the following: headaches, abnormal liver function, abnormal kidney function, dizziness, taste alterations, and allergic reactions.

Medical Conditions Aggravated by Exposure: Data suggest any pre-existing ailments in the following organs: immune system, kidney, spleen, liver, skin, spleen. Hypersensitivity to the material and/or similar materials.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Not determined

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

Incompatibilities: Strong oxidizing agents.

6.4. Reference to other sections

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

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Industrial use
Process Intermediate
Scientific research and development

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Oritavancin Glycopeptide 118395-73-6	Not Applicable	None

8.2. Exposure controls

Engineering Controls: Use inside a hood, glovebox or process enclosure.

Respiratory Protection: An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to handling activities.

Gloves: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	White to off-white Powder
Odor:	Odor not determined.
Odor Threshold:	Not determined
pH:	7.0 as a 5% solution.
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Specific Gravity:	Not determined.
Solubility(ies):	Soluble in: water.
Partition coefficient: n-octanol/water	Not determined.
Autoignition Temp. (°C):	Not determined.
Decomposition temperature (°C):	Not determined.
Viscosity (centipoise):	Not determined.
Explosion Severity:	Not determined.
Oxidizer Properties:	Not determined.

9.2. Other information

Not determined

Min. Ignition Energy-Cloud (mJ): > 500

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Hazardous reactions: None under normal processing

Self-Heating Tendency: No exotherms seen below 200 deg C in DSC testing.

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decompostion products

Not determined

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Yes
Dermal: Yes
Inhalation: Yes

Acute Toxicity - Oral: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Oritavancin Glycopeptide 118395-73-6	LD50 >	500	mg/kg	Rats

No deaths observed.

Acute Toxicity - Dermal: Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Oritavancin Glycopeptide 118395-73-6	LD50 >	1000	mg/kg	Rabbits

No deaths observed.

Acute Toxicity - Inhalation: Not determined.

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Oritavancin Glycopeptide 118395-73-6	LD50 (iv) =	63 98 98.5	mg/kg	Male Rats Female Rats Mice	

Corrosivity: Not Corrosive.

Dermal Irritation: A similar material is a skin irritant.

Eye Irritation: Not determined.

Sensitization: Reported to be sensitizer in humans. Reported to be sensitizer in animals.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: By analogy, possible target organs include: skin, liver, immune system. Data for similar material given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Oritavancin Glycopeptide 118395-73-6	Liver Kidney Spleen Immune System	Rats Dogs	5-30	mg/kg, for a similar material	Intravenous Infusion	30 days

By analogy Oritavancin has produced headache, strange taste, dizziness, back pain, rash and temporary changes to the liver, and histamine reactions during clinical trials. In animals, oritavancin produced allergic-like reactions, an increase in liver and spleen weight, and a mild decrease in kidney function.

Reproductive Effects: None expected from normal clinical use of this product.

Carcinogenicity: Not determined.

Mutagenicity: Negative in mutagenicity assays. Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Oritavancin Glycopeptide 118395-73-6	Negative	Negative	Negative	Negative

Aspiration hazard: Not determined

Notes:
1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Data for similar components (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Oritavancin Glycopeptide 118395-73-6	100	3.2	Rainbow Trout	96 Hours Similar Material

Chemical Name	Percent	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Oritavancin Glycopeptide 118395-73-6	100	30	Daphnia magna	48 Hours Similar Material

Chemical Name	Percent	72h IC50 (algae - mg/l) (72HICA)	Species	Duration
Oritavancin Glycopeptide 118395-73-6	100	1.3	Selenastrum Capricornutum	0- 72 Hours Similar Material

12.2. Persistence and degradability

Similar Material : 91% biodegradation within 14 days Data for similar component (s) given below.

Chemical Name	Percent	% Degradation	Duration
Oritavancin Glycopeptide 118395-73-6	100	0	1 Day Similar Material

12.3. Bioaccumulative potential

Data for similar component(s) given below.

Chemical Name	Percent	Log Po/w
Oritavancin Glycopeptide 118395-73-6	100	-0.11

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:
1. **EC50: Concentration in water that produces 50% mortality in Daphnia sp.**
2. **LC50: Concentration in water that produces 50% mortality in fish.**
3. **EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.**

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

Section 14. Transport information

DOT

Status: Not regulated

14.1. UN Number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

ADR ICAO/IATA IMDG/IMO

Status: Regulated
14.1. UN Number: UN3077
14.2. Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Oritavancin Glycopeptide Nucleus)
14.3. Hazard Class: 9
14.4. Packing group: III
14.5. Environmental hazard: Yes
14.6. Special Provisions: IATA - A197 (not subject to air regulations if 5 kg/L or less)

Section 15. Regulatory Information

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

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS

Oritavancin Glycopeptide 118395-73-6	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Oritavancin Glycopeptide 118395-73-6	-	-	-	-	-	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
ISHL - Japan Industrial Safety and Health Law
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Oritavancin Glycopeptide	100	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Oritavancin Glycopeptide	100	No	Not Applicable	Not applicable

Immediate Health: Yes
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

RCRA Status: Not determined.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

NFPA Rating:
Health: 1
Fire: 1
Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

Product Name: **Oritavancin Glycopeptide Nucleus**
Issued: **Jun-23-2015**

Risk Phrases:
R38 - Irritating to skin
R42 - May cause sensitization by inhalation
R43 - May cause sensitization by skin contact
R48 - Danger of serious damage to health by prolonged exposure
R51 - Toxic to aquatic organisms
R53 - May cause long-term adverse effects in the aquatic environment

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