

Positive Control GlutenTox ELISA Rapid G12

Version number: 1.0

Date of compilation: 2020-03-23

SECTION 1: Identification

1.1 Product identifier

Trade name **Positive Control GlutenTox ELISA Rapid G12**
 Product code(s) ASY3200

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses Laboratory and analytical use

1.3 Details of the supplier of the safety data sheet

Hygiena USA
 941 Avenida Acaso
 Camarillo California 93012
 United States

Telephone: +1 (805) 388-8007
 Telefax: +1 (805) 388-5531
 e-mail: info@hygiena.com

e-mail (competent person) info@hygiena.com

1.4 Emergency telephone number

Emergency information service 1-888-494-4362
 This number is only available during the following
 office hours: Mon-Fri 08:00 AM - 05:00 PM

SECTION 2: Hazard(s) identification

2.1 Classification of the substance or mixture

Classification acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

Section	Hazard class	Category	Hazard class and category	Hazard statement
A.6	carcinogenicity	1A	Carc. 1A	H350
B.6	flammable liquid	2	Flam. Liq. 2	H225

For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects

The product is combustible and can be ignited by potential ignition sources.

2.2 Label elements

Labelling acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

- Signal word danger

- Pictograms

GHS02, GHS08



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- Hazard statements

H225 Highly flammable liquid and vapor.
H350 May cause cancer.

- Precautionary statements

P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P233 Keep container tightly closed.
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.
P280 Wear protective gloves/eye protection/face protection.
P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P308+P313 If exposed or concerned: Get medical advice/attention.
P370+P378 In case of fire: Use sand, carbon dioxide or powder extinguisher to extinguish.
P403+P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.
P501 Dispose of contents/container to industrial combustion plant.

- Hazardous ingredients for labelling Ethyl alcohol

2.3 Other hazards

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.


SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture)

3.2 Mixtures


Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
Pyrogen Free Water	CAS No 7732-18-5	≥ 90		
Ethyl alcohol	CAS No 64-17-5	3 - < 5	Eye Irrit. 2 / H319 Carc. 1A / H350 Flam. Liq. 2 / H225	
Bovine Serum Albumin	CAS No 9048-46-8	3 - < 5		
D-Sorbitol	CAS No 50-70-4	1 - < 3		
Tris	CAS No 77-86-1	0.1 - < 1		
PWG Gliadin		< 0.1		

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Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
CMIT/MIT dilution 2.5%	CAS No 55965-84-9	< 0.1	Acute Tox. 3 / H301 Acute Tox. 3 / H311 Acute Tox. 3 / H331 Skin Corr. 1B / H314 Eye Dam. 1 / H318 Skin Sens. 1 / H317	

For full text of abbreviations: see SECTION 16.

SECTION 4: First-aid measures

4.1 Description of first-aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

Following skin contact

Wash with plenty of soap and water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO₂)

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

In case of insufficient ventilation and/or in use, may form flammable/explosive vapor-air mixture. Solvent vapors are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO₂)

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5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Coordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapors/dust/aerosols/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Avoidance of ignition sources. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge. Use only in well-ventilated areas. Due to danger of explosion, prevent leakage of vapours into cellars, flues and ditches. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools.

- Specific notes/details

Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures. Vapors are heavier than air, spread along floors and form explosive mixtures with air. Vapors may form explosive mixtures with air.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

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7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- Explosive atmospheres

Keep container tightly closed and in a well-ventilated place. Use local and general ventilation. Keep cool. Protect from sunlight.

- Flammability hazards

Keep away from sources of ignition - No smoking. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge. Protect from sunlight.

Control of the effects

Protect against external exposure, such as

Frost

- Ventilation requirements

Use local and general ventilation. Ground/bond container and receiving equipment.

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)											
Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Ceiling-C [ppm]	Ceiling-C [mg/m ³]	Notation	Source
US	ethanol	64-17-5	TLV®			1,000					ACGIH® 2019
US	ethyl alcohol	64-17-5	REL	1,000 (10 h)	1,900 (10 h)						NIOSH REL
US	ethyl alcohol (ethanol)	64-17-5	PEL (CA)	1,000	1,900						Cal/ OSHA PEL
US	ethyl alcohol (ethanol)	64-17-5	PEL	1,000	1,900						29 CFR 1910.1000

Notation

Ceiling-C

STEL

TWA

ceiling value is a limit value above which exposure should not occur

short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

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Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state	liquid
Color	various
Odor	characteristic

Other safety parameters

pH (value)	not determined
Melting point/freezing point	not determined
Initial boiling point and boiling range	64.7 °C at 1,013 hPa
Flash point	9.7 °C at 1,013 hPa
Evaporation rate	not determined
Flammability (solid, gas)	not relevant, (fluid)

Explosive limits

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- Lower explosion limit (LEL)	2.5 vol%
- Upper explosion limit (UEL)	13.5 vol%
Vapor pressure	169.3 hPa at 25 °C
Density	not determined
Vapor density	this information is not available
Relative density	information on this property is not available
Solubility(ies)	not determined

Partition coefficient

- n-octanol/water (log KOW)	this information is not available
Auto-ignition temperature	455 °C (auto-ignition temperature (liquids and gases))
Viscosity	not determined
Explosive properties	none
Oxidizing properties	none

9.2 Other information

Solvent content	99 %
Solid content	1 %
Temperature class (USA, acc. to NEC 500)	T1 (maximum permissible surface temperature on the equipment: 450°C)

SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials". The mixture contains reactive substance(s). Risk of ignition.

If heated:

Risk of ignition

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

No known hazardous reactions.

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10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints to prevent fire or explosion

Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

10.5 Incompatible materials

Oxidizers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification acc. to OSHA "Hazard Communication Standard" (29 CFR 1910.1200)

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components of the mixture			
Name of substance	CAS No	Exposure route	ATE
CMIT/MIT dilution 2.5%	55965-84-9	oral	100 mg/kg
CMIT/MIT dilution 2.5%	55965-84-9	dermal	300 mg/kg

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitization

Shall not be classified as a respiratory or skin sensitizer.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

May cause cancer.

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IARC Monographs on the Evaluation of Carcinogenic Risks to Humans

Name of substance	CAS No	Classification	Number
Ethyl alcohol	64-17-5	1	

Legend

1 Carcinogenic to humans

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Other adverse effects

Endocrine disrupting potential

None of the ingredients are listed.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste treatment-relevant information

Solvent reclamation/regeneration.

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packages

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

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Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

- | | |
|--|---|
| 14.1 UN number | 1993 not subject to transport regulations |
| 14.2 UN proper shipping name | Flammable liquid, n.o.s. |
| Technical name (hazardous ingredients) | Ethyl alcohol, CMIT/MIT dilution 2.5% |
| 14.3 Transport hazard class(es) | |
| Class | 3 (flammable liquids) |
| 14.4 Packing group | II (substance presenting medium danger) |
| 14.5 Environmental hazards | non-environmentally hazardous acc. to the dangerous goods regulations |
| 14.6 Special precautions for user | |
| There is no additional information. | |
| 14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code | |
| The cargo is not intended to be carried in bulk. | |

Information for each of the UN Model Regulations

Transport of dangerous goods by road or rail (49 CFR US DOT)

Not subject to transport regulations.

International Maritime Dangerous Goods Code (IMDG)

Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR)

Not subject to ICAO-IATA.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

National regulations (United States)

Superfund Amendment and Reauthorization Act (SARA TITLE III)

- The List of Extremely Hazardous Substances and Their Threshold Planning Quantities (EPCRA Section 302, 304)

none of the ingredients are listed

- Specific Toxic Chemical Listings (EPCRA Section 313)

none of the ingredients are listed

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

- List of Hazardous Substances and Reportable Quantities (CERCLA section 102a) (40 CFR 302.4)

none of the ingredients are listed

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Clean Air Act

none of the ingredients are listed

Right to Know Hazardous Substance List

- Hazardous Substance List (NJ-RTK)

Name of substance	CAS No	Remarks	Classifications
Ethyl alcohol	64-17-5		CA MU TE F3

Legend

CA	Carcinogenic
F3	Flammable - Third Degree
MU	Mutagenic
TE	Teratogenic

California Environmental Protection Agency (Cal/EPA): Proposition 65 - Safe Drinking Water and Toxic Enforcement Act of 1987

Proposition 65 List of chemicals			
Name acc. to inventory	CAS No	Remarks	Type of the toxicity
ethanol (ethyl alcohol)	64-17-5	in alcoholic beverages	developmental

VOC content

Regulated Volatile Organic Compounds (VOC-EPA): Regulated Volatile Organic Compounds (VOC-Cal ARB):

Industry or sector specific available guidance(s)

NPCA-HMIS® III

Hazardous Materials Identification System. American Coatings Association.

Category	Rating	Description
Chronic	*	chronic (long-term) health effects may result from repeated overexposure
Health	0	no significant risk to health
Flammability	3	material that can be ignited under almost all ambient temperature conditions
Physical hazard	0	material that is normally stable, even under fire conditions, and will not react with water, polymerize, decompose, condense, or self-react. Non-explosive
Personal protection	-	

NFPA® 704

National Fire Protection Association: Standard System for the Identification of the Hazards of Materials for Emergency Response (United States).

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Category	Degree of hazard	Description
Flammability	3	material that can be ignited under almost all ambient temperature conditions
Health	0	material that, under emergency conditions, would offer no hazard beyond that of ordinary combustible material
Instability	0	material that is normally stable, even under fire conditions
Special hazard		

15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information, including date of preparation or last revision

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
29 CFR 1910.1000	29 CFR 1910.1000, Tables Z-1, Z-2, Z-3 - Occupational Safety and Health Standards: Toxic and Hazardous Substances (permissible exposure limits)
49 CFR US DOT	49 CFR U.S. Department of Transportation
ACGIH® 2019	From ACGIH®, 2019 TLVs® and BEIs® Book. Copyright 2019. Reprinted with permission. Information on the proper use of the TLVs® and BEIs®: http://www.acgih.org/tlv-bei-guidelines/policies-procedures-presentations/tlv-bei-position-statement
Acute Tox.	Acute toxicity
ATE	Acute Toxicity Estimate
Cal/OSHA PEL	California Division of Occupational Safety and Health (Cal/OSHA): Permissible Exposure Limits (PELs)
Cal ARB	California Air Resources Board
Carc.	Carcinogenicity
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
DGR	Dangerous Goods Regulations (see IATA/DGR)
EPA	Environmental Protection Agency. An agency of the federal government of the United States charged with protecting human health and the environment
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
Flam. Liq.	Flammable liquid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")

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Abbr.	Descriptions of used abbreviations
NIOSH REL	National Institute for Occupational Safety and Health (NIOSH): Recommended Exposure Limits (RELs)
NPCA-HMIS® III	National Paint and Coatings Association: Hazardous Materials Identification System - HMIS® III, Third Edition
OSHA	Occupational Safety and Health Administration (United States)
PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible exposure limit
ppm	Parts per million
RTECS	Registry of Toxic Effects of Chemical Substances (database of NIOSH with toxicological information)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
Skin Sens.	Skin sensitization
STEL	Short-term exposure limit
TLV®	Threshold Limit Values
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data

OSHA Hazard Communication Standard (HCS), 29 CFR 1910.1200.

Transport of dangerous goods by road or rail (49 CFR US DOT). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

List of relevant phrases (code and full text as stated in chapter 2 and 3)

Code	Text
H225	Highly flammable liquid and vapor.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H350	May cause cancer.

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Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.