

According to OSHA HazCom Standard [2012]

Printing date: 03/11/2022 Reviewed on: 03/11/2022 Version 02

1 Identification

Product identifier: 315

Trade name: VueWay

Synonyms: Solution of gadolinium complex of 2,2',2'' – [3, 6, 9, 15 – tetrazabicyclo [9.3.1] pentadeca – 1(15), 11. 13 – triene 3, 6, 9 – triyl] tris (5 – [(2,3 – dihydroxypropryl) amino] – 5 – oxopentanoic acid).

Application of the substance / the mixture:

VueWay is a gadolinium-based contrast agent indicated in adult and pediatric patients aged 2 years and older for use with magnetic resonance imaging (MRI) to detect and visualize lesions with abnormal vascularity in:

- the central nervous system (brain, spine, and associated tissues),
- the body (head and neck, thorax, abdomen, pelvis, and musculoskeletal system).

Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Bracco Diagnostics Inc. P.O. Box 5225 Princeton, NJ 08543 Phone number: 1-800-257-5181 Email: <u>HSE@bracco.com</u> (responsible for the SDS)

Emergency telephone number:

EMERGENCY CONTACT: Health: 1-800-257-5181 U.S. Transport - Chemtrec: 1-800-424-9300 International Transport - Chemtrec: 1-703-527-3887

2 Hazard(s) identification

Classification of the substance or mixture

The classification in hazard categories, in compliance with Regulation 29 CFR 1910.1200, does not apply to drugs which are dispensed by a pharmacy to a health care provider for direct administration to a patient.

Label elements

GHS label elements: Not applicable,

Hazard pictograms: Not applicable,

Signal word: Not applicable,

Hazard statements: Not applicable.

Additional Information

Classification system: NFPA ratings (scale 0 - 4)



HMIS-ratings (scale 0 - 4)HEALTH0Health = 0FIRE0Fire = 0REACTIVITY0Reactivity = 0



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Other hazards: No further relevant information available. Results of PBT and vPvB assessment PBT: Not applicable vPvB: Not applicable

3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture consisting of the following components.

Hazardous component: Not applicable

Non-Hazardous Components			
CAS No.	Name	Qty.	
933983-77-8	Gadolinium, [a3,a6,a9-tris[3-[(2,3-dihydroxypropyl)amino]-3-oxopropyl]- 3,6,9,15-tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene-3,6,9- triacetato(3-)-кN3,кN6,кN9,кN15,кO3,кO6,кO9]-	48.5 %	

Information on components			
CAS No.	Name	Qty.	
933983-77-8	Gadolinium, [a3,a6,a9-tris[3-[(2,3-dihydroxypropyl)amino]-3-oxopropyl]- 3,6,9,15-tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene-3,6,9- triacetato(3-)-кN3,кN6,кN9,кN15,кO3,кO6,кO9]-	48.5 %	

Additional information: No further relevant information available.

4 First-aid measures

Description of first aid measures

After inhalation: Remove victim to fresh air. If you feel unwell, seek medical advice (show the label where possible)

After skin contact: Wash exposed area with water and soap. Get medical advice if irritation develops.

After eye contact: In case of eye contact, immediately flush and rinse eyes with plenty of water for at least 15 minutes keeping the eyelids open. Seek medical advice if irritation develops.

After swallowing: Do not give water to drink, induce vomiting, and seek medical advice.

Most important symptoms and effects (acute and delayed)

Symptoms/effects: No specific effects and/or symptoms are known

Indication of any immediate medical attention and special treatment needed

Threat symptomatically.

5 Fire-fighting measures

Extinguishing media

The product is not flammable

Suitable extinguishing agents: All extinguishing agents can be used.

Unsuitable extinguishing agents: Use any means suitable for extinguishing surrounding fire.

Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Carbon oxides (CO, CO2). Toxic fumes.



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Special protective equipment and precautions for fire-fighters

Protective equipment: Do not attempt to take action without suitable protective equipment. Put on breathing apparatus. Complete protective clothing.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes.

Environmental precautions: Containerize unusable material for disposal in an approved waste facility. Do not release in the environment.

Methods and material for containment and cleaning up:

Take up liquid spill into absorbent material. Clean with Water. Collect all waste in suitable and labeled containers and disposes according to local legislation.

Reference to other sections

See section 8 and 13.

Protective Action Criteria for Chemicals

PAC-1:

None of the ingredients are listed.

PAC-2:

None of the ingredients are listed.

PAC-3:

None of the ingredients are listed.

7 Handling and storage

Precautions for safe handling

Avoid contact with skin and eyes. Wear recommended personal protective equipment. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

Conditions for safe storage, including any incompatibilities

Store tightly closed in a dry, cool and well-ventilated place at a temperature \leq 25 °C. Protect against physical damage. Do not freeze.

Incompatible products: Strong acid, Strong bases and strong oxidizers.

Specific end use(s)

See Section 1.

8 Exposure controls/personal protection

Control parameters

Components with limit values that require monitoring at the workplace: Not established.

Additional information: Not established.



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Appropriate engineering controls

Environmental exposure controls: Avoid release to the environment.

Individual protection measures/Personal protective equipment

Breathing equipment: No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation.

Protection of hands: Wear protective gloves. For the breakthrough time refer to the supplier.

Eye protection: Wear protective glasses.

Body protection: Suitable protective clothing.

9 Physical and chemical properties

Information on basic physical and chemical properties

General Information:

Appearance				
Form:	Liquid			
Color:	Colorless to yellow solution			
Odor:	Odorless			
Odor threshold:	Not applicable (odorless)			
pH – Value:	5.5 – 7			
Melting point/Melting range:	No further information			
Boiling point/Boiling range:	No further information			
Flash Point:	No further information			
Flammability (Solid, Gaseous)	No further information			
Ignition temperature:	No further information			
Danger of explosion:	No further information			
Flammability Limits				
Lower:	No further information			
Upper:	No further information			
Explosion Limits				
Lower:	No further information			
Upper:	No further information			
Oxidizing properties:	Not oxidizing.			
Vapor pressure:	Not explosive.			
Density	1.21 g/cm at 20° C			
Relativity Density at 20° C (68° F):	No further information			
Vapor Density at 20° C (68° F):	No further information			



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Evaporation rate:	No further information		
Solubility in / Miscibility with			
Water:	Miscible		
Partition coefficient (n-octanol/water):	No further information		
Viscosity			
Dynamic:	No further information		
Kinematic:	No further information		
Water:	No further information		
VOC Content:	No further information		
Solid Content:	No further information		
Other Information:	No further information		

10 Stability and Reactivity

Reactivity

The product is stable under normal conditions.

Chemical stability

The product is stable at normal handling and storage conditions.

Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

Conditions to avoid

Storage temperature < 25° C. No freezing.

Incompatible materials

Strong acids, strong bases and strong oxidizers.

Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11 Toxicological Information

Information on toxicological effects

Symptoms/effects: No specific effects and/or symptoms are known.

12 Ecological information

Toxicity

To our knowledge, the product does not present any particular risk, under normal conditions of use.

Persistence and degradability

No further information available.





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Bio accumulative potential

No further information available.

Mobility in soil

No further information available.

Results of PBT and vPvB assessment

PBT: Not applicable **vPvB:** Not applicable

Other adverse effects

No further information available.

13 Disposal considerations

Waste treatment methods

Comply with local regulations for disposal.

Ecology - waste materials

Do not discharge into drains or rivers.

14 Transport information

According to the current legislation about the transport of Hazardous goods, this product is not classified as Hazardous Material.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code	Not applicable
Special precautions for user	Not applicable
Environmental Hazards: Marine pollutant:	Not applicable
Packing Group DOT, ADR, IMDG, IATA	Not applicable
Transport hazard class(es) DOT, ADR, ADN, IMDG, IATA Class:	Not applicable
UN proper shipping name: DOT, ADR, ADN, IMDG, IATA	Not applicable
UN Number DOT, ADR, ADN, IMDG, IATA	Not applicable

15 Regulatory Information

US Federal Regulations

Name	Cas-No.	Listing	Commercial status	Flags
Gadolinium, [a3,a6,a9-tris[3-[(2,3- dihydroxypropyl)amino]-3-oxopropyl]- 3,6,9,15-tetraazabicyclo[9.3.1]pentadeca- 1(15),11,13-triene-3,6,9- triacetato(3-)-ĸN3,ĸN6,ĸN9,ĸN15,ĸO3,ĸO6,ĸO9]-	933983-77-8	Not present		



International Regulations

Canada

Gadolinium, [a3,a6,a9-tris[3-[(2,3-dihydroxypropyl)amino]-3-oxopropyl]- 3,6,9,15 tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene-3,6,9-triacetato(3-)-κN3,κN6,κN9,κN15,κO3,κO6,κO9]-

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List

EU-Regulations

Gadolinium, [a3,a6,a9-tris[3-[(2,3-dihydroxypropyl)amino]-3-oxopropyl]- 3,6,9,15 tetraazabicyclo[9.3.1]pentadeca-1(15),11,13-triene-3,6,9-triacetato(3-)-ĸN3,ĸN6,ĸN9,ĸN15,ĸO3,ĸO6,ĸO9]-Not listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

National Regulations

No additional information available.

US State Regulations

No additional information available.

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. Training Hints: All persons handling this product should be informed on the existence of the hazard, on any possible risk they might be subjected to and about all required protective measures to prevent such a damage or to reduce the exposition.

Contact:

Bracco Diagnostics Inc. P.O. Box 5225 Princeton, NJ 08543

Date of preparation / last revision: 03/11/2022, Rev 02 **Changes:** Minor changes in section 1, Alignment to PI.

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail) ICAO: International Civil Aviation Organisation 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 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) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) VOC: Volatile Organic Compounds (USA, EU) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent