

Safety Data Sheet

According to OSHA HazCom Standard [2012]

Printing date 02/22/2019

Version 4

Reviewed on 03/05/2022

1 Identification**Product identifier** Sheet Code: 271**Trade name:** SonoVue (25 mg under sulfur hexafluoride gas) / Lumason

Chemical Name: For active, sulfur hexafluoride.

Synonyms: Sulfur hexafluoride microbubbles for injection

Application of the substance / the mixture:

Ultrasound imaging agent.

We recommend that you use this product in a manner consistent with the listed use. If your intended use is not consistent with the stated use, please contact your sales or technical service representative.

Kit consists of a clear glass vial containing 25 mg of lyophilized powder sealed under sulfur hexafluoride gas and capped, transfer system and a 5-mL vial of sterile physiological saline for reconstitution.

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: Hse@bracco.com (responsible for the SDS)

Information department:

B-Lands Consulting

WTC, 5 Place Robert Schuman, BP 1516

38025 Grenoble, FRANCE

Tel: +33 476 295 869

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Emergency telephone number:

EMERGENCY CONTACT:

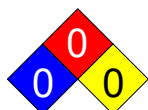
Health: 1-800-257-5181

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 product is not classified, according to the Globally Harmonized System (GHS).

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)**

Health = 0

Fire = 0

Reactivity = 0

HMIS-ratings (scale 0 - 4)

HEALTH 0 Health = 0

FIRE 0 Fire = 0

REACTIVITY 0 Reactivity = 0

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

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3 Composition/information on ingredients

Chemical characterization: Mixtures

Description: Mixture: consisting of the following components.

Hazardous Components			
CAS No.	Name	Classification	Qty.
2551-62-4	Sulphur hexafluoride	Press. Gas, H280	50 – 100 %
25322-68-3	Polyethylene glycol 4000		25 – 50 %

Information on components		
CAS No.	Name	Qty.
2551-62-4	Sulphur hexafluoride	50 – 100 %

4 First-aid measures

Description of first aid measures

General information: No special measures required.

After inhalation:

Move patient to fresh air, if symptom arise consult a doctor.

Supply fresh air. If required, provide artificial respiration. Consult doctor if symptoms persist.

After skin contact:

Immediately wash with water and soap and rinse thoroughly. If skin irritation continues, consult a doctor.

After eye contact:

Rinse opened eye for several minutes under running water. If irritation persists get medical attention.

After swallowing:

Immediately call a doctor.

Vomiting may be induced only if a person is conscious and if ingestion has occurred within the past three hours. Never induce vomiting in a person who is unconscious or experiencing convulsions.

Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Fire-fighting measures

Extinguishing media

Suitable extinguishing agents: In case of fire, flood with Water

Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Carbon Dioxide (CO₂)

In the absence of Oxygen: Carbon Monoxide (CO)

Hydrogen Fluoride (HF)

Sulfur Oxides (SO_x)

Advice for firefighters

Protective equipment:

Firefighters should wear adequate personal protective equipment with protection of respiratory tract (self-contained breathing apparatus) (SCBA).

In addition, firefighters should wear flame and chemicals resistant clothing, boots and gloves.

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6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid inhaling dust and fumes.

Environmental precautions: No special measures required.

Methods and material for containment and cleaning up:

Retrieve product by mechanical means.

Sweep material onto paper and place into a fiber drum for reclamation or disposal. The spill area should be ventilated and decontaminated after material has been picked up.

Reference to other sections

No dangerous substances are released.

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

Protective Action Criteria for Chemicals

PAC-1:		
57-10-3	Palmitic acid	0.19 mg/m ³
PAC-2:		
57-10-3	Palmitic acid	2.1 mg/m ³
PAC-3:		
57-10-3	Palmitic acid	12 mg/m ³

7 Handling and storage

Precautions for safe handling

Provide suction extractors if dust is formed.

Avoid contact with the eyes and skin.

Information about protection against explosions and fires:

No special measures required.

Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles:

Store in a cool, dry place in well-sealed receptacles.

Information about storage in one common storage facility:

Not required.

Further information about storage conditions:

Container Requirements: Kit consists of a clear glass vial, transfer system and a 5 mL of sterile physiological saline. Five kits are provided per carton. Storage Conditions: Store at 15-30 degrees C (59 to 86 degrees F).

Specific end use(s)

No further relevant information available.

8 Exposure controls/personal protection

Control parameters

Components with limit values that require monitoring at the workplace:

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

25322-68-3 Polyethylene glycol 4000	
OSHA-PEL	Long-term value: 15 mg/m ³
TLV-TWA	Long-term value: 10 mg/m ³

Additional information:

The lists that were valid during the creation were used as basis.

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Exposure controls

Personal protective equipment

General protective and hygienic measures:

The usual precautionary measures for handling chemicals should be followed. Ensure good ventilation/exhaustion at the workplace. Wash hands before breaks and at the end of work.



Do not eat, drink and smoke while working.

Breathing equipment:

Not anticipated for normal clinical environment. In non-routine exposure conditions, where risk assessment shows air-purifying respirators are appropriate, use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Self-contained breathing apparatus should be available for emergency use.

Protection of hands:



Protective gloves

The glove material must be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves Natural rubber, NR Nitrile rubber, NBR

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:



Safety glasses

Body protection: Protective work clothing

9 Physical and chemical properties

Information on basic physical and chemical properties

General Information

Appearance:

Form: Powder

Color: White

Odor: PEG 4000: Mild Odor
SF6: Odorless

Odor threshold: Not determined.

pH-value: 4.5 - 7.5 (of solution)

Melting point/Melting range: 51 °C (123.8 °F)

Boiling point/Boiling range: Not determined.

Flash point: PEG 4000: Fp = 246°C (Closed Cup)
SF6: Fp = Not Flammable.

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Flammability (solid, gaseous):	Not determined.
Ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard. Not determined.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Oxidizing properties	Not determined.
Vapor pressure at 50 °C (122 °F):	>110 hPa (>82.5 mm Hg) (SF ₆ , T = 20 °C) 16500 mmHg
Density at 20 °C (68 °F):	1.108 g/cm ³ (9.24626 lbs/gal)
Relative density	Not determined.
Vapor density	5.1 (SF6; Air = 1.0)
Evaporation rate	Not applicable.
Solubility in / Miscibility with Water:	Very soluble.
Partition coefficient (n-octanol/water):	Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
VOC content:	0.00 %
Other information	No further relevant information available.

10 Stability and reactivity**Reactivity**

No data available.

No further relevant information available.

Chemical stability**Thermal decomposition / conditions to be avoided:**

No decomposition if used 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:**

No dangerous decomposition products known.

Sulfur oxides (SO_x)**11 Toxicological information****Information on toxicological effects****Acute toxicity:****LD/LC50 values that are relevant for classification:****2551-62-4 sulphur hexafluoride**

LD50 iv | 5,790 mg/kg (Rabbit)

**Primary irritant effect:
on the skin:**

No irritant effect.

Material contains low concentration of components that are mild irritants or possible irritants. It may have potential to cause mild irritation, however, moderate or severe irritation is not expected.

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on the eye:

No irritating effect.

May cause irritation. Significant exposure to cold sulfur hexafluoride gas can cause frostbite of the eye.

Sensitization:

No sensitizing effects known.

This material may act as a sensitizer (allergen) for those persons who are allergic to the formulation or components in the formulation.

Other information (about experimental toxicology):

By Inhalation: Inhaling small amounts of sulfur hexafluoride or airborne dust from the powder would not be expected to produce symptoms.

By Ingestion: Inadvertent ingestion of trace amounts of this material would not be expected to result in symptoms

Germ Cell Mutagenicity: A number of in vitro and in vivo mutagenicity studies did not show mutagenicity for SonoVue.

Carcinogenicity: Not Available.

Reproductive Toxicity: Reproduction studies with SonoVue in rats and rabbits at daily doses up to 17 times and 35 times the normal dose, respectively, did not show impaired fertility or harm to the fetus. SonoVue did not cause acute toxicity in monkeys when administered intravenously at a dose at least 139 times the human exposure based upon body surface area.

Subacute to Chronic Toxicity: No harmful effects are expected from SonoVue under normal use conditions

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 to our experience and the information provided to us.

Contact with small quantities of material for short periods is not expected to result in pharmacologic or toxic effects. The safety of SonoVue in patients with cardiac shunts has not been studied. Extreme caution should be exercised when considering administration of SonoVue to patients with congenital heart defects. Significant exposure to cold sulfur hexafluoride gas can cause frostbite.

Carcinogenic categories

IARC (International Agency for Research on Cancer)
None of the ingredients are listed.
NTP (National Toxicology Program)
None of the ingredients are listed.
OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients are listed.

12 Ecological information**Toxicity****Aquatic toxicity:**

No further relevant information available.

Persistence and degradability

No further relevant information available.

Bio accumulative potential

No further relevant information available.

Mobility in soil

No further relevant information available.

Additional ecological information**General notes:**

Avoid transfer into the environment.

Not hazardous for water.

Results of PBT and vPvB assessment**PBT:** Not applicable.**vPvB:** Not applicable.**Other adverse effects**

No further relevant information available.

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13 Disposal considerations

Waste treatment methods

Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Reutilise if possible or contact a waste processors for recycling or safe disposal.

Uncleaned packagings:

Recommendation:

Disposal must be made according to official regulations.

Packagings that cannot be cleansed are to be disposed of in the same manner as the product.

Recommended cleansing agent: Water, if necessary with cleansing agents.

14 Transport information

UN-Number

DOT, ADR, ADN, IMDG, IATA

Not applicable.

UN proper shipping name

DOT, ADR, ADN, IMDG, IATA

Not applicable.

Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA

Class

Not applicable.

Packing group

DOT, ADR, IMDG, IATA

Not applicable.

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.

15 Regulatory information

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

Sara

Section 355 (extremely hazardous substances):

None of the ingredients are listed.

Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

TSCA new (21st Century Act) (Substances not listed)

2551-62-4	sulphur hexafluoride
25322-68-3	Polyethylene glycol 4000

Proposition 65

Chemicals known to cause cancer:

None of the ingredients is 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 are listed.

Chemicals known to cause developmental toxicity:

None of the ingredients are listed.

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Carcinogenic categories

EPA (Environmental Protection Agency)
None of the ingredients are listed.
TLV (Threshold Limit Value established by ACGIH)
None of the ingredients are listed.
NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients are listed.

GHS label elements Not applicable.**Hazard pictograms** Not applicable.**Signal word** Not applicable.**Hazard statements** Not applicable.**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.

WARNINGS: Diagnostic agents are intended for use under direction of a physician and/or under the conditions of use described on the label and in the product's package insert. As a general precaution, personnel who handle drug substances should avoid contact (ingestion, inhalation, skin and eye contact) with these substances.

Contact:

Bracco Diagnostics Inc.

P.O. Box 5225

Princeton, NJ 08543

Date of preparation / last revision 03/05/2022, revision**Changes:** general revision of the entire Safety DataSheet, changes in section 1 and section 3.**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

Press. Gas: Gases under pressure – Liquefied gas