Safety Data Sheet

Monsel's Solution

*1. Identification

Product name: Monsel's Solution

Product Use: Styptic agent used after minor surgical procedures, such as curettage and biopsies, to achieve hemostasis.

Restrictions: Hypersensitivity to iron

Contact:

Premier Dental Products Company

1710 Romano Drive

Plymouth Meeting, PA 19462

Phone: 610-239-6000 Fax: 610-239-6171

Emergency Phone: 610-239-6000

2. Hazard(s) Identification

Classification of the substance or mixture



Health hazard

May cause damage to organs



Causes skin irritation

Causes serious eye irritation

Label elements

GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms





Signal word Warning

Hazard-determining components of labeling:

Ferric Subsulfate Hydrate

Hazard statements

Causes skin irritation

Causes serious eye irritation

May cause damage to organs

Precautionary statements

Do not breathe dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

Specific treatment (see on this label).

Take off contaminated clothing and wash before reuse.

If skin irritation occurs: Get medical advice/attention.

If eye irritation persists: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:

NFPA ratings (scale 0 - 4)



Health = 1 Fire = 0Reactivity = 0

HMIS-ratings (scale 0 - 4)



 $\begin{aligned} & Health = 1 \\ & Fire = 0 \\ & Reactivity = 0 \end{aligned}$

*3. Composition/information on ingredients

15244-10-7 Thickeners 30-50% 7732-18-5 water, distilled, conductivity or of similar purity 25-50%

Chemical characterization: Mixtures

Description: Mixture of the substances listed below with nonhazardous additions.

Dangerous Components:

1310-45-8 Ferric Subsulfate Hydrate

♦ STOT SE 2, H371; ♦ Acute Tox. 4, H302; Acute Tox. 4,

H312; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2A, H319

Additional information:

Trade Secret/Proprietary made in accordance with paragraph (i) of 1910.1200 of 29 CF 1910.1200, the OSHA Communication Standard

*4. First-aid Measures

Description of first-aid measures

General information:

Symptoms of poisoning even may occur after several hours; therefore, medical observation for at least 48 hours after the accident

After inhalation:

Supply fresh air.

If having difficulty breathing, contact emergency personnel immediately

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

In case of unconsciousness, place patient securely on side position for transportation.

After skin contact: Immediately wash with water and soap and rinse thoroughly.

After eye contact:

Hold eyelids apart and flush eyes with plenty of water for at least 20 minutes.

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After swallowing:

Never give anything by mouth to an unconscious person

If conscious, drink large quantities of lemon water or lemon-lime soda and seek medical attention immediately. Immediately call a doctor

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:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol-resistant foam.

Special hazards arising from the substance or mixture: No further relevant information available.

Advice for firefighters

Protective equipment:

Full protective clothing and self-contained breathing apparatus should be worn.

Mouth-respiratory protective device

20-22%

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Not required

Environmental precautions: No special measures required

Methods and material for containment and cleaning up:

Absorb with liquid-binding material (i.e, sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

*7. Handling and Storage

Precautions for safe handling

Keep away from heat and direct sunlight.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Information about protection against explosions and fires: No special measures required.

Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles:

Do not store in aluminum, carbon steel, copper, copper alloys, fiberglass, brass, zinc, nickel or galvanized containers.

Information about storage in one common storage facility: Not required

Further information about storage conditions:

Use amber glass or PET for suitable containers. Do not store in metal containers.

Keep receptacle tightly sealed.

Specific end-use(s) No further relevant information available.

*8. Exposure Controls/Personal Protection

Additional information about design of technical systems: No further data; see section 7.

Control parameters

Components with occupational exposure limits:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

Exposure controls

Personal protective equipment:

General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

Breathing equipment: Not required

Protection of hands:



Protective gloves

The glove material has to 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.

Select glove material based on penetration times, rates of diffusion and degradation.

Material of gloves

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 determined and observed by the manufacturer of the protective gloves.

Eye protection:

Have a safety shower and eyewash fountain readily available in the immediate work area

Tightly sealed goggles **Body protection:** Apron

*9. Physical and Chemical Properties

Information on basic physical and chemical properties

General Information

Appearance:

Form: Viscous

Color: Orange to light brown
Odor: Light metallic/acidic
Odor threshold: Not determined

pH-value @ **20** °C (**68** °F): 2.3

Change in condition

Melting point/Melting range:Not determinedBoiling point/Boiling range:100 °C (212 °F)Flash point:Not applicableFlammability (solid, gaseous):Not applicable

Ignition temperature:

Decomposition temperature: Not determined

Auto igniting: Product is not self-igniting.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:

Lower: 0.0 Vol % **Upper:** 0.0 Vol %

Vapor pressure @ 20 °C (68 °F):23 hPa (17 mm Hg)Density:Not determinedRelative densityNot determinedVapour densityNot determinedEvaporation rateNot determined

Solubility in / Miscibility with

Water: Not miscible or difficult to mix

Partition coefficient (n-octanol/water): Not determined

Viscosity:

Dynamic: Not determined **Kinematic:** Not determined

Solvent content:

 Organic solvents:
 0.0 %

 Water:
 38.9 %

 VOC content:
 38.9 %

Other information No further relevant information available.

10. Stability and Reactivity

Reactivity: No further relevant information available.

Chemical stability: Product is stable under normal conditions.

Thermal decomposition/conditions to be avoided: No decomposition if used according to specifications.

Possibility of hazardous reactions: No dangerous reactions known.

Conditions to avoid Avoid heating the product or mixing with acid/alkalies and detergents

Incompatible materials: Strong oxidizing agents, reducing agents and alcohols (aliphatic or aromatic)

Hazardous decomposition products: No dangerous decomposition products known.

11. Toxicological Information

Information on toxicological effects

Acute toxicity:

Primary irritant effect:

on the skin: Irritant to skin and mucous membranes

on the eye: Irritating effect

Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Harmful Irritant

Carcinogenic categories

IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

NTP (National Toxicology Program)

None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

*12. Ecological Information

Toxicity

Aquatic toxicity: No further relevant information available.

Persistence and degradability No further relevant information available. **Bioaccumulative potential** No further relevant information available.

Mobility in soil No further relevant information available.

Additional ecological information:

General notes: Generally not hazardous for water

Results of PBT and vPvB assessment

PBT: Not applicable **vPvB:** Not applicable

Other adverse effects: No further relevant information available.

*13. Disposal Considerations:

Waste-treatment methods

Recommendation:

Do not allow product to reach sewage system.

Observe all federal, state and local environmental regulations when disposing of this material.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

14. Transport Information:

UN-Number

DOT, ADR, ADN, IMDG, IATA Non-Regulated Material

UN proper shipping name

DOT, ADR, ADN, IMDG, IATA Non-Regulated Material

Transport hazard class(es)

DOT, ADR, ADN, IMDG, IATA

Class Non-Regulated Material

Packing group

DOT, ADR, IMDG, IATANon-Regulated Material

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

UN "Model Regulation":

*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 is listed.

Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

TSCA (Toxic Substances Control Act):

1310-45-8 Ferric Subsulfate Hydrate

532-32-1 sodium benzoate

7732-18-5 water, distilled, conductivity or of similar purity

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 is listed.

Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

Carcinogenic categories

EPA (Environmental Protection Agency)

None of the ingredients is listed.

TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

GHS label elements

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Hazard pictograms





Signal word Warning

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Specific treatment (see on this label).

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If eye irritation persists: Get medical advice/attention.

IF ON SKIN: Wash with plenty of water.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

National regulations:

The product is subject to be labeled according with the prevailing version of the regulations on hazardous substances.

State Right to Know

15244-10-7	Thickeners	30-50%
1310-45-8	Ferric Subsulfate Hydrate	20-22%
	STOT SE 2, H371; (1) Acute Tox. 4, H302; Acute Tox. 4, H312;	
	Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2A, H319	
532-32-1	sodium benzoate	0.1%
	(1) Acute Tox. 4, H302; Skin Irrit. 2, H315; STOT SE 3, H335;	
	Eye Irrit. 2B, H320	
7732-18-5	water, distilled, conductivity or of similar purity	25-50%
All ingredients are listed.		

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

Premier's revision date: 09-17-2014

Revision Number: 5

Abbreviations and acronyms:

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: U.S. 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)

Acute Tox. 4: Acute toxicity, Hazard Category 4

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Irrit. 2A: Serious eye damage/eye irritation, Hazard Category 2A

STOT SE 2: Specific target organ toxicity - Single exposure, Hazard Category 2

* Data compared to the previous version altered.

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