SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Contact information

General

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Product identifier	QBREXZA® (glycopyrronium) Cloth, 2.4% - NDC Number 69489-411-30 QBREXZA® (glycopyrronium) Cloth, 2.4% - NDC Number 69489-411-05
Synonyms	Glycopyrronium tosylate; glycopyrronium tosylate monohydrate
Trade names	QBREXZA® (glycopyrronium) Cloth, 2.4%
Chemical family	Mixture
Relevant identified uses of the substance or mixture and uses advised against	Bulk solution formulated pharmaceutical product approved for use in the treatment of hyperhidrosis. Topical prescription medicine used on the skin to treat primary axillary hyperhidrosis (excessive underarm sweating) in adults and children 9 years of age and older.
Note	This product contains glycopyrronium tosylate monohydrate and is approved as a topical treatment for primary axillary hyperhidrosis (excessive sweating). As a muscarinic receptor antagonist, it inhibits the action of acetylcholine on structures innervated by postganglionic cholinergic nerves, such as the sweat glands.

SECTION 2 - HAZARDS IDENTIFICATION

Classification of the substance or mixture

Globally Harmonized System [GHS]	Flammable liquid - Category 3.

Label elements

SECTION 2 - HAZARDS IDENTIFICATION …continued

GHS hazard pictogram



GHS signal word Warning

GHS hazard statements H226 - Flammable liquid and vapor. H373 - May cause damage to central nervous system through prolonged or repeated exposure.

GHS precautionary statements P210 - Keep away from heat/sparks/open flames/hot surfaces - No smoking. P240 - Ground/bond container and receiving equipment. P241 - Use explosion-proof electrical/ventilating/lighting equipment. P242 - Use only non-sparking tools. P243 - Take precautionary measures against static discharge. P260 - Do not breathe dust/ mist/vapors/spray. P273 - Avoid release to the environment. P280 - Wear protective gloves/eye protection/face protection. P314 - Get medical advice/ attention if you feel unwell. P370 + P378 - In case of fire: Use water spray (fog), foam, dry powder or carbon dioxide for extinction. P403 + P235 - Store in a well-ventilated place. Keep cool. P501 - Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Other hazards In clinical studies to date, glycopyrronium tosylate monohydrate has been well tolerated. The most common adverse effect (AE) has been dry mouth. Other AEs include dry eye, constipation, mydriasis, nasal dryness, urinary hesitation, urinary retention, blurred vision and vulvovaginal dryness. These adverse effects have all been reversible. Contact of ethanol with the eye causes immediate stinging and burning. Consumption of ethanol may have fetal effects when ingested by pregnant women, but this is not applicable with normal use of the product.

Note This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	EINECS/ELINCS#	Amount	GHS Classification
Ethanol	64-17-5	200-578-6	55-60%	FL2: H225
Glycopyrronium Tosylate	N/A	N/A	2-4%	ATO4: H302; STOT-R2: H373; CA3: H412

Note The ingredient(s) listed above are considered hazardous. The remaining components are non-hazardous and/or present at amounts below reportable limits. See Section 16 for full text of GHS classifications.

SECTION 4 - FIRST AID MEASURES

Description of first aid measures

Immediate Medical Attention Needed	Yes
Eye Contact	In the event of a chemical exposure, immediately irrigate eyes with copious quantities of water for at least 15 minutes. Remove contact lenses as soon as practical. Do not delay irrigation while waiting for contact lens removal. If irritation occurs or persists, notify medical personnel and supervisor.
Skin Contact	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion	If swallowed, call a physician immediately. Notify medical personnel and supervisor. Use general measures to eliminate the substance and reduce absorption.
Protection of first aid responders	See Section 8 for Exposure Controls/Personal Protection recommendations.
Most important symptoms and effects, both acute and delayed	See Sections 2 and 11
Indication of immediate medical attention and special treatment needed, if necessary	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

SECTION 5 - FIREFIGHTING MEASURES

Extinguishing media	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Specific hazards arising from the substance or mixture	No information identified. May emit carbon monoxide, carbon dioxide, and oxides of nitrogen.
Flammability/Explosivity	Product/mixture is flammable. Keep away from heat, sparks and flame. Vapors are heavier than air and may flow along surfaces to remote ignition sources and flashback.
Advice for firefighters	In case of fire in the surroundings: use the appropriate extinguishing agent. Wear full protective clothing and an approved, positive pressure, self-contained breathing apparatus. Decontaminate all equipment after use.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe vapors.
Environmental precautions	Do not empty into drains. Avoid release to the environment.
Methods and material for containment and cleaning up	Remove sources of ignition. Dike area to contain spill. Maintain ventilation until all vapors have been eliminated. Take precautions as necessary to prevent contamination of ground and surface waters.
Reference to other sections	See Sections 8 and 13 for more information.

SECTION 7 - HANDLING AND STORAGE

Precautions for safe handling	Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Keep away from heat, sparks and open flames. Keep container tightly closed when not in use. Use only with adequate local exhaust ventilation. Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with eyes, skin and other mucous membranes. Wash thoroughly after handling. Avoid breathing vapor.
Conditions for safe storage including any incompatibilities	Store at room temperature 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature].
Specific end use(s)	No information identified.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters/Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Ethanol	ACGIH, NIOSH	TWA-8 HR	1000 ppm
	NIOSH	IDLH (Immediately dangerous to life or health)	3300 ppm

Control Parameters/Occupational Exposure Limit Values
…continued

Compound	Issuer	Type	OEL
Ethanol	Austria, Belgium, Denmark, Estonia, Finland, France, Greece, Ireland, Portugal, Romania, Slovenia, Spain, United Kingdom, Mexico, Singapore	TWA-8 HR	1000 ppm
	Austria	STEL (3 x 60 min)	2000 ppm
	Bulgaria, Czech Republic, Latvia	TWA-8 HR	1000 mg/m³
	Czech Republic	Ceiling	3000 mg/m³
	Estonia, Lithuania, Sweden	STEL	1000 ppm
	Estonia, Germany, Lithuania, Netherlands, Slovak Republic, Sweden	TWA-8 HR	500 ppm
	Finland	STEL	1300 ppm
	France, Romania	STEL	5000 ppm
	Germany, Lithuania	Ceiling	1000 ppm
	Hungary	STEL	7600 mg/m³
	Hungary, Poland	TWA-8 HR	1900 mg/m³
	Slovak Republic	Ceiling	1920 mg/m³
	Slovenia	STEL	4000 ppm
	United Kingdom	STEL	3000 ppm
	Brazil	TWA-8 HR	780 ppm

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION …continued

Control Parameters/Occupational Exposure Limit Values
…continued

Compound	Issuer	Type	OEL
Glycopyrronium Tosylate	Journey Medical Corporation	8-hour TWA	1 µg/m³

Exposure/Engineering controls
Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at vapor/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling. High-energy operations should be done within an approved emission control or containment system.

Respiratory protection
If handling bulk quantities: choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine handling tasks, an approved and properly fitted air-purifying respirator with appropriate HEPA or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air-supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where a lower level of respiratory protection may not provide adequate protection.

Hand protection
Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered.

Skin protection
Wear appropriate gloves, lab coat, or other protective over-garment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Environmental Exposure Controls
Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

Other protective measures
Wash hands in the event of contact with this product/mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance
White to off-white moist cloth

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES …continued

Color	Clear and colorless solution wetted onto a white to off-white fabric.
Odor	No information identified.
Odor threshold	No information identified.
pH	4.0 - 5.0 (Glycopyrronium Topical Solution, 2.4%)
Melting point/freezing point	No information identified.
Initial boiling point and boiling range	78 °C (100% ethanol)
Flash point	24 °C (~50% ethanol in aqueous solution)
Evaporation rate	No information identified.
Flammability (solid, gas)	No information identified.
Upper/lower flammability or explosive limits	LEL - 3.3%; UEL - 19% (100% ethanol)
Vapor pressure	~59 mm Hg @ 20 °C (100% ethanol)
Vapor density	1.59 (100% ethanol)
Relative density	No information identified.
Water solubility	Miscible in water (ethanol).
Solvent solubility	Soluble in alcohol; practically insoluble in chloroform and ether.
Partition coefficient (*n-octanol/water*)	~0.32 (100% ethanol)
Auto-ignition temperature	No information identified.
Decomposition temperature	No information identified.
Viscosity	No information identified.
Explosive properties	No information identified.
Oxidizing properties	No information identified.

Other information

Molecular formula	Not applicable (Mixture)
Molecular weight	Not applicable (Mixture)

SECTION 10 - STABILITY AND REACTIVITY

Reactivity No information identified.

Chemical stability No information identified.

Possibility of hazardous reactions Not expected to occur.

Conditions to avoid Avoid contact with heat, sparks, flames or other ignition sources. Avoid extreme temperatures.

Incompatible materials Strong oxidizing agents. Do not store near perchlorates, peroxides, chromic acid or nitric acid.

Hazardous decomposition products No information identified.

SECTION 11 - TOXICOLOGICAL INFORMATION

Note The pharmacological activity of the active pharmaceutical ingredient, glycopyrronium tosylate monohydrate resembles that of glycopyrrolate and is mediated by the active moiety glycopyrronium. Following absorption, glycopyrrolate and glycopyrronium tosylate monohydrate dissociate generating the glycopyrronium cation; the glycopyrronium content of glycopyrrolate and glycopyrronium tosylate monohydrate are 0.80 and 0.63, respectively.

Information on toxicological effects

Route of entry May be absorbed via inhalation of vapors associated with normal use, and also via skin contact with cloth and/or inadvertent ingestion.

Acute toxicity

Compound	Type	Route	Species	Dose
Ethanol	LD_{50}	Oral	Rat	7060 mg/kg
	LD_{50}	Oral	Mouse	3400 mg/kg
	LC_{50}	Inhalation	Rat	20000 ppm/10 hours
	LC_{50}	Inhalation	Mouse	39 g/m^3/4 hours
Glycopyrronium Tosylate	LD_{50}	Oral	Mouse	550 mg/kg
	LD_{50}	Oral	Rat	1280 mg/kg

Irritation/Corrosion In rabbits, slight edema and persistent erythema were observed with topical doses of up to 2000 mg/kg/day glycopyrrolate, applied to abraded rabbit skin.

Ethanol is a strong skin and eye/respiratory irritant. Alcohols may also have vesicant properties.

Sensitization Glycopyrrolate and glycopyrronium tosylate monohydrate were not skin sensitizers in the mouse local lymph node assay.

STOT-single exposure No studies identified.

STOT-repeated exposure/Repeat-dose toxicity	In 28- and 90-day studies in mice, oral doses of up to 300 mg/kg/day glycopyrrolate were well tolerated. No mortality attributable to treatment was observed. There was no indication of systemic toxicity, and no target organs were identified. The NOAEL was considered to be 300 mg/kg/day. Dermal studies in animals performed with glycopyrronium tosylate monohydrate involved daily administration of 2, 6, or 20% formulations. Dermal glycopyrronium tosylate monohydrate administration to rats at doses of 2 and 6% daily for 92 days was well tolerated. Five animals treated with the 20% formulation developed reactions that necessitated the cessation of dosing; these reactions were severe enough to result in the early sacrifice of three animals. The predominant dermal observations were edema and erythema in the 20% dose group. Based on these findings, the NOAEL was 6% glycopyrronium tosylate monohydrate . Glycopyrronium tosylate monohydrate was well tolerated in minipigs when administered topically daily for 39 weeks at concentrations of 2%, 6%, or 20%. No target organs were identified; the NOAEL was considered to be 20%.
Reproductive toxicity	Glycopyrrolate was assessed for effects on fertility or general reproductive function in rats. Rats of both genders received glycopyrrolate at dosages up to 100 mg/kg/day via oral gavage. No treatment-related effects on fertility or reproductive parameters were observed in either gender in this study. In rats, a dose-related decrease in conception and survival at weaning was reported with an oral dose of 65 mg/kg/day glycopyrrolate. In dogs, diminished levels of seminal secretion were observed at high doses of glycopyrrolate (additional details not identified).
Developmental toxicity	In rats, no teratogenic effect was reported at oral doses of up to 65 mg/kg/day glycopyrronium tosylate monohydrate. In rabbits, glycopyrrolate was not teratogenic when administered at an intramuscular dose of 0.5 mg/kg/day. In other studies, oral administration to pregnant mice and rats during organogenesis at doses of up to 100 and 150 mg/kg/day glycopyrrolate was not associated with any increase in birth defects . Developmental/reproductive effects were reported in humans and experimental animals given large doses of ethyl alcohol (not occupationally relevant) which were typical of alcoholism.
Genotoxicity	Glycopyrrolate was negative in a battery of genetic toxicology studies that included a bacterial reverse mutation (Ames) assay, a mouse lymphoma assay conducted with L5178Y/TK± cells, and an in vivo micronucleus assay with mice. assay. Ethanol was positive in a number of genotoxicity assays. These effects may be due to a metabolite, acetaldehyde.

SECTION 11 - TOXICOLOGICAL INFORMATION …continued

Carcinogenicity

Glycopyrronium tosylate was not carcinogenic when topically applied to rats daily for up to 24 months in solution at concentrations of 1%, 2%, and 4% w/w.

When glycopyrrolate was administered via oral gavage to mice for up to 24 months at dosages of 2.5, 7, and 20 mg/kg/day in both genders, no significant changes in tumor incidence were observed when compared to control.

When glycopyrrolate was administered via oral gavage to rats for up to 24 months at dosages of 5, 15, and 40 mg/kg/day in both genders, no significant changes in tumor incidence were observed when compared to control.

In a six-month oral study in transgenic mice and a two-year inhalation study in rats administered glycopyrrolate, no carcinogenic effects were seen. No further details identified.

Consumption of alcohol is listed as a group 1 IARC carcinogen (carcinogenic to humans), but this is not applicable with normal use of the product. None of the other components of the mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.

Aspiration hazard

No data available.

Human health data

See "Section 2 - Other Hazards"

Additional information

The toxicological properties of this substance have not been fully characterized.

SECTION 12 - ECOLOGICAL INFORMATION

Toxicity

Compound	Type	Species	Concentration
Ethanol	LC_{50}/96h	Rainbow trout	12900 mg/L (flow through)
	LC_{50}/96h	Fathead minnow	15000 mg/L
	EC_{50}/48h	Daphnia magna	9268 mg/L
	EC_{50}/5-30 min	Photobacterium phosphoreum	~35000 mg/L
Glycopyrronium Tosylate	LC_{50} (96 h)	Danio rerio (zebra fish)	>100 mg//L
	EC_{50} (48h)	Daphnia magna (water flea)	33 mg/L
	EbC_{50} (72h)	Pseudokirchneriella subcapitata (algae)	>100 mg/mL
	EC_{50} (3h respiratory inhibition test)	Activated sludge microorganisms	>1000 mg/mL
	ErC_{50} (72h)	Pseudokirchneriella subcapitata (algae)	>100 mg/mL
	NOEC (72h)	Pseudokirchneriella subcapitata (algae)	7.5 mg/mL

SECTION 12 - ECOLOGICAL INFORMATION …continued

Persistence and Degradability	Not readily degradable. Degradation: 0 % (aerobic: Temperature: 22 - 24 °C DOC) Initial conc.: 55 mg/l, Duration: 28 days
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Results of PBT and vPvB assessment	No data available.
Other adverse effects	No data available.
Note	The environmental characteristics of this product/mixture have not been fully investigated. The data above are for individual components. Releases to the environment should be avoided. Avoid release into soil, rivers or drains.

SECTION 13 - DISPOSAL CONSIDERATIONS

Waste treatment methods	Used product should be disposed of according to local, state, and federal regulations. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

SECTION 14 - TRANSPORT INFORMATION

Note	Special Provision A46 (IATA) or 47 (US-DOT): small inner packagings consisting of sealed packets containing <10 mL of a Packing Group II or III flammable liquid absorbed into a solid material are not subject to these regulations (dangerous goods regulations under Division 4.1), provided there is no free liquid present in the packet or article. IF volume ≥ 10 mL, the following are applicable to this mixture: UN 3175; Solids containing flammable liquid, n.o.s.; Division 4.1, Packing Group II.
Transport	Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.
UN number	None assigned.
UN proper shipping name	None assigned.
Transport hazard classes and packing group	None assigned.

SECTION 14 - TRANSPORT INFORMATION …continued

Environmental hazards	Based on the available data, this product/mixture is not regulated as an environmental hazard or listed as a marine pollutant.
Special precautions for users	Avoid release to the environment.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

SECTION 15 - REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.
Chemical safety assessment	Not conducted.
TSCA status	All components of this material are on the TSCA Inventory or are exempt.
SARA section 313	Not listed.
California proposition 65	Ethyl alcohol (ethanol) as contained in alcoholic beverages (and consumed) is listed as a reproductive toxicant, but this is not applicable with normal use and handling of this product/mixture.
Additional information	No other information identified.

SECTION 16 - OTHER INFORMATION

Full text of H phrases and GHS classifications	CA3 - Chronic Aquatic Toxicity Category 3. H412 - Harmful to aquatic life with long lasting effects. STOT-R2 - Specific Target Organ Toxicity Following Repeated Exposure Category 2. H373 - May cause damage to central nervous system through prolonged or repeated exposure. ATO4 - Acute Toxicity (Oral) Category 4. H302 - Harmful if swallowed. FL2 - Flammable Liquid Category 2. H225 - Highly flammable liquid and vapor. FL3 - Flammable Liquid Category 3. H226 - Flammable liquid and vapor.
Sources of data	Information from published literature and internal company data.
Abbreviations	ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest

SECTION 16 - OTHER INFORMATION …continued

Abbreviations …continued	Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System
Issue Date	19 April 2021
Revisions	This is the sixth version of this SDS.
Disclaimer	The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.