

SECTION 1 Identification**1.1. Product identifier**

Product form : Mixture
Trade name : Agamree
Product code : 69616-264-38

1.2. Other means of identification

Other means of identification : Oral Suspension

1.3. Recommended use of the chemical and restrictions on use

Recommended use : For the treatment of Duchenne muscular dystrophy (DMD)
Restrictions on use : For patients 2 years of age and older

1.4. Supplier's details

Catalyst Pharmaceuticals Inc
355, Alhambra Circle
Ste. 801
Coral Gables, Florida 33134
T 305-420-3200
sds@catalystpharma.com

1.5. Emergency phone number

Emergency number : For Hazardous Materials or Dangerous Goods Incident Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC Day or Night: 1-800-424-9300 (Toll Free, USA) / 703-527-3887 (Virginia, USA)
CCN 1017517
Back-up Emergency Number: +1 703-741-5970 (Washington, DC)

SECTION 2 Hazard Identification**2.1. Classification of the substance or mixture****GHS US classification**

Specific target organ toxicity — Repeated exposure, Category 2 H373 May cause damage to organs (adrenal glands, immune system, ovary) through prolonged or repeated exposure.

Full text of H statements : see section 16

2.2. Label elements**GHS US labeling**

Hazard pictograms (GHS US) :



Signal word (GHS US) : Warning
Hazard statements (GHS US) : H373 - May cause damage to organs (adrenal glands, immune system, ovary) through prolonged or repeated exposure
Precautionary statements (GHS US) : Do not breathe mist, spray, vapors.
Get medical advice or attention if you feel unwell.
Dispose of contents and/or container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations.

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2.3. Hazards associated with known or reasonably anticipated uses

No additional information available

2.4. Hazards not otherwise classified

No additional information available

2.5. Unknown acute toxicity

No additional information available

SECTION 3 Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS US classification
Hydrochloric acid	CAS-No.: 7647-01-0	< 10	Acute Tox. 3 (Inhalation), H331 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335
Glycerine	CAS-No.: 56-81-5	5	Not classified
Vamorolone	CAS-No.: 13209-41-1	4	Acute Tox. 4 (Oral), H302 STOT RE 2, H373

Full text of hazard classes and H-statements : see section 16

SECTION 4 First aid measures

4.1. Description of necessary first-aid measures

First-aid measures general	: First aider: Pay attention to self-protection. Never give anything by mouth to an unconscious person. Give artificial respiration if necessary. Induce artificial respiration with mask fitted with one-way valve or other suitable device but, not mouth-to-mouth. Call a poison center/doctor/physician if you feel unwell.
First-aid measures after inhalation	: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a poison center or a doctor.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin areas with mild soap and water, followed by warm water rinse. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Rinse eyes with water as a precaution. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth out with water. Do NOT induce vomiting. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Call a physician immediately.

4.2. Most important symptoms/effects, acute and delayed

Symptoms/effects after inhalation	: Inhalation may cause irritation, cough, shortness of breath.
Symptoms/effects after skin contact	: Not expected to present a significant skin hazard under anticipated conditions of normal use.
Symptoms/effects after eye contact	: May cause eye irritation.
Most Important Symptoms/Effects	: Active Pharmaceutical Ingredient (API). Occupational exposure may cause adverse physiological effects.
Chronic symptoms	: May cause damage to organs (adrenal glands, immune system, ovary) through prolonged or repeated exposure.

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

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

Other medical advice or treatment : Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Carbon dioxide (CO₂), dry chemical powder, foam.
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Specific hazards arising from the chemical

Fire hazard : No fire hazard.
Explosion hazard : No direct explosion hazard.
Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon dioxide. Carbon monoxide. Hydrogen.

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions : Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection. Use water spray or fog for cooling exposed containers. Move containers from fire area if it can be done without personal risk. Prevent fire-fighting water from entering environment.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.
Emergency procedures : Evacuate the danger area. If outdoors, move to an area upwind of the danger area. If possible without taking personal risks, remove ignition sources, ventilate area. Prevent other non-emergency personnel from entering the danger area.

For emergency responders

Protective equipment : Wear the recommended personal protective equipment.
Emergency procedures : Evacuate personnel to a safe area. Do not touch spilled material. Ventilate spillage area.

Environmental precautions : Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.2. Methods and materials for containment and cleaning up

For containment : Contain with non-combustible inert absorbent.
Methods for cleaning up : Take up in non-combustible inert absorbent and place into container for disposal. Contaminated absorbent material may pose the same hazard as the spilt product. Decontaminate surfaces and equipment with water and detergent. Until a sufficient level of dilution is achieved, the decontamination water may pose the same hazards as the product. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

For further information refer to section 8: "Exposure controls/personal protection", For further information refer to section 13

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

SECTION 7 Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Ensure good ventilation of the work station. Wear personal protective equipment. Avoid breathing mist, spray, vapors. Avoid contact with skin, eyes and clothing. Take precautionary measures against static discharge.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including incompatibilities

Storage conditions	: Store in a cool, dry and well-ventilated area away from incompatible substances. Keep container closed when not in use.
Incompatible materials	: Strong acids. Strong bases.
Storage temperature	: Store the bottle upright at room temperature between 20°C to 25°C (68°F to 77°F). Excursions permitted between 15°C to 30°C (59°F to 86°F) in the original carton. See USP controlled room temperature. After opening, store the bottle upright in a refrigerator 2°C to 8°C (36°F to 46°F). Do not freeze.

SECTION 8 Exposure controls/personal protection

8.1. Control parameters

Vamorolone (13209-41-1)

USA - ACGIH® - Threshold Limit Values

ACGIH® TLV® TWA	53 µg/m ³
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Glycerine (56-81-5)

USA - OSHA - Occupational Exposure Limits

Local name	Glycerin (mist)
OSHA PEL TWA	15 mg/m ³ (Total dust) 5 mg/m ³ (Respirable fraction)
Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1

Hydrochloric acid (7647-01-0)

USA - ACGIH® - Threshold Limit Values

Local name	Hydrogen chloride
ACGIH® TLV® C	2 ppm
Remark (ACGIH®)	TLV® Basis: Irritation; Corrosion. Notations: A4 (Not classifiable as a Human Carcinogen)
Regulatory reference	ACGIH 2025

USA - OSHA - Occupational Exposure Limits

Local name	Hydrogen chloride
OSHA PEL C	7 mg/m ³ 5 ppm
Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Hydrochloric acid (7647-01-0)

USA - NIOSH - Occupational Exposure Limits

Local name	Hydrogen chloride
NIOSH REL C	5 ppm
Regulatory reference (US-NIOSH)	OSHA Annotated Table Z-1 (NIOSH Pocket Guide to Chemical Hazards (NPG))

8.2. Appropriate engineering controls

Appropriate engineering controls	: Ensure good ventilation of the work station. Use general ventilation, local exhaust ventilation, or process enclosure to keep the airborne concentrations below the permissible exposure limits.
Environmental exposure controls	: Avoid release to the environment. Take measures to reduce or limit air emissions and releases to soil and the aquatic environment.

8.3. Individual protection measures, such as personal protective equipment

Personal protective equipment:

Personal protective equipment should be chosen according to national standards and in discussion with the supplier of the protective equipment. Wear recommended personal protective equipment.

Hand protection:

Wear protective gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Eye protection:

Chemical goggles or safety glasses. Wear safety glasses which protect from splashes

Skin and body protection:

Wear suitable protective clothing. Wear suitable coveralls to prevent exposure to the skin

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Device	Filter type	Condition
Aerosol mask	Type P3	Protection for Liquid particles

Personal protective equipment symbol(s):



SECTION 9 Physical and chemical properties

9.1. Basic physical and chemical properties

Physical state	: Liquid
Appearance	: Suspension.
Color	: Off-white
Odor	: Orange-like
Odor threshold	: No data available
pH	: 3.5 – 4.5
Melting point	: < 0 °C
Freezing point	: No data available

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Boiling point	: 100 °C
Flash point	: No data available
Flammability (solid, gas)	: Not flammable
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: ≈ 1
Solubility	: Sparingly soluble: Ethanol. Acetone. Soluble in methanol. Water: Very slightly soluble
Partition coefficient n-octanol/water (Log Pow)	: cLogP=2.54, LogD (pH 7.4)=2.5
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Explosion limits	: No data available
Particle characteristics	: No data available

9.2. Data relevant with regard to physical hazard classes (supplemental)

No additional information available

SECTION 10 Stability and reactivity

10.1. Reactivity

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

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Incompatible materials.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Thermal decomposition generates: Carbon dioxide. Carbon monoxide. Hydrogen.

SECTION 11 Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

Vamorolone

LD50 oral	> 500 mg/kg body weight (mouse)
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Glycerine

LD50 oral rat	12600 mg/kg
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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Glycerine	
LD50 dermal rabbit	> 10000 mg/kg
LC50 Inhalation - Rat	5.85 mg/l air
LC50 Inhalation - Rat (Vapors)	> 2.75 mg/l

Skin corrosion/irritation : Not classified.
pH: 3.5 – 4.5

Glycerine	
Additional information	Not irritating to rabbits on cutaneous application

Hydrochloric acid	
Specific Concentration Limits	Eye Irrit. 2; H319: 10 % ≤ C < 25 % STOT SE 3; H335: C ≥ 10 % Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 %

Serious eye damage/irritation : Not classified.
pH: 3.5 – 4.5

Glycerine	
Additional information	Not irritating to rabbits on ocular application

Respiratory or skin sensitization : Not classified

Glycerine	
Method, LLNA, mouse	(Not sensitive)

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Hydrochloric acid	
IARC group	3 - Not classifiable

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

Hydrochloric acid	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : May cause damage to organs (adrenal glands, immune system, ovary) through prolonged or repeated exposure.

Vamorolone	
STOT-repeated exposure	May cause damage to organs (adrenal glands, immune system, ovary) through prolonged or repeated exposure.

Aspiration hazard : Not classified

Symptoms/effects after inhalation : Inhalation may cause irritation, cough, shortness of breath.

Symptoms/effects after skin contact : Not expected to present a significant skin hazard under anticipated conditions of normal use.

Symptoms/effects after eye contact : May cause eye irritation.

Most Important Symptoms/Effects : Active Pharmaceutical Ingredient (API). Occupational exposure may cause adverse physiological effects.

Chronic symptoms : May cause damage to organs (adrenal glands, immune system, ovary) through prolonged or repeated exposure.

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

SECTION 12 Ecological information

12.1. Ecotoxicity

Ecology - general	: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

Glycerine

LC50 - Fish [1]	54000 mg/l
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12.2. Persistence and degradability

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Persistence and degradability	Not established.
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Vamorolone

Persistence and degradability	Rapidly degradable
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Glycerine

Persistence and degradability	Rapidly degradable
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12.3. Bioaccumulative potential

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Partition coefficient n-octanol/water (Log Kow)	cLogP=2.54, LogD (pH 7.4)=2.5
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Bioaccumulative potential	Bioaccumulation unlikely.
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Glycerine

Partition coefficient n-octanol/water (Log Pow)	-1.75
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12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Ozone	: Not classified
Fluorinated greenhouse gases	: No

SECTION 13 Disposal considerations

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Disposal must be done according to official regulations. Refer to all applicable national, international and local regulations or provisions.
Additional information	: Do not re-use empty containers.
Ecological waste information	: Avoid release to the environment.

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

SECTION 14 Transport information

In accordance with DOT / IMDG / IATA

DOT	IMDG	IATA
14.1. UN number		
Not regulated for transport		
14.2. Proper Shipping Name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
	Not regulated	
No supplementary information available		

14.6. Transport in bulk

Not applicable

14.7. Special precautions for user

DOT

Not regulated

IMDG

Not regulated

IATA

Not regulated

SECTION 15 Regulatory information

15.1. Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

Vamorolone	CAS-No. 13209-41-1	4%
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Chemical(s) subject to the reporting requirements of Section 313 or Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 and 40 CFR Part 372.

Hydrochloric acid	CAS-No. 7647-01-0	< 10%
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Hydrochloric acid (7647-01-0)

Listed on EPA Hazardous Air Pollutant (HAPS)
Listed on EPA HAPs Chronic Dose Response Assessment List - Carcinogens
Listed on EPA HAPs Acute Dose Response Assessment List – Exposure limits

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According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Hydrochloric acid (7647-01-0)	
CERCLA RQ	5000 lb
RQ (Reportable quantity, section 304 of EPA's List of Lists)	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb

15.2. International regulations

CANADA

Vamorolone (13209-41-1)
Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

Glycerine (56-81-5)
Listed on the Canadian DSL (Domestic Substances List)

Hydrochloric acid (7647-01-0)
Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

Glycerine (56-81-5)
Listed on INSQ (Mexican National Inventory of Chemical Substances)

Hydrochloric acid (7647-01-0)
Listed on INSQ (Mexican National Inventory of Chemical Substances) Listed on EPA HAPs Chronic Dose Response Assessment List - Carcinogens Listed on EPA HAPs Acute Dose Response Assessment List – Exposure limits

15.3. State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

Component	State or local regulations
Glycerine(56-81-5)	U.S. - Massachusetts - Right To Know List; U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - Pennsylvania - RTK (Right to Know) List
Hydrochloric acid(7647-01-0)	U.S. - Massachusetts - Right To Know List; U.S. - New Jersey - Right to Know Hazardous Substance List; U.S. - New York City - Right to Know Hazardous Substances List; U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16 Other information

According to 29 CFR § 1910.1200, Hazard Communication Standard (HCS)

Issue date : 6/17/2025

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Full text of hazard classes and H-statements	
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H331	Toxic if inhaled
H335	May cause respiratory irritation
H373	May cause damage to organs through prolonged or repeated exposure

Indication of changes:		
Section	Changed item	Comments
	Issue date	Modified
1	Product code	Modified

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.