SAFETY DATA SHEET

Version 2.0

Revision Date 06/09/2016

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name : Nizatidine Oral Solution 15 mg/ml

Product code : 659

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

Identified uses : Pharmaceutical preparation
Uses advised against : All other uses

1.3 Details of the supplier of the safety data sheet

Company : Amneal Pharmaceuticals
1 New England Avenue
Piscataway, NJ 08854
USA
Telephone : +1 732-645-3030

1.4 Emergency telephone number

Emergency Phone # (24hrs) : CHEMTREC 1-800-424-9300 CCN796801 [US and Canada]
+1 703-527-3887 (collect calls accepted)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
Physical Hazards: Not classified.
Health Hazards: Not classified

This formulated product is not classified as hazardous under OSHA HCS.

2.2 GHS Label elements, including precautionary statements

No GHS label required.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS – none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Active Ingredient	CAS Number	GHS* Classification Active Ingredient	%
Nizatidine	76963-41-2	Acute oral Cat 4, H 302	1.5
Excipients	**CAS Number**	**GHS* Classification**	**%**
Glycerin		Not Classified	15

Povidone, USP	9003-39-8	Not classified	0.1
Methylparaben	99-76-3	Not classified, combustible dust	0.1
Propylparaben	94-13-3	Skin corrosion/irritation Cat 2 Serious eye damage/irritation Cat 2 STOT-RE Cat 2 (respiratory system)	0.01
Xanthan Gum	11138-66-2	Not classified	0.1
Saccharin sodium	122-44-9	Not classified	0.2
Sodium chloride	7647-14-5	Not classified	0.3
Citric Acid, anhydrous	77-92-9	Eye damage/irritation Cat 2A STOT-SE Cat 3	0.15
Sodium citrate[PWJ1]	6132-04-3	Not classified	0.1
Sucrose	57-50-1	Not classified, combustible dust	30
Magnasweet 110	Proprietary blend	Not classifiable	0.8
Peppermint Extract FN-2356	NA	Not classified	0.5
Water	7732-18-5	Not classified	40-60

* based on active ingredient
For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid

INHALATION: Move individual to fresh air. Seek medical advice if symptoms develop or persist.

SKIN: In the event of occupational skin contact, remove contaminated clothing and rinse off exposed area with water.

EYES: In case of eye contact, rinse immediately with water for 15 minutes and seek medical advice.

INGESTION: In the event of accidental ingestion, seek medical advice. Do Not Induce Vomiting.

4.2 Measures-General Advice

Consult a physician or poison control center. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

4.3 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling (see section 2.2) and/or in section 11

4.4 Indication of any immediate medical attention and special treatment needed

Evidence of accidental or purposeful ingestion overdose requires immediate medical attention. Individual may be lethargic and/or nonresponsive.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture
Carbon oxides

5.3 Advice for firefighters
Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information
No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. For personal protection see section 8.

6.2 Environmental precautions
Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections
For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.
Provide appropriate exhaust ventilation at places where dust is formed.

7.2 Conditions for safe storage, including any incompatibilities
Store locked up.

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: room temperature or refrigerated

7.3 Specific end use(s)
Nizatidine Oral Solution is a pharmaceutical preparation used for treatment of ulcers and reduction of stomach acid.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters
Components with workplace control parameters

Component	CAS Number	OSHA
Glycerin	56-81-5	15 mg/m^3 (total mist)

8.2 Exposure controls

Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Follow approved Good Manufacturing Practices. Local exhaust ventilation normally not required.

Personal protective equipment

Eye/face protection
Safety glasses with side-shields.

Skin protection
Handle with gloves to prevent skin contact and product contamination. Product components may be absorbed through the skin.

Body Protection
Wear appropriate covering to prevent dusting and contamination of work clothing.

Respiratory protection
Use approved respirators and components when mixing, formulating or packaging product.

This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use. This SDS is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. Patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Control of environmental exposure
Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a)	Appearance	Clear solution
b)	Odor	Peppermint odor
c)	Odor Threshold	no data available
d)	pH	no data available
e)	Melting point/freezing point	no data available
f)	Initial boiling point and boiling range	no data available
g)	Flash point	no data available
h)	Evaporation rate	no data available
i)	Flammability (solid, gas)	no data available
j)	Upper/lower flammability or explosive limits	no data available
k)	Vapor pressure	no data available
l)	Vapor density	no data available
m)	Relative density	no data available
n)	Water solubility	no data available
o)	Partition coefficient: n- octanol/water	no data available
p)	Auto-ignition temperature	no data available
q)	Decomposition temperature	no data available
r)	Viscosity	no data available
s)	Explosive properties	no data available
t)	Oxidizing properties	no data available

9.2 Other safety information
No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity
No data available

10.2 Chemical stability
Stable under normal use and storage conditions.

10.3 Possibility of hazardous reactions
No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
No data available

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity
LD50 Oral - rat - 1653 mg/kg (based on 100% nizatidine)
Dermal: no data available
Inhalation: no data available

Skin corrosion/irritation
Product not classified. Skin irritation possible.

Serious eye damage/eye irritation
Product not classified. Eye irritation possible.

Respiratory or skin sensitization
Product not classified for respiratory or skin sensitization

Germ cell mutagenicity
Product not classified

Carcinogenicity
No components of this product present at levels greater than or equal to 0.1% have been identified as probable, possible or confirmed human carcinogen by IARC, ACGIH, NTP or OSHA.

Reproductive toxicity
No data available for formulated product

Specific target organ toxicity - single exposure
No data available for formulated product

Specific target organ toxicity - repeated exposure
No data available for formulated product

Aspiration hazard
No data available

Additional Information
None.

12. ECOLOGICAL INFORMATION

12.1 Toxicity
No data available on formulated product

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Dispose in accordance with local, state and federal regulations. Do not dispose in sanitary waste sewer. Ensure product waste disposal follows FDA guidelines.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not regulated as a hazardous material/dangerous good.

IMDG
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

Product is a FDA regulated product: follow proper FDA regulations for packaging and transport of product.

15. REGULATORY INFORMATION

This product is a FDA regulated pharmaceutical product that is not classified, not regulated or exempt from requirements contained in 2012 OSHA Hazard Communication Standard (29 CFR 1910.122). Consult product packaging insert for additional health and safety information on dosage and potential side effects from use of this product.

16. OTHER INFORMATION

The above information is presented in good faith and believed to be accurate as of the date indicated. No warranty, expressed or implied is granted by Amneal Pharmaceuticals in regard to this information. Amneal Pharmaceuticals shall not be held liable for any damage resulting from improper handling or misuse of the above product.

Preparation Information
Amneal Pharmaceuticals
Regulatory Affairs
Version: 2.0 Revision Date: 06/09/2016