



WELLY HEALTH PBC

Safety Data Sheet Welly Triple Antibiotic Ointment

SECTION 1: Identification

1.1 GHS Product identifier

Product name **Welly Triple Antibiotic Ointment**

1.4 Supplier's details

Name Welly Health PBC
Address 700 Nicollet Mall
Suite 800
Minneapolis, MN 55402
United States

Telephone 1-833-239-3559
email hello@getwelly.com

1.5 Emergency phone number 1-833-239-3559 (24-Hour Coverage)

SECTION 2: Hazard identification

General hazard statement

Personal Care applications. No restrictions on use. Chemical Family: Mixture

2.1 **Classification of the substance or mixture:** White gel. Mild odor. This product is sold as a personal care item that is safe for consumers and other users under normal and reasonably foreseeable use. As such, it is not regulated under Hazcomm 2012/WHMIS 2015 labeling and SDS requirements do not apply.

GHS classification in accordance with: OSHA (29 CFR 1910.1200)

2.2 GHS label elements, including precautionary statements

Hazard Pictogram(s): None required under US OSHA Hazcom 2012 and Canadian WHMIS 2015 regulations
Signal Word: None required under US OSHA Hazcom 2012 and Canadian WHMIS 2015 regulations
Hazard Statement(s): None required under US OSHA Hazcom 2012 and Canadian WHMIS 2015 regulations
Precautionary Statement(s): None required under US OSHA Hazcom 2012 and Canadian WHMIS 2015 regulations

2.3 Other hazards which do not result in classification

None known.

Statement regarding ingredients of unknown toxicity

Not a hazardous substance or mixture.

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SECTION 3: Composition/information on ingredients

Mixture

Chemical Name	Common Name and Synonyms	CAS #	Concentration (% by weight)
Bacitracin Zinc	Not available	1405-89-6	Proprietary
Neomycin Sulfate	Not available	1405-10-3	Proprietary
Polymyxin b, Sulfate (salt)	Not available	1405-20-5	Proprietary

The exact concentrations and/or specific chemical identities of the above listed chemicals are being withheld as a trade secret as allowed by 29CFR1910.1200.

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

General advice	Consult a physician. Show this safety data sheet to the doctor in attendance
If inhaled	Under normal conditions of intended use, no harmful effects are expected. use. If symptomatic, move to fresh air. Get medical attention if symptoms persist.
In case of skin contact	Harmful effects are not expected under normal usage. If skin irritation or rash occurs, get medical advice/attention
In case of eye contact	If in the eye(s), rinse cautiously with water for several minutes. If eye irritation persists, get medical advice/attention
Personal protective equipment for first-aid responders	Not applicable

4.2 Most important symptoms/effects, acute and delayed:

None expected, when used as intended

4.3 Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

<i>Suitable extinguishing media:</i>	Dry chemicals. Foam. Carbon dioxide (CO2). Water or fog spray.
<i>Unsuitable extinguishing media:</i>	Do not use water jet as extinguisher, as this will spread the fire.

5.2 Specific hazards arising from the chemical

Vapors are heavier than air and may spread along the floors.

5.3 Flammability classification (OSHA 29CFR 1910.106)

Not flammable

5.4 Hazardous combustion products

Carbon Oxides

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SECTION 5: Fire-fighting measures (continued)

5.3 Special protective actions for fire-fighters

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA.

Special fire-fighting procedures: Fight fires from a safe distance. Move containers from fire area if safe to do so. Cool containers exposed to heat with water spray.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Eliminate all sources of ignition (no smoking, flares, sparks, or flames in immediate area). Wear appropriate personal protective equipment.

6.2 Environmental precautions

Do not allow material to contaminate ground water system. For large spills, dike the area to prevent spreading.

6.3 Methods and materials for containment and cleaning up

Wipe up with absorbent material (e.g. – cloth, fleece)

6.4 Special spill response procedure

Not applicable.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources – no smoking. Do not ingest or swallow. Observe good industrial hygiene practices.

7.2 Conditions for safe storage, including any incompatibilities

Storage Conditions: Keep containers closed when not in use.

Incompatible materials:

Strong oxidizing agents. Acids.

Specific end use(s)

The product is used for temporary relief of itching.

SECTION 8: Exposure controls/personal protection

Exposure Limits:				
Chemical Name	ACGIH TLV		OSHA PEL	
	TWA	STEL	PEL	STEL
Bacitracin Zinc	N/Av	N/Av	N/Av	N/Av
Neomycin Sulfate	N/Av	N/Av	N/Av	N/Av
Polymyxin b, sulfate (salt)	N/Av	N/Av	N/Av	N/Av

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SECTION 8: Exposure controls/personal protection (continued)

- 8.2 Appropriate engineering controls** : None required under normal conditions.
- 8.3 Individual protection measures, such as personal protective equipment (PPE)**
- General Hygiene considerations** : Always observe good person hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking.
- Eye/face protection** : None required under normal conditions.
- Skin protection** : None required under normal conditions.
- Body protection** : None required under normal conditions.
- Respiratory protection** : None required under normal conditions.
- Other protective equipment** : None required under normal conditions.

SECTION 9: Physical and chemical properties and safety characteristics

Basic physical and chemical properties

Physical state	Ointment
Appearance	White
Odor	Mild odor
Odor threshold	Not available
Melting point/freezing point	Not available
Boiling point or initial boiling point and boiling range	Not available
Flammability (solid, gas)	Not available
Lower and upper explosion limit/flammability limit	Not applicable
Flashpoint	>93.3°C (>199.9°F)
Auto-ignition temperature	Not available
Decomposition temperature	Not available
pH	None
viscosity	Not available
Solubility in water	Insoluble
Relative density/Specific Gravity	Not available
Partition coefficient n-octanol/water (log value)	Not available
Vapor pressure	Not available
Evaporation rate	Not available
Relative vapor density	Not available

SECTION 10: Stability and reactivity

- 10.1 Reactivity**
Stable and non-reactive under normal conditions for use, storage and transport.
- 10.2 Chemical stability**
Stable under normal conditions.
- 10.3 Possibility of hazardous reactions**
Hazardous polymerization does not occur.

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SECTION 10: Stability and reactivity (continued)

10.4 Conditions to avoid

Keep away from heat, sparks and open flames.

10.5 Incompatible materials

See Section 7 (Handling and Storage) for further details.

10.6 Hazardous decomposition products

See Section 5 (Fire Fighting Measures).

SECTION 11: Toxicological information

Information on likely routes of exposure:

Routes of entry - inhalation : YES

Routes of entry – skin & eye : YES

Routes of entry – ingestion : YES

Routes of exposure skin absorption: YES

Information on toxicological effects

Skin corrosion/irritation

Product not expected to be a skin hazard under normal use.

Serious eye damage/irritation

Based on intended use, not expected. Direct contact with eye will cause irritation.

Respiratory or skin sensitization

Not expected to be skin or respiratory sensitizer

Germ cell mutagenicity

Based on intended use, not expected.

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA

Reproductive toxicity

This product is not expected to cause reproductive or developmental effects.

STOT-single exposure

None expected when used as intended.

STOT-repeated exposure

None expected when used as intended.

Aspiration hazard

None expected when used as intended.

Potential Chronic Health Effects

Prolonged or repeated skin contact may cause drying and irritation. Prolonged overexposure may cause liver and kidney effects.

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SECTION 12: Ecological information

Toxicity

This product is not classified as environmentally hazardous. Avoid release to the environment.

Ecotoxicity Data:

<u>Ingredients</u>	CAS No	Toxicity to Fish		
		LC50 / 96h	NOEC / 21 day	M Factor
Bacitracin zinc	1405-89-6	N/Av	N/Av	None.
Neomycin sulfate	1405-10-3	N/Av	N/Av	None.
Polymyxin b, sulfate (salt)	1405-20-5	N/Av	N/Av	None.

<u>Ingredients</u>	CAS No	Toxicity to Daphnia		
		EC50 / 48h	NOEC / 21 day	M Factor
Bacitracin zinc	1405-89-6	N/Av	N/Av	None.
Neomycin sulfate	1405-10-3	N/Av	N/Av	None.
Polymyxin b, sulfate (salt)	1405-20-5	N/Av	N/Av	None.

<u>Ingredients</u>	CAS No	Toxicity to Algae		
		EC50 / 96h or 72h	NOEC / 96h or 72h	M Factor
Bacitracin zinc	1405-89-6	N/Av	N/Av	None.
Neomycin sulfate	1405-10-3	N/Av	N/Av	None.
Polymyxin b, sulfate (salt)	1405-20-5	N/Av	N/Av	None.

Persistence and degradability

Not available.

Bio accumulative potential

Not available.

<u>Components</u>	<u>Partition coefficient n-octanol/water (log Kow)</u>	<u>Bioconcentration factor (BCF)</u>
Bacitracin zinc (CAS 1405-89-6)	N/Av	N/Av
Neomycin sulfate (CAS 1405-10-3)	N/Av	N/Av
Polymyxin b, sulfate (salt) (CAS 1405-20-5)	N/Av	N/Av

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SECTION 12: Ecological information (continued)

Mobility in soil

Not available.

Other adverse effects

Not available.

SECTION 13: Disposal considerations

Handling for Disposal: Dispose of in accordance with all federal, state, provincial and local regulations.

Methods of Disposal: Dispose in accordance with all applicable federal, state, provincial and local regulations.

RCRA: Not applicable

SECTION 14: Transport information

Regulatory Information	UN Number	UN proper shipping name	Transport hazard class(es)	Packing Group	Label
49CFR/DOT	None.	Not regulated.	not regulated	none	
49CFR/DOT Additional information	None.				
TDG	None.	Not regulated.	not regulated	none	
TDG Additional information	None.				
ICAO/IATA	None.	Not regulated.	not regulated	none	
ICAO/IATA Additional information	None.				
IMDG	None.	Not regulated.	not regulated	none	
IMDG Additional information	None.				

Special precautions for user: Keep away from heat and flame.

Environmental Hazards: This product does not meet the criteria for an environmentally hazardous mixture, according to the IMDG Code. See Section 12 for more environmental information.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: not established

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SECTION 15: Regulatory information

US Federal Information:

Components listed below are present on the following US Federal chemical lists:

<u>Ingredients</u>	CAS #	TSCA Inventory	CERCLA Reportable Quantity(RQ) (40 CFR 117.302):	SARA TITLE III: Sec. 302, Extremely Hazardous Substance, 40 CFR 355:	SARA TITLE III: Sec. 313, 40 CFR 372, Specific Toxic Chemical	
					Toxic Chemical	de minimus Concentration
Bacitracin zinc	1405-89-6	Yes	N/Ap	N/Av	No	N/Ap
Neomycin sulfate	1405-10-3	Yes	N/Ap	N/Av	No	N/Ap
Polymyxin b, sulfate (salt)	1405-20-5	NL	N/Ap	N/Av	No	N/Ap

SARA TITLE III: Section 313, Toxic Chemicals Notification, 40 CFR 372: None. Under Sections 311 and 312, the EPA has established threshold quantities for the reporting of hazardous chemicals. The current thresholds are 500 pounds or the threshold planning quantity (TPQ), whichever is lower, for extremely hazardous substances and 10,000 pounds for all other hazardous chemicals.

US State Right to Know Laws:

The following chemicals are specifically listed by individual states:

<u>Ingredients</u>	CAS #	California Proposition 65		State "Right to Know" Lists					
		Listed	Type of Toxicity	CA	MA	MN	NJ	PA	RI
Bacitracin zinc	1405-89-6	No	N/Ap	No	No	No	No	No	No
Neomycin sulfate	1405-10-3	Yes	Developmental	No	No	No	No	No	No
Polymyxin b, sulfate (salt)	1405-20-5	No	N/Ap	No	No	No	No	No	No

Canadian Information:

All components of this product are on the Canadian DSL list.

WHMIS Classification: See Section 2

International Information:

Components listed below are present on the following International Inventory lists:

<u>Ingredients</u>	CAS #	European EINECS	Australia AICS	Philippines PICCS	Japan ENCS	Korea KECI/KECL	China IECSC	NewZealand IOC
Bacitracin zinc	1405-89-6	215-787-8	Present	Present	(8)-475	N/Av	N/Av	HSR003849
Neomycin sulfate	1405-10-3	215-773-1	Present	Present	N/Av	KE-25806	Present	HSR003798
Polymyxin b, sulfate (salt)	1405-20-5	215-774-7	Present	Present	N/Av	KE-05-1072	Present	HSR003906

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SECTION 16: Other information

Legend:

ACGIH: American Conference of Governmental Industrial Hygienists
CA: California
CAS: Chemical Abstract Service
CEPA: Canadian Environmental Protection Act
CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act of 1980
CFR: Code of Federal Regulations
CPR: Controlled Products Regulation
CSA: Canadian Standards Association
DOT: Department of Transportation
DSL: Domestic Substances List
EPA: Environmental Protection Agency
HPA: Hazardous Product Act
HSDB: Hazardous Substances Data Bank
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
IMDG: International Maritime Dangerous Goods
Inh: Inhalation
LC: Lethal Concentration
LD: Lethal Dose
MA: Massachusetts
MN: Minnesota
N/Ap: Not Applicable
N/Av: Not Available
NIOSH: National Institute of Occupational Safety and Health
NJ: New Jersey
NOEC: No observable effect concentration
NTP: National Toxicology Program
OECD: Organization for Economic Co-operation and Development
OEL: National occupational exposure limits
OSHA: Occupational Safety and Health Administration
PA: Pennsylvania
PEL: Permissible exposure limit
PPE: Personal Protective Equipment
RCRA: Resource Conservation and Recovery Act
RI: Rhode Island
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
TDG: Canadian Transportation of Dangerous Goods Act & Regulations
TLV: Threshold Limit Values
TWA: Time Weighted Average
WEL: Workplace Exposure Limit
WHMIS: Workplace Hazardous Materials Identification System

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DISCLAIMER

This Safety Data Sheet was prepared by Welly Health PBC using information provided by its contract manufacturer. The information in the Safety Data Sheet is offered for your consideration and guidance when exposed to this product. Welly Health PBC expressly disclaims all expressed or implied warranties and assumes no responsibilities for the accuracy or completeness of the data contained herein. The data in this Safety Data Sheet does not apply to use with any other product or in any other process.

This Safety Data Sheet may not be changed, or altered in any way without the expressed knowledge and permission of Welly Health PBC.



WELLY HEALTH PBC

Safety Data Sheet Welly 1% Hydrocortisone Cream

SECTION 1: Identification

1.1 GHS Product identifier

Product name **Welly 1% Hydrocortisone Cream**

1.4 Supplier's details

Name Welly Health PBC
Address 700 Nicolette Mall
 Suite 800
 Minneapolis, MN 55402
 United States

Telephone 1-833-239-3559
email hello@getwelly.com

1.5 Emergency phone number 1-833-239-3559 (24-Hour Coverage)

SECTION 2: Hazard identification

General hazard statement

Personal Care applications. No restrictions on use. Chemical Family: Mixture

2.1 **Classification of the substance or mixture:** White cream. This product is sold as a personal care item that is safe for consumers and other users under normal and reasonably foreseeable use. As such, it is not regulated under Hazcomm 2012/WHMIS 2015 labeling and SDS requirements do not apply.

GHS classification in accordance with: OSHA (29 CFR 1910.1200)

2.2 GHS label elements, including precautionary statements

Hazard Pictogram(s): None required under US OSHA Hazcom 2012 and Canadian WHMIS 2015 regulations
Signal Word: None required under US OSHA Hazcom 2012 and Canadian WHMIS 2015 regulations
Hazard Statement(s): None required under US OSHA Hazcom 2012 and Canadian WHMIS 2015 regulations
Precautionary Statement(s): None required under US OSHA Hazcom 2012 and Canadian WHMIS 2015 regulations

2.3 Other hazards which do not result in classification

None known.

Statement regarding ingredients of unknown toxicity

Not a hazardous substance or mixture.

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SECTION 3: Composition/information on Ingredients

Mixture

Chemical Name	Common Name and Synonyms	CAS #	Concentration (% by weight)
Hydrocortisone	Hydrocortisone	50-23-7	0.5 – 1.5
Mineral Oil	Paraffin Oil Liquid petrolatum	8042-47-5	1.0 – 5.0

The exact concentrations and/or specific chemical identities of the above listed chemicals are being withheld as a trade secret as allowed by 29CFR1910.1200.

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

General advice	Consult a physician. Show this safety data sheet to the doctor in attendance
If inhaled	Under normal conditions of intended use, none required under normal conditions of use. If symptomatic, move to fresh air. Get medical attention if symptoms persist.
In case of skin contact	No treatment is necessary under ordinary use. If skin irritation or rash occurs, get medical advice/attention.
In case of eye contact	If eye contact is made. Rinse cautiously with water for several minutes. If eye irritation persists, get medical advice/attention
If swallowed	Under normal conditions of intended use, this product is not ingested. In case of an accident or if you feel unwell, seek medical advice immediately (show the label when possible).
Personal protective equipment for first-aid responders	Not applicable

4.2 Most important symptoms/effects, acute and delayed

None expected when used as intended.

4.3 Indication of immediate medical attention and special treatment needed, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Dry chemicals. Foam. Carbon dioxide (CO₂). Water or fog spray.

5.2 Specific hazards arising from the chemical

None

5.3 Flammability classification (OSHA 29 CFR 1910.106)

Not applicable

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SECTION 5: Fire-fighting measures (continued)

5.3 Special protective actions for fire-fighters

Firefighters should wear an approved full-face, self-contained breathing apparatus (SCBA) and impervious clothing.

Special fire-fighting procedures: Fight fires from a safe distance. Move containers from fire area if safe to do so.

Water spray may be useful in cooling equipment exposed to heat and flame.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Eliminate all ignition sources (no smoking, flames, sparks, or flames in the immediate area). Wear appropriate personal protective equipment.

6.2 Environmental precautions

Avoid release to the environment.

6.3 Methods and materials for containment and cleaning up

Wipe up with absorbent material (e.g. – cloth, fleece)

6.4 Special spill response procedure

Not applicable.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Do not ingest or swallow. Observe good industrial hygiene practices.

7.2 Conditions for safe storage, including any incompatibilities

Storage Conditions: Keep containers closed when not in use.

Incompatible materials:

Strong oxidizing agents. Acids.

Specific end use(s)

This product is used to relieve itching.

SECTION 8: Exposure controls/personal protection

Exposure Limits:			
Chemical Name	ACGIH TLV		OSHA PEL
	TWA	STEL	PEL STEL
Hydrocortisone	N/Av	0.5 mg/m ³	0.5 mg/m ³ N/Av
Mineral Oil	5 mg/m ³ (inhalable) N/Av (As "Oil Mist")		N/Av N/Av

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SECTION 8: Exposure controls/personal protection (continued)

8.2 Appropriate engineering controls

None required under normal conditions.

8.3 Individual protection measures, such as personal protective equipment (PPE)

General Hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking and/or smoking.

Eye/face protection

None required under normal conditions.

Skin protection

None required under normal conditions.

Respiratory protection

None required under normal conditions.

Other protective equipment

None required under normal conditions.

SECTION 9: Physical and chemical properties and safety characteristics

Basic physical and chemical properties

Physical state	Cream
Appearance	White cream
Odor	Slight odor
Odor threshold	Not available
Melting point/freezing point	Not Available
Boiling point or initial boiling point and boiling range	Not available
Flammability (solid, gas)	Not available
Lower and upper explosion limit/flammability limit	Not applicable
Flashpoint	>230°C (446°F)
Flashpoint (method)	Closed cup
Auto-ignition temperature	Not available
Decomposition temperature	Not available
pH	6.0 - 8.0
viscosity	Not available
Solubility in water	Complete
Relative density/Specific Gravity	Not available
Partition coefficient n-octanol/water or coefficient of water/oil distribution	Not available
Vapor pressure	Not available
Evaporation rate	Not available
Relative vapor density	Not available

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SECTION 10: Stability and reactivity

10.1 Reactivity

Stable and non-reactive under normal conditions for use, storage and transport.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerization does not occur.

10.4 Conditions to avoid

Keep away from heat, sparks and open flames.

10.5 Incompatible materials

See Section 7 (Handling and Storage) for further details.

10.6 Hazardous decomposition products

See Section 5 (Fire Fighting Measures).

SECTION 11: Toxicological information

Information on likely routes of exposure:

Routes of entry - inhalation	:	YES
Routes of entry – skin & eye	:	YES
Routes of entry – ingestion	:	YES
Routes of exposure skin absorption:		YES

Potential Health Effects

Signs and symptoms of short-term (acute) exposure

Signs and symptoms Inhalation:	None expected, when used as intended
Signs and symptoms Ingestion:	None expected, when used as intended
Signs and symptoms Skin:	None expected, when used as intended
Signs and symptoms Eyes	None expected, when used as intended. Direct eye contact may cause irritation. Symptoms may include tearing, redness and discomfort.

Potential Chronic Health Effects

Mutagenicity

Carcinogenicity

None expected, when used as intended
Not expected to be mutagenic
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA

Reproductive effects & Teratogenicity

This product is not expected to cause reproductive or developmental effects

Sensitization to material

Specific target organ effects

Medical conditions aggravated by overexposure

Synergistic materials

Toxicological data

Not expected to be a skin or respiratory sensitizer
Not expected to have any, when used as intended

None

None

See below for individual ingredient acute toxicity data

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SECTION 11: Toxicological information (continued)

<u>Chemical Name</u>	LC50(4hr)	LD50	
	<u>inh, rat</u>	<u>(Oral, Rat)</u>	<u>(Rabbit, dermal)</u>
Hydrocortisone	N/Av	2,000 mg/kg	>5,000 mg/kg
Mineral Oil	> 5 mg/L (mist (no mortality))	> 5000 mg/kg	> 2000 mg/kg

Other important toxicological hazards None known

SECTION 12: Ecological information

Ecotoxicity

This product is not classified as environmentally hazardous. Avoid release to the environment.

Ecotoxicity data:

<u>Ingredients</u>	<u>CAS No.</u>	Toxicity to Fish		
		LC₅₀ 96h	NOEC / 21 day	M Factor
Hydrocortisone	50-23-7	N/Av	N/Av	None
Mineral Oil	8024-47-5	> 1000 mg/L (Rainbow trout)	> 1000 mg/L/28-day	None

<u>Ingredients</u>	<u>CAS No.</u>	Toxicity to Daphnia		
		EC₅₀ 48h	NOEC / 21 day	M Factor
Hydrocortisone	50-23-7	100 mg/L (Daphnia magna)	25 mg/L	None
Mineral Oil	8024-47-5	> 100 mg/L (Daphnia magna)	> 10 mg/L (Read-across)	None

<u>Ingredients</u>	<u>CAS No.</u>	Toxicity to Algae		
		EC₅₀ 96h or 72h	NOEC / 96h or 72h	M Factor
Hydrocortisone	50-23-7	1 mg/L/72hr (Green algae)	0.1 mg (96h)	10
Mineral Oil	8024-47-5	N/Av	> 100 mg/L/72hr (NOEL) (Green Algae)	None

Persistence and degradability

Not available.

Bio accumulative potential

Not available.

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SECTION 12: Ecological information (continued)

Component	Partition coefficient n-octanol/water (log Kow)	Bioconcentration factor (BCF)
Hydrocortisone (CAS #50-23-7)	3.5	N/Av

Mobility in soil

Not available.

Other adverse environmental effects

Not available.

SECTION 13: Disposal considerations

Handling for Disposal:

Dispose of in accordance with local regulations

Methods of Disposal:

Dispose of in accordance with local regulations.

RCRA:

Not applicable

SECTION 14: Transport information

Regulatory Information	UN Number	UN proper shipping name	Transport hazard class(es)	Packing Group	Label
49CFR/DOT	None.	Not regulated.	not regulated	none	
49CFR/DOT Additional information	Not regulated for road or rail shipment if packaged in non-bulk containers (450 Litres or less each).				
TDG	None.	Not regulated.	not regulated	none	
TDG Additional information	None.				
ICAO/IATA	None.	Not regulated.	not regulated	none	
ICAO/IATA Additional information	None.				
IMDG	None.	Not regulated.	not regulated	none	
IMDG Additional information	None.				

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SECTION 14: Transport information (continued)

Special precautions for user: Appropriate advice on safety must accompany the package.

Environmental Hazards: This product does not meet the criteria for an environmentally hazardous mixture, according to the IMDG Code. See Section 12 for more environmental information.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: not established

SECTION 15: Regulatory information

US Federal Information:

Components listed below are present on the following US Federal chemical lists:

Ingredients	CAS #	TSCA Inventory	CERCLA Reportable Quantity (RQ) (40 CFR 117.302)	SARA TITLE III: Sec 302, Extremely Hazardous Substance, 40 CFR 355	SARA Title III: Sec 313, 40 CFR 372, Specific Toxic Chemical	
					Toxic Chemical	de minimus Concentration
Hydrocortisone	50-23-7	Yes	None	None	No	N/Ap
Mineral Oil	8042-47-5	Yes	None	None	No	N/Ap

SARA TITLE III: Section 313, Toxic Chemicals Notification, 40 CFR 372: None. Under Sections 311 and 312, the EPA has established threshold quantities for the reporting of hazardous chemicals. The current thresholds are 500 pounds or the threshold planning quantity (TPQ), whichever is lower, for extremely hazardous substances and 10,000 pounds for all other hazardous chemicals.

US State Right to Know Laws:

The following chemicals are specifically listed by individual states:

Ingredients	CAS #	California Proposition 65		State "Right to Know Lists					
		Listed	Type of Toxicity	CA	MA	MN	NJ	PA	RI
Hydrocortisone	50-23-7	No	N/Ap	No	No	No	No	No	No
Mineral Oil	8042-47-5	No	N/Ap	No	No	No	No	No	No

Canadian Information:

All components of this product are on the Canadian DSL list.

WHMIS Classification: See Section 2

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SECTION 15: Regulatory information (continued)

International Information:

Components listed below are present on the following International Inventory lists:

Ingredients	CAS#	European EINECS	Australia AICS	Philippines PICCS	Japan ENCS	China IECSC	New Zealand IOC
Hydrocortisone	50-23-7	200-020-1	Present	Present	Present	Present	Present
Mineral Oil	8042-47-5	232-455-8	Present	Present	Present	Present	Present

SECTION 16: Other information

Legend:

ACGIH: American Conference of Governmental Industrial Hygienists

CA: California

CAS: Chemical Abstract Service

CEPA: Canadian Environmental Protection Act

CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act of 1980

CFR: Code of Federal Regulations

CPR: Controlled Products Regulation

CSA: Canadian Standards Association

DOT: Department of Transportation

DSL: Domestic Substances List

EPA: Environmental Protection Agency

HPA: Hazardous Product Act

HSDB: Hazardous Substances Data Bank

IARC: International Agency for Research on Cancer

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

IMDG: International Maritime Dangerous Goods

Inh: Inhalation

LC: Lethal Concentration

LD: Lethal Dose

MA: Massachusetts

MN: Minnesota

N/Ap: Not Applicable

N/Av: Not Available

NIOSH: National Institute of Occupational Safety and Health

NJ: New Jersey

NOEC: No observable effect concentration

NTP: National Toxicology Program

OECD: Organization for Economic Co-operation and Development

OEL: National occupational exposure limits

OSHA: Occupational Safety and Health Administration

Safety Data Sheet

Welly 1% Hydrocortisone Cream

SECTION 16: Other information (continued)

PA: Pennsylvania
PEL: Permissible exposure limit
PPE: Personal Protective Equipment
RCRA: Resource Conservation and Recovery Act
RI: Rhode Island
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
TDG: Canadian Transportation of Dangerous Goods Act & Regulations
TLV: Threshold Limit Values
TWA: Time Weighted Average
WEL: Workplace Exposure Limit
WHMIS: Workplace Hazardous Materials Identification System

Revision: Original
Date Prepared: 04/12/2024

DISCLAIMER

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Benzalkonium Chloride Antiseptic Wipe

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SECTION 1. IDENTIFICATION

Product identifier used on the label

: **Benzalkonium Chloride Antiseptic Wipe**

Other means of identification : Not available

Recommended use of the chemical and restrictions on use

: Personal Care Applications
Restriction on use: Topical

Chemical family

: Mixture.

Name, address, and telephone number of the manufacturer:

Safetec of America, Inc.

887 Kensington Avenue

Buffalo, NY, USA 14215

Manufacturer's Telephone # : (716) 895 1822

Name, address, and telephone number of the supplier:

Welly Health PBC

30 South 9th Street, 7th Floor

Minneapolis, MN, USA 55402

Supplier's Telephone # : 1 (833) BE WELLY

24 Hr. Emergency Tel # : 1-800-222-1222

SECTION 2. HAZARDS IDENTIFICATION

Classification of the chemical: Towelette saturated with clear liquid. Alcohol odor. This product is sold as a personal care item that is safe for consumers and other users under normal and reasonably foreseeable use. As such, it is not regulated under Hazcom 2012/WHMIS 2015 labeling and SDS requirements do not apply.

Label elements

Hazard pictogram:



Signal Word

Warning

Hazard statement(s)

Flammable Liquids - Category 3

Precautionary statement(s)

None

Other hazards

None known.



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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

<u>Chemical name</u>	<u>Common name and synonyms</u>	<u>CAS #</u>	<u>Concentration (% by weight)</u>
Ethanol	Ethyl alcohol Ethyl hydrate	64-17-5	5.0 - 10.0
Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides	Benzalkonium Chloride	63449-41-2	0.1 - 1.0

The exact concentrations of the above listed chemicals are being withheld as a trade secret.

SECTION 4. FIRST-AID MEASURES

Description of first aid measures

- Ingestion* : Harmful effects are not expected under normal usage. In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- Inhalation* : Harmful effects are not expected under normal usage. In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- Skin contact* : Harmful effects are not expected under normal usage. If skin irritation or rash occurs: Get medical advice/attention.
- Eye contact* : If in eyes: Rinse cautiously with water for several minutes. If eye irritation persists: get medical advice/attention.

Most important symptoms and effects, both acute and delayed

- : None expected, when used as intended.

Indication of any immediate medical attention and special treatment needed

- : Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

Extinguishing media

- Suitable extinguishing media* : Dry chemicals. Foam. Carbon dioxide (CO₂). Water or fog spray.
- Unsuitable extinguishing media* : Do not use water jet as extinguisher, as this will spread the fire.

Special hazards arising from the substance or mixture / Conditions of flammability

- : Flammable liquid contained in a towelette.

Flammability classification (OSHA 29 CFR 1910.106)

- : Flammable Liquids - Category 3

Hazardous combustion products

- : Carbon oxides

Special protective equipment and precautions for firefighters

- Protective equipment for fire-fighters* : Firefighters should wear an approved full-face, self-contained breathing apparatus (SCBA) and impervious clothing.
- Special fire-fighting procedures* : Cool containers exposed to heat with water spray and remove container, if no risk is involved.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

- : Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate personal protective equipment.

Environmental precautions : Avoid release to the environment.



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Methods and material for containment and cleaning up

: Wipe up with absorbent material (e.g. cloth, fleece).

Special spill response procedures

: Not applicable.

SECTION 7. HANDLING AND STORAGE

Precautions for safe handling

: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources - No smoking. Do not ingest or swallow. Observe good industrial hygiene practices.

Conditions for safe storage : Keep containers closed when not in use.

Incompatible materials : Strong oxidizing agents. Acids.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:			
Chemical Name	ACGIH TLV		OSHA PEL
	TWA	STEL	PEL STEL
Ethanol	N/Av	1000 ppm	1000 ppm (1900 mg/m ³) N/Av
Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides	N/Av	N/Av	N/Av N/Av

Exposure controls

Ventilation and engineering measures

: None required under normal conditions.

Respiratory protection : None required under normal conditions.

Skin protection : None required under normal conditions.

Eye / face protection : None required under normal conditions.

Other protective equipment : None required when used as intended.

General hygiene considerations

: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Towellette saturated with clear liquid.

Odour : Alcohol odour.

Odour threshold : Not available.

pH : Not available.

Melting Point/Freezing point : Not available.

Initial boiling point and boiling range

: Not available.

Flash point : 25°C (77°F)

Flashpoint (Method) : Closed cup

Evaporation rate (BuAe = 1) : Not available.

Flammability (solid, gas) : Not applicable.



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Lower flammable limit (% by vol.)

: Not available.

Upper flammable limit (% by vol.)

: Not available.

Oxidizing properties : Not applicable

Explosive properties : Not explosive

Vapour pressure : Not available.

Vapour density : Not available.

Relative density / Specific gravity

: 0.98

Solubility in water : Complete

Other solubility(ies) : Not available.

Partition coefficient: n-octanol/water or Coefficient of water/oil distribution

: Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Not available.

Volatiles (% by weight) : Not available.

Volatile organic Compounds (VOC's)

: Not available.

Absolute pressure of container

: Not available.

Flame projection length : Not available.

Other physical/chemical comments

: None known or reported by the manufacturer.

SECTION 10. STABILITY AND REACTIVITY

Reactivity : The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability : Material is stable under normal conditions.

Possibility of hazardous reactions

: Hazardous polymerization does not occur.

Conditions to avoid : Keep away from heat, sparks and open flames.

Incompatible materials : See Section 7 (Handling and Storage) for further details.

Hazardous decomposition products

: See Section 5 (Fire Fighting Measures).

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:

Routes of entry inhalation : YES

Routes of entry skin & eye : YES

Routes of entry Ingestion : YES

Routes of exposure skin absorption

: YES



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Potential Health Effects:

Signs and symptoms of short-term (acute) exposure

Sign and symptoms Inhalation

: None expected, when used as intended.

Sign and symptoms ingestion

: None expected, when used as intended.

Sign and symptoms skin

: None expected, when used as intended.

Sign and symptoms eyes

: None expected, when used as intended. Direct eye contact may cause irritation. Symptoms may include tearing, redness and discomfort.

Potential Chronic Health Effects

: None expected, when used as intended.

Mutagenicity

: Not expected to be mutagenic.

Carcinogenicity

: This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive effects & Teratogenicity

: This product is not expected to cause reproductive or developmental effects.

Sensitization to material

: Not expected to be a skin or respiratory sensitizer.

Specific target organ effects : None expected, when used as intended.

Medical conditions aggravated by overexposure

: None reported by the manufacturer.

Synergistic materials

: None reported by the manufacturer.

Toxicological data

: See below for individual ingredient acute toxicity data.

<u>Chemical name</u>	LC₅₀(4hr) <u>inh, rat</u>	LD₅₀	
		<u>(Oral, rat)</u>	<u>(Rabbit, dermal)</u>
Ethanol	> 32 380 ppm (61 mg/L) (vapour)	7060 mg/kg	> 15 800 mg/kg
Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides	N/Av	N/Av	1420 mg/kg

Other important toxicological hazards

: None known or reported by the manufacturer.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

: The product is not classified as environmentally hazardous. Avoid release to the environment.

Ecotoxicity data:

<u>Ingredients</u>	CAS No	Toxicity to Fish		
		LC50 / 96h	NOEC / 21 day	M Factor
Ethanol	64-17-5	> 100 mg/L (Fathead minnow)	N/Av	None.



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<u>Ingredients</u>	CAS No	Toxicity to Daphnia		
		EC50 / 48h	NOEC / 21 day	M Factor
Ethanol	64-17-5	5012 mg/L (Daphnia magna)	N/Av	None.

<u>Ingredients</u>	CAS No	Toxicity to Algae		
		EC50 / 96h or 72h	NOEC / 96h or 72h	M Factor
Ethanol	64-17-5	1000 mg/L/96hr (Green algae)	N/Av	None.

Persistence and degradability

: Not available.

Bioaccumulation potential

: Not available.

<u>Components</u>	<u>Partition coefficient n-octanol/water (log Kow)</u>	<u>Bioconcentration factor (BCF)</u>
Ethanol (CAS 64-17-5)	- 0.31	N/Av
Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides (CAS 63449-41-2)	N/Av	N/Av

Mobility in soil

: Not available.

Other Adverse Environmental effects

: None known or reported by the manufacturer.

SECTION 13. DISPOSAL CONSIDERATIONS

Handling for Disposal

: Dispose of in accordance with local regulations.

Methods of Disposal

: Dispose of in accordance with local regulations.

RCRA

: Not applicable.



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SECTION 14. TRANSPORT INFORMATION

Regulatory Information	UN Number	UN proper shipping name	Transport hazard class(es)	Packing Group	Label
49CFR/DOT	UN3175	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.	not regulated	II	
49CFR/DOT Additional information	Special provision 47 allows for UN3175, Solids, Containing flammable liquid, N.O.S. in sealed packages, containing less than 10 ml to be exempted from the regulations, provided there is no free liquid in the packet.				
ICAO/IATA	UN3175	Solids containing flammable liquid, n.o.s.	not regulated	II	
ICAO/IATA Additional information	Special provision A46 allows for UN 3175, Solids, Containing flammable liquid, N.O.S. in sealed packages, containing less than 10 ml to be exempted from the regulations, provided there is no free liquid in the packet.				
IMDG	UN3175	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.	not regulated	II	
IMDG Additional information	Special provision 216 allows for UN 3175, Solids, Containing flammable liquid, N.O.S. in sealed packages, containing less than 10 ml to be exempted from the regulations, provided there is no free liquid in the packet.				
TDG	UN3175	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.	not regulated	II	
TDG Additional information	Special provision 56 allows for UN3175, Solids, Containing flammable liquid, N.O.S. in sealed packages, containing less than 10 ml to be exempted from the regulations, provided there is no free liquid in the packet.				

Special precautions for user : Appropriate advice on safety must accompany the package.

Environmental hazards : This product does not meet the criteria for an environmentally hazardous mixture, according to the IMDG Code. See Section 12 for more environmental information.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

: Not established.

SECTION 15 - REGULATORY INFORMATION

US Federal Information:

Components listed below are present on the following U.S. Federal chemical lists:

<u>Ingredients</u>	CAS #	TSCA Inventory	CERCLA Reportable Quantity(RQ) (40 CFR 117.302):	SARA TITLE III: Sec. 302, Extremely Hazardous Substance, 40 CFR 355:	SARA TITLE III: Sec. 313, 40 CFR 372, Specific Toxic Chemical	de minimus Concentration
Ethanol	64-17-5	Yes	None.	None.	No	N/Ap
Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides	63449-41-2	Yes	N/Ap	N/Av	No	N/Ap



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SARA TITLE III: Sec. 313, Toxic Chemicals Notification, 40 CFR 372: None. Under SARA Sections 311 and 312, the EPA has established threshold quantities for the reporting of hazardous chemicals. The current thresholds are 500 pounds or the threshold planning quantity (TPQ), whichever is lower, for extremely hazardous substances and 10,000 pounds for all other hazardous chemicals.

US State Right to Know Laws:

The following chemicals are specifically listed by individual States:

<u>Ingredients</u>	CAS #	California Proposition 65		State "Right to Know" Lists					
		Listed	Type of Toxicity	CA	MA	MN	NJ	PA	RI
Ethanol	64-17-5	Yes	Cancer (in alcoholic beverages) Developmental (in alcoholic beverages)	Yes	Yes	Yes	Yes	Yes	Yes
Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides	63449-41-2	No	N/Ap	No	No	No	No	No	No

Canadian Information:

All components of this product are on the Canadian DSL list.
WHMIS Classification: See Section 2.

International Information:

Components listed below are present on the following International Inventory list:

<u>Ingredients</u>	CAS #	European EINECS	Australia AICS	Philippines PICCS	Japan ENCS	Korea KECI/KECL	China IECSC	NewZealand IOC
Ethanol	64-17-5	200-578-6	Present	Present	(2)-202	KE-13217	Present	HSR001144
Quaternary ammonium compounds, benzyl-C8-18-alkyldimethyl, chlorides	63449-41-2	264-151-6	Present	Present		KE-05-1137	Present	HSR003940

SECTION 16. OTHER INFORMATION

Legend

: ACGIH: American Conference of Governmental Industrial Hygienists
CA: California
CAS: Chemical Abstract Services
CEPA: Canadian Environmental Protection Act
CERCLA: Comprehensive Environmental Response, Compensation, and Liability Act of 1980
CFR: Code of Federal Regulations
CSA: Canadian Standards Association
DOT: Department of Transportation
DSL: Domestic Substances List
EPA: Environmental Protection Agency
HPA: Hazardous Products Act
HSDB: Hazardous Substances Data Bank
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association



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ICAO: International Civil Aviation Organisation
IMDG: International Maritime Dangerous Goods
Inh: Inhalation
LC: Lethal Concentration
LD: Lethal Dose
MA: Massachusetts
MN: Minnesota
N/Ap: Not Applicable
N/Av: Not Available
NJ: New Jersey
NOEC: No observable effect concentration
NTP: National Toxicology Program
OECD: Organisation for Economic Co-operation and Development
OEL: National occupational exposure limits
OSHA: Occupational Safety and Health Administration
PA: Pennsylvania
PEL: Permissible exposure limit
PPE: Personal Protective Equipment
RCRA: Resource Conservation and Recovery Act
RI: Rhode Island
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
TDG: Canadian Transportation of Dangerous Goods Act & Regulations
TLV: Threshold Limit Values
TWA: Time Weighted Average
WEL: Workplace Exposure Limit
WHMIS: Workplace Hazardous Materials Identification System

- References**
- : 1. ACGIH, Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices for 2018.
 - 2. International Agency for Research on Cancer Monographs, searched 2019.
 - 3. Canadian Centre for Occupational Health and Safety, CCInfoWeb databases, 2019 (Chempendium, HSDB and RTECs).
 - 4. Safety Data Sheets from manufacturer.
 - 5. US EPA Title III List of Lists - June 2019 version.
 - 6. California Proposition 65 List - September 2019 version.
 - 7. OECD - The Global Portal to Information on Chemical Substances - eChemPortal, 2019.

Preparation Date

: 10/04/2022

Other special considerations for handling

: Provide adequate information, instruction and training for operators.



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