



SAFETY DATA SHEET

Version 1.0

Revision Date 08/20/2015

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name : Morphine Oral Solution, 100 mg per 5 ML

Product code : 082

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 : Tris Pharma
2033 Route 130 Suite D
Monmouth NJ 08852
USA

Telephone : +1 732-940-0358

Fax : +1 732-940-0374

1.4 Emergency telephone number

Emergency Phone # : Regulatory Affairs (732) 940-0374

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, oral : Category 4
Respiratory sensitization : Category 1B
Skin sensitization : Category 1B
Specific organ toxicity : Category 2 (narcotic effects)

2.2 GHS Label elements, including precautionary statements

Signal Word: **Danger**

H302 Harmful if swallowed.

H317 May cause allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

P261 Avoid breathing dust/fume/gas/vapors/mist/spray.

P301+P312 If SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell.

P302+P352 If ON SKIN: wash with plenty of soap and water.

P332+P313 If skin irritation or rash occurs: Get medical attention or advice.

P305+P351+P338 If IN EYES: Rinse continuously with water for several minutes. Remove contacts if present and easy to do. Get medical attention or advice.

P304+P341	If INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a comfortable position for breathing.
P308+P313	If exposed or concerned: Get medical attention or advice.
P273	Avoid release to the environment.
P501	Dispose of contents/ container to an approved waste disposal plant.

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	%
Morphine sulfate pentahydrate	6211-15-0	Acute toxicity oral Cat 4 Respiratory sensitization Cat 1 Skin sensitization Cat 1 STOT, single exp Cat 2 (narcotic effects)	1-2

* based on active ingredient

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 labelling (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 (15 - 25° C) or refrigerated

7.3 Specific end use(s)

Morphine Sulfate is an opioid agonist indicated for the relief of moderate to severe acute and chronic pain where use of an opioid analgesic is appropriate.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Control parameters**

Components with workplace control parameters

Component	CAS Number	OSHA	ACGIH
No components found with PEL or TLV's			

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 for handling of the formulated product.

Personal protective equipment**Eye/face protection**

Safety glasses with side-shields.

Skin protection

Handle with gloves to prevent skin contact and product contamination.

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.

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	Form: clear, colorless solution
b)	Odor	no data available
c)	Odor Threshold	no data available
d)	pH	2.5-4.5
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	not applicable
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 (based on morphine sulfate)

Acute toxicity

Ingestion: 973 mg/kg (Rat oral LD50: based on 100% morphine sulfate)
1125 mg/kg (Mouse oral LD50: based on 100% morphine sulfate)

Inhalation: irritating to upper respiratory tract and mucous membranes

Dermal: no data available

Skin corrosion/irritation

May cause skin irritation

Serious eye damage/eye irritation

May be irritating to eyes

Respiratory or skin sensitization

Morphine sulfate is a Category 1 respiratory and skin sensitizer

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

Narcosis and drowsiness

Specific target organ toxicity - repeated exposure

Narcosis and drowsiness

Aspiration hazard

No data available

Additional Information

No data available for formulated product

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. Product is not a RCRA regulated hazardous waste. Ensure waste disposal follows DEA guidelines.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

Product is a FDA Controlled Substance (Schedule II): follow proper DEA 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 Tris Pharma in regard to this information. Tris Pharma shall not be held liable for any damage resulting from improper handling or misuse of the above product.

Preparation Information

Tris Pharma

Regulatory Affairs

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