

Gebauer's Ethyl Chloride[®]

Topical Anesthetic Spray

TECHNICAL DATA DOCUMENT

GEBAUER'S ETHYL CHLORIDE®

Topical Anesthetic Skin Refrigerant

Description

Gebauer's Ethyl Chloride is a topical anesthetic spray that consists of ethyl chloride. Upon contact with the skin, the product evaporates immediately, due to the low evaporation rate created by the chemical and the unique proprietary delivery system.

Gebauer's Ethyl Chloride is available in the form of a fine stream, medium stream, or mist spray. The type of delivery system chosen depends on the end user preference and the procedure they are performing.

Mechanism of Action

When topically applied to the skin, Gebauer's Ethyl Chloride creates an instantaneous cooling effect on the surface of the application site by the immediate evaporation of the product from the skin surface. The coldness created by the spray decreases the nerve conduction velocity of the C fibers and the A-delta fibers that make up the peripheral nervous system, thus interrupting the nociceptive inputs to the spinal cord.¹

When used with the spray and stretch technique, it is thought that the tactile stimulation produced by the changing gradient of the skin temperature and the impact of the product transmits a barrage of impulses to the spinal cord blocking the trigger point impulse activity.²

Cooling Effect: When Gebauer's Ethyl Chloride begins to evaporate from the surface of the target area after application, a cooling effect results. The cooling sensation produced is directly related to the type of

stream and the distance from the point of contact.

The mist spray produces very fine droplets that create instantaneous cold at the points of contact. The fine droplets are dispersed in a circular pattern with an approximate two-inch diameter when sprayed from a distance of 4 inches from the target.

The fine and medium stream sprays produce a pinpoint stream that contacts the skin surface at a specific single location. The difference between the fine and medium stream sprays is the amount of product being applied over a similar time frame. The dosage for the medium stream is approximately twice that of the fine stream.

As the distance from the target surface is increased, the dispersion of the droplets in both the mist and stream products is increased. Increasing the surface area of contact and decreasing the size of the droplets increases the evaporation rate. The increase in evaporation rate correlates to an increase in the cooling effect.

Gebauer's Ethyl Chloride Mist is most effective for general cooling of the target area where precise contact is not indicated. Since the evaporation rate is increased due to the dispersion, a more intense cooling effect will be created at the initial point of application over a larger area.

Gebauer's Ethyl Chloride Fine Stream and Medium Stream are most effective for cooling of the skin at a specific site or to create specific cooling patterns. The fine stream product was produced for use with a sweeping motion to cool along the length of

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the muscles necessary for the spray and stretch myofascial technique.

Gebauer's Ethyl Chloride Medium Stream and Fine Stream are most effective for creating an anesthetic effect on the intact skin at a specific pinpoint location.

Temperature data has been collected on all Gebauer products across the range of labeled distances. The temperature studies were performed using validated laboratory equipment to measure the various temperatures. These studies performed by Merrick found that Ethyl Chloride with the medium stream nozzle produced skin surface temperatures ranging from $-11^{\circ}\text{C} \pm 1^{\circ}\text{C}$ (spray-distance of 7 inches and spray-duration until blanching) up to $-3^{\circ}\text{C} \pm 1^{\circ}\text{C}$ (spray-distance of 3 inches and spray-duration of 4 seconds). Furthermore, Ethyl Chloride with the mist nozzle produced skin surface temperatures ranging from $-11^{\circ}\text{C} \pm 1^{\circ}\text{C}$ (spray-distance of 3 inches and spray-duration until blanching) up to $4^{\circ}\text{C} \pm 1^{\circ}\text{C}$ (spray-distance 7 inches and spray-duration 4 seconds).³

Indications and Use

Gebauer's Ethyl Chloride products are FDA cleared prescription medical devices. The products are for use as a vapocoolant (skin refrigerant) intended for topical application on intact skin for the following indications:

Temporary pain management for:

- Injections
- Starting IV and venipuncture
- Minor surgery
- Minor sports injuries

The fine and medium stream configurations are also intended as a counterirritant in the management of:

- Myofascial pain and trigger points
- Restricted motion
- Muscle tension

Contraindications

Gebauer's Ethyl Chloride is contraindicated in individuals with a history of hypersensitivity to ethyl chloride. If skin irritation develops, discontinue use.

Warnings

Gebauer's Ethyl Chloride is for external use only. Do not spray in eyes.

Skin absorption of ethyl chloride can occur; no cases of chronic poisoning have been reported.

Keep out of reach of children. For use on children over the age of 3 years.

Adverse Reactions

Cutaneous sensitization may occur but appears to be extremely rare.

Freezing can occasionally alter skin pigmentation. Injury to the skin due to extreme cold or irritation may create post-inflammatory hypopigmentation due to death of melanocytes in the epidermal layer of the skin. This reaction may be more apparent in people with dark complexions. Often, pigmentary changes slowly return to normal over several months. The effects of post-inflammatory hypopigmentation may be permanent.⁴

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Precautions

The following precautions should be observed when using Gebauer's Ethyl Chloride:

1. Use in a well-ventilated room
2. Intentional misuse by deliberately concentrating or inhaling the contents can be harmful or fatal.
3. Gebauer's Ethyl Chloride is **FLAMMABLE** and should never be used in the presence of an open flame or electrical cautery device.
4. Over application of the product may lead to frostbite and or altered skin pigmentation.

Biocompatibility

As the grade and quality of ethyl chloride varies significantly from source to source, Gebauer Company only purchases and uses ethyl chloride that meets strict specifications.

Gebauer's Ethyl Chloride meets high quality standards with all raw materials used in its production. Gebauer has a unique, known, and repeatable process that limits the type and amount of impurities in both the raw material and the finished product. Gebauer Company's strict manufacturing requirements control and limit the type and quantity of impurities such as residue, purity, and color. Gebauer's Ethyl Chloride product and packaging are unique due to controls throughout the supply chain.

General reports on the ethyl chloride chemical done at high dosing and chronic exposure levels are not representative of Gebauer's Ethyl Chloride. Gebauer Company conducted exposure testing with the high-quality ethyl chloride used in their finished product. The following study conducted by an external third party portrays a more accurate depiction of the finished product exposure.

Inhalation:

A representative clinical scenario study was performed by an external third party which evaluated both a typical and worst-case scenario end-user exposure levels to Gebauer's Ethyl Chloride. In a typical representative clinical scenario, Ethyl Chloride was sprayed for 10 seconds every 10 minutes for 1 hour in a well-ventilated area. In this typical representative clinical scenario, the concentration of Gebauer's Ethyl Chloride the end user was exposed to was measured to be 35 parts per million (ppm), which equates to an 8-hour time weighted average (TWA) of 4 ppm.

In the worst-case representative clinical scenario, the entire contents of the Ethyl Chloride container were dispensed over a 30-minute period in a well-ventilated area. In this worst-case representative clinical scenario, the concentration of Ethyl Chloride in the air was monitored and the exposure level was found to be 324 ppm, which equates to an 8-hour TWA of 20 ppm.

The current Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) for ethyl chloride is

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1000 ppm as an 8-hour TWA concentration as identified in 29 CFR 1910.1000, Table Z-1, which is a 49-fold increase than the worst-case representative clinical scenario exposure level. Thus, when used in a well-ventilated area as indicated, Gebauer's Ethyl Chloride concentration in the air is well below the occupational exposure limit.

Exposure is limited by the nature of the use of Gebauer's product as a vapocoolant. Since the product is applied in short topical sprays in a well-ventilated environment, it quickly evaporates with little absorption into the skin. The amount of Ethyl Chloride dispensed in a spray is approximately 0.41 grams/second for the Mist Spray, 0.22 grams/second for the Fine Spray, and 0.45 grams/second for the Stream Spray products. For an average spray of 3-7 seconds for pain management prior to injections and minor surgical procedures, and approximately 10 seconds for the spray and stretch technique, exposure would be minimal for both patients and professionals due to the small dose applied to the skin.

Additionally, biocompatibility testing per ISO 10993 conducted on Gebauer's Ethyl Chloride finished product shows the product meets requirements for Cytotoxicity, Skin Irritation and Dermal Sensitization.

Cytotoxicity:

Gebauer's Ethyl Chloride was evaluated to determine the potential for cytotoxicity based on the requirements of ISO 10993-5. The test article showed no evidence of causing any cell lysis or toxicity and had a grade of 0 (no reactivity).

Skin Irritation

Gebauer's Ethyl Chloride was evaluated for primary skin irritation in rabbits in accordance with ISO 10993-10. There was no erythema and no edema observed on the skin of the animals treated with Ethyl Chloride. The primary Irritation Index for the test article was calculated to be 0.0 (negligible)

Dermal Sensitization:

Ethyl Chloride was evaluated for the potential to elicit delayed dermal contact sensitization based on the requirements of ISO 10993-10. The test article showed no evidence of causing delayed dermal contact sensitization.

Carcinogenicity

There is no recorded data of carcinogenicity in humans. The U.S. EPA has not classified ethyl chloride as a carcinogen.

Ethyl chloride falls under California's Proposition 65. Ethyl chloride has the same labelling requirements under this proposition as many drugs, cosmetics, food, and consumer products. This list includes ingredients such as estrogen and iron dextran.

When Gebauer's Ethyl Chloride is used as intended, the long-term toxicity due to exposure is low. Many of the studies for Prop 65 were done at high dosing and chronic exposure levels and are not representative of Gebauer's Ethyl Chloride's intended uses.

Teratogenic Effects:

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Ethyl chloride has not been formally assigned to a pregnancy category by the FDA. Animal studies have failed to reveal evidence of teratogenicity with exposure below the recommended occupational exposure limits. There is no controlled data in human pregnancy.

Performance

Gebauer Company has executed the following performance testing to verify that Gebauer's Ethyl Chloride provides a safe and effective product.

Number of Applications: When using Gebauer's Ethyl Chloride for pre-injection anesthesia or to control pain associated with minor surgery, there are approximately 40 to 50 5-second spray applications per bottle or can.

When being used for myofascial pain, the spray and stretch technique, muscle spasm or minor sports injury, the number of doses varies depending on how long the area is sprayed and the size of the affected area.

Stability Studies: Real time stability is performed in accordance with the FDA's Q1A *Stability Testing of New Drug Substances and Products, ICH Guidance for Industry*. All data generated supports a two-year expiration date for Gebauer's Ethyl Chloride can products, and a three-year expiration date for Gebauer's Ethyl Chloride bottle products.

Microbial Limits Testing: Microbial limit testing has been performed in accordance to United States Pharmacopeia <61> and <62> Microbial Limits. The results were negative

for aerobic bacteria growth, mold and yeast growth, and the presence of *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Salmonella*.

In addition to the microbial limits testing, additional testing was performed to demonstrate that Gebauer's Ethyl Chloride will not support growth in the product's packaging system. Testing was conducted against a variety of species. The following was demonstrated:

- *S. Aureus*, *S. epidermidis*, *P. mirabilis*, *S. margescens*, *E. aerogenes*, *A. baumannii*, *C. albicans*, *P. aeruginosa*, and *A. niger* were reduced by $>10^{-6}$ logs at the ten minute time interval when exposed to ethyl chloride.
- *E. faecalis* and *B. fragilis* were reduced by $>10^{-3}$ logs at the ten minute time interval, and $>10^{-6}$ logs at the six hour time point when exposed to ethyl chloride.

It is important to note that this testing was done in the product packaging for Gebauer's Ethyl Chloride and no human testing was performed. These test results cannot be extrapolated to performance on intact skin in a clinical setting.

Material Compatibility:

The packaging materials used for Gebauer's Ethyl Chloride products show excellent material compatibility characteristics. Based on the results, there was no evidence of leachables or breakdown of the packaging components that would lead to contamination or product malfunction.

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A wide variety of materials are used in the manufacture of medical devices. Gebauer Company lacks compatibility information that would support the use of Ethyl Chloride on the vast materials used in other medical devices. Therefore, Gebauer's Ethyl Chloride is not indicated for spraying on any medical devices such as external catheters, IV tubing, or wound drains.

Clinical Data

A significant body of clinical data supporting the safety and effectiveness of Gebauer's Ethyl Chloride, as well as other Gebauer vapocoolant products, has been published in a variety of peer reviewed clinical journals. A comprehensive listing of clinical trial references and abstracts can be reviewed at www.gebauer.com/resources, under Clinical Research.

Dosage and Administration

Amber Bottle:

To apply Gebauer's Ethyl Chloride from the amber bottle, hold the bottle inverted while spraying. Open the dispenser spring valve completely.

Mist Aerosol Can:

To apply Gebauer's Ethyl Chloride from the mist aerosol can, hold can upright over the treatment area and depress the actuator completely.

ACCU-STREAM 360 Aerosol Can:

To apply Gebauer's Ethyl Chloride ACCU-STREAM 360™ with Sure Lock Technology™, turn the blue locking ring counterclockwise in the direction of the

open arrow. Aim spray at the intended area. To spray the product, fully depress the handle. Do not unintentionally aim towards the face. The can may be sprayed at any angle, upright, upside down, and any angle in between. Note that when the can is almost empty, the last sprays will only exit the can when the can is in an upright position. Turn the blue locking ring clockwise in the direction of the close arrow to lock the can.

Pre-Injection: Prepare the syringe and prep the treatment area. Spray the treatment area with Gebauer's Ethyl Chloride continuously for 3 to 7 seconds (amber bottle) or 4 to 10 seconds (can) from a distance of 3 to 9 inches (8 to 23 cm) or until the skin just turns white, whichever comes first. Do not frost the skin. Quickly introduce the needle.

These directions are also to be followed for other types of needle insertion procedures such as starting IV's, pre-injection, and venipuncture.

Topical Anesthesia in Minor Surgery: Clean the operative site with a suitable antiseptic. Apply petrolatum to protect the adjacent area. When using the amber bottle spray Gebauer's Ethyl Chloride on the target area continuously for 3 to 7 seconds (when using aerosol can spray for 4 to 10 seconds) from a distance of 3 to 9 inches (8 to 23 cm). Spray until the skin just begins to turn white; do not frost the skin and promptly make incision. The anesthetic action of Gebauer's Ethyl Chloride lasts a few seconds to a minute.

Temporary Relief of Minor Sports Injuries: The pain of bruises, contusions, swelling,

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and minor sprains may be controlled with Gebauer's Ethyl Chloride. The amount of cooling depends on the dosage. Dosage varies with duration of application. The smallest dose needed to produce the desired effects should be used. The anesthetic effect of ethyl chloride rarely lasts more than a few seconds to a minute. This time interval is usually sufficient to help reduce or relieve the initial trauma of the injury. Determine the extent of the injury (fracture, sprain, etc.). Spray the affected area from a distance of 3 to 9 inches (8 to 23 cm) for 3 to 7 seconds (bottle) or 4 to 10 seconds (can) until the skin just turns white or after 7 seconds (bottle) or 10 seconds (can) has elapsed, whichever comes first. Do not frost the skin. Avoid spraying the skin beyond this state. Use as you would ice.

Spray and Stretch Technique for Myofascial Pain: Gebauer's Ethyl Chloride (**stream sprays only**) may be used as a counterirritant in the management of myofascial pain, restricted motion, and muscle tension. Clinical conditions that may respond to Gebauer's Ethyl chloride include low back pain (due to tight muscles), acute stiff neck, torticollis, acute bursitis of the shoulder, tight hamstrings, sprained ankle, tight masseter muscles, and referred pains due to irritated trigger points. Relief of pain facilitates early mobilization and restoration of muscle function. The spray and stretch technique is a therapeutic system that involves three stages: Evaluation, Spraying and Stretching. The therapeutic value of the spray and stretch technique is most effective when the practitioner has mastered all of the

stages and applies them in the proper sequence.

a. Evaluation

If a patient has been evaluated to have pain caused by an active, irritated trigger point then proceed to Step b.

b. Spraying

1. Have the patient assume a comfortable position.
2. Take precautions to cover the patient's eyes, nose and mouth if spraying near the face.
3. Hold the bottle inverted (Hold the can upright). From a distance of approximately 12 to 18 inches (30 to 46 cm), aim the stream so it meets the skin at an acute angle, lessening the shock of impact.
4. Direct the spray in parallel sweeps 0.5 to 1 inch (1.5 to 2 cm) apart at the rate of approximately 4 inches/second (10 cm/second). Continue until the entire muscle has been covered. The number of sweeps is determined by the size of the muscle. The spray should be applied from the muscle attachment over the trigger point, through and over the reference zone.

c. Stretching

Passively stretch the muscle during spray application. Gradually increase the force with successive sweeps. As the muscle relaxes, smoothly take up

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the slack by establishing a new stretch length. It is necessary to reach the full normal length of the muscle to completely inactivate the trigger point and relieve the pain. Rewarm the muscle. If necessary, repeat the procedure. Apply moist heat for 10 to 15 minutes following treatment. For lasting benefit, eliminate any factors that perpetuate the trigger mechanism.

Storage

Ethyl Chloride is flammable and should be stored per facility protocol.

- Joint Commission states to refer to the manufacturers' Safety Data Sheet (SDS) for storage requirements and does not require storage of Gebauer's Ethyl Chloride in a flammable cabinet.
- Occupational Safety and Health Administration (OSHA) states flammable liquids in glass containers less than 1 pint (Gebauer's Ethyl Chloride bottles) and flammable liquids in metal containers less than 1 gallon (Gebauer's Ethyl Chloride cans) may be stored outside of the flammable closet. [29CFR 1910.106]

Contents under pressure. Store in a cool, dry, well-ventilated place. Do not subject to temperatures above 120°F (50°C). Do not use near fire, flame, or place on hot surfaces.

Do not store Ethyl Chloride near high-frequency ultrasound equipment or non-explosion proof electrical equipment.

Protect against physical damage to container.

Disposal

Due to the flammability of the product, Gebauer's Ethyl Chloride is considered to be hazardous waste even if the can or bottle is empty. Dispose of can/bottle in accordance with local, state, and national regulations as with other hazardous wastes such as expired pharmaceuticals and sharps.

Bibliography

¹Melzack R; Wall PD; *Pain Mechanisms: A New Theory*, Science, New Series, Vol. 150, No. 3699 (Nov. 19, 1965), 971-979.

²Travell, Janet and Simons, David; *Myofascial Pain and Dysfunction, The Trigger Point Manual*; Maryland, 1983.

³Martin, KD; Merrick, MA; Cold perception, surface, *Subcutaneous and Intramuscular Temperatures Provided by Gebauer's Ethyl Chloride Topical Vapocoolant Spray*; Journal of Athletic Training, May 2012.

⁴Goodheart, Herbert P. MD; Pigmentary Disorders Part 2: Nonvitiliginous Forms of Hypopigmentation, *Dermatology Rounds*, Vol. 2, No. 11; November 1999.

Ordering Information

Rx Only. The FDA has designated Gebauer's Ethyl Chloride products as Prescription only (Rx) medical devices. This designation means that Ethyl Chloride can be sold to and purchased by any licensed healthcare practitioner who is licensed in the

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state in which they practice. Healthcare practitioners include doctors, chiropractors, physical therapists, etc. Any healthcare professional should be able to purchase prescription devices without restriction.

Gebauer's Ethyl Chloride may be purchased by any patient who receives a prescription or "other order" which is defined as an instruction from a healthcare practitioner to use a prescription device.

Gebauer's Ethyl Chloride 3.9 fl. oz.(116 ml.) is available in the following configurations:

Medium Stream Aerosol Can
ACCU-STREAM 360
P/N 0386-0001-11

Fine Stream Aerosol Can
ACCU-STREAM 360
P/N 0386-0001-13

Medium Stream Glass Bottle
P/N 0386-0001-03

Fine Stream Glass Bottle
P/N 0386-0001-04

Mist Spray Aerosol Can
P/N 0386-0001-02

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