Field Trauma Kit with QuikClot	2064-0291
Trauma Pak with QuikClot	2064-0292
Trauma Pack Pro with QuikClot and Swat-T	2064-0293
Rapid Response Trauma Pak with QuikClot	2064-0294
Trauma Pak 1	2064-0295
Trauma Pak III	2064-0298

Safety Data Sheet – Adventure® Medical Kits

To Whom It May Concern,

Our First Aid kits comply with the regulations of the US Food and Drug Administration and other International Medical Regulatory bodies. These standards and quality requirements ensure safe labelling, use, and handling.

In response to your request for a (Material) Safety Data Sheet for one of our First Aid Kits, please be advised that all such kits (and the medical supplies, drugs, pills and pharmaceuticals found in these kits) are exempt from OSHA and other regulatory SDS requirements. OSHA exempts:

> "Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies)" 29 CFR 1910.1200(b)(6)(vii)

The above-mentioned section expressly exempts any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is:

- in solid, final form for direct administration to the patient (e.g., tablets or pills) OR
- drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs) OR
- drugs intended for personal consumption (e.g., first aid supplies)

Our First Aid Kits clearly meet these express exemptions.

If you have any further questions regarding this matter, please contact us directly by email.

Thank you,

Regulatory Compliance
e-mail: regulatory@adventurereadybrands.com

Field Trauma Kit with QuikClot
Item No. 2064-0291
UPC 707708102912

Contents
Bandage Materials
4 - Bandage, Adhesive, Fabric, 1" x 3"
3 - Bandage, Adhesive, Fabric, Knuckle
2 - Bandage, Butterfly Closure
1 - Bandage, Elastic, Self Adhering, 2"
2 - Dressing, Gauze, Sterile, 2" x 2", Pkg./2
2 - Dressing, Gauze, Sterile, 4" x 4", Pkg./2
1 - Dressing, Non-Adherent, Sterile, 3" x 4"
Bleeding
2 - Gloves, Nitrile (Pair), Hand Wipe
1 - QuikClot Gauze 3" x 2'
2 - Trauma Pad, 5" x 9"
Blister / Burn
11 - Moleskin, Pre-Cut & Shaped (11 pieces)
Instrument
3 - Safety Pins
1 - Splinter Picker/Tick Remover Forceps
Medical Information
1 - Comp. Guide to Wilderness & Travel Medicine
Medication
1 - After Bite Wipe
2 - Antihistamine (Diphenhydramine 25 mg)
1 - Aspirin (325 mg), Pkg./2
2 - Ibuprofen (200 mg), Pkg./2
Wound Care
8 - Antiseptic Wipe
1 - Dressing, Petrolatum, 3" x 3"
1 - Tape, 1/2" x 10 Yards
2 - Triple Antibiotic Ointment, Single Use

Trauma Pak with QuikClot
Item No. 2064-0292
UPC 707708202926

Contents
Bandage Materials
1 - Bandage, Conforming Gauze, 3"
1 - Dressing, Gauze, Sterile, 2" x 2", Pkg./2
1 - Dressing, Gauze, Sterile, 4" x 4", Pkg./2
Bleeding
1 - Gloves, Nitrile (Pair), Hand Wipe
1 - QuikClot Gauze 3" x 2'
1 - Trauma Pad, 5" x 9"
Duct Tape
1 - Duct Tape, 2" x 26"
Fracture / Sprain
1 - Bandage, Triangular
Wound Care
4 - Antiseptic Wipe
Medical Information
1 - Trauma and Accident Management Instructions

Trauma Pack Pro with QuikClot & Swat-T
Item No. 2064-0293
UPC 707708002939

Contents
Bleeding
1 - QuikClot Gauze 3" x 2'
1 - SWAT-T™ Tourniquet
1 - Gloves, Nitrile (Pair), Hand Wipe & Disposal Bag
1 - Trauma Pad, 5" x 9"
Duct Tape
1 - Duct Tape, 2" x 26"
Medical Instructions
1 - Trauma Response Instructions

Rapid Response Trauma Pak with QuikClot
Item No. 2064-0294
UPC 707708002946

Contents
Bandage Materials
1 - Bandage, Conforming Gauze, 3"
1 - Dressing, Gauze, Sterile, 2" x 2", Pkg./2
1 - Dressing, Gauze, Sterile, 4" x 4", Pkg./2
Bleeding
1 - Gloves, Nitrile (Pair), Hand Wipe
1 - QuikClot Gauze 3" x 2'
1 - Trauma Pad, 5" x 9"
Duct Tape
1 - Duct Tape, 2" x 26"
Fracture / Sprain
1 - Bandage, Triangular
Wound Care
5 - Antiseptic Wipe
Medical Information
1 - Trauma and Accident Management Instructions

Trauma Pak 1
Item No. 2064-0295
UPC 707708002953

Contents
1 – Trauma Bandage
2 – Sterile Gauze Dressing, 3" x 3"
1 – EMT Shears, 4"
2 – Latex-Free Glove

Trauma Pak III
Item No. 2064-0298
UPC 707708002984

Contents
1 – Emergency Bandage, 4"
1 – SWAT-T Tourniquet
1 – EMT Shears, 4"
2 – Latex-Free Glove
1 – Trauma Response Instructions
1 – Triangular Bandage, 42" x 42" x59", 1 ea.

Prepared according to 29CFR 1910.1200, Regulation (EC) No. 1272/2008 (GHS) and Canadian Controlled Products Act (CPR)

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME:	After Bite® with 5% Sodium bicarbonate
Product Code:	0001-1101
SDS Date:	January 23, 2019
SDS Revision No.:	3
USE:	Insect bite treatment

HMIS Hazard Rating

HEALTH	2
FLAMMABILITY	0
REACTIVITY	0
PERSONAL PROTECTION	X

MANUFACTURER:	Tender Corporation
ADDRESS:	944 Industrial Park Littleton, NH 03561
INFORMATION CALLS:	800-258-4696
CUSTOMER SERVICE:	cs@tendercorp.com
TECHNICAL QUESTIONS:	regulatory@tendercorp.com
FAX PHONE:	603-444-6735
EMERGENCY PHONE:	Spills:(800) 354-2382 (Veolia) Medical Information:(800) 258-4696 (Tender Corporation)

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: Clear non-flammable water soluble liquid with a strong ammonia odor

HAZARD CLASSIFICATION:
Acute Aquatic Hazard – Category 3
Acute Oral Toxicity – Catgory 4
Eye Irritation – Category 2A
Skin Irritation – Category 2

GHS Label elements, including precautionary statements

Pictogram

Signal word: WARNING

Hazard statement(s)

H302	Harmful if swallowed
H319	Causes serious eye irritation
H315	Causes skin irritation
H4102	Harmful to aquatic life

Precautionary statement(s)

P102	Keep out of the reach of children
P234	Keep in original container
P305+P351+P338	IF IN EYES; Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P301+330+331+315	IF SWALOWED: Rinse mouth. DO NOT induce vomiting. Get immediate medical advice/attention.
P304+340+312	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a Poison Center or doctor/physician if yo feel unwell.
P273	Avoid release to the environment

ROUTES OF EXPOSURE: Dermal, oral

POTENTIAL HEALTH EFFECTS

INHALATION: May cause irritation to lungs

SKIN CONTACT: Do not use over cuts, wounds or irritated skin
Pre-existing skin disorders may be aggravated by exposure

EYE CONTACT: Prolonged contact may cause irritation, with redness, pain, tearing, blurred vision and conjunctivitis.

INGESTION: May be harmful if swallowed.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	Conc.(%)	CAS NO.	EINECS NO.	Classification
Sodium Bicarbonate	4.0 to 6.0	144-55-8	205-633-8	None
Ammonia	2.0 to 4.0	7664-41-7	231-635-3	EU-X_i ;WHMIS-Class E
Water	80 to 90	7732-18-5	231-791-2	None
Glycerin	0.5 to 2.5	56-81-5	200-289-5	None
Other ingredients	< 1.0			

See Section 8 – "EXPOSURE CONTROLS/PERSONAL PROTECTION" for exposure guidelines

SECTION 4: FIRST AID MEASURES

INHALATION: Move victim to fresh air. Apply artificial respiration if indicated. Contact a physician if warranted.

CONTACT WITH SKIN: Take off contaminated clothing. Immediately wash gently and thoroughly with luke warm, gently flowing water and non-abrasive soap for 15-20 mins. If skin irritation or rash occurs, see a doctor. Thoroughly clean clothing before reuse or dispose of safely.

CONTACT WITH EYES: Immediately flush the contaminated eye(s) with lukewarm, gently flowing water for 15-20 minutes, while holding the eyelid(s) open. Remove contact lenses, if present and easy to do. Take care not to rinse contaminated water into the unaffected eye or onto the face. If irritation or pain persists, see a doctor.

INGESTION: Have victim rinse mouth with water. NEVER give anything by mouth if the victim is rapidly losing consciousness, or is unconscious or convulsing. DO NOT INDUCE VOMITING. Contact a physician if warranted.

SECTION 5: FIRE-FIGHTING MEASURES

FIRE AND EXPOLSIVE PROPERTIES: Non Flammable - This product is not flammable, combustible or explosive
Flash Point: Not applicable **Flammable Limits:** Not applicable
EXTINGUISHING MEDIA: Water spray
Carbon dioxide
Dry Chemical or foam

SPECIFIC HAZARDS: In case of fire, hazardous combustion gases may be formed:
Carbon monoxide (CO)
Carbon Dioxide (CO2)
Nitrogen oxides (NOx)

PROTECT EQUIPMENT FOR FIREFIGHTERS: Use self-contained breathing apparatus and full protective clothing
FURTHER INFORMATION: Fire residues and contaminated firefighting water must be disposed of in accordance with local regulations

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: For Large Spills**;** Isolate the hazard area. Keep out unnecessary and unprotected personnel. Increase ventilation to area or move leaking container to a well-ventlated and secure area. Use the Personal Protective Equipment recommended in Section 8 of this SDS. Review Section 7 (Handling) of this SDS before proceeding with cleanup.

ENVIRONMENTAL PRECAUTIONS: Do not allow into any sewer, on to ground or into any waterway.

METHOD FOR CONTAINMENT AND CLEAN-UP:
Prevent product from entering drains and ventilation systems. Contain and soak up spill with absorbent that does not react with spilled product. Place used absorbent into suitable, covered labeled containers for disposal. Large Spills: Dike spill product to prevent runoff. Recover contaminated water for appropriate disposal. Report spills to local health, safety and environmental authorities, as required.

SECTION 7: HANDLING AND STORAGE

HANDLING: Read entire label before using. Use strictly in accordance with label precautionary statements and directions. Do not contaminate food or feed.

STORAGE: Keep product in its original container. Keep container tightly closed. Store this product in a cool, dry place away from heat or direct sunlight. Protect from freezing.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: General ventilation is usually adequate. When handling large quantities of concentrated product; Use local exhaust ventilation, if necessary.

PERSONAL PROTECTIVE EQUIPMENT (PPE): None required.

EXPOSURE GUIDELINES:

INGREDIENT:	CAS NO.	%	Exposure Limits		
			ACGIH TLV-TWA	ACGIH TLV-STEL	OSHA PEL-TWA
Ammonia	7664-41-7	< 3.5	18 mg/m^3 (TWA -25ppm)	40 ppm as STEL	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear liquid

ODOR: Ammonia

pH: 9.5 to 11.5

BOILING POINT: Not determined

MELTING POINT: Not applicable

RELATIVE DENSITY (H2O = 1) @25˚C: 1.03 gm/ml

VAPOR PRESSURE (mmHg) @ ˚C: Not applicable

VAPOR DENSITY (AIR = 1): Not applicable

FLASH POINT: Not expected for water-based product

SOLUBILITY IN WATER: Complete

SOLUBILITY IN SOLVENTS: Not determined

VISCOSITY: Not applicable

VOLATILE ORGANIC COMPOUNDS (VOC): Not determined

PARTITION COEFFICIENT: Not determined

SECTION 10: STABILITY AND REACTIVITY

STABILITY: Stable

CONDITIONS TO AVOID: Extreme temperatures, Sunlight

INCOMPATIBILITY (MATERIAL TO AVOID): **Metals and Oxidizing agents**. Attacks many metals forming explosive gas. Reacts violently with acids Strong acids, most common metals, strong oxidizing agents, bromine, chlorine, aluminum, copper, brass, bronze, hypochlorite, acids, monoammonium phosphate, sodium potassium alloy, strong alkalis or mineral acids.

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: Ammonia, Carbon dioxide, Carbon monoxide, Nitrogen oxides

HAZARDOUS POLYMERIZATION: Will not occur

SECTION 11: TOXICOLOGICAL INFORMATION

The preparation has not been tested for all toxicological effects; some are classified on the basis of the known hazards of the components.

Acute oral toxicity:	**LD50** – Not determined **Method:** **Source:**
Acute inhalation toxicity:	**LC50** – Not determined **Method** **Source:**
Acute dermal toxicity:	**LD50** – Not determined **Method:** **Source:**
Irritant effect on skin:	Not determined **Method:** **Source:**
Irritant effect on eyes:	Not determined **Method:** **Source:**
Sensitization:	Not determined **Method** **Source:**
Mutagenicity:	Not determined **Method** **Source:**
Carcinogenicity/Reproductive toxicity:	No components present in this material at concentrations of 0.1% or greater are listed by IARC, NTP, OSHA or ACGIH as being carcinogens. **Source:** Safety Data Sheets of components
Specific Target Organ Toxicity	**Single exposure (GHS) –** no data available **Repeated exposure (GHS) -** no data available
Signs and Symptoms of Exposure	Redness, rash or blistering

POTENTIAL HEALTH EFFECTS

INHALATION:	May cause irritation to lungs
SKIN CONTACT:	Pre-existing skin disorders may be aggravated by exposure
EYE CONTACT:	Prolonged contact may cause irritation, with redness, pain, tearing, blurred vision and conjunctivitis.
INGESTION:	Harmful if swallowed

SECTION 12: ECOLOGICAL INFORMATION

General Comments: Ecotoxicological data have not been determined specifically for this product, but it is classified on the basis of the known hazards of the components. This section is not required by WHMIS.

Mobility	The product is water-based and expected to be mobile in the aquatic environment.
Persistence/degradability	Ammonium Hydroxide is readily biodegradable in the environment, according to ECBI/07/00 Rev. 3 (29/8/00). Glycerin is inherently biodegradable in water under aerobic conditions.
Bioaccumulation	Ammonium Hydroxide has been shown to have a low bioaccumulation. (Log POW=2,02)
Toxicity	The Ammonium Hydroxide has been shown to be toxic to aquatic organisms. (10mg/l<LC50 <100 mg/l)

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Do not reuse any empty containers.

US: This product is not a hazardous solid waste as defined in Resource Conservation Recovery Act Regulations (40 CFR 261)and should be disposed of according to local, state and Federal regulations Dispose of partially filled and empty containers by wrapping and discarding in trash.
International: This product should not be disposed of via the drains or by landfill. Disposal must be in accordance with current national and local regulations. Chemical residues generally count as special waste, and their disposal may be regulated in the EC member countries through corresponding laws and regulations. We recommend that you contact either the authorities or approved waste disposal companies who will advise you on how to dispose of special waste. Packaging may contain residues of the product and should be treated accordingly.
General EU requirements are given in the Waste Framework Directive (75/442/EEC) and the Hazardous Waste Directive (91/689/EEC).

SECTION 14: TRANSPORT INFORMATION

SHIPPING INFORMATION: **Marine Pollutant:** No

Regulation	UN No.	Proper Shipping Name	Class	Package Group	Label	Additional Information
U.S. Department of Transportation (DOT) – Non-Bulk	–	–	–	–	–	Not regulated
U.S. Department of Transportation (DOT) – Bulk	–	–	–	–	–	Not regulated
Canadian Transportation of Dangerous Goods (TDG) Non-Bulk	–	–	–	–	–	Not regulated
International Maritime Dangerous Goods (IMDG) Non-Bulk	–	–	–	–	–	Not regulated
International Air Transport Assoc. (IATA) Non-Bulk	–	–	–	–	–	Not regulated

The transportation regulations are cited according to international regulations and in the form applicable to the United States and Canada. Possible national deviations in other countries are not considered.

SECTION 15: REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

TSCA (TOXIC SUBSTANCE CONTROL ACT): All components of this product are listed or exempt on the TSCA list
CERCLA (COMPREHENSIVE RESPONSE COMPENSATION, AND LIABILITY ACT):
CERCLA HAZARDOUS SUBSTANCE: Ammonium hydroxide (CAS # 1336-21-6)
CERCLA REPORTABLE QUANITIY: RQ= 500lbs
RCRA 261 (RESOURCE CONSERVATION RECOVERY ACT): Ammonium hydroxide (CAS # 1336-21-6)
SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT)
Section 302 Extremely Hazardous Substances (TPQ): TPQ=500lbs.
311/312 HAZARD CLASS: Acute Health and Chronic Health Hazard.
313 REPORTABLE INGREDIENTS: Ammonium hydroxide (CAS # 1336-21-6)
California Proposition 65: None
States Right to Know: This product contains Ammonium hydroxide (CAS # 1336-21-6)

CANADIAN REGULATIONS:

WHMIS CLASSIFCATION: Class E- Corrosive
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all the information required by the CPR.
DOMESTIC SUBSTANCE LIST (DSL)/NON-DOMESTIC SUBSTANCE LIST (NDSL): All components are listed or exempt
Canadian Ingredient Disclosure List: Ammonium hydroxide (CAS # 1336-21-6)

Prepared according to 29CFR 1910.1200, Regulation (EC) No. 1272/2008 (GHS) and Canadian Controlled Products Act (CPR)

EU REGULATIONS:
Labeling in accordance with EC-Directives

Hazard symbols


Irritant


Corrosive


Toxic to Aquatic Organisms

Hazardous component(s) to be indicated on label: Contains Ammonium hydroxide

EC Number

R phrases

22	Harmful if swallowed
36/37/38	Irritating to eyes, skin and respiratory system
65	Harmful: may cause lung damage if swallowed

S phrases

1/2	Keep locked and out of the reach of children
26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
45	In case of accident or if you feel unwell seek medical advise immediately
49	Keep only in the original container
61	Avoid release to the environment. Refer to special instructions/safety data sheet.

SECTION 16: OTHER INFORMATION

HMIS		
Health: 2	**Flammability:** 0	**Reactivity:** 0
Special:		

4=extreme 3=High 2=Moderate 1=Slight 0=Insignificant

REVISED SECTIONS OR REASON FOR REVISION:
ORIGIN DATE: JUNE 7,2013
REV 1 OCTOBER 21,2013-CORRECTED TYPO'S AND CHANGED DOT TABLE TO NON-HAZ. CHANGED AMMONIA RANGE TO 2-4%.
REV 2 JUNE 15, 2016 – ADDRESS UPDATES & UPDATES TO SDS
REV 3 JANUARY 23, 2019 – UPDATES FOR GHS COMPLIANCE

DISCLAIMER: The information provided herein was believed to be accurate, to the best knowledge of Tender Corporation, at the time of preparation from a compilation of sources believed to be reliable and is furnished without warranty, expressed or implied. It is the responsibility of the user to investigate and understand other pertinent sources of information, to comply with all laws and procedures applicable to the safe handling, storage and use of this product and to determine the suitability of the product for its intended use. This data sheet relates only to the specific product listed and does not relate to use in combination or in any process with other materials

Safety Data Sheet

Antiseptic Towelettes

Issue Date: 6 November 2015

Section 1 - Chemical Product and Company Identification

Product Name	Antiseptic Towelettes		
Synonyms	Not applicable	**CAS No.**	Not applicable
Molecular formula	Not applicable	**Molecular mass**	Not applicable
Manufacturer/Supplier	GFA PRODUCTION XIAMEN CO., LTD.		
Address	NO.20 HULI INDUSTRIAL PARK,MEI XI ROAD,TONG AN,XIAMEN,FUJIAN,CHINA		

Section 2 - Hazards Identification

Emergency overview	Wet paper. Not a hazardous substance or mixture.
OSHA regulatory	This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Potential health effects	Likely Routes of Exposure: Skin, eye, inhalation and ingestion. Skin Contact: No adverse health effects expected. Eye Contact: No adverse health effects expected. Inhalation: No adverse health effects expected. Ingestion: Large quantities swallowed may cause irritation to the gastrointestinal tract. See Section 11 for more information.
Potential environmental effects	This material is not expected to be toxic to aquatic life. See Section 12 for more information.

Section 3 - Composition/Information on Ingredient

Component	Range % by Wt.	CAS No.
Benzalkonium chloride	0.13	8001-54-5
Water	99.87	7732-18-5

Section 4 - First Aid Measures

Skin contact	Not expected to require first aid measures. Immediately flush skin with plenty of water.
Eye contact	Not expected to require first aid measures. Immediately flush eyes with water. Get medical attention if irritation develops.
Inhalation	Not expected to require first aid measures. Get medical attention.
Ingestion	Not expected to require first aid measures. If swallowed, rinse thoroughly. Get medical attention immediately.
Note to Physicians	No information found.

Section 5 - Fire Fighting Measures

Flammable properties	Not considered to be a fire hazard.
Extinguishing media	Use fire extinguishing methods suitable to surrounding conditions.
Unsuitable extinguishing media	None.
Hazardous combustion products	Carbon oxides.
Protection of firefighters	No information found.

Section 6 - Accidental Release Measures

Personal precautions	Use personal protection recommended in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering.
Environmental precautions	Contain and recover liquid when possible. Avoid runoff into storm sewers and ditches which lead to waterways.
Methods for containment	Sweep up and containerize for reclamation or disposal.
Methods for clean-up	Place in suitable container or tanks, recycle or ship to the waste plant.
Other information	None.

Section 7 - Handling and Storage

Handling	Keep container tightly closed. Wash thoroughly after handling.
Storage	Stored in a cool, dry, ventilated area.

Section 8 - Exposure Controls, Personal Protection

Exposure guidelines	None established.
Engineering controls	No engineering controls required.
Eye/face protection	Generally protection.
Skin protection	Generally protection.
Respiratory protection	Generally protection.
General hygiene considerations	Generally protection.

Section 9 - Physical and Chemical Properties

Appearance and odor	Wet paper.	**pH**	No information found.
Freezing point (℃)	No information found.	**Boiling point (℃)**	No information found.
Density(water=1)	No information found.	**Relative vapour density (air=1)**	No information found.
Vapour pressure (kPa)	No information found.	**Heat of combustion (kJ/mol)**	No information found.
Critical temperature (℃)	No information found.	**Critical pressure (MPa)**	No information found.
Octanol/water partition coefficient as log Pow	No information found.	**Flash point (℃)**	Not applicable.
Auto-ignition temperature(℃)	No information found.	**Solubility**	No information found.
Upper explosive limits %(V/V)	No information found.	**Lower explosive limits %(V/V)**	No information found.
Other properties	No information found.	**End uses**	To help prevent infection.

Section 10 - Stability and Reactivity

Chemical stability	Stable under ordinary conditions of use and storage.
Conditions to avoid	Heat, flames, ignition sources and incompatibles.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon oxides.
Possibility of hazardous reactions	Will not occur.

Section 11 - Toxicological Information

Acute toxicity	Benzalkonium chloride (CAS: 8001-54-5): Oral, mouse: LD50 = 150 mg/kg.
Inhalation	No information.
Eye irritation	No information.
Skin irritation	No information.
Sensitisation	No information.
Repeated dose toxicity	No information.
Carcinogenicity	All ingredients are not listed by IARC.
Mutagenicity	No information.
Reproductive effects	No information.
Delevopment effects	No information.

Section 12 - Ecological Information

Ecotoxicity	This material is not expected toxic to aquatic life. Benzalkonium chloride (CAS: 8001-54-5): Lepomis macrochirus LC50 = 0.31 mg/kg (96h).
Persistence/ Degradability	No information.
Bioaccumulation/ Accumulation	No information.
Mobility in environment	No information.

Section 13 - Disposal Considerations

Disposal measures	Not regulated.
Notes	Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

Section 14 - Transport Information

Regulations	**US DOT**	**IATA DGR**	**IMDG Code**
UN No.	Not regulated as a hazardous material.	Not regulated as a hazardous material.	Not regulated as a hazardous material.
Hazard Class	Not regulated.	Not regulated.	Not regulated.
Shipping Name	Not regulated.	Not regulated.	Not regulated.
Packing Group	Not regulated.	Not regulated.	Not regulated.
Packing method	Not regulated.	Not regulated.	Not regulated.

Section 15 - Regulatory Information

Component	**CAS No.**	**TSCA**	**DSL**	**Section 302 (EHS)**	**Section 304 EHS RQ**	**CERC LARQ**	**Section 313**	**RCRA CODE**	**CAA 112(r) TQ**
Benzalkonium chloride	8001-54-5	Yes	Yes	No	No	No	No	No	No
Water	7732-18-5	Yes	Yes	No	No	No	No	No	No

Section 16 - Additional Information

Revision	0
Issue date	November 6, 2015
Prepared by	TÜV SÜD Products Testizng (Shanghai) Co.,Ltd. Guangzhou Branch
Checked by	TÜV SÜD Products Testizng (Shanghai) Co.,Ltd. Guangzhou Branch
Other information	-

Disclaimer: This MSDS conforms to the requirements of 29CFR 1910.1200 and ANSI Z400.1/Z 129.1-2010. This MSDS is offered to you in good faith as accurate. We have reviewed any information contained in this data sheet which we received from sources outside our company. We believe that information to be correct but cannot guarantee its accuracy or completeness. Health and safety precautions in this data sheet may not be adequate for all individuals and/or situations. It is the user's obligation to evaluate and use this product safely and to complywith all applicable laws and regulations. No statement made in this data sheet shall be construed as a permissionor recommendation for the use of any product in a manner that might infringe existing patents. No warranty ismade, either express or implied.

This report replaces the original report 721622569-7-A

-END OF THE TEST REPORT-

Safety Data Sheet

Triple Antibiotic Ointment

Issue Date: 6 November 2015

Section 1 - Chemical Product and Company Identification

Product Name	Triple Antibiotic Ointment		
Synonyms	Not applicable	**CAS No.**	Not applicable
Molecular formula	Not applicable	**Molecular mass**	Not applicable
Manufacturer/Supplier	GFA PRODUCTION XIAMEN CO., LTD.		
Address	NO.20 HULI INDUSTRIAL PARK,MEI XI ROAD,TONG AN,XIAMEN,FUJIAN,CHINA		

Section 2 - Hazards Identification

Emergency overview	Offwhite gel. Not a hazardous substance or mixture.
OSHA regulatory	This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).
Potential health effects	Likely Routes of Exposure: Skin, eye, inhalation and ingestion. Skin Contact: No adverse health effects expected. Eye Contact: No adverse health effects expected. Inhalation: No adverse health effects expected. Ingestion: Large quantities swallowed may cause irritation to the gastrointestinal tract. See Section 11 for more information.
Potential environmental effects	This material is not expected to be toxic to aquatic life. See Section 12 for more information.

Section 3 - Composition/Information on Ingredient

Component	Range % by Wt.	CAS No.
Vaseline	96.41	8009-03-8
Mineral oil	2.00	8042-47-5
Bacitracin Zinc	1.00	1405-87-4
Neomycin Sulfate	0.51	1404-04-2
Polymyxin B sulfate	0.08	1405-20-5

Section 4 - First Aid Measures

Skin contact	Not expected to require first aid measures. Immediately flush skin with plenty of water.
Eye contact	Not expected to require first aid measures. Immediately flush eyes with water. Get medical attention if irritation develops.
Inhalation	Not expected to require first aid measures. Get medical attention.
Ingestion	Not expected to require first aid measures. If swallowed, rinse thoroughly. Get medical attention immediately.
Note to Physicians	No information found.

Section 5 - Fire Fighting Measures

Flammable properties	Not considered to be a fire hazard.
Extinguishing media	Use fire extinguishing methods suitable to surrounding conditions.
Unsuitable extinguishing media	None.
Hazardous combustion products	Carbon oxides, nitrogen oxides (NOx), Sulphur oxides.
Protection of firefighters	No information found.

Section 6 - Accidental Release Measures

Personal precautions	Use personal protection recommended in Section 8. Isolate hazard area. Keep unnecessary and unprotected personnel from entering.
Environmental precautions	Contain and recover liquid when possible. Avoid runoff into storm sewers and ditches which lead to waterways.
Methods for containment	In case of a small amount of release, absorb spill with inert material (e.g. vermiculite, sand or earth), as well as flush with plenty of water and dilute into the wastewater system. In case of great amount of release, collect spill with causeway or trench.
Methods for clean-up	Removal of ignition sources. A vapor suppressing foam may be used to reduce vapors. Place in suitable container or tanks, recycle or ship to the waste plant.
Other information	None.

Section 7 - Handling and Storage

Handling	Keep container tightly closed. Wash thoroughly after handling.
Storage	Stored in a cool, dry, ventilated area.

Section 8 - Exposure Controls, Personal Protection

Exposure guidelines	Petroleum Jelly (CAS: 8009-03-8): -Occupational Exposure Limits (OSHA): 5 mg/m3 (TWA); -ACGIH Threshold Limit Values: 5 mg/m3 (TWA).
Engineering controls	Use general ventilation and use local exhaust, where possible, in confined or enclosed spaces. Provide emergency eyewash and shower equipment.
Eye/face protection	Use tight-fitting goggles, face shield or safety glasses with side shields if eye contact might occur.
Skin protection	Wear general protective clothing.
Respiratory protection	Suitable respiratory protective device recommended.
General hygiene considerations	Wash thoroughly after handing. Have eye-wash facilities immediately available.

Section 9 - Physical and Chemical Properties

Appearance and odor	Offwhite gel.	**pH**	No information found.
Freezing point (℃)	No information found.	**Boiling point (℃)**	No information found.
Density(water=1)	No information found.	**Relative vapour density (air=1)**	No information found.
Vapour pressure (kPa)	No information found.	**Heat of combustion (kJ/mol)**	No information found.
Critical temperature (℃)	No information found.	**Critical pressure (MPa)**	No information found.
Octanol/water partition coefficient as log Pow	No information found.	**Flash point (℃)**	No information found.
Auto-ignition temperature(℃)	No information found.	**Solubility**	No information found.
Upper explosive limits %(V/V)	No information found.	**Lower explosive limits %(V/V)**	No information found.
Other properties	No information found.	**End uses**	To help prevent infection.

Section 10 - Stability and Reactivity

Chemical stability	Stable under ordinary conditions of use and storage.
Conditions to avoid	Heat, flames, ignition sources and incompatibles.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon oxides, nitrogen oxides (NOx), Sulphur oxides.
Possibility of hazardous reactions	Will not occur.

Section 11 - Toxicological Information

Acute toxicity	Bacitracin Zine (CAS: 1405-87-4): oral mouse LD50 > 3787.5 mg/kg. Polymyxin B sulfate (CAS: 1405-20-5): oral mouse LD50 = 790 mg/kg.
Inhalation	No information.
Eye irritation	No information.
Skin irritation	No information.
Sensitisation	No information.
Repeated dose toxicity	No information.
Carcinogenicity	All ingredients are not listed by IARC.
Mutagenicity	No information.
Reproductive effects	No information.
Delevopment effects	No information.

Section 12 - Ecological Information

Ecotoxicity	This material is not expected toxic to aquatic life.
Persistence/ Degradability	No information.
Bioaccumulation/ Accumulation	No information.
Mobility in environment	No information.

Section 13 - Disposal Considerations

Disposal measures	Not regulated.
Notes	Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. US EPA guidelines for the classification determination are listed in 40 CFR Parts 261.3. Additionally, waste generators must consult state and local hazardous waste regulations to ensure complete and accurate classification.

Section 14 - Transport Information

Regulations	**US DOT**	**IATA DGR**	**IMDG Code**
UN No.	Not regulated as a hazardous material.	Not regulated as a hazardous material.	Not regulated as a hazardous material.
Hazard Class	Not regulated.	Not regulated.	Not regulated.
Shipping Name	Not regulated.	Not regulated.	Not regulated.
Packing Group	Not regulated.	Not regulated.	Not regulated.
Packing method	Not regulated.	Not regulated.	Not regulated.

Section 15 - Regulatory Information

Component	**CAS No.**	**TSCA**	**DSL**	**Section 302 (EHS)**	**Section 304 EHS RQ**	**CERC LARQ**	**Section 313**	**RCRA CODE**	**CAA 112(r) TQ**
Vaseline	8009-03-8	Yes	Yes	No	No	No	No	No	No
Mineral oil	8042-47-5	Yes	Yes	No	No	No	No	No	No
Bacitracin Zinc	1405-87-4	Yes	Yes	No	No	No	No	No	No
Neomycin Sulfate	1404-04-2	Yes	Yes	No	No	No	No	No	No
Polymyxin B sulfate	1405-20-5	Yes	Yes	No	No	No	No	No	No

Section 16 - Additional Information

Revision	0
Issue date	November 6, 2015
Prepared by	TÜV SÜD Products Testizng (Shanghai) Co.,Ltd. Guangzhou Branch
Checked by	TÜV SÜD Products Testizng (Shanghai) Co.,Ltd. Guangzhou Branch
Other information	-

Disclaimer: This MSDS conforms to the requirements of 29CFR 1910.1200 and ANSI Z400.1/Z 129.1-2010. This MSDS is offered to you in good faith as accurate. We have reviewed any information contained in this data sheet which we received from sources outside our company. We believe that information to be correct but cannot guarantee its accuracy or completeness. Health and safety precautions in this data sheet may not be adequate for all individuals and/or situations. It is the user's obligation to evaluate and use this product safely and to complywith all applicable laws and regulations. No statement made in this data sheet shall be construed as a permissionor recommendation for the use of any product in a manner that might infringe existing patents. No warranty ismade, either express or implied.

This report replaces the original report 721622569-6-A

-END OF THE TEST REPORT-

MEDI-FIRST IBUPROFEN- ibuprofen tablet, coated
MEDI-FIRST PLUS IBUPROFEN- ibuprofen tablet, coated
MEDIQUE IPRIN- ibuprofen tablet, coated
DOVER ADDAPRIN- ibuprofen tablet, coated
OTIS CLAPP ULTRAPRIN- ibuprofen tablet, coated
Unifirst First Aid Corporation

UniFirst First Aid Ibuprofen

Drug Facts

Active ingredient

Ibuprofen 200 mg (NSAID)

*nonsteroidal antinflamatory drug

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves minor aches and pains associated with

■ headache ■ toothache ■ backache ■ menstrual cramps

■ common cold ■ muscular aches ■ minor arthritis pain

Temporarily reduces fever.

Warnings

Allergy alert:

Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

■ hives ■ skin reddening ■ asthma (wheezing) ■ facial swelling ■ rash ■ shock ■ blisters

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

■ are age 60 or older

■ have had stomach ulcers or bleeding problems

■ take a blood thinning (anticoagulant) or steroid drug

■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

■ have 3 or more alcoholic drinks every day while using this product

■ take more or for a longer time than directed

Heart attack or stroke warning: NSAIDS, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

■ if you have ever had an allergic reaction to any other pain reliever/fever reducer

■ right before or after heart surgery

Ask a doctor before use if

■ you have problems or serious side effects from taking pain relievers or fever reducers

■ stomach bleeding warning applies to you

■ you have a history of stomach problems such as heartburn

■ you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma or had a stroke

■ you are taking a diuretic

Ask a doctor or pharmacist before use if you are

■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin

■ under a doctor’s care for any serious condition

■ taking any other drug

When using this product

■ take with food or milk if stomach upset occurs

Stop use and ask a doctor if

■ you experience any of the following signs of stomach bleeding:

■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better

■ you have symptoms of heart problems or stroke

■ chest pain ■ trouble breathing ■ weakness in one part or side of body ■ slurred speech ■ leg swelling

■ pain gets worse or lasts for more than 10 days

■ fever gets worse or lasts for more than 3 days

■ redness or swelling is present in the painful area

■ any new or unexpected symptoms occur

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or

complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

■ **do not use more than directed**

■ **the smallest effective dose should be used**

■ do not take longer than 10 days, unless directed by a doctor (see Warnings)

Adults and children:(12 years and older)

Take 1 tablet every 4 to 6 hours while symptoms persist. If pain or fever does not respond to 1 tablet, 2 tablets may be used.
Do not exceed 6 tablets in 24 hours, unless directed by a doctor.

Children under 12 years:

Ask a doctor

Other information

■ read all product information before using

■ store at 68-77°F (20-25°C)

■ avoid excessive heat 104°F (above 40°C)

■ tamper evident sealed packets

■ do not use any opened or torn packets

Inactive ingredients

carnauba wax*, corn starch, hypromellose*, iron oxide red, lactose*, magnesium stearate*, microcrystalline cellulose*, polydextrose*, polyethylene glycol, polyvinyl alcohol*, povidone K30*, silicon dioxide, sodium starch glycolate, stearic acid, talc*, titanium dioxide

**may contain*

Questions or comments? 1-800-634-7680

Medi-First Ibuprofen Label

100 tablets (50 x 2)

Medi-First®

Ibuprofen 200 mg

Pain Reliever/Fever Reducer (NSAID)

Aches, Fever • Ibuprofen (NSAID) 200 mg

Pull to Open

Compare active ingredient to:

Advil®

Registered Trademark of Pfizer Consumer Healthcare

This package is for Households without Young Children

Tamper Evident Unit Dose Packets

Medi-First Plus Ibuprofen Label

250 tablets (125 x 2’s)

Medi-First® Plus

Ibuprofen

This Package isfor Households without Young Children

Pull To Open

Ibuprofen 200 mg (NSAID)

Pain Reliever/Fever Reducer

Compare active ingredient to:

Advil®

Registered Trademark of Pfizer Consumer Healthcare

Tamper Evident Unit Dose Packets

Medique Iprin Label

Medique®

I-Prin

Ibuprofen 200 mg

Anti-Inflammatory (NSAID)

This Package is for Households without Young Children

Pain Reliever/Fever Reducer •Ibuprofen 200 mg

24 Tablets (12 x 2)

Compare active ingredient to Advil®

Registered PFizer Consumer Healthcare

Tamper Evident Unit Dose Packets

.

Dover Addaprin Label

Dover Addaprin™

Pain Reliever-Fever Reducer

Ibuprofen 200 MG. Tablets (NSAID)

This Package is for Households Without Young Children

Dover Pharmaceutical

Products of the highest quality and effectiveness

Tamper Evident

Sealed Packets

Unit Dose Packs

500 Tablets

(250 Packets of 2)

Otis Clapp Ultraprin Label

OC Otis Clapp

Quality & Integrity Since 1840

Ultraprin ™

Pain Reliever-Fever Reducer (NSAID)

Ibuprofen Tablets USP 200 mg

For Deep Seated Pain

See Warnings and Directions on Side Panel

Tear Out Along Perforation To Dispense

Professional Healthcare

500 Tablets (250 Packets of 2)

MEDI-FIRST IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-718
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TALC (UNII: 7SEV7J4R1U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	red (Reddish Brown)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-718-13	250 in 1 BOX	01/26/2017	
1	NDC:47682-718-99	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-718-48	125 in 1 BOX	01/26/2017	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-718-33	50 in 1 BOX	01/26/2017	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:47682-718-30	4 in 1 BOX	01/26/2017	
4		2 in 1 PACKET; Type 0: Not a Combination Product		

5	NDC:47682-718-50	25 in 1 BOX	04/16/2019	
5		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	01/26/2017	

MEDI-FIRST PLUS IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-709
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	red (Reddish Brown)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-709-48	125 in 1 BOX	01/26/2017	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-709-33	50 in 1 BOX	01/26/2017	
2		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	01/26/2017	

MEDIQUE IPRIN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-700
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE K30 (UNII: U725QWY32X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	red (Reddish Brown)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G;2

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-700-69	3 in 1 BOX	01/26/2017	
1	NDC:47682-700-99	2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-700-64	12 in 1 BOX	01/26/2017	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-700-47	100 in 1 BOX	01/26/2017	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:47682-700-13	250 in 1 BOX	01/26/2017	
4		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	01/26/2017	

DOVER ADDAPRIN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-714
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

POVIDONE K30 (UNII: U725QWY32X)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	red (Reddish Brown)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-714-13	250 in 1 BOX	01/26/2017	
1	NDC:47682-714-99	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	01/26/2017	

OTIS CLAPP ULTRAPRIN

ibuprofen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-702
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
TALC (UNII: 7SEV7J4R1U)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics

Color	red (Reddish Brown)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-702-13	250 in 1 BOX	02/01/2017	04/03/2017
1	NDC:47682-702-99	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	11/17/2014	04/03/2017

Labeler - Unifirst First Aid Corporation (832947092)

Establishment

Name	Address	ID/FEI	Business Operations
Prestige Packaging		080667761	relabel(47682-700, 47682-702, 47682-709, 47682-714, 47682-718) , repack(47682-700, 47682-702, 47682-709, 47682-714, 47682-718)

Revised: 8/2021 Unifirst First Aid Corporation

MEDI-FIRST PLUS ASPIRIN- aspirin tablet, coated
MEDIQUE PRODUCTS ASPIRIN- aspirin tablet, coated
MEDI-FIRST PLUS ASPIRIN- aspirin tablet, film coated
MEDI-FIRST ASPIRIN- aspirin tablet, film coated
MEDIQUE PRODUCTS ASPIRIN- aspirin tablet, film coated
MEDI-FIRST ASPIRIN- aspirin tablet, coated
Unifirst First Aid Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Medique Aspirin

Drug Facts

Active ingredient (in each tablet)

Aspirin (NSAID*) 325 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Uses

Temporarily relieves
- headache
- minor pain of arthritis
- toothache
- muscle pain
- pain and fever of colds
- menstrual pain

Warnings

Reye's syndrome:

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert:

Aspirin may cause a severe allergic reaction which may include:
- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcohol drinks every day while using this product
- take more or for a longer time than directed

Do not use if you are allergic to aspirin or to any other pain reliever/fever reducer

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are taking a prescription drug for

- gout
- diabetes
- arthritis

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:

■ feel faint ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- if ringing in the ears or loss of hearing occurs
- redness or swelling is present in the painful area
- any new symptoms occur

If pregnant or breast-feeding, ask a health professional before use. **It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.**

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- drink a full glass of water with each dose

Adults and children: Take 1 or 2 tablets with water every 4 hours or 3 tablets every 6 hours, not to exceed 12 tablets in 24 hours
(12 years and older)

Children under 12 years: Consult a doctor

Other information

- store at room temperature
- avoid excessive heat and humidity
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

corn starch, hypromellose*, microcrystalline cellulose*, polyethylene glycol*, povidone*, propylene glycol*

*m *ay contain*

Questions or comments?

1-800-634-76870

Medique Products Aspirin Label

Medique®

Aspirin

5 Grain (325 mg)

Pain Reliever/Fever Reducer

(NSAID)

This Package is for Households without Young Children.

Pull to Open

Aches/Fever • Aspirin 325 mg

200 Tablets (100 x 2)

Tamper Evident Unit Dose Packets

Medi-First Aspirin Label

250 Tablets

(125 x 2)

Medi-First®

Aspirin 5 Grain (325 mg)

Compare Acrive Ingredients to:

Genuine Bayer®

Registered Trademark of Pfizer Consumer

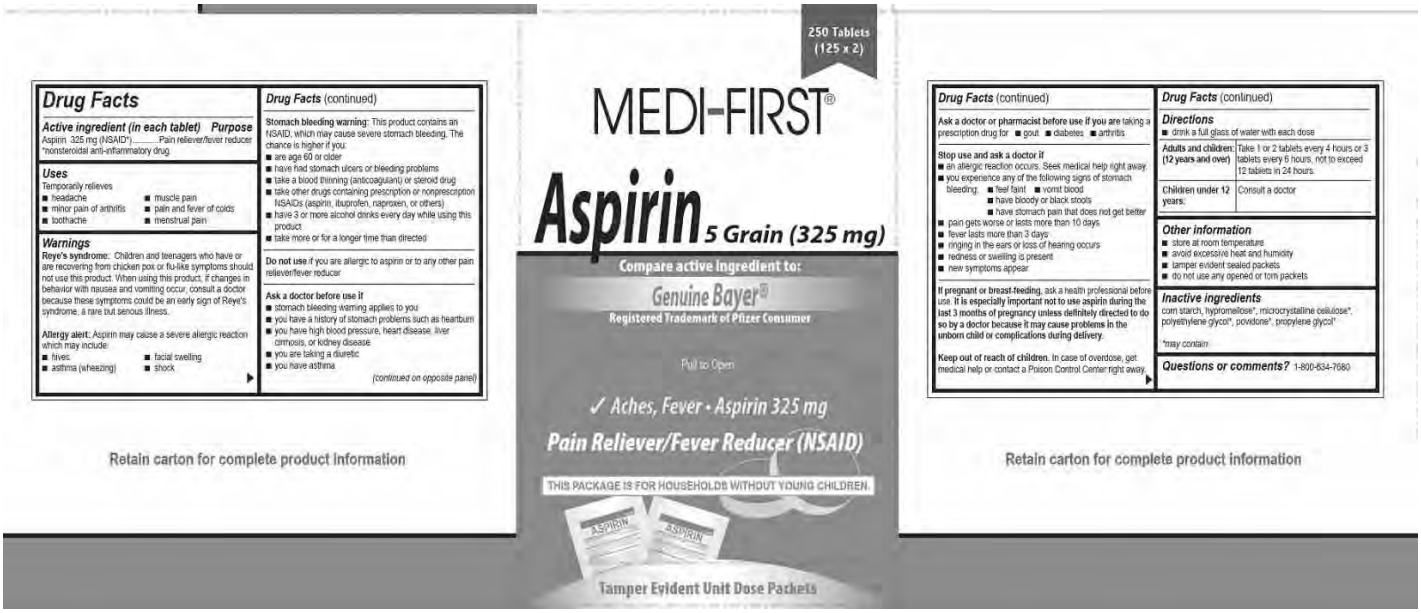
Pull To Open

Aches, Fever • Aspirin 325 mg

Pain Reliever/Fever Reducer (NSAID)

This Package is for Households without Young Children.

Tamper Evident Unit Dose Packets



Medi-First Plus Aspirin Label

250 Tablets

(125 x 2's)

Medi First® Plus

Aspirin

This Package is for Households without Young Children.

Pull To Open

Aspirin 325 mg (NSAID)

Pain Reliever/Fever Reducer

Compare active ingredient to:

Genuine Bayer®

Registered Trademark of Bayer Corporation

Tamper Evident Unit Dose Packets

Medique®

Aspirin

5 Grain (325 mg)

Pain Reliever/Fever Reducer

(NSAID)

This Package is for Households without Young Children.

Pull to Open

Aches/Fever • Aspirin 325 mg

200 Tablets (100 x 2)

Tamper Evident Unit Dose Packets

250 Tablets

(125 x 2)

Medi-First®

Aspirin 5 Grain (325 mg)

Compare Active Ingredients to:

Genuine Bayer®

Registered Trademark of Pfizer Consumer

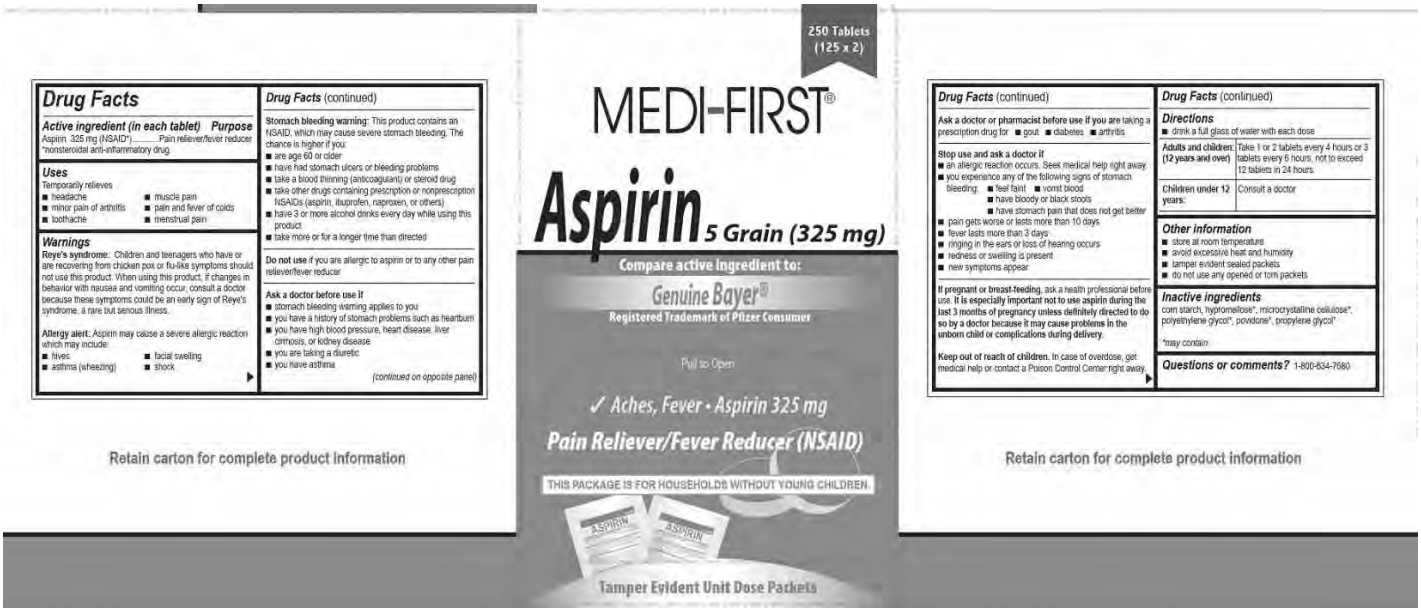
Pull To Open

Aches, Fever • Aspirin 325 mg

Pain Reliever/Fever Reducer (NSAID)

This Package is for Households without Young Children.

Tamper Evident Unit Dose Packets



250 Tablets

(125 x 2's)

Medi First® Plus

Aspirin

This Package is for Households without Young Children.

Pull To Open

Aspirin 325 mg (NSAID)

Pain Reliever/Fever Reducer

Compare active ingredient to:

Genuine Bayer®

Registered Trademark of Bayer Corporation

Tamper Evident Unit Dose Packets

MEDI-FIRST PLUS ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-622
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	FR21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-622-...	50 in 1 BOX	01/04/2021	

1	33	50 in 1 BOX	01/04/2021	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-622-48	125 in 1 BOX	01/04/2021	
2		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/04/2021	

MEDIQUE PRODUCTS ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-620
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	FR21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-620-13	250 in 1 BOX	01/04/2021	
		2 in 1 PACKET; Type 0: Not a Combination		

1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-620-47	100 in 1 BOX	01/04/2021	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-620-64	12 in 1 BOX	01/04/2021	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:47682-620-99	2 in 1 PACKET; Type 0: Not a Combination Product	01/04/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/04/2021	

MEDI-FIRST PLUS ASPIRIN

aspirin tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-618
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	44;157;ASPIRIN
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-618-33	50 in 1 BOX	07/20/2020	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-618-48	125 in 1 BOX	07/20/2020	
2		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/20/2020	

MEDI-FIRST ASPIRIN

aspirin tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-617(NDC:50844-254)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	44;157;ASPIRIN
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-617-13	250 in 1 BOX	07/20/2020	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-617-33	50 in 1 BOX	07/20/2020	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-617-48	125 in 1 BOX	07/20/2020	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:47682-617-64	12 in 1 BOX	07/20/2020	
4		2 in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:47682-617-99	2 in 1 PACKET; Type 0: Not a Combination Product	07/20/2020	
6	NDC:47682-617-50	25 in 1 BOX	07/20/2020	
6		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/20/2020	

MEDIQUE PRODUCTS ASPIRIN

aspirin tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-616
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	44;157;ASPIRIN
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-616-13	250 in 1 BOX	07/20/2020	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-616-47	100 in 1 BOX	07/20/2020	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-616-64	12 in 1 BOX	07/20/2020	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:47682-616-99	2 in 1 PACKET; Type 0: Not a Combination Product	07/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/20/2020	

MEDI-FIRST ASPIRIN

aspirin tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-621
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	FR21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-621-13	250 in 1 BOX	01/04/2021	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-621-33	50 in 1 BOX	01/04/2021	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-621-48	125 in 1 BOX	01/04/2021	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:47682-621-64	12 in 1 BOX	01/04/2021	
4		2 in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:47682-621-99	2 in 1 PACKET; Type 0: Not a Combination Product	01/04/2021	
6	NDC:47682-621-50	25 in 1 BOX	01/04/2021	
6		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/04/2021	

Labeler - Unifirst First Aid Corporation (832947092)

Establishment

Name	Address	ID/FEI	Business Operations

Prestige Packaging		080667761	relabel(47682-616, 47682-617, 47682-618, 47682-620, 47682-621, 47682-622) , repack(47682-616, 47682-617, 47682-618, 47682-620, 47682-621, 47682-622)

MEDIQUE DIPHEN- diphenhydramine hydrochloride tablet, film coated
Unifirst First Aid Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Medique Diphen

Drug Facts

Active ingredient (in each caplet)

Diphenhydramine HCl 25 mg

Purpose

Antihistamine

Uses

Temporarily relieves these symptoms due to hay fever or other respiratory allergies
- runny nose
- sneezing
- itching of the nose or throat
- itchy-watery eyes

Temporarily relieves these symptoms due to the common cold
- runny nose
- sneezing

Warnings

Warnings

Do not use
- to make a child sleepy
- with any other product containing diphenhydramine, even one that is used on skin.

Ask a doctor before use if you have

■ a breathing problem such as emphysema or chronic bronchitis

■ trouble urinating due to an enlarged prostate gland

■ glaucoma

Ask a doctor or pharmacist before use if you are
- taking sedatives or tranquilizers

When using this product
- marked drowsiness may occur
- avoid alcohol beverages
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast feeding, ask a health professional before use.

Keep out of the reach of children.

In case of overdose, contact a physician or poison control center right away (1-800-222-1222).

Directions

- take every 4-6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

Adults and children: (12 years and over) 1 to 2 caplets

Children under 12 years: do not use

Other information

- store at room temperature 68°-77°F (20°-25°C)
- protect from light
- tamper-evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

croscarmellose sodium, D&C red #27 aluminum lake, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide

Questions or comments? 1-800- 634-7680

184R Medique Diphen Label

Collect MediBucks See inside flap for more details

Medique®

Diphen

Hay Fever / Allergies

Fiebre del Heno / Alergias

This Package is for Households without Young Children.

Este Paquete Es Para Hogares Sin Ninos Pequenos.

Antihistamine • Diphenhydramine HCl 25 mg

Antihistaminico • Hidrocloruro de Difenhidramina 25mg

200 Caplets

(200 x 1)

Tamper Evident Unit Dose Packets

Empaquetado con Sellado Evidente en Dosis Unitarias

Medique 167 Diphen Principal Display Panel

Collect MediBucks See inside flap for more details

Medique®

Diphen

Hay Fever / Allergies

Fiebre del Heno / Alergias

This Package is for Households without Young Children.

Este Paquete Es Para Hogares Sin Ninos Pequenos.

Antihistamine • Diphenhydramine HCl 25 mg

Antihistaminico • Hidrocloruro de Difenhidramina 25mg

200 Caplets

(200 x 1)

Tamper Evident Unit Dose Packets

Empaquetado con Sellado Evidente en Dosis Unitarias

MEDIQUE DIPHEN

diphenhydramine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-184
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	pink (pink)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	061;T
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-184-32	12 in 1 BOX	01/01/2012	11/01/2012
1	NDC:47682-184-46	1 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-184-64	24 in 1 BOX	01/01/2012	08/01/2023
2		1 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-184-47	200 in 1 BOX	01/01/2012	08/01/2023
3		1 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:47682-184-46	1 in 1 PACKET; Type 0: Not a Combination Product	01/01/2012	08/01/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2012	08/01/2023

MEDIQUE DIPHEN

diphenhydramine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:47682-167
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	pink (pink)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	11mm
Flavor		**Imprint Code**	048;D
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:47682-167-32	12 in 1 BOX	01/01/2012	11/01/2012
1		1 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-167-64	24 in 1 BOX	01/01/2012	
2		1 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-167-47	200 in 1 BOX	01/01/2012	
3	NDC:47682-167-46	1 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:47682-167-46	1 in 1 PACKET; Type 0: Not a Combination Product	01/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/01/2012	

Labeler - Unifirst First Aid Corporation (832947092)

Establishment

Name	Address	ID/FEI	Business Operations
Prestige Packaging		170837962	relabel(47682-167, 47682-184) , repack(47682-167, 47682-184)

Revised: 2/2021 Unifirst First Aid Corporation

SAFETY DATA SHEET

ADAPTIC® Non-Adherent Dressing

This Safety Data Sheet contains information concerning the potential risks to those involved in handling, transporting and working with the material, as well as describing potential risks to the consumer and the environment. This information must be made available to those who may come into contact with the material or are responsible for the use of the material. This Safety Data Sheet is prepared in accordance with formatting described in the REACH Regulation (EC) No 1907/2006, and described in CLP Regulation (EC) No 1272/2008.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
ADAPTIC® Non-Adherent Dressing

1.2 Relevant identified uses of the substance or mixture and uses advised against
Wound dressing. This product is only supplied for professional use as a medical device.

1.3 Details of the supplier of the safety data sheet
Systagenix Wound Management Ltd.
Gargrave
North Yorkshire BD23 3RX
United Kingdom
Phone: +44 (0)1756 747200
Email: (UK): customercareuk@systagenix.com
(US): nccorderdocintake@acelity.com

1.4 Emergency telephone number

In case of emergency Tel. **(UK):** 0800-917-5403 / 020-3027-8716 (Mon-Fri 09.00-17.00hrs)
(US): 1-800-275-4524 (Mon-Fri 8:00am EST – 5:00pm EST)

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture
This product is not classified as hazardous in accordance with EU regulations (Dangerous Preparations Directive 1999/45/EC or CLP Regulation (EC) No 1272/2008).

2.2 Label elements
No labelling is required in accordance with EU regulations (Dangerous Preparations Directive 1999/45/EC or CLP Regulation (EC) No 1272/2008).

2.3 Other hazards
This product is not expected to be hazardous under foreseen conditions of use. However, as with all health care products, care should be taken to carefully read the instructions before use.

SECTION 3: Composition / information on ingredients

3.1 Substances
Not applicable. Product is not a substance.

3.2 Mixtures
ADAPTIC® Non-Adherent Dressings are primary dressings made of knitted cellulose acetate fabric and impregnated with a specially formulated petrolatum emulsion.

SECTION 4: First Aid Measures

4.1 Description of first aid measures
EYE CONTACT: Rinse eye with plenty of water.
INHALATION: Inhalation is not likely to occur.
SKIN CONTACT: Wash skin with plenty of soap and water.
INGESTION: Ingestion is not likely to occur.

4.2 Most important symptoms and effects, both acute and delayed
No effects from skin or eye contact are anticipated.

4.3 Indication of any immediate medical attention and special treatments needed
Symptomatic treatment as required

SECTION 5: Firefighting Measures

5.1 Extinguishing media
No known adverse reactions with any extinguishing media. Use extinguisher appropriate to surrounding conditions.

5.2 Special hazards arising from the substance or mixture
Normal combustion products are considered to be carbon dioxide, although incomplete combustion may lead to the formation of organic decomposition products.

5.3 Advice for fire fighters
No special precautions required. Wear normal fire-fighting kit and breathing apparatus as appropriate.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures
No special precautions required for unused dressings.

6.2 Environmental precautions
No special precautions required.

6.3 Methods and materials for containment and clearing up
Unused dressings should be collected and disposed of according to local and national regulations.
Used dressing should be collected and disposed of as clinical waste.

6.4 References to other sections
None.

SECTION 7: Handling and Storage

7.1 Precautions for safe handling
Normal sterile working procedures will provide adequate protection.

7.2 Conditions for safe storage, including any incompatibilities
Store in a cool dry place. Avoid extremes of temperature.

7.3 Specific end uses(s)
None

SECTION 8. Exposure Controls/Personal Protection

8.1 Control parameters
No exposure limits applicable

8.2 Exposure controls
Engineering controls are not required.

Respiratory protection
No special precautions required. Inhalation is not likely to occur.

Hand Protection
Surgical gloves should be worn in accordance with normal working procedures.

Eye protection
No special precautions required.

Skin protection
No special precautions required.

Environmental exposure controls
None required.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance:	White gauze dressing impregnated with a petrolatum emulsion.
Odour:	None
Odour threshold:	Not applicable
pH:	Not applicable
Melting point:	Not applicable
Boiling point:	Not applicable
Flashpoint:	Not applicable
Evaporation rate:	Not applicable
Flammability:	Combustible
Upper/lower flammability limits:	Not applicable
Vapour pressure:	Not applicable
Vapour density	Not applicable
Relative density	Not applicable
Solubility in water:	Not soluble
Solubility in other solvents:	Not applicable
Partition coefficient (log Kow)	Not applicable
Autoignition temperature	No data
Decomposition temperature	No data
Viscosity	Not applicable
Explosive properties	Not considered explosive
Oxidising properties	Not considered oxidising

9.2 Other information
None

SECTION 10: Stability and Reactivity

10.1 Reactivity
No reactive hazards known.

10.2 Chemical stability
Stable under normal conditions of use.

10.3 Possibility of hazardous reactions
No hazardous reactions expected.

10.4 Conditions to avoid
Avoid extremes of temperature

10.5 Incompatible materials
Avoid contact with strong oxidizing agents

10.6 Hazardous decomposition products
Normal combustion products.

SECTION 11: Toxicological Information

11.1 Information on toxicological effects

This product has not been tested. Judgements on the expected toxicity of this product have been made based upon consideration of its major components.

(a) acute toxicity No effects are anticipated from the product as supplied.
(b) skin corrosion/irritation No effects are anticipated from the product as supplied.
(c) serious eye damage/irritation No effects are anticipated from the product as supplied.
(d) respiratory/skin sensitisation No effects are anticipated from the product as supplied.
(e) germ cell mutagenicity Contains no known mutagens
(f) carcinogenicity Contains no known carcinogens
(g) reproductive toxicity Contains no known reproductive toxins
(h) STOT-single exposure No effects are anticipated from the product as supplied.
(i) STOT-repeated exposure No effects are anticipated from the product as supplied.
(j) aspiration hazard Not applicable to this product

SECTION 12: Ecological Information

12.1 Toxicity
No effects are anticipated from the product as supplied.

12.2 Persistence and degradability
This product is expected to biodegrade slowly in the environment.

12.3 Bioaccumulative potential
None of the components are known to be bioaccumulative.

12.4 Mobility in soil
Not expected to be mobile.

12.5 Results of PBT and vPvB assessment
None of the components are known to be PBT or vPvB.

12.6 Other adverse effects
None known.

SECTION 13: Disposal Considerations

13.1 Waste treatment methods
Disposal should be in accordance with local and national regulations.
Used dressings should be disposed of as clinical waste.

SECTION 14: Transport Information

Not regulated as hazardous for transport.

	ADR	IMDG	ICAO
14.1 UN Number	None	None	None
14.2 UN Proper shipping name	None	None	None
14.3 Transport hazard class(es)	None	None	None
14.4 Packing group	None	None	None

14.5 Environmental hazards	None	None	None
14.6 Special precautions for user	None	None	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	None	None	None

SECTION 15: Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

All components are listed as existing substances in Europe

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out for this product.

SECTION 16: Other Information

Revision information: Update to US contact details.

Approved for use as a medical device. Refer to full Instructions For Use.

Special training: no specialist training required with respect to chemical hazards

List of Abbreviations used in this SDS:

CAS Chemical Abstracts Service
CLP Classification, Labelling and Packaging Regulation (EC) no 1272/2008
DSD Dangerous Substances Directive 67/548/EEC
DPD Dangerous Preparations Directive 1999/45/EC
EC European Community/Commission
PBT Persistent, Bioaccumulative and Toxic
REACH Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) no 1907/2006
vPvB very Persistent, very Bioaccumulative

Material Safety Data Sheet (MSDS) for QuikClot® Gauze™ CE

1. CHEMICAL PRODUCT & COMPANY INFORMATION

1.1. Product Name: QuikClot® Gauze™ CE

1.2. Product Use: An adjunct to manual pressure for temporary control of moderate external bleeding from surgical wounds or cuts and lacerations.

1.3. Company Information: Z-Medica Corporation, 4 Fairfield Blvd., Wallingford, CT 06492 USA
Tel: +1-203-294-0000 x262, Fax: +1-203-294-0688, www.z-medica.com

2. COMPOSITION/INFORMATION ON INGREDIENTS

2.1. Product Contents:

2.1.1. QuikClot® Gauze™ CE = One (1) Sterile Strip 3 in. wide x 4 yds. long coated with Hemostatic Agent

2.2. Composition of Strip: medical fabric (synthetic blend)

2.3. Composition of Hemostatic Agent:

CAS #	Component	Percent (Dry Weight)
56-81-5	Glycerin	Proprietary %
1332-58-7	Kaolin	Proprietary %
14808-6-7	Silica	< 0.05 %

NOTE: The Silica is bound to the medical fabric with the Kaolin under normal conditions, preventing its respiratory exposure pathway to an individual, therefore QuikClot® Gauze™ CE is not considered to produce airborne particles of a respirable size.

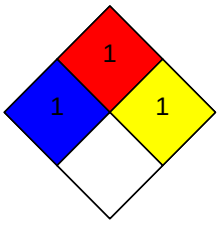
3. HAZARDS IDENTIFICATION

3.1. HMIS™ - Hazardous Material Information System

3.1.1. Health Hazard: Irritation possible if exposed to dust from heated and dried medical fabric.

3.1.2. Flammability: Medical fabric will burn when exposed to flame.

3.1.3. Reactivity/Physical Hazard: Components are stable and produce no hazardous decomposition products.



3.2. Potential Health Effects:

3.2.1. **Primary Routes of Exposure:** Dust may be generated if medical fabric is heated and dried—resulting in possible contact of dust with eyes and lungs.

3.2.2. **Skin Contact:** None

3.2.3. **Eye Contact:** Dust from heated and dried medical fabric may cause eye discomfort and/or irritation.

3.2.4. **Ingestion:** May cause irritation to gastrointestinal tract.

3.2.5. **Inhalation:** Dust from heated and dried medical fabric may cause lung discomfort and/or irritation.

3.2.6. **Chronic Effects:** None

4. **FIRST-AID MEASURES**
   - **4.1. Eye Contact:** Flush immediately with plenty of water for at least 15 minutes. If eye irritation persists, consult a physician.
   - **4.2. Skin Contact:** None
   - **4.3. After Inhalation:** Remove to fresh air; artificial respiration if necessary.
   - **4.4. After Ingestion:** Drink two or three glasses of water to dilute stomach contents. DO NOT induce vomiting. Call a physician immediately.
   - **4.5. Notes to physician:** Carefully read instructions for use printed on the primary packaging. Contact the company directly to report any adverse events.
5. **FIRE FIGHTING MEASURES**
   - 5.1. **Suitable extinguishing media:** Water spray, dry chemical, and carbon dioxide.
   - **5.2. Unsuitable extinguishing media:** None.
   - **5.3. Fire and explosion hazards:** Medical fabric will burn when exposed to flame.
   - **5.4. Special protective equipment:** In the case of smoke, use self-contained breathing apparatus.
   - **5.5. Flash Point:** N/A
6. **ACCIDENTAL RELEASE MEASURES**
   - **6.1. Personal protection:** None
   - **6.2. Environmental precautions:** None
   - **6.3. Clean-up:** Sweep, shovel or vacuum product into appropriate containers (do not use vacuum if materials has contacted a hydrocarbon material). Dispose of spilled product in accordance with all applicable government regulations.
7. **HANDLING & STORAGE**
   - **7.1. Handling:** No special handling required. Discard packages that are damaged or open.
   - 7.2. **Storage:** Store in original package. Discard unused portion. Do not reuse. No special storage conditions required.
8. **EXPOSURE CONTROLS/PERSONAL PROTECTION**
   - **8.1. Engineering Controls:** N/A
   - **8.2. Personal protection equipment:** N/A
9. **PHYSICAL & CHEMICAL PROPERTIES**
   - **9.1. Form:** QuikClot® Combat Gauze™ = One (1) Sterile Strip 3 in. wide x 4 yds. long
   - **9.2. Odor:** Slightly Sweet
   - **9.3. pH:** 5.5-6.5 in Water
   - **9.4. Boiling Point/Range:** N/A
   - **9.5. Melting Point/Range:** Polyester component of medical fabric will melt @ 464-500˚F (240-260˚C).
10. **STABILITY**
    - **10.1. Stability:** Stable
    - 10.2. **Hazardous decomposition products:** There are no decomposition products if product is used as directed. Smoke, carbon dioxide, and carbon monoxide are the hazardous combustion byproducts emitted from the medical fabric.
    - **10.3. Conditions/Materials to avoid:** None
11. **TOXICOLOGICAL INFORMATION**

    Product has passed the appropriate biocompatibility/toxicology testing for a medical device intended for use on breached or compromised surfaces (traumatic wounds) in accordance with ISO 10993-1:2003(E). This testing includes: cytotoxicity, skin sensitization, and intracutaneous reactivity.
12. **ECOLOGICAL INFORMATION**
    - **12.1. Mobility:** No data available

12.2. Biodegradation: No data available
12.3. Bioaccumulation: No data available
12.4. Aquatic Toxicity: No data available

13. DISPOSAL CONSIDERATIONS

13.1. Provisions relating to waste: EPA – Resource Conservation and Recovery Act (RCRA) Hazardous and Solid Waste Management Regulations.

13.2. Disposal Information: This product or any of its components are not listed by generic name or trademark name in the U.S. EPA's RCRA regulations and does not possess any of the identifying characteristics of hazardous waste (ignitability, corrosivity, reactivity or toxicity). Materials of a hazardous nature that contact the product may be retained on the product. The user of the product must identify the hazards associated with the retained material in order to assess the waste disposal options.

14. TRANSPORT INFORMATION

14.1. UN-No.: N/A

14.2. Proper Shipping Name: Medical Goods, Blood Clotting Agent (Harmonized Tariff (Export) Schedule B Code 3005900000 (Non-Adhesive Wound Dressing). No Export License Required.

14.3. Packing Group: N/A

14.4. Transport Mode:

14.4.1. **U.S. DOT –** Not Regulated
14.4.2. ADR/RID – Not Regulated
14.4.3. IMDG – Not Regulated
14.4.4. IATA – Not Regulated

15. REGULATORY INFORMATION

15.1. US FDA/CDRH – Unclassified, Product Code = FRO, K072474

15.2. EU – Class IIb, NB=BSI, AR=Emergo Europe, Molenstraat 15, 2513 BH, The Hague, The Netherlands

15.3. Canada – Class II, Canadian License 77763

16. CONTACT INFORMATION

For technical, health, safety and environmental information, please contact:

Sheila K Wallin /VP, Clinical & Regulatory Affairs
Z-Medica Corporation, 4 Fairfield Blvd., Wallingford, CT 06492 USA
Tel: +1-203-294-0000 x308, Fax: +1-203-294-0688, swallin@z-medica.com