

DNAllergen2 PCR tests (Cat. nr. HU00302xx)

SECTION 1: Identification of the substance/preparation and of the Company/Undertaking

1.1. Product Identifiers

Product Name	Cat. Nr.
DNAllergen2 Almond	HU0030225
DNAllergen2 Cashew	HU0030229
DNAllergen2 Celery	HU0030216
DNAllergen2 Crustacea	HU0030222
DNAllergen2 Hazelnut	HU0030228
DNAllergen2 Lupine	HU0030218
DNAllergen2 Macadamia nut	HU0030235

Product Name	Cat. Nr.
DNAllergen2 Mustard	HU0030215
DNAllergen2 Peanut	HU0030224
DNAllergen2 Pecan nut	HU0030233
DNAllergen2 Pistachio	HU0030226
DNAllergen2 Sesame	HU0030219
DNAllergen2 Walnut	HU0030227

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

DNAllergen2 PCR kits provides materials for the qualitative detection and/or for the quantitative analysis of DNA from food samples for allergens, according to directive (EC) 1169/2011. The allergen is detected using real-time PCR and specific primers and probes and not with intercalating fluorescent dyes.

DNAllergen2 PCR components: OligoMix; BasicMix; Positive Control; Calibration DNA; Diluent; Negative Control; ROX™ dye

1.3. Details of the supplier of the safety data sheet

Gold Standard Diagnostics Budapest Kft.

Fóti út 56/A.

1047 BUDAPEST

HUNGARY

Contact information: www.goldstandarddiagnostics.com/contacts

Phone: + 36 20 457 1204

Responsible person's E-mail adress: CustomerService.Bud@eu.goldstandarddiagnostics.com

1.4. Emergency telephone number

Hungary: Egészségügyi Toxikológiai Tájékoztató Szolgálat (ETTSZ)

1097 Budapest, Nagyvárad tér 2.

Tel.: +36 1 476 6464, +36 80 201 199

e-mail: ettsz@nngyk.gov.hu

For national Poison Centres in EU see: <https://poisoncentres.echa.europa.eu/appointed-bodies>.

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 :

Not classified.

For the full text of H-statements mentioned in this Section: see Section 16.

2.2. Label elements

Hazard Pictograms:

-

Signal word:

-

Hazard statements:

-

Precautionary statements:

-

Supplemental hazard information:

-

Substances contributing of hazard identification:

-|

2.3. Other hazards

None.

See PBT and vPvB assesment results in section 12.5.

Endocrine disrupting properties: see sections 11.2. and 12.6.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

There are no components present which, within the current knowledge of the manufacturer and in the concentrations applicable, are considered hazardous to health or the environment, are PBTs, vPvBs or substances of equivalent concern, or which have a workplace exposure limit and therefore need to be listed in this section.

For the full text of H-statements mentioned in this Section: see Section 16.

The product does not contain Substances of Very High Concern (SVHC).

SECTION 4: First Aid Measures

4.1. Description of first aid measures

GENERAL INFORMATION:

In case of accident or feeling sick immediately consult a physician. Show this safety data sheet or the product label to the doctor in attendance!

First aider: Pay attention for self-protection!

Remove contaminated clothing immediately.

Eye –washing and skin-washing facilities should be available at the workplace for specific and immediate treatment.

FOLLOWING INGESTION:

If chemical has been swallowed, wash out mouth with water. Do not swallow mouthwash. DO NOT induce vomiting. Do not administer anything if victim is unconscious. Get medical aid.

FOLLOWING INHALATION:

There is a minimal risk of inhalation. In case there appear to be symptoms of exposure, supply fresh air. Monitor respiration. If breathing becomes difficult, consult a doctor and give oxygen. Get medical aid.

FOLLOWING SKIN CONTACT:

Immediately flush with large amounts of water and soap. Remove all contaminated clothing and wash them before reusing. In case of irritation consult a physician. After massive or prolonged skin contact: Medical advice absolutely required!

FOLLOWING EYE CONTACT:

Rinse thoroughly with plenty of water for at least 15 minutes. Insure adequate washing by keeping eyelids open with fingers. Consult a physician.

4.2. Most important symptoms and effects, both acute and delayed

No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptoms : Symptoms of poisoning may even occur after several hours; therefore, medical observation for at least 48 hours after the accident.

SECTION 5: Firefighting Measures

5.1. Extinguishing media

Suitable extinguishing media: use agent most appropriate to extinguish surrounding fire. CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Keep surrounding materials cool with water spray.

Unsuitable extinguishing media: For this mixture no limitations of extinguishing agents are given

5.2. Special hazards arising from the mixture

In the event of fire development of hazardous combustion gases or vapours possible

5.3. Advice for firefighters

In case of fire, if necessary, wear approved self-contained breathing apparatus and appropriate protective clothing. Keep surrounding materials cool with water spray.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

The small supplied volumes and packaging insure minimal risk of accidental release. In case of spill, wear protective clothing as indicated in section 8. Ensure adequate ventilation.

6.1.2 For emergency personnel
In case of spill, wear protective clothing as indicated in section 8. Ensure adequate ventilation.
See sections 7 and 8.

6.2. Environmental precautions

Do not allow to enter sewers/ground water or penetrate the soil..

6.3. Methods and materials for containment and cleaning up

Absorb with liquid binding material (sand diatomite, acid binders, universal binders).
Dispose of the material according to regulations.
Ensure adequate ventilation.

6.4. Reference to other sections

See sections 7, 8 and 13.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace
Avoid skin and eyes contact. Avoid inhalation of vapour or mist. Wear appropriate personal protective equipment as specified in section 8.
Remove contaminated clothing immediately. Wash hands and face after working with substance.
Advice on protection against fire and explosion: Keep ignition sources away – Do not smoke

7.2. Conditions for safe storage, including any incompatibilities

Keep products tightly sealed in their original containers. Avoid physical damage to containers. Do not expose to heat or direct light. Store away from foodstuffs

7.3. Specific end use(s)

See Section 1.2.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

Exposure limit values

There are no components with European Union workplace control parameters. (Source :GESTIS)

DNEL values :

No information available

PNEC values :

No information available

8.2. Exposure controls

5/2020. (II. 6.) ITM decree on the protection of the health and safety of workers exposed to chemical pathogenic factors, pursuant to Section 11(2) in the case of hazardous substances not regulated by limit values, the employer is obliged to reduce the level of exposure to the lowest level expected according to scientific and technical standards, at which level, according to the current state of science, the dangerous substance has no health-damaging effect. When using in an open system, use local exhaust where possible. If local extraction is not possible or is insufficient, adequate ventilation of the work area must be ensured.

General protective and hygienic measures

Adhere to instructions and good laboratory practice. Always avoid direct contact of the solution with eyes, skin and clothing.

Avoid inhalation. Avoid prolonged or repeated exposure. Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing.

Clean skin thoroughly immediately after handling the product

Handle in accordance with good industrial hygiene and safety practice. Caution is necessary to prevent skin contact, eye contact, cloth contact and spilling into the floor.

Appropriate engineering controls

Handle in a fume cupboard or under local exhaust ventilation. Have emergency shower and eye wash stations available

Individual protection measures, such as personal protective equipment:



a) eye/face protection

Safety eyewear or face protection complying with an approved standard (European Standard EN 166) should be used. Safety glasses with shields.

b) skin protection

- i. hand protection: Chemical-resistant, impervious gloves complying with an approved standard (European Standard EN374) should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- ii. other: body protection: Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier. Protective work clothing.

c) respiratory protection

Not required if used as directed.

d) thermal hazards

None.

Environmental exposure controls

Do not let product enter drains.

Personal protective equipment selections vary based on potential exposure conditions such as applications, handling practices, concentration and ventilation. Information on the selection of protective equipment for use with this material, as

provided above, is based upon intended, normal usage. If there is different than normal usage of the material it is advised to consult a safety specialist about the type of personal protective equipment and other actions that should be taken.

SECTION 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

The following data is applicable for all kit component solutions.

Property	Value
Physical state:	fluid
Colour:	colourless, transparent
Odour:	n.a.
Odour threshold:	No information available
Melting point/Melting range:	No information available
Initial boiling point and boiling range	No information available
Flammability	not flammable.
Upper/lower flammability or explosive limits	No information available
Flash point:	No information available
Auto Ignition temperature:	The mixture is not self-igniting
Decomposition temperature:	No information available
pH	No information available
Dynamic viscosity	No information available
Kinematic viscosity:	No information available
Solubility	No information available
Partition coefficient (n- Octanol/Water)	No information available
Vapour pressure at 20 °C:	No information available
Density and/or relative density:	No information available
Relative Vapour density:	No information available
Particle characteristics	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Not classified.

9.2.2. Other safety characteristics

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Thermal decomposition / conditions to be avoided

No decomposition if used and stored according to specifications.

10.3. Possibility of hazardous reactions:

No hazardous reactions known.

10.4. Conditions to avoid

Avoid heat, flame, sparks, direct light.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No dangerous decomposition products known. In case of fire see Section 5.

SECTION 11: Toxicological Information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008:

Acute toxicity:

Nor classified.

Skin corrosion / irritation:

Nor classified.

Serious eye damage/irritation:

Nor classified.

Respiratory or skin sensitization:

Nor classified as sensitizer.

Germ cell mutagenicity:

Not classified as mutagen.

Carcinogenicity:

Not classified as carcinogen.

Reproductive toxicity:

Not classified as reproductive toxic.

STOT-single exposure:

Not classified as specific target organ toxicant.

STOT-repeated exposure:

Not classified as specific target organ toxicant

Aspiration hazard:

Not classified as aspiration hazard.

Relevant toxicological data:

No information available.

Information on likely routes of exposure:

No information available.

Symptoms related to the physical, chemical and toxicological characteristics:

- Skin contact: No information available.
- Eye contact: No information available.
- Inhalation: No information available
- Ingestion: No information available.
- Other: No information available.

Delayed and immediate effects as well as chronic effects from short and long term exposure:

No information available

Interactive effects:

No information available.

Absence of specific data:

No information available.

Mixtures:

No information available.

Mixture versus substance information:

No information available.

11.2 Information on other hazards

Endocrine disrupting properties

The mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Other information

The product should be handled with the care usual when dealing with chemicals.

SECTION 12: Ecological Information

Do not allow product to reach surface water, waterways or soil.

12.1 Toxicity

No classified as hazardous to the aquatic environment.

12.2.Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5.Results of PBT and vPvB assessment

PBT:Not applicable.

vPvB:Not applicable.

12.6.Endocrine disrupting properties

The mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7.Other adverse effects

The components are furnished in volumes that do not represent hazard for the environment if used and disposed of correctly. Do not allow to enter waters, sewers or soil.

SECTION 13: Disposal Considerations

13.1.Waste treatment methods

Product disposal:

Avoid release to the environment

Dispose of contents in accordance with local/regional/national/international regulations.

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Send surplus and non-recyclable solutions to a licensed disposal company. Waste codes should be assigned by the user based on the application for which the product was used.

Packaging disposal:

Dispose of container in accordance with local/regional/national/international regulations.

Recommended Cleansing agents:

Water, if necessary together with cleansing agents.

Physical, chemical properties, which could influence waste management:

No information available.

Sewage disposal-relevant information:

Do not allow product to reach sewage system.

SECTION 14: Transport Information

Product is not classified as a dangerous good for transport.

ADR/RID

- 14.1 UN number or ID number: -
- 14.2 UN proper shipping name: -
- 14.3 Transport Hazard Class(es): -
- 14.4 Packing group: -
- 14.5 Environmental hazards: -
- 14.6 Special precautions for user: -

ADN:

- 14.1 UN number or ID number: -
- 14.2 UN proper shipping name: -
- 14.3 Transport Hazard Class(es): -
- 14.4 Packing group: -
- 14.5 Environmental hazards: -
- 14.6 Special precautions for user: -

IMDG

- 14.1 UN number or ID number: -
- 14.2 UN proper shipping name: -
- 14.3 Transport Hazard Class(es): -
- 14.4 Packing group: -
- 14.5 Environmental hazards: -
- 14.6 Special precautions for user:-

ICAO-TI/IATA-DGR

- 14.1 UN number or ID number: -
- 14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory Information

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

EU Regulations:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance)

15.2. Chemical safety assessment:

Chemical safety assessment has not been carried out for this product.

SECTION 16: Other information

Identification of changes

Rev: 01 Revision and harmonization of the data sheet in accordance with applicable international legislation.

Rev: 02 Addition of new products (DNAllergen2 Celery, DNAllergen2 Lupine, DNAllergen2 Sesame)

Rev: 03 Addition of new products (DNAllergen 2 Peanut)

Abbreviations and acronyms:

ATE: Acute Toxicity Estimate. PBT: persistent, bioaccumulative and toxic. vPvB: very persistent, very bioaccumulative. LD50 lethal dose, LC50 Lethal concentration. EC50 Effective concentration. EWC: European Waste Catalog. IARC: International Agency for Research on Cancer. RTECS: Registry of Toxic Effects of Chemical Substances. VOC: Volatile Organic Carbon. PNEC: Predicted no effect concentration. LFL: Lower Inflammatory Limit. UFL: Upper Flammability Limit. LEL lower explosion limit. UEL: Upper explosion limit. STOT: Specific Target Organ Toxicity. LDLo Lethal dose, low. IC50: Inhibitory concentration. SVHC: Substances of very high concern. NOAEL: No-observed-adverse-effect level. LOAEL: Lowest-observed-adverse-effect level

Full text of H-statements from section 2 and 3:

-

Precautionary statements:

-

Further training advices:

No information available.

Recommended restrictions on use:

Employment restrictions concerning juveniles must be observed.

This product is intended to be used for laboratory use only by technical staff trained in microbiological techniques. Classification and labelling have been performed according to CLP Regulations.

Read the Instructions for Use for further information on limitations of use.

This Safety Data Sheet was prepared on the basis of documentation provided by the manufacturer and complies with the requirements of Regulation (EC) No. 878/2020

The above information is based on data available 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 shall make their own determinations of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty or guarantee, expressed or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the material, 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.

IMPORTANT! Read the safety data sheets before the use and disposal of this product. Insure that this information is understood by the operators exposed to this product. Use this product for the intended purpose as indicated in the instruction manual.

The above information is believed to be accurate and up to date. It is, however, liable to change due to the continuous modification of legislation and of standards and security data. Since the correct or incorrect use of this product is beyond our jurisdiction, this information cannot be expressed or implied to be comprehensive. Gold Standard Diagnostics Budapest cannot be held responsible for any improper use of the product, including those uses that could violate current patents or other copyrights. Only the user is responsible for the evaluation of this product's conformity and of the risks involved before use, and must adopt appropriate precautions towards self and other persons involved.