

Safety Data Sheet (SDS)

05/2022

SECTION 1: IDENTIFICATION

1.1. (a) Product Identifier

Product Form: Solution

Product Name: Procainamide Hydrochloride Injection, USP **Product Code:** NDC 14789-900-02 and 14789-900-10

Common/Trade Name: Procainamide Hydrochloride Injection, USP

Chemical Name: Benzamide, 4-amino-N-[2-(diethylamino)ethyl]-, monohydrochlorideide

Container Information: Vial

(b) Other means of identification: None

(c) Intended Use of the Product substance/mixture: Group 1A cardiac antiarrhythmic drug.

1.2. (d) Name, Address, and Telephone of the Responsible Party Company

Nexus Pharmaceuticals, Inc. 400 Knightsbridge Parkway Lincolnshire, IL. 60069

USA

1-847-996-3790

www.nexuspharma.net

1.3. (e) Emergency Telephone Number, Hazardous Materials or Dangerous Goods Incident, Spill, Leak, Fire,

Exposure, or Accident:

Call CHEMTREC 24 Hours: 1-800-424-9300 / 1-703-527-3887 Customer Service Team email: CHEMTREC@chemtrec.com

SECTION 2: HAZARDS IDENTIFICATION

2.1. (a) Classification of the Substance or Mixture: Classification (GHS-US)

Respiratory sensitization: Category 1 – (H334) Skin sensitization: Category 1 – (H317)

2.2. (b) Label Elements GHS-US Labeling:



Signal Word: Danger Hazard statements

H317 - May cause an allergic skin reaction

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

2.3. (c) Other Hazards:

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

P272 - Contaminated work clothing must not be allowed out of the workplace

P280 - Wear protective gloves/protective clothing/eye protection/face protection P284 - Wear respiratory protection

P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

P342 + P311 - If experiencing respiratory symptoms: Call a Poison Center or doctor/physician

P302+ P352 - IF ON SKIN: Wash with plenty of soap and water

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P362 - Take off contaminated clothing and wash before reuse

P501 - Dispose of contents/container in accordance with all local and national regulations

2.4. (d) Unknown Acute Toxicity (GHS-US): No data available.



Safety Data Sheet (SDS)

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances: Not applicable

3.2. Mixtures:

(a)Chemical Name	(b) Common Name/Synonym	(c) CAS-No	% Composition or other measurements	Impurities/Stabilizing Additives
Procainamide Hydrochloride	N/A	614-39-1	<50%	N/A
Methylparaben	N/A	99-76-3	<1%	Preservative
Sodium Metabisulfite	N/A	7681-57-4	<1%	Antioxidant
Sodium Hydroxide	N/A	1310-73-2	N/A	To adjust pH
Hydrochloric Acid	N/A	7647-01-0	N/A	To adjust pH
Water for Injection	N/A	7732-18-5	q.s. to 100%	N/A

SECTION 4: FIRST AID MEASURES

4.1. (a) Description of First Aid Measures First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.

First- aid Measures After Inhalation: When symptoms occur go into open air and ventilate suspected area. Seek medical attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Flush with copious quantities of water for 15 minutes. Seek medical advice.

First-aid Measures After Eye Contact: Immediately flush eyes thoroughly with water for at least 15 minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting.

(b) Most important symptoms and effects, both acute and delayed Symptoms/Injuries:

Not expected to present a significant hazard under anticipated conditions of normal use. Please refer to the package insert for more detailed information.

Indication of Any Immediate Medical Attention and Special Treatment Needed: If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. (a) Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: A heavy water stream may spread burning liquid. CAUTION: Carbon dioxide is an asphyxiant. Lack of oxygen can be fatal.

- **(b) Special Hazards Arising from the Substance or Mixture:** Hazardous reactions will not occur under normal conditions.
- **5.2. (c) Special protective equipment and precautions for fire-fighters:** Firefighters must use full bunker gear including NIOSH-approved positive-pressure self-contained breathing apparatus to protect against potential hazardous combustion and decomposition products.

Firefighting Instructions: Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. (a) Personal Precautions, Protective Equipment and Emergency Procedures General Measures Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors.

For Non-emergency Personnel Protective Equipment: Avoid all unnecessary exposure. Do not breathe vapor or mist.

Protective Equipment: Use appropriate personal protection equipment (PPE). Refer to section 8.2.

Emergency Procedures: Evacuate unnecessary personnel.



Safety Data Sheet (SDS)

SECTION 6 CONTINUED: ACCIDENTAL RELEASE MEASURES

Emergency Procedures: Evacuate the area and alert emergency team.

For Emergency Responders Protective Equipment: Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".

Environmental Precautions: Prevent entry into waterways, sewers, basements, or confined areas. Prevent further leakage or spillage if safe to do so.

- **6.2. (b) Methods and Material for Containment and Cleaning Up Methods:** Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.
- **6.3. (c) Reference to Other Sections**: See heading 8, Exposure Controls and Personal Protection.

SECTION 7: HANDLING AND STORAGE

- **7.1.** (a) Precautions for Safe Handling Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.
- **(b) Conditions for Safe Storage, Including Any Incompatibilities Technical Measures:** Comply with applicable regulations.

Storage Conditions: No special storage required for hazard control. Protect from light. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Exposure Scenario: No information available. **Other Guidelines**: No information available

7.2. (c) Incompatible Products: Not applicable.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. (a) Exposure Limit: For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

Refer to available public information for specific member state Occupational Exposure Limits.

Procainamide Hydrochloride:

Pfizer OEL TWA-8 Hr: 100 µg/m³, Sensitizer

Procainamide Hydrochloride:

Russia:

MAC: 0.5 mg/m³

Sodium metabisulfite USP ACGIH TLV: 5 mg/m³

Denmark: 5 mg/m3 France:

5 mg/m3 Ireland:

5 mg/m3 STEL: 15 mg/m3

Spain: 5 mg/m3 Switzerland:

OSHA PEL (vacated) TWA:

5 mg/m3 OSHA PEI 5 mg/m3

United Kingdom TWA:

5 mg/m3

United Kingdom STEL:

15 mg/m3



Safety Data Sheet (SDS)

SECTION 8 CONTINUED: EXPOSURE CONTROLS/PERSONAL PROTECTION

Methyl-p-hydroxybenzoate:

Russia MAC:

4 mg/m3

Sodium hydroxide:

ACGIH OEL (Ceiling):

2 mg/m3

ACGIH TLV (Ceiling):

2 mg/m3

Austria:

2 mg/m3

STEL 4 mg/m3

Bulgaria:

2.0 mg/m³

Czech Republic:

 1 mg/m^3

Ceiling: 2 mg/m³

Denmark:

Ceiling: 2 mg/m³

Estonia: 1 mg/m³

STEL: 2 mg/m³

Finland:

Ceiling: 2 mg/m³

France:

2 mg/m³

Hungary:

2 mg/m³

STEL: 2 mg/m³

Ireland:

STEL: 2 mg/m³

Ceiling Limit Value: 2 mg/m³

Latvia: 0.5 mg/m³

Poland:

STEL: 1 mg/m³

0.5 mg/m³

Romania:

 1 mg/m^3

STEL: 3 mg/m³

Slovakia:

2 ma/m³

Spain:

STEL: 2 mg/m³

Switzerland:

2 mg/m³

OSHA PEL:

2 mg/m3,

(vacated) Ceiling: 2 mg/m3

United Kingdom: STEL: 2 mg/m3 Hydrochloric Acid

ACGIH OEL (Ceiling): 2 ppm



Safety Data Sheet (SDS)

SECTION 8 CONTINUED: EXPOSURE CONTROLS/PERSONAL PROTECTION

ACGIH TLV: Ceiling: 2 ppm Austria: 5 ppm 8 mg/m3 STEL 10 ppm STEL 15 mg/m3

Bulgaria: STEL: 10 ppm STEL: 15.0 mg/m3

5 ppm 8.0 mg/m3 Czech Republic: 8 mg/m3

Ceiling: 15 mg/m3

Denmark: Ceiling: 5 ppm Ceiling: 8 mg/m3

Estonia: 5 ppm 8 mg/m3 STEL: 10 ppm STEL: 15 mg/m3 Finland:

STEL: 5 ppm STEL: 7.6 mg/m3 Germany: 2 ppm

2 ppm 3.0 mg/m3

Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m3

Germany: 2 ppm 3 mg/m3 Hungary: 8 mg/m3

STEL: 16 mg/m3

Ireland: 8 mg/m3 5 ppm STEL: 10 ppm STEL: 15 mg/m3

Italy: 5 ppm 8 mg/m3 STEL: 10 ppm STEL: 15 mg/m3 Ceiling Limit Value: 2 ppm

2 ppm 3.0 mg/m3 Latvia: 5 ppm 8 mg/m3 STEL: 10 ppm STEL: 15 mg/m3



Safety Data Sheet (SDS)

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Netherlands:

8 mg/m3

STEL: 15 mg/m3

Poland:

STEL: 10 mg/m3 5 mg/m3

Romania:

5 ppm 8 mg/m3 STEL: 10 ppm STEL: 15 mg/m3

Russia:

MAC: 5 mg/m3 Slovakia:

5 ppm 8.0 mg/m3 **Spain:**

Spain: 5 ppm 7.6 mg/m3 STEL: 10 ppm STEL: 15 mg/m3 Switzerland:

2 ppm 3 mg/m3 STEL: 4 ppm STEL: 6 mg/m3

U.S. - OSHA - Final PELs - Ceiling Limits:

5 ppm 7 mg/m3 **OSHA PEL:**

(vacated) Ceiling: 5 ppm

(vacated) Ceiling: 7 mg/m3 Ceiling: 5 ppm

Ceiling: 7 mg/m3 United Kingdom: TWA: 1 ppm TWA: 2 mg/m3 STEL: 5 ppm STEL: 8 mg/m3

8.2. (b) Appropriate Engineering Controls: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

8.3. (c) Personal Protective Equipment: Gloves. Safety glasses.





RESPIRATORY PROTECTION: In case of inadequate ventilation wear respiratory protection.

EYE PROTECTION: Chemical goggles or safety glasses.

HAND PROTECTION: Wear chemically resistant protective gloves.

SKIN and BODY PROTECTION: Wear suitable protective clothing. Wash contaminated clothing before reuse.

SPECIAL NOTE: When using, do not eat, drink, or smoke.



Safety Data Sheet (SDS)

9.1. Information on Basic Physical and Chemical Properties

(a) Appearance (physical state. Color, etc.), : Liquid, colorless to slightly yellow

(b) Odor : Not applicable (c) Odor Threshold : Not applicable

(d) pH : 4.0 - 6.0

(d) pH : 4.0 – 6.0

(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
 : Not available

(k) Vapor Pressure : No data available (l) Vapor Density : Not available

(m) Relative Density at 20 °C : No data available (n) Solubility (ies) : Not applicable

(o) Partition Coefficient: N-Octanol/Water : Not applicable
(p) Auto-ignition temperature : Not applicable

(q) Decomposition temperature: Not applicable(r) Viscosity: Not applicable

Other Information : No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. (a) Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. (b) Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. (c) Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. (d) Conditions to Avoid: Direct sunlight. Extremely high or low temperatures.

10.5. (e) Incompatible Materials: Strong oxidizers. Strong bases.

10.6. (f) Hazardous Decomposition Products: Thermal decomposition generates: Carbon oxides (CO, CO2),

Halogenated compounds, Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

The most common adverse effects seen during clinical use of this drug include gastrointestinal disturbances, abdominal pain, nausea, vomiting, diarrhea, dizziness, seizure, mental depression, confusion, impaired mental state (psychosis), hallucinations, hives, redness and swelling of the skin (urticaria), itching sensation (pruritus), skin rash, increased heart rate (tachycardia).

(a) Likely Route of entry: Skin, eyes, or inhalation.

INHALATION: Prolonged exposure may cause irritation.

CONTACT WITH SKIN or EYES:

Irritation / Sensitization: (Study Type, Species, Severity) Methyl-p-hydroxybenzoate

Skin Irritation Rabbit Non-Irritating Eye Irritation Rabbit SlightSkin Sensitization Guinea Pig Negative

Sodium hydroxide

Eye Irritation Rabbit Severe Skin Irritation Rabbit Severe

Hydrochloric Acid

Skin Irritation Severe Eye Irritation Severe

INGESTION: Ingestion may cause adverse effects.

(b) Symptoms related to the chemical, and toxicological characteristics:

Acute: (Species, Route, End Point, Dose) Procainamide Hydrochloride



Safety Data Sheet (SDS)

SECTION 11 CONTINUED: TOXICOLOGICAL INFORMATION

Mouse Oral LD50

701 mg/kg Rat Oral LD50

1509 mg/kg Rat IV LD50 95 mg/kg.

(c) Delayed and immediate effects and chronic effects from short- and long-term exposure: Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ) Methyl-p-hydroxybenzoate 28 Day(s) Rat Oral 250 mg/kg/day NOAEL Gastrointestinal System, Spleen, Thymus.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s)) Methyl-p-hydroxybenzoate Embryo / Fetal Development Rabbit Oral 300 mg/kg/day NOEL Maternal toxicity, Developmental toxicity.

(Species, Route, End Point, Dose) Procainamide Hydrochloride

Mouse Oral LD50

701 mg/kgRat Oral LD50

1509 mg/kg Rat IV LD50 95 mg/kg

(d) Acute Toxicity:

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Procainamide Hydrochloride	= 1509 mg/kg (Rat)	-	-
Water	> 90 mL/kg (Rat)	-	-
Sodium metabisulfite USP	= 1310 mg/kg (Rat)	> 2000 mg/kg (Rat) > 2 g/kg (Rat)	-
Methyl-p-hydroxybenzoate	= 2100 mg/kg (Rat)	-	-
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	•
Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was notachievable at the highest dose used in the test.

(e) Hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Sodium metabisulfite USP

IARC Group 3 (Not Classifiable)

Hvdrochloric Acid

ARC Group 3 (Not Classifiable)

SECTION 12: ECOLOGICAL INFORMATION

- **12.1. (a) Ecotoxicity**: Not applicable
- 12.2. (b) Persistence and Degradability: Not established.
- 12.3. (c) Bio accumulative Potential: Not established.
- **12.4. (d) Mobility in Soil:** No additional information available.
- 12.5. (e) Other Adverse Effects: Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

- (a) Sewage Disposal Recommendations: Do not empty into drains; dispose of this material and its container in a safe way.
- **(b) Waste Disposal Recommendations:** Dispose of waste material in accordance with all local, regional, national, and international regulations.



Safety Data Sheet (SDS)

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT: Not regulated for transport

(a) UN Number: Not applicable

(b) UN Proper Shipping Name: Not applicable.

(c) Transportation Hazardous Class (es): Not applicable.

(d) Packing group: Not applicable.

(e) Environmental Hazards (e.g., Marine pollutant): Not regulated for transport.

(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable.

(g) Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises: Not applicable.

14.2. In Accordance with IMDG: Not regulated for transport

14.3. In Accordance with IATA: Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. U.S. REGULATIONS:

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

alth and Environmental Regulations/Legislation Specific for the Substa Procainamide Hydrochloride	ince or wixture
CERCLA/SARA Section 313 de minimus %	Not listed
California Proposition 65	Not listed
TSCA	Present
EINECS	210-381
AICS	Present
Water for Injection	
CERCLA/SARA Section 313 de minimus %	Not listed
California Proposition 65	Not listed
TSCA	Present
EINECS	231-791-2
AICS	Present
Sodium metabisulfite USP	
CERCLA/SARA Section 313 de minimus %	Not listed
California Proposition 65	Not listed
TSCA	Present
EINECS	231-673-0
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5
Methyl-p-hydroxybenzoate	
CERCLA/SARA Section 313 de minimus %	Not listed
California Proposition 65	Not listed
TSCA	Present
EINECS	202-785-7
AICS	Present
Sodium hydroxide	
CERCLA/SARA Section 313 de minimus %	Not listed
Hazardous Substances RQs	1000 lb.
California Proposition 65	Not listed
TSCA	Present
EINECS	215-185-5
AICS	Present



Safety Data Sheet (SDS)

SECTION 15 CONTINUED: REGULATORY INFORMATIO	

Sodium hydroxide continued:	
Standard for Uniform Scheduling of Medicines and Poisons	Schedule 5
(SUSMP)	Schedule 6
Hydrochloric Acid	
CERCLA/SARA Section 313 de minimus %	1%
Hazardous Substances RQs	5000 lb.
California Proposition 65	Not listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons	Schedule 5
(SUSMP)	Schedule 6

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

16.1. Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

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

10, 01 10801141 10 4	
ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health



Safety Data Sheet (SDS)

16 CONTINUE	D: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases: Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed H314 - Causes severe skin burns and eye damage H317 - May cause an allergic skin reaction H318 - Causes serious eye damage H331 - Toxic if inhaled H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled H335 - May cause respiratory irritation H411 - Toxic to aquatic life with long lasting effects.

Refer to Nexus Pharmaceuticals, Inc prescribing information for further information at: https://www.nexuspharma.net/products/

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Date of issue/ Date of revision: 05/06/2022

SDS US (GHS HazCom)