

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version 1.1 Revision Date: 05/09/2026 SDS Number: 11619678-00002 Date of last issue: 01/07/2026
Date of first issue: 01/07/2026

SECTION 1. IDENTIFICATION

Product name : Ensifentrine Suspension Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards for the product as supplied

Not a hazardous substance or mixture.

Other hazards

None known.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Ensifentrine	1884461-72-6*	>= 0.1 - <= 1	TSC

* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.
In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.
In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/07/2026
1.1	05/09/2026	11619678-00002	Date of first issue: 01/07/2026

If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.
Notes to physician	:	Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	No hazardous combustion products are known
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide diking or other appropriate

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version 1.1 Revision Date: 05/09/2026 SDS Number: 11619678-00002 Date of last issue: 01/07/2026
Date of first issue: 01/07/2026

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.

Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Gases
-

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Ensifentrine	1884461-72-6	TWA	OEB 4 ($\geq 1 < 10$ $\mu\text{g}/\text{m}^3$)	Internal

- Engineering measures** : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.
All engineering controls should be implemented by facility
-

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/07/2026
1.1	05/09/2026	11619678-00002	Date of first issue: 01/07/2026

design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

- Respiratory protection : No personal respiratory protective equipment normally required.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : suspension
- Color : light yellow, opaque
- Odor : No data available
- Odor Threshold : No data available
- pH : 6.7
- Melting point/freezing point : No data available

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/07/2026
1.1	05/09/2026	11619678-00002	Date of first issue: 01/07/2026

Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/07/2026
1.1	05/09/2026	11619678-00002	Date of first issue: 01/07/2026

tions
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ensifentrine:

Species : Bovine cornea
Result : No eye irritation
Method : OECD Test Guideline 437

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:

Ensifentrine:

Genotoxicity in vitro : Test Type: Ames test
Result: negative
Test Type: Chromosome aberration test in vitro
Result: negative
Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Rat
Result: negative

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version 1.1 Revision Date: 05/09/2026 SDS Number: 11619678-00002 Date of last issue: 01/07/2026
Date of first issue: 01/07/2026

Carcinogenicity

Not classified based on available information.

Components:

Ensifentrine:

Species : Rat
Application Route : Inhalation
Exposure time : 2 years
NOAEL : 7 mg/kg bw/day

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Ensifentrine:

Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Inhalation
Fertility: NOAEL: 6 mg/kg body weight
Method: Study of Fertility and Early Embryonic Development to Implantation

Test Type: Fertility
Species: Rat
Application Route: Inhalation
Fertility: LOAEL: 16 mg/kg body weight
Target Organs: male reproductive organs
Method: Study of Fertility and Early Embryonic Development to Implantation

Effects on fetal development : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Inhalation
Teratogenicity: NOAEL: 15 mg/kg body weight

Test Type: Reproduction/Developmental toxicity screening test
Species: Rabbit
Application Route: Inhalation
Teratogenicity: NOAEL: 12 mg/kg body weight

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version 1.1 Revision Date: 05/09/2026 SDS Number: 11619678-00002 Date of last issue: 01/07/2026
Date of first issue: 01/07/2026

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Ensifentrine:

Species : Dog
NOAEL : 2 mg/kg
LOAEL : 5.5 mg/kg
Application Route : Inhalation
Exposure time : 6 Weeks
Number of exposures : BID
Target Organs : Cardio-vascular system

Species : Dog
LOAEL : 6 mg/kg
Application Route : Inhalation
Exposure time : 40 Weeks
Target Organs : Cardio-vascular system

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ensifentrine:

Toxicity to algae/aquatic plants : EC50 (Raphidocelis subcapitata (freshwater green alga)): > 0.65 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC10 (Raphidocelis subcapitata (freshwater green alga)): > 0.65 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.39 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Daphnia magna (Water flea)): 0.6 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 1000 mg/l

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/07/2026
1.1	05/09/2026	11619678-00002	Date of first issue: 01/07/2026

Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1000 mg/L
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Ensifentrine:

Biodegradability : Method: OECD Test Guideline 301B
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

Bioaccumulative potential

Components:

Ensifentrine:

Partition coefficient: n-octanol/water : log Pow: 3.19

Mobility in soil

Components:

Ensifentrine:

Distribution among environmental compartments : log Koc: 4.1 - 5.2
Method: OECD Test Guideline 106

Other adverse effects

Components:

Ensifentrine:

Results of PBT and vPvB assessment : Remarks: Not classified due to lack of data.

Endocrine disrupting properties

Components:

Ensifentrine:

Remarks : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/07/2026
1.1	05/09/2026	11619678-00002	Date of first issue: 01/07/2026

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Domestic regulation

49 CFR

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Water	7732-18-5
Sodium phosphate, dihydrate	10028-24-7

The ingredients of this product are reported in the following inventories:

AICS : not determined

CA. DSL : not determined

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

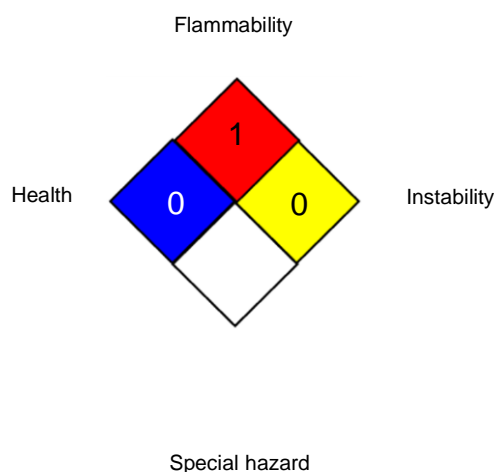
Version 1.1 Revision Date: 05/09/2026 SDS Number: 11619678-00002 Date of last issue: 01/07/2026
Date of first issue: 01/07/2026

CN IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV / CED:

HEALTH	/	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardization; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Ensifentrine Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 01/07/2026
1.1	05/09/2026	11619678-00002	Date of first issue: 01/07/2026

of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 05/09/2026

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8