

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
US - OSHA Hazard Communication Standard (29 CFR 1910.1200)

Issuing Date 06-Apr-2021

Revision Date 06-Apr-2021

Revision Number 1

1. Identification

Product identifier

Product Name Arformoterol Tartrate Inhalation Solution, 15 mcg/2 mL

Other means of identification

Product Code(s) HPI-098

Synonyms formamide,
N-[2-hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methylethyl]amino]ethyl]phenyl]-, (2R,3R)-2,3-dihydroxybutanedioate (1:1 salt)

Recommended use of the chemical and restrictions on use

Recommended use Indicated for the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema

Restrictions on use Not indicated to treat acute deteriorations of chronic obstructive pulmonary disease. Not indicated to treat asthma

Details of the supplier of the safety data sheet

Supplier Address

Slate Run Pharmaceuticals, LLC.
277 West Nationwide Blvd.
Suite 260
Columbus, Ohio 43215
1-855-962-7547

Manufacturer Address

Horizon Pharmaceuticals, Inc.
971 W 15th Street
Riviera Beach, FL 33404
1-877-BFS-HRZN

E-mail info@slaterunpharma.com

Emergency telephone number

Emergency telephone 1-888-341-9214

2. Hazard(s) identification

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Hazards not otherwise classified (HNOC)

Not applicable.

Label elements

Hazard statements

Not classified.

Other information

No information available.

3. Composition/information on ingredients**Substance**

Not applicable.

Mixture

The product contains no substances which at their given concentration are considered to be hazardous to health.

Synonymsformamide,
N-[2-hydroxy-5-[(1R)-1-hydroxy-2-[[[(1R)-2-(4-methoxyphenyl)-1-methylethyl]amino]ethyl]phenyl]-, (2R,3R)-2,3-dihydroxybutanedioate (1:1 salt)

Chemical name	CAS No	Weight-%	Trade secret
Water	7732-18-5	98.0-99.5	*
Sodium chloride	7647-14-5	0.7-0.9	*
Sodium Citrate	6132-04-3	0.08-0.11	*
Citric acid monohydrate	5949-29-1	0.02-0.04	*
Arformoterol tartrate	200815-49-2	0.0011-0.01	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures**Description of first aid measures**

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. Get medical attention if symptoms occur.
Skin contact	Wash skin with soap and water. Get medical attention if symptoms occur.
Ingestion	Rinse mouth.

Most important symptoms and effects, both acute and delayed**Symptoms** None known.**Indication of any immediate medical attention and special treatment needed****Note to physicians** Treat symptomatically.**5. Fire-fighting measures****Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media	None known based on information supplied.
Specific hazards arising from the chemical	None known based on information supplied.
Explosion data	
Sensitivity to mechanical impact	None.
Sensitivity to static discharge	None.
Special protective equipment and precautions for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with eyes. Avoid breathing vapors or mists.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. Small spill: Wipe up with absorbent material (eg. cloth, fleece). Large spill: Cordon off spill area to minimize spreading of spilled material. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Follow recommendations for handling potent pharmaceutical agents handling (i.e., use of engineering controls and/or other protective equipment if needed). Avoid contact with eyes. Avoid breathing vapors or mists. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep refrigerated at 2°C to 8°C (36°F to 46°F) or store at room temperature at 20°C to 25°C (68°F to 77°F) for up to 6 weeks.

8. Exposure controls/personal protection

Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	No special protective equipment required.
Hand protection	No special protective equipment required.
Skin and body protection	No special protective equipment required.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties**Information on basic physical and chemical properties**

Appearance	Clear liquid
Physical state	Liquid
Color	Colorless
Odor	No data available
Odor threshold	No data available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	4.5 - 5.5	No data available
Melting point / freezing point		No data available
Initial boiling point and boiling range		No data available
Flash point		No data available
Evaporation rate		No data available
Flammability		No data available
Flammability Limit in Air		
Upper flammability or explosive limits		No data available
Lower flammability or explosive limits		No data available
Vapor pressure		No data available
Vapor density		No data available
Relative density		No data available
Water solubility		No data available
Solubility(ies)		No data available
Partition coefficient		No data available
Autoignition temperature		No data available
Decomposition temperature		No data available
Kinematic viscosity		No data available
Dynamic viscosity		No data available

Other information

Explosive properties	No information available.
Oxidizing properties	No information available.
Softening point	No information available
Molecular weight	494.49 (arformoterol)
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	None under normal use conditions.
Chemical stability	Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid Extremes of temperature and direct sunlight.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available. Contact with eyes may cause irritation.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms None known.

Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water 7732-18-5	> 90 mL/kg (Rat)	-	-
Sodium chloride 7647-14-5	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 g/m ³ (Rat) 1 h
Arformoterol tartrate 200815-49-2	>1000 mg/kg (Rat)	-	= 0.26 - 1.25 mg/L (Rat) 4h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity The environmental impact of this product has not been fully investigated.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Sodium chloride 7647-14-5	-	LC50: 4747 - 7824mg/L (96h, Oncorhynchus mykiss) LC50: 5560 - 6080mg/L (96h, Lepomis macrochirus) LC50: 6020 - 7070mg/L (96h, Pimephales promelas) LC50: 6420 - 6700mg/L (96h, Pimephales promelas) LC50: =12946mg/L (96h, Lepomis macrochirus) LC50: =7050mg/L (96h, Pimephales promelas)	-	EC50: 340.7 - 469.2mg/L (48h, Daphnia magna) EC50: =1000mg/L (48h, Daphnia magna)

Persistence and degradability	No information available.
Bioaccumulation	There is no data for this product.
Other adverse effects	No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations, Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

14. Transport information

DOT	Not regulated
IATA	Not regulated
IMDG	Not regulated

15. Regulatory information

International Inventories

Contact supplier for inventory compliance status

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations.

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

<u>NFPA</u>	Health hazards 0	Flammability 0	Instability 0	Special hazards -
<u>HMIS</u>	Health hazards 0	Flammability 0	Physical hazards 0	Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Key literature references and sources for data used to compile the SDS

- Agency for Toxic Substances and Disease Registry (ATSDR)
- U.S. Environmental Protection Agency ChemView Database
- European Food Safety Authority (EFSA)
- EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

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Disclaimer

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet