



Dirección: Cra. 53 N° 50-09
Guarne (Antioquia) COLOMBIA.
Teléfonos: (57-60-4) 550 00 00 - 403 87 60
Fax: (57-60-4) 551 31 34
infocolombia@newstetic.com

SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

1 PRODUCT IDENTIFICATION

1.1 Chemical name:

- Articaine Hydrochloride: methyl 4-methyl-3-[2-(propylamino)propanoylamino]thiophene-2-carboxylate; hydrochloride
- Epinephrine: 4-[(1R)-1-hydroxy-2-(methylamino)ethyl]benzene-1,2-diol

1.2 Product name:

- Articaine Hydrochloride 4% with Epinephrine 1:100.000 Injectable solution

1.3 Synonyms:

- Articaine Hydrochloride: Articaine HCl
- Epinephrine: Adrenaline

1.4 Recommended use and restrictions of the product:

- Recommended use: Local anesthetic for dental use
- Restrictions for use: Health care professionals only

1.5 Emergency telephone:

In case of emergency, contact the emergency/poison attention line available in your country/state/province/department

You can also contact New Stetic S.A. Carrera 53 N° 50-09, Medellín-Bogotá, Km 22, Guarne, Antioquia, Colombia. Telephone (604) 550 00 00, ext. 1304 or 1306. Website www.newstetic.com

2 HAZARDS IDENTIFICATIONS

2.1 GHS classification:

Health	Environment	Physical
Not classified as dangerous ¹	Not classified as dangerous ¹	Not classified as dangerous ¹
¹ substance or mixture exempt from GHS classification		

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	1 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

2.2 GHS Label:

Symbol	Signal word	Hazard statements
Not classified as dangerous ²	Not classified as dangerous ²	Not classified as dangerous ²
² substance or mixture exempt from GHS classification		

2.3 Caution statement:

Not available

2.4 Appearance in case of emergency:

Not available

2.5 Potential side effects:

Not available

2.6 NFPA:

Not available

2.7 OSHA state:

Not considered as dangerous for OSHA HCS

3 COMPOSITION INFORMATION

Description: Mixture (Pharmaceutical product)

DANGEROUS COMPONENTS		
Common name	Concentration	CAS number
Articaine Hydrochloride	4%	23964-57-0
Epinephrine	0,001%	51-43-4
Sodium Metabisulfite	Not available ³	7681-57-4

³ the concentration is considered a trade secret.

NON-DANGEROUS COMPONENTS		
Common name	Concentration	CAS number
Mixture of non-hazardous excipients	No applicable	No applicable

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	2 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

4 FIRST AID MEASURES

4.1 Emergency procedures and first aid measures in case of:

- Inhalation: In the event of any symptoms, remove from source of exposure and supply fresh air. If symptoms persist, consult a doctor.
- Contac with eyes: Wash with plenty of water for at least 15 minutes with your eyes open. If symptoms persist, consult a doctor.
- Contac with skin: Remove contaminated clothing (if applicable), wash with plenty of soap and water. In case the symptoms persist, consult a doctor.
- Ingestion: Perform mouthwash with water. Do not induce vomiting. If symptoms persist, consult a doctor.

4.2 Most important symptoms/effects (acute and/or delayed):

Inadvertent contact with this product may cause irritation, followed by numbness. Ingestion may cause numbness of the tongue and anesthetic effects on the stomach. In clinical use, this product produces numbness when injected.

In normal clinical use, adverse effects may include fever, headaches, agitation, tingling of extremities, general hypotension, bradycardia, dizziness, nausea, vomiting, anemia, back pain, post-operative pain and fetal distress.

Systemic absorption can produce central nervous system (CNS) stimulation and/or CNS depression. CNS depression may progress to coma and cardio-respiratory arrest. Signs of cardiovascular toxicity may include changes in cardiac conduction, excitability, refractoriness, contractility, and peripheral vascular resistance. Toxic blood levels may cause atrioventricular block, ventricular arrhythmias, cardiac arrest, and sometimes death. In addition, decreased cardiac output and arterial blood pressure may occur.

Allergic-type reactions are rare but may occur due to sensitivity to the local anesthetic or to other formulation ingredients. These reactions are characterized by signs such as urticaria, pruritus, erythema, angioneurotic edema (including laryngeal, edema), tachycardia, sneezing, nausea, vomiting, dizziness, syncope, excessive sweating, elevated temperature, and possibly, anaphylactic-like symptoms (including severe hypotension). Cross sensitivity with other amide-type local anesthetics has been reported.

4.3 Antidote:

No available

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	3 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

4.4 Information for health care professionals:

It does not require immediate medical attention in normal handling situations. In case of overdose or inappropriate practice, treat symptoms. The safety and efficacy of local anesthetics depend on the appropriate dose, the correct technique, the necessary precautions for administration.

5 FIRE-FIGHTING MEASURES

5.1 Flammability:

No available

5.2 Adequate Extinguishing Media

Water, dry chemical, carbon dioxide, or foam as appropriate for fire and surrounding materials.

5.3 Inadequate Extinguishing Media:

No available

5.4 Fire-fighting instructions:

Evacuate the surrounding personnel, extinguish the fire using any of the means described and allow the containers and/or structures exposed to the fire to cool down. Heat can cause expansion or decomposition with violent rupture of the packaging units. Container system materials can emit toxic and/or corrosive fumes when burning.

5.5 Fire-fighters protection:

No available

5.6 Protection equipment for fire-fighters:

Fire-fighters must wear full emergency equipment and approved positive pressure self-contained breathing apparatus.

6 ACCIDENTAL REALESE MEASURES

6.1 Techniques, procedures, materials and protective equipment in case of:

- Small Spills: Caution should be exercised to prevent ingestion and eye contact. Clean up spills with normal procedures used for non-hazardous liquids. Absorb spill with inert material, then place in chemical waste container. Clean the surface thoroughly with water to remove residual contamination.

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	4 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

- Large Spills: Caution should be exercised to prevent ingestion and eye contact. Wear safety glasses with side shields and wear impervious gloves to avoid skin contact. Alert the environmental or disaster response authorities. Clean up spills with normal procedures used for non-hazardous liquids. Absorb spill with inert material, then place in chemical waste container. Clean the surface thoroughly with water to remove residual contamination.

6.2 Environment cautions:

- Do not allow the product to enter water courses.
- Avoid sewer drainage
- Inform the respective authorities in case of release.

6.3 Other information:

- See Section 7 for information on safe handling.
- See Section 8 for information on personal protective equipment.
- See Section 13 for information on final disposal.

7 HANDLING AND STORAGE

7.1 Handling:

- Avoid contact with the eyes and skin.
- Wash thoroughly with soap and water after handling.
- Use according to the insert instructions.
- Keep out of the reach of children

7.2 Storage:

- Store in a cool and dry place at temperatures below 30°C
- Store protected from the direct impact of sources of heat and light.
- Store in its original packaging.
- Review product insert.

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	5 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

8 EXPOSURE CONTROL AND PERSONAL PROTECTION

8.1 Conditions for exposure control:

No specific controls are required

8.2 Engineering controls:

No specific controls are required

8.3 Personal protection equipment:

- Skin: Waterproof gloves (Material: nitrile or natural rubber), protective clothing (Material: antifuide, leather or waterproof synthetics)
- Airways: Not normally required. In case of spill or leak, wear a mask.
- Eyes: Safety glasses with side shields
- Face: Not normally required. In case of spills or leaks wear a mask (Material: acetate)

8.4 Exposure parameters:

- Articaine Hydrochloride: No available
- Epinephrine: No available
- Sodium Metabisulfite: 5 mg/m³ (TWA)
- Mixture of non-hazardous excipients: No available

9 PHYSICAL AND CHEMICAL PROPERTIES

- Appearance: Colorless clear solution
- Odor: Odorless
- Odor threshold: Not applicable
- Physical state: Liquid
- pH: 2.7 to 5.2

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	6 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



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SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

- Freezing or melting point: $\approx 0^{\circ}\text{C}$
- Evaporation rate: Not available
- Initial boiling point and boiling range: $\approx 100^{\circ}\text{C}$
- Flash point: Not flammable
- Evaporation rate: Not available
- Flammability (solid gas): Not applicable
- Upper / lower flammability or explosive limit: Not applicable
- Vapor pressure: Not available
- Vapor density: Not available
- Specific gravity or relative density: ≈ 1
- Solubility: Very soluble
- Partition coefficient n-octanol / water: Not available
- Auto-ignition temperature: Not available
- Decomposition temperature: Not available
- Heat value: Not available
- Particle size: Does not apply
- Volatile organic compound content: Not available
- Softening point: Not applicable
- Pour point: Not available
- Viscosity: Not available
- Bulk density: Not applicable
- Percent volatility: Not available

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	7 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

- Saturated vapor concentration: Not available
- Molecular weight: Not available
- Molecular formula: Not available
- Other: Not applicable

10 ESTABILITY AND REACTIVITY

10.1 Chemical stability:

Stable under normal storage and handling conditions

10.2 Possible hazardous reaction:

No known

10.3 Conditions to avoid:

- Avoid exposing to high temperatures
- Avoid exposing to sources of heat and intense light
- Avoid freezing
- Avoid autoclaving
- Avoid using the solution if it shows coloration or precipitate.

10.4 Incompatibility materials:

- Avoid contact with water reactive species
- Avoid contact with strong reducing agents
- Avoid contact with acrylic monomers

10.5 Hazardous decompositions products:

No available

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	8 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

10.6 Dangerous polymerization:

No available

11 TOXICOLOGICAL INFORMATION

11.1 Possible exposure routes:

- Dermal
- Ingestion
- Eyes

11.2 Acute toxicity:

Health effects: In case of exceeding maximum recommended doses, signs such as hypersensitivity, perioral and lingual paresthesia, metallic taste and dizziness, difficulty speaking, diplopia, tinnitus, confusion, restlessness and muscle spasms may occur that progress to neuronal depression and lead to seizures and coma.

11.3 Chronic toxicity:

Health effects: Inflammation, neural ischemia, neurotoxicity and cardiac toxicity can occur due to modification of action potentials and ionic currents at the heart level. Allergic reactions can be generated in asthmatic or sulfite-sensitive patients over time.

11.4 Other information:

- Carcinogenicity: This product is not expected to cause carcinogenicity.
- Mutagenicity: This product is not expected to cause mutagenic activity.
- Fertility Toxicity: This product is not expected to cause reproductive or developmental toxicity.
- Specific Target Organ Toxicity: Causes central nervous system effects such as drowsiness, confusion, excitability, and nervousness. The product acts as a depressant of the cardiovascular system.

12 ECOLOGICAL INFORMATION

12.1 Ecotoxicity:

- Articaine Hydrochloride: No available

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	9 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

- Epinephrine: No available
- Sodium Metabisulfite: LC50: 32 mg/L, 96h (*Pimephales promelas*); EC50: 89 mg/L 48 h (*Daphnia magna*). EC50: 48 mg/L, 72h (*Pseudokirchneriella subcapitata*)
- Mixture of non-hazardous excipients: No available

12.2 Persistence in the environment and degradability:

No available

12.3 Bioaccumulation potential

No available

12.4 Mobility in soil:

No available

12.5 Other adverse effects:

No applicable

13 DISPOSAL CONSIDERATIONS

- Do not be disposed of with household garbage.
- Do not allow product to enter sewer system.
- Dispose according to applicable regulations according to the corresponding country/state/province/department

WARNING: Local laws, regulations and restrictions may change or be reinterpreted, and differ from national ones, so the considerations for disposing of the material and its packaging may vary with respect to those indicated in this document.

14 TRANSPORT INFORMATION

14.1 Hazardous material:

Not classified as dangerous

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	10 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

14.2 Risk class:

Not classified as dangerous

14.3 UN number:

Not classified as dangerous

14.4 IATA classification:

Not classified as dangerous

14.5 Packing group:

Not classified as dangerous

14.6 Maritime pollutant (Yes/No):

No

15 REGULATORY INFORMATION

15.1 Colombia:

- Decree 1496 of 2018: This product is a medicine and is not subject to requirements for classification or control of chemical substances.
- Legend: Keep out of the reach of children
- Contraindications: Contraindicated in children under 4 years

15.2 International:

- Canadian Environmental Protection Act: This product is a drug and is not subject to chemical notification requirements.
- European Inventory of Existing Chemicals (EINECS): This product is a medicine and is not subject to chemical notification requirements.
- European Union (EU REACH): This product is a medicine and is not subject to chemical notification requirements.
- Australian Inventory of Chemicals - This product is a drug and is not subject to chemical notification requirements.

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	11 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07



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SAFETY DATA SHEET ARTHEEK 4% SP DPFMFS-018

- Inventory of Chemicals and Existing Chemicals in China: This product is a drug and is not subject to chemical notification requirements.
- New and Existing Chemicals in Japan: This product is a drug and is not subject to chemical notification requirements.
- List of Existing Chemicals in Korea: This product is a drug and is not subject to chemical notification requirements.
- Philippine Inventory of Chemicals and Chemical Substances - This product is a drug and is not subject to chemical notification requirements.

16 OTHER INFORMATION

The information in this document is based on our current knowledge and is given in good faith, but no express or implied warranty is given, nor is any liability assumed for improper handling of the product. This document is prepared in accordance with:

- Globally Harmonized System of Classification and Labeling of Chemicals - GHS (Globally Harmonized System of Classification and Labeling of Chemicals).
- Colombian technical standard NTC 4435: 2010. Merchandise transports. Material Safety Data Sheets. Preparation.
- Decree 1496 of 2018. By which the Globally Harmonized System (GHS) for the classification and labeling of chemical products is adopted and other provisions on chemical safety are issued.

Creation date		Written by:	Reviewed by:	
2022-01-03		Pharmaceutical Analyst	Anesthetic Quality Assurance Coord	
Class	Page	Approved by:	Actualization date	Version
D	12 of 12	Anesthetic Technical Director	2024-12-07	01

REFERENCE DOCUMENT: DPDDPR-003

ACTUALIZATION DATE: 2023-11-29

VERSION: 07