

Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product Name: **Positive Control Kit**
Product Number: CK25
Brand: Hygiena

1.2 Recommended use and restrictions on use

Identified use: Validating efficacy and quality of Hygiena test devices
Restriction on use: Use per manufacturer's instructions only

1.3 Details of the supplier of the safety data sheet

Company: Hygiena USA
941 Avenida Acaso
Camarillo, CA 93012
USA
Telephone: 805-388-8007
Fax: 805-388-5531
E-mail: info@hygiena.com

1.4 Emergency telephone number

Emergency Phone: 1-888-494-4362

2. HAZARDS IDENTIFICATION

2.1 Hazard Classification:

Not classified as hazardous according to OSHA Hazard Communication Standard 29 CFR 1910.1200, Regulation EC No. 1272:2008 [CLP/GHS] and WHIMS 2015 (HPR) Hazardous Products Regulation SOR 2015-17.

2.2 Label elements:

Not applicable

Pictograms:

Not applicable

Hazard codes:

Not applicable

2.3 Hazards not otherwise clarified:

None

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	% by Wt
Sucrose	57-50-1	40 – 60%
Tris	1185-53-1	40 – 60%
ATP	34369-07-8	0.01%
FORM: Lyophilized reagent in low concentration (5×10^{-13} moles) in glass vial. If used according to manufacturer's instructions; the reagent will not come in contact with the operator.		

4. FIRST AID MEASURES

4.1 Description of first aid measures

4.2 Inhalation:

If breathed in, move person into fresh air. If not breathing give artificial respiration.

4.3 Skin contact:

Wash with soap and plenty of water.

4.4 Eye contact:

Flush eyes with water as a precaution.

4. FIRST AID MEASURES (Continued)

4.5 If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.6 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling section 2.2 and/or in section 11.

4.7 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

None inherent in the products. Burning plastic will create carbon and nitrogen oxides.

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

Use water spray to cool unopened containers.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions protective equipment and emergency procedure

Ensure adequate ventilation. For personal protection see section 8.

6.2 Environmental precautions

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Contain spill, collect using commercially available inorganic absorbent material and place in container for disposal according to local regulations (see section 13).

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Wash hands after handling.

7.2 Conditions for safe storage, including any incompatibilities

Store at 2 – 8°C in original packaging. No incompatibilities noted.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

None required.

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands after use.

Personal protective equipment

Eye/face protection

No eye protection required, safety goggles may be used for added protection.

Skin/hand protection

No protective gloves are required, but may be used for added protection. Wash hands after use.

Respiratory protection

Respiratory protection is not required for intended use.

Control of environmental exposure

Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance	Form: Lyophilized reagent in glass vial
b)	Color: White powder
c) Odor	No data available
d) Odor Threshold	Not applicable
e) pH	Neutral
f) Melting point/ freezing point	No data available
g) Initial boiling point and boiling range	No data available
h) Flash point	No data available
i) Evaporation rate	No data available
j) Flammability (solid, gas)	Not applicable
k) Upper/lower flammability or explosive limits	No data available
l) Vapour pressure	No data available
m) Vapour density	No data available
n) Specific Gravity	No data available
o) Water solubility	Readily miscible with water
p) Partition coefficient: n-octanol/water	No data available
q) Auto-ignition temperature	Not applicable
r) Decomposition temperature	No data available
s) Viscosity	No data available
t) Explosive properties	No data available
u) Oxidizing properties	No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

Product is considered non reactive under normal intended use.

10.2 Chemical stability

Stable under recommended storage conditions.

10.2 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Heat and direct sunlight.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

Carbon and Nitrogen oxides from burning plastic.

11. TOXICOLOGICAL INFORMATION

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

No data available

11. TOXICOLOGICAL INFORMATION (Continued)

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: Not available

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

13. DISPOSAL CONSIDERATIONS

Product

Observe local, State and Federal environmental regulations.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

No special precautions needed for transport either within or outside premises.

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of OSHA Hazard Communication Standard 29 CFR 1910.1200, Regulation EC No. 1272:2008 [CLP/GHS] and WHIMS 2015 (HPR) Hazardous Products Regulation SOR 2015-17.

Safety, health and environmental regulations/legislation specific for the substance or mixture

No data available

SARA 302 Components

No components are subject to reporting levels established by SARA Title III, Section 302.

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.



15. REGULATORY INFORMATION (Continued)

SARA 311/312 Components

No SARA Hazards

Massachusetts Right To Know Components

Sucrose

CAS-No.

57-50-1

Pennsylvania Right To Know Components

Sucrose

CAS-No.

57-50-1

New Jersey Right To Know Components

No components are subject to the New Jersey Right To Know Act.

California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

The product is non hazardous according to OSHA Hazard Communication Standard 29 CFR 1910.1200, EC No. 1272:2008 [CLP/GSH] and WHIMS 2015 HPR Hazardous Products Regulation SOR 2015-17, and therefore the product is not considered hazardous.

The information on this SDS is based on the SDSs for the ingredients provided by the manufacturers.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Hygiena and its affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.

Preparation Information

Hygiena USA

Product Safety

1-888-494-4362

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Revision: C

End of Safety Data Sheet