

SAFETY DATA SHEET

Pepsin for HER2 FISH pharmDx

Section 1. Identification

1.1 Product identifier

Product name : Pepsin for HER2 FISH pharmDx
Part No. : K5331, K5731, K5733, K5736, K5799, SK109, GM302
Validation date : 12/14/2016

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

Material uses : Laboratory use
Container type: vials
K5331 // Pepsin // HER2 FISH pharmDx Kit // 7.5 mL
K5731 // Pepsin // HER2 IQFISH pharmDx // 4 x 6.0 mL
K5733 // Pepsin // TOP2A IQFISH pharmDx // 4 x 6.0 mL
K5736 // Pepsin // MET IQFISH // 4 x 6.0 mL
K5799 // Pepsin // Histology FISH Accessory Kit // 4 x 6.0 mL
SK109 // Pepsin // HER2 CISH pharmDx // 7.5 mL
GM302 // Pepsin // ISH Pepsin // 7 mL
Reference number: SDS157

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer : Dako North America, Inc.
6392 Via Real
Carpinteria, California 93013
United States
Tel: (805) 566-6655
www.agilent.com

1.4 Emergency telephone number

In case of emergency : CHEMTREC®: 1-800-424-9300

Section 2. Hazards identification


2.1 Classification of the substance or mixture

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture

H227 FLAMMABLE LIQUIDS - Category 4
H334 RESPIRATORY SENSITIZATION - Category 1
H317 SKIN SENSITIZATION - Category 1
H373 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (kidneys) - Category 2

2.2 GHS label elements

Hazard pictograms : 

Signal word : Danger

Section 2. Hazards identification

- Hazard statements** : H227 - Combustible liquid.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 - May cause an allergic skin reaction.
H373 - May cause damage to organs through prolonged or repeated exposure. (kidneys)
- Precautionary statements**
- Prevention** : P280 - Wear protective gloves. Wear eye or face protection.
P284 - Wear respiratory protection.
P210 - Keep away from flames and hot surfaces. - No smoking.
P260 - Do not breathe vapor.
P272 (OSHA) - Contaminated work clothing must not be allowed out of the workplace.
- Response** : P314 - Get medical attention if you feel unwell.
P304 + P341 (OSHA) - IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or physician.
P302 + P352 + P363 - IF ON SKIN: Wash with plenty of soap and water. Wash contaminated clothing before reuse.
P333 + P313 - If skin irritation or rash occurs: Get medical attention.
- Storage** : P403 - Store in a well-ventilated place.
P235 - Keep cool.
- Disposal** : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

2.3 Other hazards

- Hazards not otherwise classified** : None known.

Section 3. Composition/information on ingredients

- Substance/mixture** : Mixture

Ingredient name	%	CAS number
Propan-2-ol	≤5	67-63-0
pepsin A	≤0.3	9001-75-6
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	≤0.1	55965-84-9

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

4.1 Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention following exposure or if feeling unwell.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In the event of any

Section 4. First aid measures

- complaints or symptoms, avoid further exposure.
- Skin contact** : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention following exposure or if feeling unwell. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

4.2 Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Skin contact** : May cause an allergic skin reaction.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : Adverse symptoms may include the following:
wheezing and breathing difficulties
asthma
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No specific data.

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

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)


Section 5. Fire-fighting measures

5.1 Extinguishing media


- Suitable extinguishing media** : Use dry chemical, CO₂, water spray (fog) or foam.
- Unsuitable extinguishing media** : Do not use water jet.

Section 5. Fire-fighting measures

5.2 Special hazards arising from the substance or mixture


- Specific hazards arising from the chemical** :  Combustible liquid. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion. Runoff to sewer may create fire or explosion hazard.
- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

5.3 Advice for firefighters

- Special protective actions for fire-fighters** :  Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.


Section 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** :  No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".


- 6.2 Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and materials for containment and cleaning up

- Methods for cleaning up** :  Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. The spilled material may be neutralized with sodium carbonate, sodium bicarbonate or sodium hydroxide. Dispose of via a licensed waste disposal contractor.

Section 7. Handling and storage

7.1 Precautions for safe handling

- Protective measures** :  Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems or asthma, allergies or chronic or recurrent respiratory disease should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not breathe vapor or mist. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Keep away from alkalis. Empty containers retain product residue and can be hazardous. Do not reuse container.

- : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Store between the following temperatures: 2 to 8°C (35.6 to 46.4°F). Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from alkalis. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. Do not allow to dry out.

- Industrial applications, Professional applications.

: Not applicable.

Section 8. Exposure controls/personal protection

Occupational exposure limits

Ingredient name	Exposure limits
Propan-2-ol	<p>ACGIH TLV (United States, 3/2016). TWA: 200 ppm 8 hours. STEL: 400 ppm 15 minutes.</p> <p>OSHA PEL 1989 (United States, 3/1989). TWA: 400 ppm 8 hours. TWA: 980 mg/m³ 8 hours. STEL: 500 ppm 15 minutes. STEL: 1225 mg/m³ 15 minutes.</p> <p>NIOSH REL (United States, 10/2013). TWA: 400 ppm 10 hours. TWA: 980 mg/m³ 10 hours. STEL: 500 ppm 15 minutes. STEL: 1225 mg/m³ 15 minutes.</p> <p>OSHA PEL (United States, 6/2016). TWA: 400 ppm 8 hours. TWA: 980 mg/m³ 8 hours.</p>
pepsin A	None.
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	None.

- Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Section 8. Exposure controls/personal protection

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Liquid.

Color : Not available.

Odor : Not available.

Odor threshold : Not available.

pH : 2

Melting point : Not available.

Boiling point : Not available.

Flash point : Closed cup: 55 to 60°C (131 to 140°F) [Product does not sustain combustion.]

Evaporation rate : Not available.

Flammability (solid, gas) : Not applicable.




Lower and upper explosive (flammable) limits : Not available.

Vapor pressure : Not available.

Section 9. Physical and chemical properties

Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Soluble in the following materials: cold water and hot water.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.

Section 10. Stability and reactivity

10.1 Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: The product is stable.
10.3 Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	:  Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.
10.5 Incompatible materials	:  Attacks many metals producing extremely flammable hydrogen gas which can form explosive mixtures with air. Reactive or incompatible with the following materials: alkalis oxidizing materials  Reactive or incompatible with the following materials: acids.
10.6 Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Propan-2-ol	LD50 Dermal	Rabbit	12800 mg/kg	-
	LD50 Oral	Rat	5000 mg/kg	-
reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	LD50 Oral	Rat	53 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Propan-2-ol	Eyes - Moderate irritant	Rabbit	-	24 hours 100 milligrams	-
	Eyes - Moderate irritant	Rabbit	-	10 milligrams	-
	Skin - Mild irritant	Rabbit	-	500 milligrams	-

Sensitization

Section 11. Toxicological information

Not available.

Conclusion/Summary

Skin : May cause sensitization by skin contact.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
Propan-2-ol	-	3	-

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Propan-2-ol	Category 3	Not applicable.	Respiratory tract irritation and Narcotic effects
pepsin A	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
Propan-2-ol	Category 2	Not determined	kidneys

Aspiration hazard

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact : May cause an allergic skin reaction.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.
Inhalation : Adverse symptoms may include the following:
wheezing and breathing difficulties
asthma
Skin contact : Adverse symptoms may include the following:
irritation
redness

Section 11. Toxicological information

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

General : May cause damage to organs through prolonged or repeated exposure. Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	105969.3 mg/kg

Section 12. Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Propan-2-ol	Acute EC50 929 mg/l Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 1400000 to 1950000 µg/l Marine water	Crustaceans - Crangon crangon	48 hours
	Acute LC50 4200 mg/l Fresh water	Fish - Rasbora heteromorpha	96 hours

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Propan-2-ol	0.05	-	low

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Section 12. Ecological information

12.5 Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

13.1 Waste treatment methods

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapor from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements.

The information presented below only applies to the material as supplied. The identification based on characteristic(s) or listing may not apply if the material has been used or otherwise contaminated. It is the responsibility of the waste generator to determine the toxicity and physical properties of the material generated to determine the proper waste identification and disposal methods in compliance with applicable regulations.

Refer to Section 7: HANDLING AND STORAGE and Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION for additional handling information and protection of employees.

Section 14. Transport information

Regulatory information

DOT / IMDG / IATA : Not regulated.

Section 15. Regulatory information

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

U.S. Federal regulations : **United States inventory (TSCA 8b)**: Not determined.
Clean Water Act (CWA) 311: Hydrochloric acid; Acetic acid

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Section 15. Regulatory information

Composition/information on ingredients

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(lbs)	(gallons)	(lbs)	(gallons)
Hydrochloric acid	≤0.1	Yes.	500	-	5000	-

SARA 304 RQ : 14285714.3 lbs / 6485714.3 kg

SARA 311/312

Classification : ☒ Fire hazard
 Immediate (acute) health hazard
 Delayed (chronic) health hazard

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Propan-2-ol pepsin A reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	≤5 ≤0.3 ≤0.1	Yes. No. No.	No. No. No.	No. No. No.	Yes. Yes. Yes.	Yes. No. No.

State regulations

Massachusetts : The following components are listed: ISOPROPYL ALCOHOL; 2-PROPANOL
New York : None of the components are listed.
New Jersey : The following components are listed: ISOPROPYL ALCOHOL; 2-PROPANOL
Pennsylvania : ☒ The following components are listed: ISOPROPYL ALCOHOL MANUFACTURE (STRONG-ACID PROCESS)

California Prop. 65

No products were found.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Australia : Not determined.
Canada inventory : All components are listed or exempted.
China : All components are listed or exempted.
Europe : Not determined.

Section 15. Regulatory information

Japan	: Japan inventory (ENCS): Not determined. Japan inventory (ISHL): Not determined.
Malaysia	: Not determined.
New Zealand	: All components are listed or exempted.
Philippines	: All components are listed or exempted.
Republic of Korea	: All components are listed or exempted.
Taiwan	: <input checked="" type="checkbox"/> All components are listed or exempted.
Turkey	: Not determined.

Section 16. Other information

[History](#)

Date of issue	: 12/14/2016
Date of previous issue	: 07/11/2016.
Version	: 2.1

☒ Indicates information that has changed from previously issued version.

[Notice to reader](#)

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