

Nitrofurazone (SEM) ELISA, Microtiter Plate

Enzyme-Linked Immunosorbent Assay for the Determination
of Nitrofurazone in Contaminated Samples
Product No. 515667

Importance of Nitrofurazone Determination

Antibiotic residues in foods pose a serious threat to public health. The nitrofurans class of broad spectrum antibiotics (Nitrofurazone, furazolidone, furaltadone and nitrofurantoin) are commonly used in food producing animals. Their potential for harmful effects on human health, specifically carcinogenicity, has led to bans on their use in food producing animals in many countries including the US, Canada, and the EU. These countries have also imposed bans on all imported foods containing nitrofurans residues. The monitoring of water sources and food products, such as meat, for antibiotic residues is necessary to ascertain that these compounds are not misused and do not present a danger to human and animal health.

The detection of nitrofurans themselves has proven challenging, as the drugs are rapidly metabolized after ingestion. The protein bound metabolites which are formed, however, persist in edible tissue for a considerable amount of time after treatment. SEM (semicarbazide), the metabolite moiety derived from Nitrofurazone, is not degraded by common cooking techniques and can be released from tissue under mildly acidic conditions, making it ideal for monitoring and detection in edible tissue.

The Abraxis Nitrofurazone ELISA allows the determination of 41 samples in duplicate determination. Only a few grams or milliliters of sample are required. Hydrolysis and derivatization (overnight), and a subsequent solvent extraction step are necessary prior to assaying. The ELISA analysis can then be performed in less than 1 hour.

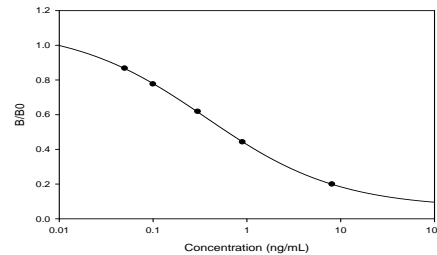
Performance Data

Test sensitivity: The limit of detection for Nitrofurazone in various matrices are as follows:

Fish, shrimp, honey, milk = 0.2 ppb
Chicken = 0.4 ppb

Standard Curve: Determinations closer to the middle of the calibration range of the test yield the most accurate results.

These values are used for demonstration purposes only; do not use these values for your determinations.



Test reproducibility: Coefficients of variation (CVs) for standards: <10%; CVs for samples: <15%.

Selectivity: This ELISA recognizes Nitrofurazone and not related compounds.

Cross-reactivities:

Nitrofurazone (SEM)	100%
Furazolidone (AOZ)	<0.01%
Furaltadone (AMOZ)	<0.01%
1-aminohydantoin (AHD)	<0.01%

Samples: To eliminate matrix effects in fish, shrimp, chicken, milk, and honey, a sample clean-up is required. See Preparation of Samples, section H.

General Limited Warranty: Abraxis, Inc. warrants the products manufactured by the Company against defects and workmanship when used in accordance with the applicable instructions for a period not to extend beyond the product's printed expiration date. **Abraxis makes no other warranty, expressed or implied. There is no warranty of merchantability or fitness for a particular purpose.**

For ordering or technical assistance contact:

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1. General Description

The Nitrofurazone ELISA is an immunoassay for the detection of the Nitrofurazone metabolite (SEM). This test is suitable for the quantitative and/or qualitative detection of Nitrofurazone in contaminated samples. Samples requiring regulatory action should be confirmed by HPLC, GC/MS, or other conventional methods.

2. Safety Instructions

The standard solutions in this test kit contain small amounts of SEM. In addition, the substrate solution contains tetramethylbenzidine and the stop solution contains diluted sulfuric acid. Avoid contact of stopping solution with skin and mucous membranes. If these reagents come in contact with the skin, wash with water.

3. Storage and Stability

The Nitrofurazone ELISA Kit should be stored in the refrigerator (4–8°C). The solutions must be allowed to reach room temperature (20-25°C) before use. Reagents may be used until the expiration date on the box.

4. Test Principle

The Abraxis Nitrofurazone (SEM) Plate Kit applies the principles of enzyme linked immunosorbent assay (ELISA) to the determination of Nitrofurazone. Calibrators (ready to use) and derivatized samples (please refer to reagent preparation section) are added, along with an SEM-HRP enzyme conjugate, to wells in a microtiter plate that contain immobilized antibodies specific for SEM. At this point, a competitive reaction occurs between the SEM which may be in the sample and the enzyme labeled SEM for the binding sites of the antibodies on the microtiter well. The reaction is allowed to continue for thirty (30) minutes. After a washing step, a substrate (Color Solution) is added.

The presence of SEM is detected by adding the "Color Solution," which contains the enzyme substrate (hydrogen peroxide) and the chromogen (3,3',5,5'-tetramethylbenzidine). The enzyme-labeled SEM bound to the SEM antibody catalyzes the conversion of the substrate/chromogen mixture to a colored product. After an incubation period, the reaction is stopped and stabilized by the addition of a diluted acid (Stopping Solution) and the color is evaluated using an ELISA plate reader. The concentrations of the samples are determined by interpolation using the standard curve constructed with each run. Since the labeled SEM (conjugate) was in competition with the unlabeled SEM (sample) for the antibody sites, **the color developed is inversely proportional to the concentration of SEM in the sample.**

5. Limitations of the Nitrofurazone ELISA, Possible Test Interference

Numerous organic and inorganic compounds commonly found in samples have been tested and found not to interfere with this test. However, due to the high variability of compounds that might be found in samples, test interferences caused by matrix effects can not be completely excluded. Mistakes in handling the test can also cause errors. Possible sources for such errors include:

Inadequate storage conditions of the test kit, incorrect pipetting sequence or inaccurate volumes of the reagents, too long or too short incubation times during the immune and/or substrate reaction, extreme temperatures during the test performance (lower than 10°C or higher than 30°C).

The Abraxis Nitrofurazone ELISA Kit provides screening results. As with any analytical technique (GC, HPLC, etc.), samples requiring regulatory action should be confirmed by an alternative method.

Working Instructions

A. Materials Provided

- Microtiter plate coated with antibodies against SEM (12 X 8 strips).
- Nitrofurazone Standards/Calibrators (6): 0, 0.05, 0.1, 0.3, 0.9, and 8.0 ppb, 1.0 mL each. Standards are ready to use (already derivatized).
- Nitrofurazone-HRP Conjugate Solution, 6 mL.
- Sample Treatment Buffer (10X) Concentrate, 50 mL (2 x 25 mL bottle). Use to dilute samples.
- Wash Solution/Sample Diluent (10X) Concentrate, 50 mL.
- Derivatization Reagent, 12 mL.
- Color (Substrate) Solution (TMB), 12 mL.
- Stop Solution, 12 mL.

B. Test Preparation

Micro-pipetting equipment and pipette tips for pipetting the standards and the samples are necessary. We recommend using a multi-channel pipette or a stepping pipette for adding the conjugate, substrate and stop solutions in order to equalize the incubation periods of the solutions on the entire microtiter plate. Please use only the reagents and standards from one package lot in one test, as they have been adjusted in combination.

1. Adjust the microtiter plate and the reagents to room temperature before use.
2. Remove the number of microtiter plate strips required from the foil bag. The remaining strips are stored in the foil bag and zip-locked closed. Store the remaining kit in the refrigerator (4-8°C).
3. The standard solutions, conjugate, substrate and stop solutions are ready to use and do not require any further dilutions.
4. Dilute the **Sample Treatment Buffer** concentrate at a ratio of 1:10. If using both bottles (50 mL), add to 450 mL of deionized or distilled water.
5. Dilute the **Wash Buffer/Sample Diluent** concentrate at a ratio of 1:10. If using the entire bottle (50 mL), add to 450 mL of deionized or distilled water.
6. The Derivatization Reagent is prepared in DMSO (Dimethylsulfoxide). It will freeze when stored at 4-8°C. The reagent bottle may be placed in a warm water bath to accelerate thawing.
7. The stop solution should be handled with care as it contains diluted H₂SO₄.

C. Assay Procedure

1. Add 100 µL of the **standard solutions and derivatized samples** into the wells of the test strips according to the working scheme given. Analysis in duplicate or triplicate is recommended.
2. Add 50 µL of **enzyme conjugate solution** to the individual wells successively using a multi-channel pipette or a stepping pipette. Cover the wells with parafilm or tape and mix the contents by moving the strip holder in a circular motion on the benchtop for 30 seconds. Be careful not to spill contents.
3. Incubate the strips for 30 minutes at room temperature.
4. After incubation, remove the covering and vigorously shake the contents of these wells into a sink. Wash the strips **four times** using the 1X washing buffer solution. Use at least a volume of 250 µL of washing buffer for each well and each washing step. Remaining buffer in the wells should be removed by patting the plate dry on a stack of paper towels.
5. Add 100 µL of **substrate (color) solution** to the wells. Cover the wells with parafilm or tape and mix the contents by moving the strip holder in a circular motion on the benchtop for 30 seconds. Incubate the strips for 20 minutes at room temperature. Protect the strips from direct sunlight.
6. Add 100 µL of **stop solution** to the wells in the same sequence as for the substrate solution.
7. Read the absorbance at 450 nm using a microplate ELISA photometer within 15 minutes after the addition of the stopping solution.

D. Evaluation

The evaluation of the ELISA can be performed using commercial ELISA evaluation programs 4-Parameter (preferred) or Logit/Log. For manual evaluation, calculate the mean absorbance value for each of the standards. Calculate the %B/B₀ for each standard by dividing the mean absorbance value for each standard by the Zero Standard (Standard 0) mean absorbance. Construct a standard curve by plotting the %B/B₀ for each standard on the vertical linear (y) axis versus the corresponding Nitrofurazone concentration on the horizontal logarithmic (x) axis on graph paper. %B/B₀ for samples will then yield levels in ppb of Nitrofurazone by interpolation using the standard curve. Samples showing lower concentrations of Nitrofurazone compared to Standard 1 (0.05 ng/mL) should be reported as containing < 0.2 ppb for fish, shrimp, milk, and honey, and < 0.4 ppb for chicken. Samples showing a higher concentration than Standard 6 (8 ng/mL) must be diluted further to obtain accurate results.

E. Additional Materials (not included with the test kit)

1. Micro-pipettes with disposable plastic tips (10-200 and 200-1000 µL)
2. Multi-channel pipette (10-250 µL) or stepper pipette with plastic tips (10-250 µL)
3. Microtiter plate reader (wave length 450 nm)
4. Centrifuge, capable of spinning at 3,000 rpm
5. Vortex Mixer
6. 50 mL centrifuge tubes
7. 10 mL glass tubes or vials
8. Mixer (Stomacher, Ultraturax)
9. Incubator (37 °C)
10. Water bath (80-100 °C)
11. Nitrogen (suggested but not essential)
12. Timer
13. Tape or Parafilm

F. Additional Reagents (not included with the test kit)

1. Ethyl Acetate
2. n-Hexane
3. 1N HCl
4. 1 N NaOH
5. Distilled or deionized water

G. Working Scheme

The microtiter plate consists of 12 strips of 8 wells, which can be used individually for the test. The standards must be run with each test. Never use the values of standards which have been determined in a test performed previously.

Std 0-Std 6: Standards
0; 0.05; 0.1; 0.3; 0.9; 8.0 ppb

Samp1, Samp2, etc.: Samples

	1	2	3	4	5	6	7	8	9	10	11	12
A	Std 0	Std 4	Samp 2									
B	Std 0	Std 4	Samp 2									
C	Std 1	Std 5	etc.									
D	Std 1	Std 5										
E	Std 2	Std 6										
F	Std 2	Std 6										
G	Std 3	Samp 1										
H	Std 3	Samp 1										

H. Preparation of Samples (Derivatization and Extraction)

a) Fish/Shrimp (0.2 ppb Sensitivity)

1. Weigh 1 g of homogenized fish or de-shelled shrimp (should have a paste-like consistency) into a 50 mL centrifuge tube.
2. Add 4 mL of distilled or deionized water, 0.5 mL 1N HCl, and 100 µL of Derivatization Reagent. Vortex thoroughly for 1 minute.
3. Incubate at 37°C overnight (approximately 16 hours).
4. Add 5 mL of the diluted **Sample Treatment Buffer**, 0.4 mL of 1N NaOH, and 5 mL of ethyl acetate and vortex thoroughly for 1 minute.
5. Centrifuge tube for 10 minutes at 3000 rpm.
6. Transfer 2 mL of the ethyl acetate layer (top layer) into a clean vial or glass tube.
7. Evaporate to dryness at 40-60°C under a gentle stream of nitrogen.
8. Dissolve the residue with 1 mL of n-hexane, vortex. Add 1.6 mL of diluted **Wash Solution/Sample Diluent Solution**, and vortex thoroughly for 1 minute.
9. Boil the sample for approximately 3 minutes at 80-100°C.
10. Centrifuge vial/tube for 10 minutes at 3000 rpm.
11. The aqueous layer (lower layer) will then be analyzed as sample (Assay Procedure, step 1).

The ELISA result will be multiplied by a factor of 4 to obtain the final SEM concentration in the sample (the factor is necessary to account for the sample dilution in the procedure). Samples showing lower concentrations than standard 1 (0.05 ppb) should not be multiplied by the factor (4) but should be reported as containing <0.2 ppb. Highly contaminated samples (those outside of the calibration range of the assay) must be diluted and re-analyzed.

b) Chicken (0.4 ppb Sensitivity)

1. Weigh 1.0 g of homogenized sample and mix with 4.0 mL of deionized water, 0.5 mL of 1M HCl, and 75 µL of Derivatization Reagent. Vortex for 1 minute.
2. Follow steps H.a.3 to 11 of the **Fish/Shrimp Derivatization and Extraction** procedure, **using 3.2 mL of Wash Solution/Sample Diluent Solution (instead of 1.6 mL) in step H.a.8.**

The ELISA result will be multiplied by a factor of 8 to obtain the final SEM concentration in the sample.

c) Honey (0.2 ppb Sensitivity)

1. Mix 1.0 g of sample with 4.0 mL of distilled water, 0.5 mL of 1M HCl, and 10 mL of hexane in a 50 mL centrifuge tube.
2. Vortex for 1 minute and centrifuge at 3000 RPM for 10 minutes.
3. Freeze at -20°C for 60 minutes, remove the upper liquid layer.
4. Melt the frozen layer, add 75 µL of Derivatization reagent and vortex for 1 minute. Follow step H.a.3 to 11 of the **Fish/Shrimp Derivatization and Extraction** procedure, **using 0.5 mL of 1N NaOH (instead of 0.4 mL) in step H.a.4.**

The ELISA result will be multiplied by a factor of 4 to obtain the final SEM concentration in the sample.

d) Milk (0.2 ppb Sensitivity)

1. Centrifuge 3-4 mL of milk at 3000 rpm for 10 minutes.
2. Carefully take 1.0 mL of the lower layer (**Must avoid taking up the upper fat layer**), then follow step H.a.2 to 11 of the **Fish/Shrimp Derivatization and Extraction** procedure.

The ELISA result will be multiplied by a factor of 4 to obtain the final SEM concentration in the sample.

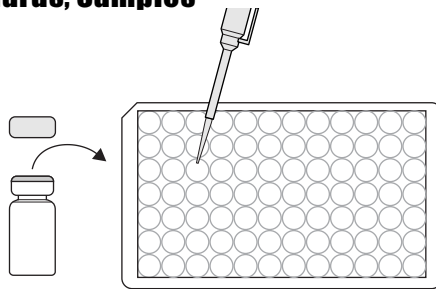
NOTE: An alternative derivatization (section H, procedure a, step 3, above) may be performed as follows: Incubate samples at 60°C for 3 hours. Proceed to step H.a.4 above.

When using unknown samples of shrimp and fish with the incubation reduced from 16 hours at 37°C to 3 hours at 60°C, as described above, the recoveries were between 80-120% of those using the 16 hours at 37°C derivatization procedure. When using known **negative** samples of shrimp and fish spiked and derivatized with the incubation reduced from 16 hours at 37°C to 3 hours at 60°C, the recoveries were between 70-110%.

Nitrofurantoin (AHD) Plate, Detailed ELISA Procedure

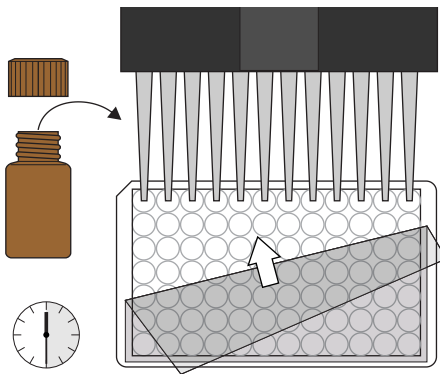
1. Addition of Standards, Samples

Add 100 uL of the standard solutions, samples or sample extracts into the wells of the test strips according to the working scheme given. We recommend using duplicates or triplicates.



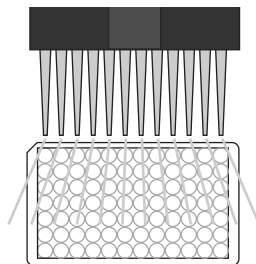
2. Addition of Enzyme Conjugate

Add 50 uL of the Nitrofurantoin enzyme conjugate to the individual wells successively using a multi-channel pipette or a stepping pipette. Cover the wells with parafilm or tape and mix the contents by moving the strip holder in a rapid circular motion on the benchtop. Be careful not to spill contents. Incubate the strips for 30 minutes at room temperature.



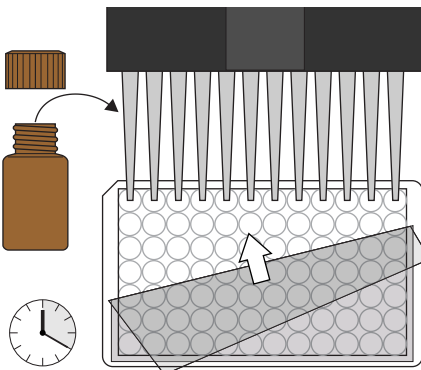
3. Washing of Plates

After incubation, remove the covering and vigorously shake the contents of the wells into a sink. Wash the strips four times with a multi-channel pipette or wash bottle using the diluted 1X washing buffer solution. Please use at least 250 uL of washing buffer for each well and each washing step. Remaining buffer in the wells should be removed by patting the plate dry on a stack of paper towels.



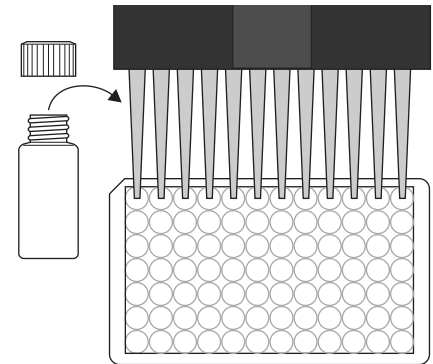
4. Addition of Substrate/Color Solution

Add 100 uL of substrate/color solution to the individual wells successively using a multi-channel pipette or a stepping pipette. Cover the wells with parafilm or tape and mix the contents by moving the strip holder in a rapid circular motion on the benchtop. Be careful not to spill contents. Incubate the strips for 20 minutes at room temperature away from direct sunlight.



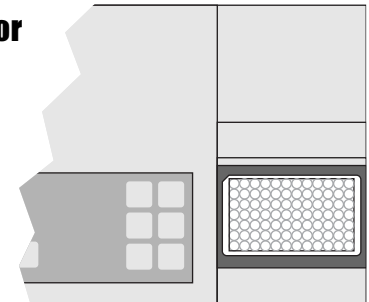
5. Addition of Stopping Solution

Add 100 uL of stop solution to the wells, in the same sequence as for the substrate solution, using a multi-channel pipette or a stepping pipette.



6. Measurement of Color

Read the absorbance at 450 nm using a microplate ELISA reader within 15 minutes. Calculate results.



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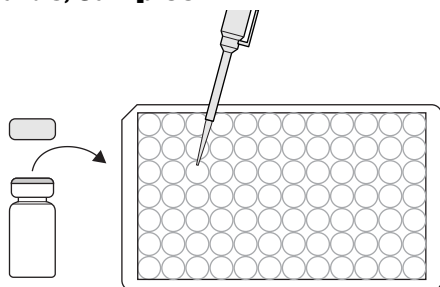
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Nitrofurantoin (AHD) Plate, Concise ELISA Procedure

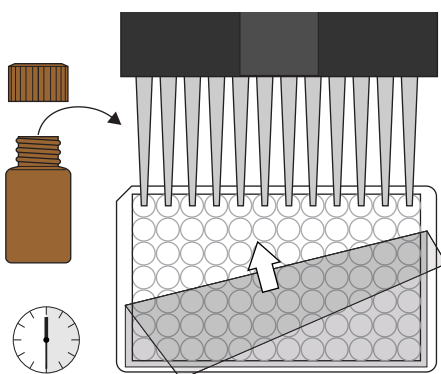
1. Addition of Standards, Samples

Add 100 uL of standard solutions, sample or sample extract.



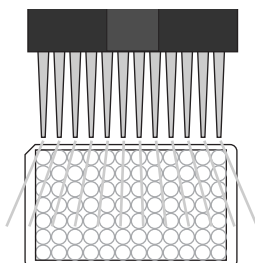
2. Addition of Enzyme Conjugate

Add 50 uL of enzyme conjugate. Cover and mix for 30 seconds by moving strip holder in a circular motion on benchtop. Incubate 30 minutes at room temperature away from direct sunlight.



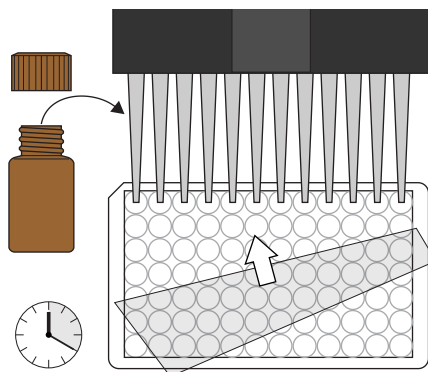
3. Washing of Plates

Wash the wells four times with 250 uL of diluted 1X washing buffer.



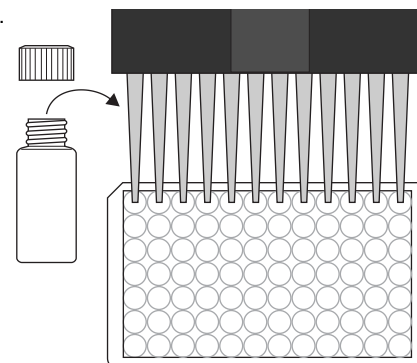
4. Addition of Substrate/Color Solution

Add 100 uL of substrate/color solution. Cover and mix for 30 seconds by moving strip holder in a circular motion on benchtop. Incubate 20 minutes at room temperature away from direct sunlight.



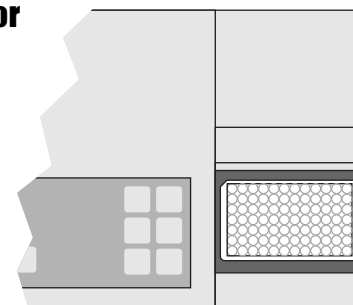
5. Addition of Stopping Solution

Add 100 uL of stop solution.



6. Measurement of Color

Measure color at 450 nm within 15 minutes. Calculate results.



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Safety Data Sheet

Section 1: Product and Company Identification

1.1 Product Identifiers:

Product Name: Nitrofurantoin (AHD) ELISA Plate Kit

Product Code: 515666

1.2 Identified Use: Determination of Nitrofurantoin (AHD) in samples. **Restrictions on Use:** For research use only.

1.3 Company: Abraxis, Inc., 124 Railroad Drive, Warminster, PA 18974 USA, info@abraxiskits.com +1(215) 357-3911, FAX +1(215) 357-5232

1.4 Emergency Telephone Number: +1(215) 357-3911

Section 2: Hazard(s) Identification

2.1 Classification of the mixture: Not a hazardous mixture.

2.2 GHS Label elements, including precautionary statements: Not applicable.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS: None known.

2.4 Unknown acute toxicity: None known.

Section 3: Composition / Information on Ingredients

3.2 Mixtures: *Contains no hazardous ingredients at levels requiring disclosure by the OSHA Hazard Communication Standard (29 CFR 1910.1200), however it contains minor amounts of materials considered hazardous. We recommend handling all substances with caution.*

Section 4: First Aid Measures

4.1 Description of first aid measures: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact: Wash off with soap and plenty of water. Consult a physician.

In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed: No data available

4.3 Indication of any immediate medical attention and special treatment needed: No data available. Treat symptomatically.

Section 5: Fire-fighting Measures

5.1 Suitable extinguishing media: Use an extinguishing agent suitable for the surrounding fire.

5.2 Special hazards arising from the substance or mixture: None known

5.3 Advice for firefighters: Wear self-contained breathing apparatus for fire-fighting if necessary.

5.4 Further information: No data available

Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures: Use personal protective equipment (see section 8). Avoid dust formation. Avoid breathing vapors, mist, dust, or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2 Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up: Solids (if applicable): Pick up and arrange disposal without creating dust. Sweep up and shovel. Liquids (if applicable): Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Keep in suitable, closed containers for disposal.

6.4 Reference to other sections: For information on safe handling see section 7.

For information on personal protection see section 8.

For information on disposal see section 13.

Section 7: Handling and Storage

7.1 Precautions for safe handling: See section 2. Avoid inhalation of vapors and contact with skin and eyes. Wear appropriate personal protective equipment. Do not eat, drink, or smoke in work area.

7.2 Precautions for safe storage: Keep container(s) tightly closed in a dry, well-ventilated place. Protect from physical damage. See label or product insert for appropriate storage temperature and additional specific information.

7.3 Specific end use(s): No data available

Section 8: Exposure Controls / Personal Protection

8.1 Control parameters: Not applicable.

8.2 Exposure controls:

Appropriate engineering controls: Provide adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday. Keep away from food and beverages.

Personal protective equipment: The usual precautionary measures, including eye/face/skin protection, should be taken when handling any chemical. Avoid contact with eyes, skin, and clothing.

Eye protection: As with handling of any chemical, wear approved safety goggles.

Skin protection: Handle with gloves. No specific information regarding glove material or thickness is available, but gloves must be impermeable and resistant to the substance being handled. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Respiratory protection: As with any chemical, where excessive vapor, mist, or dust may result, use a chemical fume hood or approved respiratory protection equipment.

Body protection: Lightweight, protective clothing.

Section 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties of the mixture

Appearance: Multiple

Odor: Characteristic

Odor Threshold: No data available

pH: Multiple

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): No data available

Upper/lower flammability or explosive limits: No data available

Vapor pressure: No data available

Vapor density: No data available

Relative density: No data available

Water solubility: Various

Partition coefficient: n-octanol/water: No data available

Auto-ignition temperature: Not applicable

Decomposition temperature: No data available

Viscosity: No data available

Explosive properties: No data available

Oxidizing properties: No data available

9.2 Other information: No data available

Section 10: Stability and Reactivity

10.1 Reactivity: No data available

10.2 Chemical stability: Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions: No data available

10.4 Conditions to avoid: No data available

10.5 Incompatible materials: No data available

10.6 Hazardous decomposition products: No data available. In the event of fire: see section 5.

Section 11: Toxicological Information

11.1 Information on toxicological effects

Acute toxicity: Not available. To the best of our knowledge, the chemical, physical, and toxicological properties of this product have not been thoroughly investigated.

Inhalation: No data available **Ingestion:** No data available

Skin contact: Irritant to skin and mucous membranes.

Eye contact: May cause eye irritation in susceptible persons.

Respiratory or skin sensitization: No data available

Aspiration hazard: No data available

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.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Teratogenicity: No data available

Reproductive/fertility toxicity: No data available

Specific target organ toxicity, single exposure: No data available

Specific target organ toxicity, repeated exposure: No data available

Section 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: No data available

12.6 Other adverse effects: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Section 13: Disposal Considerations

13.1 Waste treatment methods

Product: All waste must be handled and disposed according to local, state, and federal regulations. Avoid disposing large volumes in sewer.

Contaminated packaging: All waste must be handled and disposed according to local, state, and federal regulations.

Refer to sections 7 and 8 for safe handling guidance.

Section 14: Transport Information

UN Number: Not regulated

UN Proper shipping name: Not classified as dangerous in the meaning of transport regulations.

Transport hazard class(es): No data available

Packing group: No data available

Environmental hazard: No data available

Bulk transport: No data available

Special considerations: No data available

Section 15: Regulatory Information

To the best of our knowledge, this product contains no substances which, at their given concentrations, are considered hazardous by other regulatory agencies. Refer to section 3.

Section 16: Other information

This information is based on our present knowledge. While Abraxis , Inc. believes that the data contained herein are factual and the opinions expressed represent a best effort to present accurate information, the data are not to be taken as a warranty or representation for which Abraxis , Inc. assumes legal responsibility. The information shall not be taken as being all-inclusive and is to be used only as a guide. The data are offered solely for the user's consideration, investigation, and verification. These suggestions should not be confused with either state, municipal, or insurance requirements, or with national safety codes and constitute no warranty. Any use of these data and information must be determined by the user to be in accordance with applicable federal, state, and local regulations.

All materials and mixtures may present unknown hazards and should be used with caution. Since Abraxis , Inc. cannot control the methods, volumes, or conditions of use of this product, Abraxis , Inc. shall not be held liable for any damages or losses resulting from the handling or from contact with the product as described herein. An individual technically qualified to handle potentially hazardous chemicals must supervise the use of this material. This product is sold for research use only. It is not for any human or animal therapeutic or clinical diagnostic use.

Date this SDS was prepared: 5/24/2016

Version: 2

Changes from previous version: Abraxis, LLC changed to Abraxis, Inc.