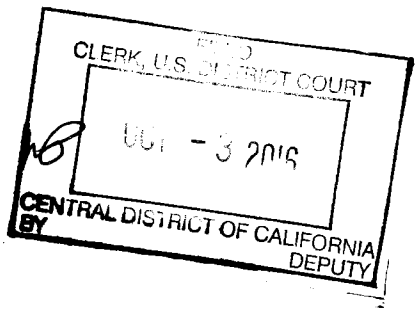
Candyce Estave
430 East Rose Avenue
Santa Maria California 93454



UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

Travis Middleton, et al., Plaintiff(s),	Incorporated Case No.: 2:16-cv-05224-SVW-AGR
vs.	NOTICE TO THE COURT
Richard Pan, et al. Defendant(s)	SUBMISSION OF CRIMINAL AFFIDAVIT BY PLAINTIFF Candyce Estave 28 U.S.C. 1361

COMES NOW:
Plaintiff, Candyce Estave, in the above encaptioned matter, to notice this honorable court of Plaintiff's criminal affidavit to be lodge on the record of this Incorporated Case.

Dated this September 23, 2016

Candyce Estave

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430 East Rose Avenue
Santa Maria California 93454

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Santa Maria California 93454

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

In re:	**: Incorporated Case No.:**
	: LA CV16-05224-SVW-AGR
Travis Middleton, et al.	**: 18 U.S.C. § 3332(a) Demand For**
	: Grand Jury Indictment;
Vs.	**: (Fed. Supp. P 199);**
	: 28 U.S.C. 1361
	: 18 U.S.C. § 4
Richard Pan, et al.	**: MISPRISON OF FELONY**
_____/	

Pursuant to Federal Rules of Evidence (F.r.e.) 102, 104(b), 201(b)(d)(f), 402, & 406.

Affidavit of Criminal Report by
Witness & Victim of Criminal Activity

State of California)
)ss:
County of Santa Barbara)

I, Candyce Estave your affiant, whose current address is 430 East Rose Avenue Santa Maria, California [93454], states that Affiant is of legal age, competent to testify, has personal first hand knowledge and believes that the truths and facts herein are true, correct, complete, certain, not misleading.

Your affiant has read the California Penal Codes, California Constitution, The United States Constitution & Criminal Statutes 18 U.S.C., specifically

Section[s] 4, "Misprison of Felony" **18 U.S.C. § 4** provides: Whoever, having knowledge of the actual commission of a felony cognizable by a court of the United States, conceals and does not as soon as possible make known the same to some judge or other person in civil or military authority under the United States, shall be fined under this title or imprisoned not more than three years, or both.

Additionally, The predicate act of Obstruction of Justice, **18 U.S.C. §1503 provides:**

-Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States (the State of California is enjoined and incorporated into the United States as an agency and or subsidiary by and through the 14th Amendment) , or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

- Whoever corruptly, or by threats or force, or by any threatening letter or communication, endeavors to influence, intimidate, or impede..... or by any threatening letter or communication, influences, obstructs, or impedes,

or endeavors to influence, obstruct, or impede, the due administration of justice, shall be punished as provided in subsection (b).

(b) The punishment for an offense under this section is—

(1) In the case of a killing, the punishment provided in sections 1111 and 1112;

(2) In the case of an attempted killing, or a case in which the offense was committed against a petit juror and in which a class A or B felony was charged, imprisonment for not more than 20 years, a fine under this title, or both; ***and;***

18 U.S.C. § 1962(d)) - Conspiracy to Obstruct or Pervert Justice by perjury of Oaths:

The California Constitution Article 20 Section 3 provides:

Members of the Legislature, and all public officers and employees, executive, legislative, and judicial, except such inferior officers and employees as may be by law exempted, shall, before they enter upon the duties of their respective offices, take and subscribe the following oath or affirmation:

"I, _____, do solemnly swear (or affirm) that I will support and defend the Constitution of the United States and the Constitution of the State of California against all enemies, foreign and domestic; that I will bear true

faith and allegiance to the Constitution of the United States and the Constitution of the State of California; that I take this obligation freely, without any mental reservation or purpose of evasion; and that I will well and faithfully discharge the duties upon which I am about to enter.

"And I do further swear (or affirm) that I do not advocate, nor am I a member of any party or organization, political or other-wise, that now advocates the overthrow of the Government of the

United States or of the State of California by force or violence or other unlawful means; that within the five years immediately preceding the taking of this oath (or affirmation) I have not

been a member of any party or organization, political or other-wise, that advocated the overthrow of the Government of the United States or of the State of California by force or violence or other unlawful means except as follows:

_____

(If no affiliations, write in the words "No Exceptions") and that during such time as I hold the office of _____ I will not advocate nor become (name of office) a member of any party or organization, political or otherwise, that advocates the overthrow of the Government of the United

States or of the State of California by force or violence or other unlawful means."

And no other oath, declaration, or test, shall be required as a qualification for any public office or employment. "Public officer and employee" includes every officer and employee of the State, including the University of California, every county, city, city and county, district, and authority, including any department, division, bureau, board, commission, agency, or instrumentality of any of the foregoing.

Government Code Section 1360 provides: Unless otherwise provided, before any officer enters on the duties of his office, he shall take and subscribe the oath or affirmation set forth in *Section 3 of Article 20 of the Constitution of California.*

Government Code Section 1368 provides: Every person who, while taking and subscribing to the oath or affirmation required by this chapter, states as true any material matter which he or she knows to be false, is guilty of perjury, and is punishable by imprisonment in the state prison for two, three, or four years.

Government Code Section 1369 provides: Every person having taken and subscribed to the oath or affirmation required by this chapter, who while holding office, advocates or becomes a member of any party or

organization, political or otherwise, that advocates the overthrow of the government of the United States by force or violence or other unlawful means, is guilty of a felony, and is punishable by imprisonment in the state prison.

Defendants, Richard Pan, Martin Jeffrey "Marty" Block, Gerald A. "Jerry" Hill, Holly Mitchell, Catharine Baker, Christina Garcia, Adrin Nazarian, Jim Wood, Ben Allen, Kevin de Leon, Hannah-Beth Jackson, Jeff Stone, Richard Bloom, Bill Quirk, Lorena Gonzalez, Reginald Jones-Sawyer, Isadore Hall, Mark Leno, Bob Wieckowski, David Chiu, Evan Low, Anthony Rendon, Jim Beall, Mike McGuire, Lois Wolk, Jim Cooper, Kevin McCarthy, Mark Stone, Edmund G. Brown Jr., all have sworn this particular oath to uphold, defend and support the California and United States Constitutions from all enemies, foreign and domestic.

During the house and senate hearings being held at the state capitol, in and around March through May of 2015, the defendants deliberately, with malice and willful intent did perjure their oaths of office to support and defend the California and united States Constitutions and the Bill of Rights and Amendments 1, 4, 5, 9, and 14 in violation of 18 U.S.C. §1503 and 18 U.S.C. § 1962(d)) - Conspiracy to Obstruct or Pervert Justice.

All the defendant legislatures have superior knowledge and cognizant awareness of the toxic and poisonous ingredients in these inoculations that they call "vaccines" with respect to SB277. These poisons include but are not limited to: Aluminum Hydroxide, Formaldehyde, Aluminum Potassium Sulfate, FD&C Yellow #6 Aluminum Lake Dye, Aluminum Phosphate, Glutaraldehyde, Vero (monkey kidney) cells, Polysorbate 80, and others. Attached as ***Appendix "A"*** are the Material Safety Data Sheets for some of these poisonous substances.

The Material Safety Data Sheets on these compounds have these warnings: **Aluminum Hydroxide** - Acute Potential Health Effects: May cause mild skin, eye and upper respiratory tract irritation. Ingestion: May cause gastrointestinal tract irritation: May affect bones (osteomalacia), metabolism, blood, behavior (muscle contraction, spasticity, change in motor activity), liver. Personal Protection in Case of a Large Spill:

Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Formaldehyde - Chronic Effects on Humans:

CARCINOGENIC EFFECTS: Classified A2 (Suspected for human.) by ACGIH, 2A (Probable for human.) by IARC [Formaldehyde]. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. [Formaldehyde]. Mutagenic for bacteria and/or yeast. [Formaldehyde]. Mutagenic for mammalian somatic cells. [Methyl alcohol]. Mutagenic for bacteria and/or yeast. [Methyl alcohol]. TERATOGENIC EFFECTS: Classified POSSIBLE for human [Methyl alcohol]. DEVELOPMENTAL TOXICITY: Not available May cause damage to the following organs: kidneys, liver, central nervous system (CNS). Very hazardous in case of ingestion. Hazardous in case of skin contact (irritant, sensitizer, permeator), of eye contact (corrosive), of inhalation (lung corrosive). Slightly hazardous in case of skin contact (corrosive). Acute Potential Health Effects: Skin: Corrosive. Causes skin irritation which may range from mild to severe with possible burns depending on the extent of exposure and concentration of solution. Other symptoms may include brownish discoloration of the skin, urticaria, and pustulovesicffular eruptions. May be absorbed through skin with symptoms paralleling those of ingestion. Eyes: Corrosive. Contact with liquid causes severe eye irritation and burns. It may cause irreversible eye damage (severe corneal Solutions containing low formaldehyde concentrations may produce transient discomfort and irritation. Inhalation:

Causes irritation of the respiratory tract (nose, throat, airways). Symptoms may include dry and sore mouth and throat, thirst, and sleep disturbances, difficulty breathing, shortness of breath, coughing, sneezing, wheezing rhinitis, chest tightness, pulmonary edema, bronchitis, tracheitis, laryngospasm, pneumonia, palpitations. It may also affect metabolism weight loss, metabolic acidosis), behavior/central nervous system (excitement, central nervous system depression, somnolence, convulsions, stupor, aggression, headache, weakness, dizziness, drowsiness, coma), peripheral nervous system, and blood. Ingestion: Harmful if swallowed. May be fatal. Causes gastrointestinal irritation with nausea, vomiting (possibly with blood), diarrhea, severe pain in mouth, throat and stomach, and possible corrosive injury to the gastrointestinal mucosa/ulceration or bleeding from stomach. May also affect the liver (jaundice), urinary system/kidneys (difficulty urinating, albuminuria, hematuria, anuria), blood, endocrine system, respiration (respiratory obstruction, pulmonary edema, bronchiolar obstruction), cardiovascular system (hypotension), metabolism (metabolic acidosis), eyes (retinal changes, visual field changes), and behavior/central nervous system (symptoms similar to those for inhalation). Contains Methanol which may cause blindness if swallowed. Chronic Potential Health Effects: Skin: Prolonged or repeated exposure may cause contact dermatits

both irritant and allergic. It may also cause skin discoloration. Inhalation: Although there is no clear evidence, prolonged or repeated exposure may induce allergic asthma. Other effects are similar to that of acute exposure. Ingestion: Prolonged or repeated ingestion may cause gastrointestinal tract irritation and ulceration or bleeding from the stomach. Other effects may be similar to that of acute ingestion.

California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute.

Aluminum Potassium Sulfate - Special Remarks on Chronic Effects on Humans: May cause adverse reproductive effects (fetotoxicity) based on animal data. Special Remarks on other Toxic Effects on Humans: Acute Potential Health Effects: Skin: May cause skin irritation particularly on abraded skin. Eyes: Dust may cause eye irritation. Inhalation: Dust may cause irritation of the respiratory tract and mucous membranes. Ingestion: May cause gastrointestinal tract irritation. Symptoms may range from mild abdominal cramping and nausea, to severe vomiting and

hemorrhagic gastroenteritis depending on the concentration and amount ingested. Ingestion may also produce a feeling of dryness and puckering of

the mucous membranes of the mouth and throat. May also affect behavior. The toxicological properties of this product have not been fully investigated.

Most all vaccines have one or more, or a combination of several of these poisons being forced on Affiant and or affiant's offspring by the named defendant legislators. See also attached Vaccine Excipient & Media Summary under ***Appendix "B"***.

In the documentary film "VAXXED" Produced by Del Bigtree, one of the Centers For Disease Control's (CDC) top scientific researchers, Dr. William Thompson admits that the CDC can no longer be trusted, and that he lied about the MMR study of 2004 linking vaccines to autism. Starting at time frames 1:44 through 2:35 Dr. Thompson makes these statements in a correspondence to Dr. Brian Hooker. *"I've waited a long time to tell my story. And I want to tell it truthfully. I was involved in deceiving millions of taxpayers regarding the potential negative side effects of vaccines. We lied about the scientific findings. The CDC can longer be trusted to do vaccine safety work. Can't be trusted to be transparent. The CDC can't be trusted to police itself. Just a few thoughts."*

- William W. Thompson, PhD, Senior Scientist, U.S. Centers For Disease Control and prevention.

Subsequently, in August of 2014, while working with a whistleblower attorney, Dr. Thompson turns over thousands of documents to Senator Posey of Florida. One of those documents is from Dr. Thompson's 2004 studies on the MMR vaccine and how African American boys were found to be statistically higher at risk for developing Autism.

See attached ***Appendix "C"***. -**Events Surrounding the DeStefano et al (2004) MMR-Autism Study**- dated September 9, 2014. In conclusion, Dr. Thompson writes:

"I believe we intentionally withheld controversial findings from the final draft of the DeStefano et al (2004) Pediatrics paper. We failed to follow the final approved study protocol and we ran detailed in depth RACE analyses from October 2001 through August 2002 attempting to understand why we were finding large vaccine effects for blacks. The fact that we found a strong statistically significant finding among black males does not mean that there was a true association between the MMR vaccine and autism-like features in this subpopulation. This result would have probably have led to designing additional better studies if we had been willing to report the findings in the study and manuscript at the time that we found them. The significant effect of early vaccination with the MMR vaccine might have also

been a proxy for the receipt of thimerosal vaccines early in life but we didn't have the appropriate data to be able to code the level of thimerosal exposure from the MADDSP school records. In addition to significant effects for black males, we also found significant effects for "isolated autism cases" and for the threshold of 24 months of age. If we had reported the 24 month effects, our justification for ignoring the 36 month significant effects would not have been supported. In the discussion section of the final published manuscript, we took the position that service seeking was the reason we found a statistically significant effect at 36 months. This was a post-hoc hypothesis regarding the findings after we confirmed one of our primary hypotheses. Because we knew that the threshold for 24 months was also statistically significant, reporting it would have undermined the hypothesis that service seeking was the reason we found an effect at 36 months. (See published paper)".

–Dr. William Thompson.

The effect of the criminal conspiracy between the Defendant legislators, certain pharmaceutical companies and the Centers for Disease Control (CDC) on the affiant and affiant's descendants with respect to the implementation of SB277 and similar bills like it amounts to genocide.

Neither the government (state of California), its agents, subsidiaries, or anyone acting in or on government's behalf, have the constitutional authority under either the State of California's or the United States constitution to mandate the administration of poisons in any form, under any pseudo government sponsored initiative, upon its citizenry. The named defendants have had full knowledge of the evidence and facts within this affidavit and have chosen to ignore it. Defendants actions constitute violations of 18 U.S.C. § 2383 - Rebellion or insurrection; 18 U.S.C. § 2384 - Seditious conspiracy.

Sedition:

The organized incitement of rebellion or civil disorder against authority or the state. An insurrectionary movement tending towards treason, but wanting an overt act; attempts made by meetings or speeches, or by publications, to disturb the tranquility of the state. (Referenced Black's Law Dictionary 6th edition.

See also 18 U.S.C.A. § 2283 et seq. See also *The Smith Act*. 18 U.S.C.A. § 2383 provides in pertinent parts:

Whoever incites, sets on foot, assists, or engages in any rebellion or insurrection against the authority of the United States or the laws thereof, or gives aid or comfort thereto, shall be fined under this title or imprisoned not

more than ten years, or both; and shall be incapable of holding any office under the United States.

The U.S. Supreme Court has stated that "No state legislator or executive or judicial officer can war against the Constitution without violating his undertaking to support it. *Cooper v. Aaron*, 358 U.S. 1, 78 S.Ct. 1401 (1958).

However, since *Ex parte Young,* 209 U. S. 123 (1908), it has been settled that the Eleventh Amendment provides no shield for a state official confronted by a claim that he had deprived another of a federal right under the color of state law.

Ex parte Young teaches that, when a state officer acts under a state law in a manner violative of the Federal Constitution, he "comes into conflict with the superior authority of that Constitution, and he is, in that case, stripped of his official or representative character, and is subjected in his person to the consequences of his individual conduct. The State has no power to impart to him any immunity from responsibility to the supreme authority of the United States."

1. And as such, all named Defendant legislatures, have used the house and senate hearings at the state capitol as a conduit to extort money, property and liberty from Affiant Candyce Estave and affiant's

descendants by theft and constructive fraud "under color of law" to adversely affect interstate and foreign commerce within the meaning of Title 18 U.S.C. section 1951 (relating to interference with commerce, robbery or extortion), section 1952 (relating to racketeering), 18 USC Section 1961(1) - 1503 (relating to obstruction of justice) and 1962(a)(b)(c)(d) (Conspiracy).

2. Prayer for Relief,
3. Affiant request this court order her protective custody; and, a federal investigation from the Department of Justice to thoroughly investigate the crimes as alleged in this affidavit pursuant to 18 U.S.C. § 3332(a).
4. Further affiant saith naught.

Next page →

Candyce Estave, Victim and Witness

Candyce Estave
430 East Rose Avenue
Santa Maria California 93454

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Santa Barbara

Subscribed and sworn to (or affirmed) before me on this 23 day of September, 20 16, by Candyce Estave,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

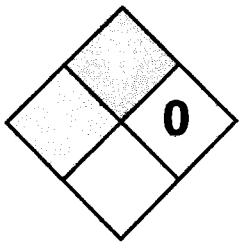
(Seal) Signature Elizabeth Bailey

ELIZABETH BAILEY
Commission #2086417
Notary Public
California
SANTA BARBARA COUNTY
My Commission Expires October 17, 2018

APPENDIX "A"

Material Safety Data Sheets

Science
Chemicals & Laboratory Equipment



Reactivity	0
Personal Protection	E

Material Safety Data Sheet
Aluminum hydroxide MSDS

Section 1: Chemical Product and Company Identification

Product Name: Aluminum hydroxide

Catalog Codes: SLA3004

CAS#: 21645-51-2

RTECS: BD0940000

TSCA: TSCA 8(b) inventory: Aluminum hydroxide

CI#: Not available.

Synonym: Aluminum Hydroxide Powder Reagent; Aluminum Trihyroxide

Chemical Name: Aluminum Hydroxide Powder

Chemical Formula: Al(OH0)3

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online:

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Aluminum hydroxide	21645-51-2	100

Toxicological Data on Ingredients: Not applicable.

Section 3: Hazards Identification

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

Skin Contact: Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops.

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: Non-flammable.

Auto-Ignition Temperature: Not applicable.

Flash Points: Not applicable.

Flammable Limits: Not applicable.

Products of Combustion: Not available.

Fire Hazards in Presence of Various Substances: Not applicable.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions: Not applicable.

Special Remarks on Fire Hazards:
A mixture of aluminum hydroxide and bismuth, coprecipated and reduced by hydrogen @ 170 to 210 C is spontaneouly flammable in air at ambient temperature.

Special Remarks on Explosion Hazards: Not available.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

Section 7: Handling and Storage

Precautions: Do not breathe dust. Keep away from incompatibles such as acids, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 24°C (75.2°F).

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:
TWA: 3 (mg/m3) from ACGIH (TLV) [United States] Inhalation Respirable. TWA: 10 (mg/m3) from ACGIH (TLV) [United States] Inhalation Total. Consult local authorities for acceptable exposure limits.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid. (crystalline powder.)

Odor: Odorless.

Taste: Not available.

Molecular Weight: 78 g/mole

Color: White. Off-white.

pH (1% soln/water): Not applicable.

Boiling Point: Not available.

Melting Point: 300°C (572°F)

Critical Temperature: Not available.

Specific Gravity: 2.42 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: Not available.

Solubility:
Insoluble in cold water. Insoluble in alcohol. Soluble in Hydrochloric acid, Sulfuric acid, alkaline aqueous solutions, in strong acids in the presence of water.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Incompatible materials

Incompatibility with various substances: Reactive with acids, alkalis.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Forms gels on prolonged contact with water; absorbs acids, carbon dioxide. When exposed to heat aluminum trihydroxide composes forming aluminum oxide and water vapor beginning at 300 C (572 F). Aluminum trihydroxide reacts vigorously with strong acids, and will dissolve in caustic solutions.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals:
LD50: Not available. LC50: Not available.

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: Not available.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects: May cauese mild skin, eye and upper respiratory tract irritaiton. Ingestion: May cause gastrointestinal tract irritation: May affect bones (osteomalacia), metabolism, blood, behavior (muscle contraction, spasticity, change in motor activity), liver.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: Aluminum hydroxide

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):
This product is not classified according to the EU regulations. Not applicable.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 0

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 0

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Safety glasses.

Section 16: Other Information

References: Not available.

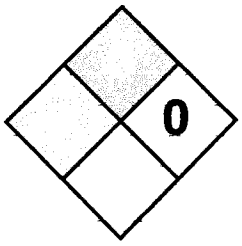
Other Special Considerations: Not available.

Created: 10/09/2005 03:40 PM

Last Updated: 05/21/2013 12:00 PM

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall ScienceLab.com be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if ScienceLab.com has been advised of the possibility of such damages.

Science
Chemicals & Laboratory Equipment



Reactivity	0
Personal Protection	E

Material Safety Data Sheet
Aluminum potassium sulfate MSDS

Section 1: Chemical Product and Company Identification

Product Name: Aluminum potassium sulfate

Catalog Codes: SLA2470, SLA3973, SLA1627, SLA3133, SLA4636

CAS#: 7784-24-9

RTECS: WS5690000

TSCA: TSCA 8(b) inventory: No products were found.

CI#: Not available.

Synonym: Potassium alum; Aluminum Potassium Sulfate Dodecahydrate; Sulfuric Acid, Aluminum Potassium Salt (2:1:1), Dodecahydrate.

Chemical Name: Aluminum Potassium Sulfate

Chemical Formula: AlK(SO4)2.12H2O

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online:

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Aluminum potassium sulfate	7784-24-9	100

Toxicological Data on Ingredients: Aluminum potassium sulfate LD50: Not available. LC50: Not available.

Section 3: Hazards Identification

Potential Acute Health Effects: Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention.

Skin Contact:
In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact:
Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek medical attention.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: Non-flammable.

Auto-Ignition Temperature: Not applicable.

Flash Points: Not applicable.

Flammable Limits: Not applicable.

Products of Combustion: Not available.

Fire Hazards in Presence of Various Substances: Not applicable.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions: Not applicable.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

Section 6: Accidental Release Measures

Small Spill:
Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:
Do not breathe dust. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If you feel unwell, seek medical attention and show the label when possible. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents, metals, alkalis.

Storage: Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 25°C (77°F).

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection:
Splash goggles. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Solid.

Odor: Odorless.

Taste: Not available.

Molecular Weight: 474.38 g/mole

Color: White.

pH (1% soln/water): Not available.

Boiling Point: Not available.

Melting Point: 92.5°C (198.5°F)

Critical Temperature: Not available.

Specific Gravity: 1.757 (Water = 1)

Vapor Pressure: Not applicable.

Vapor Density: 16.4 (Air = 1)

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water.

Solubility: Partially soluble in cold water.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Incompatible Materials

Incompatibility with various substances: Reactive with oxidizing agents, metals, alkalis.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity: Incompatible with strong oxidizing agents, bases, and metals (steel, aluminum, copper, zinc.)

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals:
LD50: Not available. LC50: Not available.

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans: Hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals: Not available.

Special Remarks on Chronic Effects on Humans: May cause adverse reproductive effects (fetotoxicity) based on animal data.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects: Skin: May cause skin irritation particularly on abraded skin. Eyes: Dust may cause eye irritation. Inhalation: Dust may cause irritation of the respiratory tract and mucous membranes. Ingestion: May cause gastrointestinal tract irritation. Symptoms may range from mild abdominal cramping and nausea, to severe vomiting and hemorrhagic gastroenteritis depending on the concentration and amount ingested. Ingestion may also produce a feeling of dryness and puckering of the mucous membranes of the mouth and throat. May also affect behavior The toxicological properties of this product have not been fully investigated.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The product itself and its products of degradation are not toxic.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: No products were found.

Other Regulations: Not available.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):
R36/38- Irritating to eyes and skin. S2- Keep out of the reach of children. S46- If swallowed, seek medical advice immediately and show this container or label.

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 0

Reactivity: 0

Personal Protection: E

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 0

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Splash goggles.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 03:40 PM

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Aluminum in the central nervous system (CNS): toxicity in humans and animals, vaccine adjuvants, and autoimmunity.

Review article

Shaw CA, et al. Immunol Res. 2013.

Abstract

We have examined the neurotoxicity of aluminum in humans and animals under various conditions, following different routes of administration, and provide an overview of the various associated disease states. The literature demonstrates clearly negative impacts of aluminum on the nervous system across the age span. In adults, aluminum exposure can lead to apparently age-related neurological deficits resembling Alzheimer's and has been linked to this disease and to the Guamanian variant, ALS-PDC. Similar outcomes have been found in animal models. In addition, injection of aluminum adjuvants in an attempt to model Gulf War syndrome and associated neurological deficits leads to an ALS phenotype in young male mice. In young children, a highly significant correlation exists between the number of pediatric aluminum-adjuvanted vaccines administered and the rate of autism spectrum disorders. Many of the features of aluminum-induced neurotoxicity may arise, in part, from autoimmune reactions, as part of the ASIA syndrome.

PMID: 23609067 [PubMed - indexed for MEDLINE]

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Entropy **2012**, *14*(11), 2227-2253 (tel:2227-2253); doi:10.3390/e14112227 (http://dx.doi.org/10.3390/e14112227) Open Access Article

Empirical Data Confirm Autism Symptoms Related to Aluminum and Acetaminophen Exposure†

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† *Expression of Concern Note* added on 17 September 2015 by the Editors: The editors of the journal have been alerted to concerns over potential bias in opinions and bias in the choice of citation sources used in this article. We note that the authors stand by the content as published. Since the nature of the claims against the paper concern speculation and opinion, and not fraud or academic misconduct, the editors would like to make readers aware that the approach to collating literature citations for this article was likely not systematic and may not reflect the spectrum of opinions on the issues covered by the article. Please refer to our policy regarding possibly controversial articles.

* Author to whom correspondence should be addressed.

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(This article belongs to the Special Issue Biosemiotic Entropy: Disorder, Disease, and Mortality (/journal/entropy/special_issues/biosemiotic_entropy))

Abstract

Autism is a condition characterized by impaired cognitive and social skills, associated with compromised immune function. The incidence is alarmingly on the rise, and environmental factors are increasingly suspected to play a role. This paper investigates word frequency patterns in the U.S. CDC Vaccine Adverse Events Reporting System (VAERS) database. Our results provide strong evidence supporting a link between autism and the aluminum in

vaccines. A literature review showing toxicity of aluminum in human physiology offers further support. Mentions of autism in VAERS increased steadily at the end of the last century, during a period when mercury was being phased out, while aluminum adjuvant burden was being increased. Using standard log-likelihood ratio techniques, we identify several signs and symptoms that are significantly more prevalent in vaccine reports after 2000, including cellulitis, seizure, depression, fatigue, pain and death, which are also significantly associated with aluminum-containing vaccines. We propose that children with the autism diagnosis are especially vulnerable to toxic metals such as aluminum and mercury due to insufficient serum sulfate and glutathione. A strong correlation between autism and the MMR (Measles, Mumps, Rubella) vaccine is also observed, which may be partially explained via an increased sensitivity to acetaminophen administered to control fever.

Keywords: autism (/search?q=autism); vaccines (/search?q=vaccines); MMR (/search?q=MMR); HEP-B (/search?q=HEP-B); glutathione (/search?q=glutathione); sulfate (/search?q=sulfate); cholesterol sulfate (/search?q=cholesterol sulfate); aluminum (/search?q=aluminum); mercury (/search?q=mercury); acetaminophen (/search?q=acetaminophen)

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Seneff, S.; Davidson, R.M.; Liu, J. Empirical Data Confirm Autism Symptoms Related to Aluminum and Acetaminophen Exposure. *Entropy* **2012**, *14*, 2227-2253 (tel:2227-2253).

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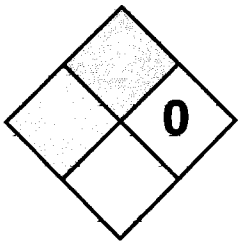

Reactivity	0
Personal Protection	G

Material Safety Data Sheet
Formaldehyde 37% solution MSDS

Section 1: Chemical Product and Company Identification

Product Name: Formaldehyde 37% solution

Catalog Codes: SLF1426

CAS#: Mixture.

RTECS: LP8925000

TSCA: TSCA 8(b) inventory: Formaldehyde; Methyl alcohol; Water

CI#: Not applicable.

Synonym: Formalin

Chemical Name: Formaldehyde

Chemical Formula: HCHO

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online:

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Formaldehyde	50-00-0	36.5-38
Methyl alcohol	67-56-1	10-15
Water	7732-18-5	47-53.5

Toxicological Data on Ingredients: Formaldehyde: ORAL (LD50): Acute: 100 mg/kg [Rat]. 42 mg/kg [Mouse]. 260 mg/kg [Guinea pig]. MIST (LC50): Acute: 454000 mg/m 4 hours [Mouse]. Methyl alcohol: ORAL (LD50): Acute: 5628 mg/kg [Rat]. DERMAL (LD50): Acute: 15800 mg/kg [Rabbit]. VAPOR (LC50): Acute: 64000 ppm 4 hours [Rat].

Section 3: Hazards Identification

Potential Acute Health Effects:
Very hazardous in case of eye contact (irritant), of ingestion, . Hazardous in case of skin contact (irritant, sensitizer, permeator), of eye contact (corrosive). Slightly hazardous in case of skin contact (corrosive). Severe over-exposure can result in death. Inflammation of the eye is characterized by redness, watering, and itching.

Potential Chronic Health Effects:
Hazardous in case of skin contact (sensitizer). CARCINOGENIC EFFECTS: Classified A2 (Suspected for human.) by ACGIH, 2A (Probable for human.) by IARC [Formaldehyde]. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. [Formaldehyde]. Mutagenic for bacteria and/or yeast. [Formaldehyde]. Mutagenic for mammalian somatic cells. [Methyl

alcohol]. Mutagenic for bacteria and/or yeast. [Methyl alcohol]. TERATOGENIC EFFECTS: Classified POSSIBLE for human [Methyl alcohol]. DEVELOPMENTAL TOXICITY: Not available The substance may be toxic to kidneys, liver, skin, central nervous system (CNS). Repeated or prolonged exposure to the substance can produce target organs damage. Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Cold water may be used. Get medical attention immediately.

Skin Contact:
In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact:
Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek immediate medical attention.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

Serious Inhalation:
Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. WARNING: It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled material is toxic, infectious or corrosive. Seek immediate medical attention.

Ingestion:
If swallowed, do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention immediately.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: Flammable.

Auto-Ignition Temperature: 430°C (806°F)

Flash Points: CLOSED CUP: 50°C (122°F). OPEN CUP: 60°C (140°F).

Flammable Limits: The greatest known range is LOWER: 6% UPPER: 36.5% (Methyl alcohol)

Products of Combustion: These products are carbon oxides (CO, CO2).

Fire Hazards in Presence of Various Substances:
Flammable in presence of open flames and sparks, of heat. Non-flammable in presence of shocks, of oxidizing materials, of reducing materials, of combustible materials, of organic materials, of metals, of acids, of alkalis.

Explosion Hazards in Presence of Various Substances: Non-explosive in presence of open flames and sparks, of shocks.

Fire Fighting Media and Instructions:
Flammable liquid, soluble or dispersed in water. SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use alcohol foam, water spray or fog. Cool containing vessels with water jet in order to prevent pressure build-up, autoignition or explosion.

Special Remarks on Fire Hazards:
Explosive in the form of vapor when exposed to heat or flame. Vapor may travel considerable distance to source of ignition and flash back. When heated to decomposition, it emits acrid smoke and irritating fumes. CAUTION: MAY BURN WITH NEAR INVISIBLE FLAME (Methyl alcohol)

Special Remarks on Explosion Hazards:
Reaction with peroxide, nitrogen dioxide, and permformic acid can cause an explosion. (Formaldehyde gas)

Section 6: Accidental Release Measures

Small Spill:
Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. If necessary: Neutralize the residue with a dilute solution of sodium carbonate.

Large Spill:
Flammable liquid. Poisonous liquid. Keep away from heat. Keep away from sources of ignition. Stop leak if without risk. Absorb with DRY earth, sand or other non-combustible material. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Call for assistance on disposal. Neutralize the residue with a dilute solution of sodium carbonate. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

Section 7: Handling and Storage

Precautions:
Keep away from heat. Keep away from sources of ignition. Ground all equipment containing material. Do not ingest. Do not breathe gas/fumes/ vapor/spray. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents, reducing agents, acids, alkalis, moisture.

Storage:
Store in a segregated and approved area. Keep container in a cool, well-ventilated area. Keep container tightly closed and sealed until ready for use. Avoid all possible sources of ignition (spark or flame).

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal Protection:
Safety glasses. Lab coat. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Gloves (impervious).

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Vapor respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:
Formaldehyde gas STEL: 0.3 (ppm) from ACGIH (TLV) [United States] STEL: 0.37 (mg/m3) from ACGIH (TLV) [United States] TWA: 0.75 STEL: 2 (ppm) from OSHA (PEL) [United States] TWA: 2 STEL: 2 (ppm) [United Kingdom (UK)] TWA: 2.5 STEL: 2.5 (mg/m3) [United Kingdom (UK)] Methyl alcohol TWA: 200 from OSHA (PEL) [United States] TWA: 200 STEL: 250 (ppm) from ACGIH (TLV) [United States] [1999] STEL: 250 from NIOSH [United States] TWA: 200 STEL: 250 (ppm) from NIOSH SKIN TWA: 200 STEL: 250 (ppm) [Canada] Consult local authorities for acceptable exposure limits.

Section 9: Physical and Chemical Properties

Physical state and appearance: Liquid.

Odor: Pungent. Suffocating. (Strong.)

Taste: Not available.

Molecular Weight: 30.02

Color: Clear Colorless.

pH (1% soln/water): 3 [Acidic.] pH of the solution as is.

Boiling Point: 98°C (208.4°F)

Melting Point: -15°C (5°F)

Critical Temperature: The lowest known value is 240°C (464°F) (Methyl alcohol).

Specific Gravity: 1.08 (Water = 1)

Vapor Pressure: 2.4 kPa (@ 20°C)

Vapor Density: 1.03 (Air = 1)

Volatility: 100% (w/w).

Odor Threshold: The highest known value is 100 ppm (Methyl alcohol)

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Non-ionic.

Dispersion Properties: See solubility in water, diethyl ether, acetone.

Solubility:
Easily soluble in cold water, hot water. Soluble in diethyl ether, acetone, alcohol

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Heat, ignition sources (flames, sparks), incompatible materials

Incompatibility with various substances:
Reactive with oxidizing agents, reducing agents, acids, alkalis. Slightly reactive to reactive with metals.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Also incompatible with urea, phenol, isocyanates, anhydrides, amines, AZO compounds, carbonyl compounds, oxides(e.g. nitrogen dioxide), performic acid, dithiocarbmates, or peroxides. Polymerization can be inhibited by the addition of methanol or stabilizers such as hydorxypropyl methyl cellulose, methyl ethyl celluloses, or isophthalobisguanamine.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Absorbed through skin. Dermal contact. Eye contact. Inhalation.

Toxicity to Animals:
Acute oral toxicity (LD50): 42 mg/kg [Mouse]. (Formaldehyde) Acute dermal toxicity (LD50): 15800 mg/kg [Rabbit]. (Methyl alcohol). Acute toxicity of the mist(LC50): 454000 mg/m 4 hours [Mouse]. (Formaldehyde) 3

Chronic Effects on Humans:
CARCINOGENIC EFFECTS: Classified A2 (Suspected for human.) by ACGIH, 2A (Probable for human.) by IARC [Formaldehyde]. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. [Formaldehyde]. Mutagenic for bacteria and/or yeast. [Formaldehyde]. Mutagenic for mammalian somatic cells. [Methyl alcohol]. Mutagenic for bacteria and/or yeast. [Methyl alcohol]. TERATOGENIC EFFECTS: Classified POSSIBLE for human [Methyl alcohol]. DEVELOPMENTAL TOXICITY: Not available May cause damage to the following organs: kidneys, liver, central nervous system (CNS).

Other Toxic Effects on Humans:
Very hazardous in case of ingestion, . Hazardous in case of skin contact (irritant, sensitizer, permeator), of eye contact (corrosive), of inhalation (lung corrosive). Slightly hazardous in case of skin contact (corrosive).

Special Remarks on Toxicity to Animals:
Formaldehyde: LD50 [Rabbit] - Route: Skin; Dose: 270 ul/kg

Special Remarks on Chronic Effects on Humans:
Exposure to Formaldehyde and Methanol may affect genetic material (mutagenic). Exposure to Formaldehyde and Methanol may cause adverse reproductive effects and birth defects(teratogenic). Adverse reproductive effects of Formaldehyde as well as Methanol are primarily based on animal studies. Very few human studies have been done on the adverse reproductive effects from exposure to Formaldehyde. Studies produced a weak association (limited evidence) between advese human female reproductive effects and occupational exposure. Furthermore, no human data could be found on adverse reproductive effects from occupational exposure to Methanol. Exposure to Formaldehyde may cause cancer.

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects: Skin: Corrosive. Causes skin irritation which may range from mild to severe with possible burns depending on the extent of exposure and concentration of solution. Other symptoms may include brownish discoloration of the skin, urticaria, and pustulovesicffular eruptions. May be absorbed through skin with symptoms paralleling those of ingestion. Eyes: Corrosive. Contact with liquid causes severe eye irritation and burns. It may cause irreversible eye damage (severe corneal Solutions containing low formaldehyde concentrations may produce transient discomfort and irritation. Inhalation: Causes irritiitation of the respiratory tract (nose, throat, airways). Symptoms may include dry and sore mouth and throat, thirst, and sleep disturbances, difficulty breathing, shortness of breath, coughing, sneezing, wheezing rhinitis, chest tightness, pulmonary edema, bronchitis, tracheitis, laryngospasm, pneumonia, palpitations. It may also affect metabolism weight loss, metabolic acidosis), behavior/central nervous system (excitement, central nervous system depression, somnolence, convulsions, stupor, aggression, headache, weakness, dizziness, drowsiness, coma), peripheral nervous system, and blood. Ingestion: Harmful if swallowed. May be fatal. Causes gastrointestinal irritation with nausea, vomiting (possibly with blood), diarrhea, severe pain in mouth, throat and stomach, and possible corrosive injury to the gastrointestinal mucosa/ulceration or bleeding from stomach. May also affect the liver(jaundice), urinary system/kidneys (difficulty urinating, albuminuria, hematuria, anuria), blood, endocrine system, respiration (respiratory obstruction, pulmonary edema, bronchiolar obstruction), cardiovascular system (hypotension), metabolism (metabolic acidosis), eyes (retinal changes, visual field changes), and behavior/central nervous system (symptoms similar to those for inhalation). Contains Methanol which may cause blindness if swallowed. Chronic Potential Health Effects: Skin: Prolonged or repeated exposure may cause contact dermatits both irritant and allergic. It may also cause skin discoloration. Inhalation: Although there is no clear evidence, prolonged or repeated exposure may induce allergic asthma. Other effects are similar to that of acute exposure. Ingestion: Prolonged or repeated ingestion may cause gastrointestinal tract irritation and ulceration or bleeding from the stomach. Other effects may be similar to that of acute ingestion.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are less toxic than the product itself.

Special Remarks on the Products of Biodegradation:
Methanol in water is rapidly biodegraded and volatilized. Aquatic hydrolysis, oxidation, photolysis, adsorption to sediment, and bioconcentration are not significant fate processes. The half-life of methanol in surfact water ranges from 24 hrs. to 168 hrs. Based on its vapor pressure, methanol exists almost entirely in the vapor phase in the ambient atmosphere. It is degraded by reaction with photochemically produced hydroxyl radicals and has an estimated half-life of 17.8 days. Methanol is physically removed from air by rain due to its solubility. Methanol can react with NO2 in pollulted to form methyl nitrate. The half-life of methanol in air ranges from 71 hrs. (3 days) to 713 hrs. (29.7 days) based on photooxidation half-life in air. (Methyl alcohol)

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification:
CLASS 3: Flammable liquid. Class 8: Corrosive material

Identification: : Formaldehyde Solution, flammable (Methyl alcohol) UNNA: 1198 PG: III

Special Provisions for Transport: Not available.

Section 15: Other Regulatory Information

Federal and State Regulations:
California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute: Formaldehyde California prop. 65 (no significant risk level): Formaldehyde: 0.04 mg/day (inhalation) California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer which would require a warning under the statute: Formaldehyde Solution Connecticut hazardous material survey.: Formaldehyde; Methyl alcohol Illinois toxic substances disclosure to employee act: Formaldehyde; Methyl alcohol Illinois chemical safety act: Formaldehyde; Methyl alcohol New York release reporting list: Formaldehyde; Methyl alcohol Rhode Island RTK hazardous substances: Formaldehyde; Methyl alcohol Pennsylvania RTK: Formaldehyde; Methyl alcohol Minnesota: Formaldehyde gas; Methyl alcohol Massachusetts RTK: Formaldehyde; Methyl alcohol Massachusetts spill list: Formaldehyde; Methyl alcohol New Jersey: Formaldehyde; Methyl alcohol New Jersey spill list: Formaldehyde; Methyl alcohol Louisiana RTK reporting list: Formaldehyde Louisiana spill reporting: Formaldehyde; Methyl alcohol California Director's List of Hazardous Substances: Formaldehyde; Methyl alcohol TSCA 8(b) inventory: Formaldehyde gas; Methyl alcohol; Water TSCA 4(f) priority risk review: Formaldehyde, Reagnt, ACS SARA 302/304/311/312 extremely hazardous substances: Formaldehyde SARA 313 toxic chemical notification and release reporting: Formaldehyde; Methyl alcohol CERCLA: Hazardous substances.: Formaldehyde: 100 lbs. (45.36 kg); Methyl alcohol: 5000 lbs. (2268 kg);

Other Regulations:
OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada):
CLASS B-3: Combustible liquid with a flash point between 37.8°C (100°F) and 93.3°C (200°F). CLASS D-1A: Material causing immediate and serious toxic effects (VERY TOXIC). CLASS D-2A: Material causing other toxic effects (VERY TOXIC).

DSCL (EEC):

HMIS (U.S.A.):

Health Hazard: 3

Fire Hazard: 2

Reactivity: 0

Personal Protection: G

National Fire Protection Association (U.S.A.):

Health: 3

Flammability: 2

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves (impervious). Lab coat. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/09/2005 05:35 PM

Last Updated: 05/21/2013 12:00 PM

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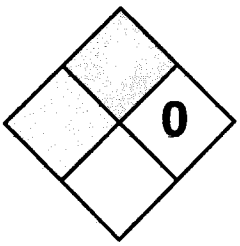

Reactivity	0
Personal Protection	H

Material Safety Data Sheet
Glutaraldehyde Solution, 50% MSDS

Section 1: Chemical Product and Company Identification

Product Name: Glutaraldehyde Solution, 50%

Catalog Codes: SLG2182

CAS#: Mixture.

RTECS: MA2450000

TSCA: TSCA 8(b) inventory: Glutaraldehyde; Water

CI#: Not available.

Synonym: Glutaraldehyde Solution, 50%; Petanedial; Glutaric Dialdehyde, 50% in water

Chemical Name: Not applicable.

Chemical Formula: C5-H8-O2

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online:

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
Glutaraldehyde	111-30-8	50
Water	7732-18-5	50

Toxicological Data on Ingredients: Glutaraldehyde: ORAL (LD50): Acute: 134 mg/kg [Rat]. 100 mg/kg [Mouse]. DERMAL (LD50): Acute: >2500 mg/kg [Rat]. >5840 mg/kg [Mouse]. VAPOR (LC50): Acute: 480 mg/m 4 hours [Rat].

Section 3: Hazards Identification

Potential Acute Health Effects:
Hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation (lung irritant, lung sensitizer). Slightly hazardous in case of skin contact (sensitizer, permeator). Liquid or spray mist may produce tissue damage particularly on mucous membranes of eyes, mouth and respiratory tract. Skin contact may produce burns. Inhalation of the spray mist may produce severe irritation of respiratory tract, characterized by coughing, choking, or shortness of breath. Severe over-exposure can result in death.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Classified A4 (Not classifiable for human or animal.) by ACGIH [Glutaraldehyde]. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. [Glutaraldehyde]. Mutagenic for bacteria and/or yeast. [Glutaraldehyde]. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female,

Reproductive system/toxin/male [SUSPECTED] [Glutaraldehyde]. The substance may be toxic to blood, the reproductive system, liver, mucous membranes, spleen, central nervous system (CNS), Urinary System. Repeated or prolonged exposure to the substance can produce target organs damage. Repeated or prolonged contact with spray mist may produce chronic eye irritation and severe skin irritation. Repeated or prolonged exposure to spray mist may produce respiratory tract irritation leading to frequent attacks of bronchial infection. Repeated exposure to a highly toxic material may produce general deterioration of health by an accumulation in one or many human organs.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention immediately.

Skin Contact:
In case of contact, immediately flush skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Cold water may be used.Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

Serious Skin Contact:
Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial cream. Seek immediate medical attention.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

Serious Inhalation:
Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. WARNING: It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled material is toxic, infectious or corrosive. Seek immediate medical attention.

Ingestion:
If swallowed, do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention immediately.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: Non-flammable.

Auto-Ignition Temperature: Not applicable.

Flash Points: Not applicable.

Flammable Limits: Not applicable.

Products of Combustion: When heated to decomposition, it emits acrid smoke and fumes.

Fire Hazards in Presence of Various Substances: Not applicable.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions: Not applicable.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

Section 6: Accidental Release Measures

Small Spill:
Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container.

Large Spill:
Poisonous liquid. Stop leak if without risk. Do not get water inside container. Do not touch spilled material. Use water spray to reduce vapors. Prevent entry into sewers, basements or confined areas; dike if needed. Call for assistance on disposal. Be careful that the product is not present at a concentration level above TLV. Check TLV on the MSDS and with local authorities.

Section 7: Handling and Storage

Precautions:
Keep locked up.. Do not ingest. Do not breathe gas/fumes/ vapor/spray. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes. Keep away from incompatibles such as oxidizing agents, alkalis.

Storage:
Light Sensitive. Refrigerate. Store in light-resistant containers. Keep containers tightly closed. Keep containers in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal Protection:
Splash goggles. Lab coat. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Gloves.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Vapor respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits:
Glutaraldehyde TWA: 0.2 (ppm) [Australia] TWA: 0.82 (mg/m3) [Australia] TWA: 0.25 CEIL: 0.2 (ppm) from NIOSH CEIL: 0.2 (ppm) from OSHA (PEL) [United States] TWA: 0.05 STEL: 0.05 (ppm) [United Kingdom (UK)] Consult local authorities for acceptable exposure limits.

Section 9: Physical and Chemical Properties

Physical state and appearance: Liquid.

Odor: Pungent. Like rotten apples

Taste: Not available.

Molecular Weight: Not applicable.

Color: Colorless to light yellow.

pH (1% soln/water): Not available

Boiling Point: 101°C (213.8°F)

Melting Point: -6°C (21.2°F) - -7

Critical Temperature: Not available.

Specific Gravity: 1.062 - 1.124 (Water = 1)

Vapor Pressure: 0 kPa (@ 20°C)

Vapor Density: 1.05 (Air = 1)

Volatility: Not available.

Odor Threshold: 0.04 ppm

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water, diethyl ether.

Solubility:
Easily soluble in cold water. Soluble in diethyl ether. Soluble in benzene, ethanol and other organic solvents.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Conditions to avoid: exposure to air, and excess heat. (Glutaraldehyde)

Incompatibility with various substances: Reactive with oxidizing agents, alkalis.

Corrosivity: Non-corrosive in presence of glass.

Special Remarks on Reactivity:
Also incompatible with amines, ammonia and other caustics (e.g. ammonium hydroxide, calcium hydroxide, potassium hydroxide, and sodium hydroxide). Alkaline solutions react with alcohol, ketones, amines, hydrazines and proteins. (Glutaraldehyde)

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Absorbed through skin. Eye contact. Inhalation. Ingestion.

Toxicity to Animals:
WARNING: THE LC50 VALUES HEREUNDER ARE ESTIMATED ON THE BASIS OF A 4-HOUR EXPOSURE. Acute oral toxicity (LD50): 100 mg/kg [Mouse]. Acute dermal toxicity (LD50): >2500 mg/kg [Rat]. Acute toxicity of the vapor (LC50): 480 mg/m 4 hours [Rat]. 3

Chronic Effects on Humans:
CARCINOGENIC EFFECTS: Classified A4 (Not classifiable for human or animal.) by ACGIH [Glutaraldehyde]. MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. [Glutaraldehyde]. Mutagenic for bacteria and/or yeast. [Glutaraldehyde]. DEVELOPMENTAL TOXICITY: Classified Reproductive system/toxin/female, Reproductive system/toxin/male [SUSPECTED] [Glutaraldehyde]. Contains material which may cause damage to the following organs: blood, the reproductive system, liver, mucous membranes, spleen, central nervous system (CNS), Urinary system.

Other Toxic Effects on Humans:
Hazardous in case of skin contact (irritant), of ingestion, of inhalation (lung irritant, lung sensitizer). Slightly hazardous in case of skin contact (sensitizer, permeator).

Special Remarks on Toxicity to Animals:
Acute Toxicity: LD50 [Rabbit] dermal: Dose: 560 ul/kg. Reproductive Effects: TDL [male Rat] oral: Dose: 875 mg/kg given 35 days prior to mating TDL [female rat] oral: Dose 4370 mg/kg given 35 days prior to mating. (Glutaraldehyde)

Special Remarks on Chronic Effects on Humans:

May affect genetic material. Reproductive Effects in animals (rat): Paternal effects: testes, epididymis, sperm duct, prostate, seminal vesicle, Cowper's gland, accessory. Maternal effects: uterus, cervix, vagina (Glutaraldehyde)

Special Remarks on other Toxic Effects on Humans:
Potential Health Effects: Eye: Causes severe eye irritation. May cause eye injury or chemical conjunctivitis. Skin: Causes moderate to severe skin irritation. It may be absorbed through the skin, although poorly. May cause allergic contact dermatitis with itching and skin rash. May cause staining of the skin and nails to a brown or golden brown color. Ingestion: Harmful if swallowed. May cause severe irritation of the digestive tract with burning sensation in the chest, abdominal pain, cramping, vomiting, diarrhea (perhaps bloody diarrhea), vascular collapse, and coma. May also affect liver (increased liver enzymes, liver damage), spleen, blood (normocytic anemia), metabolism (weight loss), behavior (somnolence, excitement, dizziness, lethargy, ataxia, seizures), metabolism (weight loss), urinary system (abnormal reneal function, anuria) Inhalation: Harmful if inhaled. Can cause respiratory tract irritation and sudden headaches, nausea, and

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are less toxic than the product itself.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: CLASS 6.1: Poisonous material.

Identification: : Toxic Liquid, Organic, n.o.s (Glutaraldehyde solution) UNNA: 2810 PG: III

Special Provisions for Transport: Not available.

Section 15: Other Regulatory Information

Federal and State Regulations:
Pennsylvania RTK: Glutaraldehyde Florida: Glutaraldehyde Massachusetts RTK: Glutaraldehyde New Jersey: Glutaraldehyde California Director's list of Hazardous Substances: Glutaraldehyde TSCA 8(b) inventory: Glutaraldehyde; Water TSCA 8(a) PAIR: Glutaraldehyde TSCA 8(d) H and S data reporting: Glutaraldehyde: 9/30/91 to 9/30/01

Other Regulations:
OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada):
CLASS D-1A: Material causing immediate and serious toxic effects (VERY TOXIC). CLASS D-2B: Material causing other toxic effects (TOXIC). CLASS E: Corrosive liquid.

DSCL (EEC):

HMIS (U.S.A.):

Health Hazard: 2

Fire Hazard: 0

Reactivity: 0

Personal Protection: h

National Fire Protection Association (U.S.A.):

Health: 2

Flammability: 0

Reactivity: 0

Specific hazard:

Protective Equipment:
Gloves. Lab coat. Vapor respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Splash goggles.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

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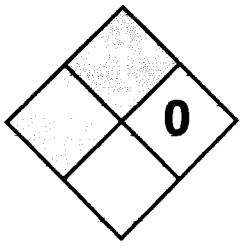

Reactivity	0
Personal Protection	A

Material Safety Data Sheet
POLYSORBATE 80 MSDS

Section 1: Chemical Product and Company Identification

Product Name: POLYSORBATE 80

Catalog Codes: SLP4093

CAS#: 9005-65-6

RTECS: WG2935000

TSCA: TSCA 8(b) inventory: POLYSORBATE 80

CI#: Not available.

Synonym: TWEEN 80; Polyoxyethylene 20 sorbitan monooleate; Polyethylene oxide sorbitan mono-oleate; Polyoxyethylene sorbitan monooleate; Polyoxyethylene sorbitan oleate; Sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivatives; Sorethytan (20) monooleate

Chemical Name: Sorbitan, monooleate polyoxyethylene deriv.

Chemical Formula: Not available.

Contact Information:

Sciencelab.com, Inc.
14025 Smith Rd.
Houston, Texas 77396

US Sales: **1-800-901-7247**
International Sales: **1-281-441-4400**

Order Online:

CHEMTREC (24HR Emergency Telephone), call: 1-800-424-9300

International CHEMTREC, call: 1-703-527-3887

For non-emergency assistance, call: 1-281-441-4400

Section 2: Composition and Information on Ingredients

Composition:

Name	CAS #	% by Weight
POLYSORBATE 80	9005-65-6	100

Toxicological Data on Ingredients: Not applicable.

Section 3: Hazards Identification

Potential Acute Health Effects: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects:
CARCINOGENIC EFFECTS: Not available. MUTAGENIC EFFECTS: Not available. TERATOGENIC EFFECTS: Not available. DEVELOPMENTAL TOXICITY: Not available. Repeated or prolonged exposure is not known to aggravate medical condition.

Section 4: First Aid Measures

Eye Contact:
Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.

Skin Contact:
Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.

Serious Skin Contact: Not available.

Inhalation:
If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Serious Inhalation: Not available.

Ingestion:
Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.

Serious Ingestion: Not available.

Section 5: Fire and Explosion Data

Flammability of the Product: May be combustible at high temperature.

Auto-Ignition Temperature: Not available.

Flash Points: CLOSED CUP: >148.89°C (300°F).

Flammable Limits: Not available.

Products of Combustion: Not available.

Fire Hazards in Presence of Various Substances: Slightly flammable to flammable in presence of heat.

Explosion Hazards in Presence of Various Substances:
Risks of explosion of the product in presence of mechanical impact: Not available. Risks of explosion of the product in presence of static discharge: Not available.

Fire Fighting Media and Instructions:
SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or foam. Do not use water jet.

Special Remarks on Fire Hazards: Not available.

Special Remarks on Explosion Hazards: Not available.

Section 6: Accidental Release Measures

Small Spill:
Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:
Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions:

Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe gas/fumes/ vapor/spray. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents.

Storage:
Keep container tightly closed. Keep container in a cool, well-ventilated area. Do not store above 32.2°C (90°F). Preferably store at temperatures between 50 deg F to 90 deg. F.

Section 8: Exposure Controls/Personal Protection

Engineering Controls:
Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal Protection: Safety glasses. Lab coat.

Personal Protection in Case of a Large Spill:
Splash goggles. Full suit. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9: Physical and Chemical Properties

Physical state and appearance: Liquid. (Oily liquid.)

Odor: fatty (Slight.)

Taste: Not available.

Molecular Weight: Not available.

Color: Clear Amber. Yellow.

pH (1% soln/water): 7 [Neutral.]

Boiling Point: >100°C (212°F)

Melting Point: -20.556°C (-5°F)

Critical Temperature: Not available.

Specific Gravity: 1.06 - 1.10 (Water = 1)

Vapor Pressure: <0.1 kPa (@ 20°C)

Vapor Density: Not available.

Volatility: Not available.

Odor Threshold: Not available.

Water/Oil Dist. Coeff.: Not available.

Ionicity (in Water): Not available.

Dispersion Properties: See solubility in water, methanol.

Solubility:
Easily soluble in cold water, hot water. Soluble in methanol. Soluble in Toluene, alcohol, cottonseed oil, corn oil, Ethyl Acetate. Insoluble in mineral oil.

Section 10: Stability and Reactivity Data

Stability: The product is stable.

Instability Temperature: Not available.

Conditions of Instability: Excess heat, incompatible materials

Incompatibility with various substances: Reactive with oxidizing agents.

Corrosivity: Non-corrosive in presence of glass, of stainless steel(304), of stainless steel(316).

Special Remarks on Reactivity: Not available.

Special Remarks on Corrosivity: Not available.

Polymerization: Will not occur.

Section 11: Toxicological Information

Routes of Entry: Inhalation. Ingestion.

Toxicity to Animals: Acute oral toxicity (LD50): 25000 mg/kg [Mouse].

Chronic Effects on Humans: Not available.

Other Toxic Effects on Humans: Slightly hazardous in case of skin contact (irritant), of ingestion, of inhalation.

Special Remarks on Toxicity to Animals:
Lethal Dose/Conc 50% Kill: LD50 [Rat] - Route: Oral; Dose: 34500 ul/kg

Special Remarks on Chronic Effects on Humans:
May cause adverse reproductive effects based on animal test data. No human data found. May cause cancer based on animal test data. No human data found. May affect genetic material (mutagenic)

Special Remarks on other Toxic Effects on Humans:
Acute Potential Health Effects: Skin: No irritation is expected, but it may cause mild/slight irritation in more sensitive individuals. It will probably not be absorbed through the skin. Eyes: It may cause eye irritation. Inhalation: No expected to be a health hazard. No irritation is expected to be associated with the inhalation of this material. No toxic effects are known to be associated with the inhalation of this material. Ingestion: This material is not likely to cause irritation upon ingestion. It is classified as "relatively harmless" by ingestion and considered to be a low ingestion hazard. Ingestion of very large doses may cause abdominal spasms and diarrhea. Animal studies have shown it to cause cardiac changes, changes in behavior (altered sleep time) and weight loss (upon repeated or prolonged ingestion). However, no similar human data has been reported.

Section 12: Ecological Information

Ecotoxicity: Not available.

BOD5 and COD: Not available.

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: Not available.

Special Remarks on the Products of Biodegradation: Not available.

Section 13: Disposal Considerations

Waste Disposal:
Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

Identification: Not applicable.

Special Provisions for Transport: Not applicable.

Section 15: Other Regulatory Information

Federal and State Regulations: TSCA 8(b) inventory: POLYSORBATE 80

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC):
This product is not classified according to the EU regulations. Not applicable.

HMIS (U.S.A.):

Health Hazard: 1

Fire Hazard: 1

Reactivity: 0

Personal Protection: a

National Fire Protection Association (U.S.A.):

Health: 1

Flammability: 1

Reactivity: 0

Specific hazard:

Protective Equipment:
Not applicable. Lab coat. Not applicable. Safety glasses.

Section 16: Other Information

References: Not available.

Other Special Considerations: Not available.

Created: 10/10/2005 11:35 AM

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Tel: (203) 267-6061 Fax: (203) 267-6065
info@naturalsourcing.com

MATERIAL SAFETY DATA SHEET

MSDS

FD & C YELLOW 6 DYE POWDER

1. PRODUCT NAME AND COMPANY IDENTIFICATION

Product Name:	FD & C Yellow 6 Dye Powder
Product Description:	**FD & C Color Additive**
Product Use:	Personal Care Formulations
Company Name:	Natural Sourcing
Company Address:	341 Christian Street, Oxford, CT 06478, USA
Date Issued:	02/06/2014
Emergency Telephone Number:	**Chemtrec Tel: (800) 262-8200**

2. COMPOSITION/INGREDIENT INFORMATION

Chemical Identity:

FD&C Yellow No. 6 CAS No: 0002783-94-0

Amounts specified are typical and do not represent a specification. Remaining components are proprietary, non-hazardous, and/or present at amounts below reportable limits.

3. HAZARDS IDENTIFICATION

Emergency Overview:	See below for product details
Routes of Entry:	• Eyes • Ingestion • Skin Contact • Inhalation
Acute Health Effects:	Solid particles on the eye (powder/dust) may cause pain and be accompanied by irritation. Skin contact is not expected to create acute health effects.
Chronic Health Effects:	None known
Signs/Symptoms of Exposure:	Skin contact may discolor skin due to pigment.
Target Organs:	Eyes, Respiratory tract, Skin
Medical Conditions Aggravated by Exposure:	Pre-existing skin problems may be aggravated by prolonged or repeated contact.
Carcinogenic Status:	The components of this mixture are not known to be listed or regulated by IARC, NTP, OSHA or ACGIH.
Reproductive Effects:	None expected

4. FIRST AID MEASURES

If irritation or other symptoms (as noted above) occur or persist from any route of exposure, remove the affected individual from the area and consult with a physician.

Eyes:	Flush with plenty of water or eye wash solution for a minimum of 5 minutes. Flush longer is there is any indication of residual chemical in the eye. Ensure adequate flushing by separating the eyelids with fingers and rolling the eyes in a circular motion while flushing. Get medical attention if irritation persists.
Skin:	Wash with soap and water- get medical attention if irritation occurs.
Ingestion:	No ingestion effects known. Treat symptomatically.
Inhalation:	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

5. FIRE FIGHTING MEASURES

Flammability of Product:	N/A
Flash Point (Method Used):	Not Applicable
Flammable Limits:	**LEL:** Not Established **UEL:** Not Established
Auto Ignition Temperature:	No information
Hazardous Combustion Products:	Not Available
Conditions Under Which Flammability Could Occur:	Not Available
Fire and Explosive Properties:	This product has not been evaluated for dust explosion potential. Dust suspended in air in critical proportions and in the presence of an ignition source may be ignited by electrical arcs, sparks, welding torches, open flame or other significant heat sources including electrostatic charge. This product is not known to present any fire hazard.
Extinguishing Media:	• Dry Chemical • Carbon Dioxide • Foam • Water **Note:** Water spray can be used to absorb heat and cool and protect surrounding exposed material. Avoid hose streams or any method which will create dust clouds.
Special Firefighting Procedures:	Wear self contained breathing apparatus and complete personal protective equipment when entering confined areas where potential for exposure to vapors or products of combustion exists. Wear SCBA equipped with a full face piece and operated in a pressure-demand mode (or other positive pressure mode) and protective clothing.
Unusual Fire & Explosion Hazards:	None Known

6. ACCIDENTAL RELEASE MEASURES (STEPS FOR SPILLS)

Containment Techniques:	No information
Methods for Cleaning Up:	Wear personal protective clothing and equipment. Using care to avoid dust generation, vacuum or sweep into a closed container for reuse or disposal. Do not sweep or flush spilled product into public sewer, streams or other water systems.
Environmental Protection:	Notify authorities if large amounts of product enters sewer.

7. HANDLING AND STORAGE

Handling

- Wear safety glasses. Avoid contact with eyes.
- Use under well-ventilated conditions.
- Wash thoroughly after handling.
- After repeated or prolonged contact with skin.
- Avoid breathing dust. Avoid routine inhalation of dust of any kind. Exercise care when emptying containers, sweeping, mixing or doing other tasks which can create dust.

Safe Handling:

Although the risk of a dust explosion is low, as a precaution, implement the following safety measures:

- Eliminate ignition sources (sparks, static buildup, excessive heat etc). In general, dust of organic materials is a static charge generator which may be ignited by electrostatic discharge, electrical arcs, sparks, welding torches, cigarettes, open flame, or other significant heat sources. Prevent accumulation of dust (e.g. well-ventilated conditions, promptly vacuuming spills, cleaning overhead horizontal surfaces etc.)

Storage

Requirements for Storage Areas and Containers:	Store in a cool, dry location, in a sealed container in a well ventilated area.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

NOTES:	General threshold value (MAK) for dust: 1.5 mg/m3 (respirable fraction) and 4 mg/m3 (inhalable fraction). As a guideline use the following for inert or nuisance dust (particulates not otherwise classified): -OSHA TWA: 5 mg/m3 respirable fraction and 15 mg/m3 total dust. -ACGIH TWA: 3 mg/m3 respirable fraction and 10 mg/m3 inhalable particulates.
Engineering Controls:	Always provide effective general and, when necessary, local exhaust ventilation to draw spray, aerosol, fume, mist and vapor away from workers to prevent routine inhalation. Ventilation must be adequate to maintain the ambient workplace atmosphere below the exposure limits(s) outlined in the MSDS.
Personal Protection	
Eye:	Eye protection (e.g. goggles) suitable for keeping dust out of the eyes.
Skin/Body:	Lab coats and gloves may be worn.
Respiratory:	In case of insufficient ventilation, wear suitable respiratory equipment, if inhalation of dust cannot be avoided, wear a particulate respirator approved by NIOSH/MSHA. Use respirator in accordance with manufacturer's use limitations and OSHA standard 1910.134 (29 CFR).

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Powder
Color:	Orange
Odor:	None
Specific Gravity (H2O = 1):	N/A
Solubility in Water:	Soluble
% Volatile by Weight:	13%
Boiling Point:	N/A
Melting Point:	N/A
Evaporation Rate:	N/A
pH:	N/A

10. STABILITY AND REACTIVITY

Stability:	Stable
Conditions to Avoid:	None known

Incompatibility (Materials to Avoid):	None known
Hazardous Decomposition or Byproducts:	Carbon dioxide, Carbon monoxide
Hazardous Polymerization:	Will Not Occur
Thermal Processing Emissions:	Not Applicable

11. TOXICOLOGICAL INFORMATION

Caution must be exercised through the prudent use of protective equipment and handling procedures to minimize exposure.

LC50 Inhalation:	Not Established
LD50 Oral:	> 6 g/kg [Mouse]
LD50 Skin:	> 10 g/kg [Rat]

As with all chemicals for which test data are limited or do not exist, caution must be exercised through the prudent use of protective equipment and handling procedures to minimize exposure.

12. ECOLOGICAL INFORMATION

Ecological Information:	No ecological testing has been conducted on the product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods:	For waste disposal purposes, this product is not known to be defined or designated as hazardous by current provisions of the Federal (EPA) Resource Conservation and Recovery Act (RCRA, 40CFR261). Land disposal should be in closed containers. Incinerate or landfill waste in a properly permitted facility in accordance with federal, state and local regulations.
US RQ:	Not Applicable

14. TRANSPORT INFORMATION

DOT Classification:	Not a DOT controlled material.
Class/Division:	Not restricted
Proper Shipping Name:	N/A
Label:	None
Packing Group:	N/A
ID Number:	N/A
Hazard:	N/A

15. REGULATORY INFORMATION

This MSDS has been prepared in accordance with the hazard criteria of the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

US Toxic Substances Control Act:	All components of this product are either on the US Toxic Substances Control Act (TSCA) inventory of chemicals or are otherwise compliant with TSCA regulations.

US CERCLA- SARA:	**SARA Title III Section 312 Hazard Category (40 CFR 311/312):**
	Not Hazardous
SARA Section 313:	This product contains the following toxic chemicals subject to the reporting requirements of Section 313 of the Emergency Planning and Community Right to Know Act of 1986 and 40 CFR 372:
	None known
California Proposition 65:	Warning: The following ingredients present in the product are known to the state of California to cause birth defects, or other reproductive hazards:
	None known to be present or none in reportable amounts for occupational exposure as per OSHA's approval of the California Hazard Communication Standard, Federal Register, page 31159 ff, 6 June 1997.
	The chemical identity of some or all components present is confidential business information (trade secret) and is being withheld as permitted by 29CFR1910.1200 (i).
Canadian Domestic Substances List (DSL):	All components in this product are on the Canadian Ingredient Disclosure List (WHMIS).
Canadian Ingredient Disclosure List:	The following components are on the Canadian Ingredient Disclosure List (WHMIS):
	None Listed
Canadian WHMIS Class:	Not Controlled

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

16. ADDITIONAL INFORMATION

HMIS Rating:

Health: 1 Flammability: 0 Reactivity: 0 Personal Protection: X

NFPA Rating:

Health: 1 Flammability: 0 Reactivity: 0

Key: 0 = insufficient 1 = slight 2 = moderate 4 = extreme

This information is provided for documentation purposes only.
The complete range of conditions or methods of use are beyond our control therefore we do not assume any responsibility and expressly disclaim any liability for any use of this product. Information contained herein is believed to be true and accurate however, all statements or suggestions are made without warranty, expressed or implied, regarding accuracy of the information, the hazards connected with the use of the material or the results to be obtained from the use thereof. Compliance with all applicable federal, state, and local laws and local regulations remains the responsibility of the user.
This safety sheet cannot cover all possible situations which the user may experience during processing. Each aspect of your operation should be examined to determine if, or where, additional precautions may be necessary. All health and safety information contained in this bulletin should be provided to your employees or customers.

APPENDIX "B"

Vaccine Excipient & Media Summary

Vaccine Excipient & Media Summary

Excipients Included in U.S. Vaccines, by Vaccine

This table includes not only vaccine ingredients (e.g., adjuvants and preservatives), but also substances used during the manufacturing process, including vaccine-production media, that are removed from the final product and present only in trace quantities.
In addition to the substances listed, most vaccines contain Sodium Chloride (table salt).

Last Updated February 2015
All reasonable efforts have been made to ensure the accuracy of this information, but manufacturers may change product contents before that information is reflected here. If in doubt, check the manufacturer's package insert.

Vaccine	Contains	Source: Manufacturer's P.I. Dated
Adenovirus	sucrose, D-mannose, D-fructose, dextrose, potassium phosphate, plasdone C, anhydrous lactose, micro crystalline cellulose, polacrilin potassium, magnesium stearate, cellulose acetate phthalate, alcohol, acetone, castor oil, FD&C Yellow #6 aluminum lake dye, human serum albumin, fetal bovine serum, sodium bicarbonate, human-diploid fibroblast cell cultures (WI-38), Dulbecco's Modified Eagle's Medium, monosodium glutamate	March 2011
Anthrax (Biothrax)	aluminum hydroxide, benzethonium chloride, formaldehyde, amino acids, vitamins, inorganic salts and sugars	May 2012
BCG (Tice)	glycerin, asparagine, citric acid, potassium phosphate, magnesium sulfate, Iron ammonium citrate, lactose	February 2009
DT (Sanofi)	aluminum potassium sulfate, peptone, bovine extract, formaldehyde, thimerosal (trace), modified Mueller and Miller medium, ammonium sulfate	December 2005
DTaP (Daptacel)	aluminum phosphate, formaldehyde, glutaraldehyde, 2-Phenoxyethanol, Stainer-Scholte medium, modified Mueller's growth medium, modified Mueller-Miller casamino acid medium (without beef heart infusion), dimethyl 1-beta-cyclodextrin, ammonium sulfate	October 2013
DTaP (Infanrix)	formaldehyde, glutaraldehyde, aluminum hydroxide, polysorbate 80, Fenton medium (containing bovine extract), modified Latham medium (derived from bovine casein), modified Stainer-Scholte liquid medium	November 2013
DTaP-IPV (Kinrix)	formaldehyde, glutaraldehyde, aluminum hydroxide, Vero (monkey kidney) cells, calf serum, lactalbumin hydrolysate, polysorbate 80, neomycin sulfate, polymyxin B, Fenton medium (containing bovine extract), modified Latham medium (derived from bovine casein), modified Stainer-Scholte liquid medium	November 2013
DTaP-HepB-IPV (Pediarix)	formaldehyde, gluteraldehyde, aluminum hydroxide, aluminum phosphate, lactalbumin hydrolysate, polysorbate 80, neomycin sulfate, polymyxin B, yeast protein, calf serum, Fenton medium (containing bovine extract), modified Latham medium (derived from bovine casein), modified Stainer-Scholte liquid medium, Vero (monkey kidney) cells	November 2013
DTaP-IPV/Hib (Pentacel)	aluminum phosphate, polysorbate 80, formaldehyde, sucrose, gutaraldehyde, bovine serum albumin, 2-phenoxethanol, neomycin, polymyxin B sulfate, Mueller's Growth Medium, Mueller-Miller casamino acid medium (without beef heart infusion), Stainer-Scholte medium (modified by the addition of casamino acids and dimethyl-beta-cyclodextrin), MRC-5 (human diploid) cells, CMRL 1969 medium (supplemented with calf serum), ammonium sulfate, and medium 199	October 2013
Hib (ActHIB)	ammonium sulfate, formalin, sucrose, Modified Mueller and Miller medium	January 2014
Hib (Hiberix)	formaldehyde, lactose, semi-synthetic medium	March 2012
Hib (PedvaxHIB)	aluminum hydroxphosphate sulfate, ethanol, enzymes, phenol, detergent, complex fermentation medium	December 2010

B

Vaccine	Contains	Source: Manufacturer's P.I. Dated
Hib/Hep B (Comvax)	yeast (vaccine contains no detectable yeast DNA), nicotinamide adenine dinucleotide, hemin chloride, soy peptone, dextrose, mineral salts, amino acids, formaldehyde, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, sodium borate, phenol, ethanol, enzymes, detergent	December 2010
Hib/Mening. CY (MenHibrix)	tris (trometamol)-HCl, sucrose, formaldehyde, synthetic medium, semi-synthetic medium	2012
Hep A (Havrix)	aluminum hydroxide, amino acid supplement, polysorbate 20, formalin, neomycin sulfate, MRC-5 cellular proteins	December 2013
Hep A (Vaqta)	amorphous aluminum hydroxyphosphate sulfate, bovine albumin, formaldehyde, neomycin, sodium borate, MRC-5 (human diploid) cells	February 2014
Hep B (Engerix-B)	aluminum hydroxide, yeast protein, phosphate buffers, sodium dihydrogen phosphate dihydrate	December 2013
Hep B (Recombivax)	yeast protein, soy peptone, dextrose, amino acids, mineral salts, potassium aluminum sulfate, amorphous aluminum hydroxyphosphate sulfate, formaldehyde, phosphate buffer	May 2014
Hep A/Hep B (Twinrix)	formalin, yeast protein, aluminum phosphate, aluminum hydroxide, amino acids, phosphate buffer, polysorbate 20, neomycin sulfate, MRC-5 human diploid cells	August 2012
Human Papillomavirus (HPV) (Cerverix)	vitamins, amino acids, lipids, mineral salts, aluminum hydroxide, sodium dihydrogen phosphate dehydrate, 3-O-desacyl-4' Monophosphoryl lipid A, insect cell, bacterial, and viral protein	November 2013
Human Papillomavirus (HPV) (Gardasil)	yeast protein, vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, L-histidine, polysorbate 80, sodium borate	June 2014
Human Papillomavirus (HPV) (Gardasil 9)	yeast protein, vitamins, amino acids, mineral salts, carbohydrates, amorphous aluminum hydroxyphosphate sulfate, L-histidine, polysorbate 80, sodium borate	December 2014
Influenza (Afluria)	beta-propiolactone, thimerosol (multi-dose vials only), monobasic sodium phosphate, dibasic sodium phosphate, monobasic potassium phosphate, potassium chloride, calcium chloride, sodium taurodeoxycholate, neomycin sulfate, polymyxin B, egg protein, sucrose	December 2013
Influenza (Agriflu)	egg proteins, formaldehyde, polysorbate 80, cetyltrimethylammonium bromide, neomycin sulfate, kanamycin, barium	2013
Influenza (Fluarix) Trivalent and Quadrivalent	octoxynol-10 (Triton X-100), α-tocopheryl hydrogen succinate, polysorbate 80 (Tween 80), hydrocortisone, gentamicin sulfate, ovalbumin, formaldehyde, sodium deoxycholate, sucrose, phosphate buffer	June 2014
Influenza (Flublok)	monobasic sodium phosphate, dibasic sodium phosphate, polysorbate 20, baculovirus and host cell proteins, baculovirus and cellular DNA, Triton X-100, lipids, vitamins, amino acids, mineral salts	March 2014
Influenza (Flucelvax)	Madin Darby Canine Kidney (MDCK) cell protein, MDCK cell DNA, polysorbate 80, cetyltrimethlyammonium bromide, β-propiolactone, phosphate buffer	March 2014
Influenza (Fluvirin)	nonylphenol ethoxylate, thimerosal (multidose vial–trace only in prefilled syringe), polymyxin, neomycin, beta-propiolactone, egg proteins, phosphate buffer	February 2014
Influenza (Flulaval) Trivalent and Quadrivalent	thimerosal, formaldehyde, sodium deoxycholate, egg proteins, phosphate buffer	February 2013
Influenza (Fluzone: Standard (Trivalent and Quadrivalent), High-Dose, & Intradermal)	formaldehyde, octylphenol ethoxylate (Triton X-100), gelatin (standard trivalent formulation only), thimerosal (multi-dose vial only) , egg protein, phosphate buffers, sucrose	2014

B

Vaccine	Contains	Source: Manufacturer's P.I. Dated
Influenza (FluMist) Quadrivalent	ethylene diamine tetraacetic acid (EDTA), monosodium glutamate, hydrolyzed porcine gelatin, arginine, sucrose, dibasic potassium phosphate, monobasic potassium phosphate, gentamicin sulfate, egg protein	July 2013
Japanese Encephalitis (Ixiaro)	aluminum hydroxide, Vero cells, protamine sulfate, formaldehyde, bovine serum albumin, sodium metabisulphite, sucrose	May 2013
Meningococcal (MCV4-Menactra)	formaldehyde, phosphate buffers, Mueller Hinton agar, Watson Scherp media, Modified Mueller and Miller medium, detergent, alcohol, ammonium sulfate	April 2013
Meningococcal (MCV4-Menveo)	formaldehyde, amino acids, yeast extract, Franz complete medium, CY medium	August 2013
Meningococcal (MPSV4-Menomune)	thimerosal (multi-dose vial only), lactose, Mueller Hinton casein agar, Watson Scherp media, detergent, alcohol	April 2013
Meningococcal (MenB – Bexsero)	aluminum hydroxide, *E. coli*, histidine, sucrose, deoxycholate, kanomycin	2015
Meningococcal (MenB – Trumenba)	polysorbate 80, histodine, *E. coli*, fermentation growth media	October 2015
MMR (MMR-II)	Medium 199 (vitamins, amino acids, fetal bovine serum, sucrose, glutamate) , Minimum Essential Medium, phosphate, recombinant human albumin, neomycin, sorbitol, hydrolyzed gelatin, chick embryo cell culture, WI-38 human diploid lung fibroblasts	June 2014
MMRV (ProQuad)	sucrose, hydrolyzed gelatin, sorbitol, monosodium L-glutamate, sodium phosphate dibasic, human albumin, sodium bicarbonate, potassium phosphate monobasic, potassium chloride, potassium phosphate dibasic, neomycin, bovine calf serum, chick embryo cell culture, WI-38 human diploid lung fibroblasts, MRC-5 cells	March 2014
Pneumococcal (PCV13 – Prevnar 13)	casamino acids, yeast, ammonium sulfate, Polysorbate 80, succinate buffer, aluminum phosphate, soy peptone broth	January 2014
Pneumococcal (PPSV-23 – Pneumovax)	phenol	May 2014
Polio (IPV – Ipol)	2-phenoxyethanol, formaldehyde, neomycin, streptomycin, polymyxin B, monkey kidney cells, Eagle MEM modified medium, calf serum protein, Medium 199	May 2013
Rabies (Imovax)	Human albumin, neomycin sulfate, phenol red indicator, MRC-5 human diploid cells, beta-propriolactone	April 2013
Rabies (RabAvert)	β-propiolactone, potassium glutamate, chicken protein, egg protein, neomycin, chlortetracycline, amphotericin B, human serum albumin, polygeline (processed bovine gelatin), sodium EDTA, bovine serum	March 2012
Rotavirus (RotaTeq)	sucrose, sodium citrate, sodium phosphate monobasic monohydrate, sodium hydroxide, polysorbate 80, cell culture media, fetal bovine serum, vero cells *[DNA from porcine circoviruses (PCV) 1 and 2 has been detected in RotaTeq. PCV-1 and PCV-2 are not known to cause disease in humans.]*	June 2013
Rotavirus (Rotarix)	amino acids, dextran, sorbitol, sucrose, calcium carbonate, xanthan, Dulbecco's Modified Eagle Medium (potassium chloride, magnesium sulfate, ferric (III) nitrate, sodium phosphate, sodium pyruvate, D-glucose, concentrated vitamin solution, L-cystine, L-tyrosine, amino acids solution, L-glutamine, calcium chloride, sodium hydrogenocarbonate, and phenol red) *[Porcine circovirus type 1 (PCV-1) is present in Rotarix. PCV-1 is not known to cause disease in humans.]*	May 2014
Smallpox (Vaccinia – ACAM2000)	human serum albumin, mannitol, neomycin, glycerin, polymyxin B, phenol, Vero cells, HEPES	September 2009

B

Vaccine	Contains	Source: Manufacturer's P.I. Dated
Td (Decavac)	aluminum potassium sulfate, peptone, formaldehyde, thimerosal, bovine muscle tissue (US sourced), Mueller and Miller medium, ammonium sulfate	March 2011
Td (Tenivac)	aluminum phosphate, formaldehyde, modified Mueller-Miller casamino acid medium without beef heart infusion, ammonium sulfate	April 2013
Td (Mass Biologics)	aluminum phosphate, formaldehyde, thimerosal (trace), ammonium phosphate, modified Mueller's media (containing bovine extracts)	February 2011
Tdap (Adacel)	aluminum phosphate, formaldehyde, glutaraldehyde, 2-phenoxyethanol, ammonium sulfate, Stainer-Scholte medium, dimethyl-beta-cyclodextrin, modified Mueller's growth medium, Mueller-Miller casamino acid medium (without beef heart infusion)	March 2014
Tdap (Boostrix)	formaldehyde, glutaraldehyde, aluminum hydroxide, polysorbate 80 (Tween 80), Latham medium derived from bovine casein, Fenton medium containing a bovine extract, Stainer-Scholte liquid medium	February 2013
Typhoid (inactivated – Typhim Vi)	hexadecyltrimethylammonium bromide, formaldehyde, phenol, polydimethylsiloxane, disodium phosphate, monosodium phosphate, semi-synthetic medium	March 2014
Typhoid (oral – Ty21a)	yeast extract, casein, dextrose, galactose, sucrose, ascorbic acid, amino acids, lactose, magnesium stearate. gelatin	September 2013
Varicella (Varivax)	sucrose, phosphate, glutamate, gelatin, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, potassium chloride, sodium phosphate monobasic, potassium chloride, EDTA, residual components of MRC-5 cells including DNA and protein, neomycin, fetal bovine serum, human diploid cell cultures (WI-38), embryonic guinea pig cell cultures, human embryonic lung cultures	March 2014
Yellow Fever (YF-Vax)	sorbitol, gelatin, egg protein	May 2013
Zoster (Shingles – Zostavax)	sucrose, hydrolyzed porcine gelatin, monosodium L-glutamate, sodium phosphate dibasic, potassium phosphate monobasic, neomycin, potassium chloride, residual components of MRC-5 cells including DNA and protein, bovine calf serum	February 2014

A table listing vaccine excipients and media *by excipient* can be found in:

Grabenstein JD. *ImmunoFacts: Vaccines and Immunologic Drugs* – 2013 (38th revision). St Louis, MO: Wolters Kluwer Health, 2012.

B

The **Vaccine Adverse Event Reporting System** (**VAERS**) is a United States program for safety, co-managed by the U.S. (CDC) and the (FDA). VAERS is a program, collecting information about (possible side effects) that occur after administration of vaccines.

VAERS, the , and the Clinical Immunization Safety Assessment (CISA) Network are tools by which the CDC and FDA vaccine safety to fulfill their duty as charged with protecting the public. Some scientists would like to do a more scientifically rigorous job of this, noting that VAERS has several limitations, including reports, , inconsistent , and absence of an unvaccinated .

Origins

The program is an outgrowth of the 1986 (NCVIA), which requires health care providers to report:

- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine.
- Any event listed in the Reportable Events Table that occurs within the specified time period after vaccination. The data are stored electronically by the CDC in the (VSD).

VAERS was established in 1990, and is managed jointly by the FDA and the CDC. It is meant to act as a sort of "early warning system"—a way for physicians and researchers to identify possible unforeseen reactions or side effects of vaccination for further study.

Operation

Each year the VAERS receives 10,000–20,000 reports of adverse events following immunization by more than 10 million vaccines. Higher-priority uses of the data include reports of death and other serious adverse events, recognizing and detecting adverse effects, and finding unexpected adverse events involving new vaccines. The VAERS data

are also used to monitor known reactions to vaccines and for vaccine lot surveillance. techniques such as methods can be used to improve the quality of data analysis.

Limitations

Like other spontaneous reporting systems, VAERS has several limitations, including underreporting, unverified reports, inconsistent data quality, absence of a control group that is not vaccinated, and inadequate data about the number of people vaccinated. Indeed, an autism activist named once reported to VAERS that a vaccine had turned him into . The report was accepted and entered into the database, but the dubious nature thereof prompted a VAERS representative to contact Mr. Laidler, who then gave his consent to delete the report.

Use in research and litigation

Many medical researchers make use of VAERS to study the effects of vaccination. VAERS warns researchers using its database that the data should not be used in isolation to draw conclusions about cause and effect. Nonetheless, data from VAERS has been used in vaccine litigation to support the claim that vaccines cause autism.

Litigation related to vaccines and autism has led to an increase in VAERS reports filed by plaintiff's attorneys. A 2006 article in found that most VAERS reports related to , and many related to , were filed in connection with litigation, leading the authors to caution that inappropriate reliance on VAERS data may be a source of bias. The study's lead author stated: "Lawyers are manipulating this system to show increases [in vaccine-related adverse events] that are based on litigation, not health research." , chief of infectious disease at , wrote:

> "Public health officials were disappointed to learn that reports of autism to VAERS weren't coming from parents, doctors, nurses, or nurse practitioners; they were coming from personal-injury lawyers... For the lawyers, VAERS reports hadn't been a self-fulfilling prophecy; they'd been

a self-generated prophecy."

References

1. Centers for Disease Control and Prevention, *Vaccine Safety Monitoring at CDC*, retrieved 2015-03-11.

2. ^ Woo EJ, Ball R, Burwen DR, Braun MM (2008). "Effects of stratification on data mining in the US Vaccine Adverse Event Reporting System (VAERS)". *Drug Saf.* **31** (8): 667–74. [redacted]

3. ^ "VAERS Data". VAERS.

4. Laidler, James R. (July 27, 2005). "Chelation and Autism". *Neurodiversity Blog*. Archived from the original on April 19, 2013. Retrieved October 8, 2013.

5. Goodman MJ, Nordin J (2006). "Vaccine adverse event reporting system reporting source: a possible source of bias in longitudinal studies". *Pediatrics*. **117** (2): 387–90. [redacted]

6. ^ [redacted] (2008). [redacted]. New York: [redacted].

External links

- vaers.hhs.gov – Vaccine Adverse Event Reporting System (official website). This also contains instructions for downloading the VAERS data.
- Vaccine Adverse Event Report System (VAERS) Overview, FDA
- VAERS request for searching the database
- Galindo, Belkys M., et al. "Vaccine-Related Adverse Events in Cuban Children", 1999–2008. *MEDICC Review*. 2012;14(1):38–43.

The **Vaccine Safety Datalink Project** (VSD) was established in 1990 by the [illegible] (CDC) to study the [illegible] of [illegible].

Four large [illegible], including [illegible], were initially recruited to provide the CDC with medical data on [illegible] histories, health outcomes, and subject characteristics. The VSD database contains data compiled from [illegible] on more than seven million [illegible], including about 500,000 children from birth through age six years (2% of the U.S. population in this age group).

The VSD data-sharing program is now being administered by the [illegible] Research Data Center. The data sharing guidelines have been revised to include comments from interested groups as well as recommendations from the [illegible] (IOM).

The [illegible] (VAERS), the VSD, and the Clinical Immunization Safety Assessment (CISA) Network are tools by which the CDC and FDA [illegible] vaccine safety to fulfill their duty as [illegible] charged with protecting the public. Data from the VSD Project have been utilized to address a number of vaccine safety concerns; examples include a study clarifying the risk of [illegible] after vaccine administration and several studies examining the hypothesis of a [illegible].

Participating healthcare organizations

The following organizations are members of the project:

- Group Health Cooperative of Puget Sound, Seattle, Washington
- Harvard Pilgrim Health Care, Boston, Massachusetts
- HealthPartners Research Foundation, Minneapolis, Minnesota
- Kaiser Permanente Northwest, Portland, Oregon
- Kaiser Permanente Medical Care Program of Northern California, Oakland, California

- Kaiser Permanente Colorado, Denver, Colorado
- Kaiser Permanente of Georgia, Atlanta, Georgia
- [redacted] Research Foundation, Marshfield, Wisconsin
- Southern California Kaiser Permanente Health Care Program, Los Angeles, California

Notes

1. Chen RT; Glasser JW; Rhodes PH; et al. (1997). "Vaccine Safety Datalink project: a new tool for improving vaccine safety monitoring in the United States. The Vaccine Safety Datalink Team". *Pediatrics*. **99** (6): 765–73. [redacted]:10.1542/peds.99.6.765. PMID 9164767.

2. Centers for Disease Control and Prevention, *Vaccine Safety Monitoring at CDC*, retrieved 2015-03-11.

3. Bohlke K, Davis RL, Marcy SM, et al. (2003). "Risk of anaphylaxis after vaccination of children and adolescents". *Pediatrics*. **112** (4): 815–20. [redacted]:10.1542/peds.112.4.815. PMID 14523172.

4. Geier DA, Geier MR (Spring 2006). "Early Downward Trends in Neurodevelopmental Disorders Following Removal of Thimerosal-Containing Vaccines" (PDF). *Journal of American Physicians and Surgeons*. **11** (1).

5. Verstraeten T, Davis RL, DeStefano F, et al. (2003). "Safety of thimerosal-containing vaccines: a two-phased study of computerized health maintenance organization databases". *Pediatrics*. **112** (5): 1039–48. [redacted]:10.1542/peds.112.2.e98. PMID 14595043.

6. Thompson WW, Price C, Goodson B, et al. (2007). "Early thimerosal exposure and neuropsychological outcomes at 7 to 10 years". *N. Engl. J. Med*. **357** (13): 1281–92. [redacted]:10.1056/NEJMoa071434. PMID 17898097.

7. http://www.cdc.gov/vaccinesafety/Activities/VSD.html

External links

- NationalAcademies.org - 'Independent Oversight of Vaccine Safety Data Program Needed To Ensure Greater Transparency and Enhance Public Trust', [redacted]

(February 17, 2005)

- WHO.int (pdf) - 'The Vaccine Safety Datalink: immunization research in health maintenance organizations in the USA', R.T. Chen, F. DeStefano, R.L. Davis, L.A. Jackson, R.S. Thompson, J.P. Mullooly, S.B. Black, H.R. Shinefield, C.M. Vadheim, J.I. Ward, S.M. Marcy & the Vaccine Safety Datalink Team, World Health Organization.

APPENDIX "C"

Events Surrounding the DeStefano et al (2004) MMR-Autism Study

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Prepared by Dr. William E. Thompson

September 9, 2014

Background

My primary job duties while working in the Immunization Safety Branch from 2000 to 2006 were to lead or co-lead three major vaccine safety studies.

1. VSD Thimerosal Neurodevelopment Study (Thompson et al, NEJM, 2007)
2. VSD Thimerosal Autism Study (Price, Thompson et al, Pediatrics, 2010)
3. MADDSP MMR-Autism Case-Control Study (DeStefano et al, Pediatrics, 2004)

The MADDSP MMR-Autism Cases Control Study was being carried out in response to the Wakefield (1998) Lancet study that suggested an association between the MMR vaccine and an autism-like health outcome. There were several major concerns among scientists and consumer advocates outside the CDC in the fall of 2000 regarding in the execution of the Verstraeten et al (2003) study[1]. The Verstraeten Study was the first study the CDC carried out to examine the association between thimerosal and neurodevelopmental outcomes including autism. Some of the major concerns included 1) many of the statistical analyses were carried out post-hoc after an initial set of analyses were run, 2) the study protocol evolved over time, and the CDC did not share many of the internal study findings with individuals and constituents outside the CDC.

004

One of the important goals that was determined up front in the spring of 2001 before any of these studies started was to have all three study protocols vetted outside the CDC prior to the start of analyses so that consumer advocates could not claim that we were presenting analyses that suited our own goals and biases.

My primary responsibilities for the MADDSP MMR-Autism Study were:

1. Lead the large majority of the study-related meetings with all coauthors.
2. Write all the SAS programs for all the statistical analyses associated with the paper.
3. Summarize and present the statistical results to the coauthors on a regular basis.

In addition, all SAS programs and statistical analyses were reviewed by both Dr. Margarette Kolzcak and Dr. Andrew Autry. All data management work was led by Tanya Karapukar and she also reviewed the data management-related activities and decisions included in the SAS programs. All of my statistical analyses were run off of data sets cleaned and provided to me by Tanya Karapukar.

On September 5, 2001, we finalized the vetted study analysis plan for MADDSP MMR-Autism Study. (See Final Analysis Plan dated September 5, 2001). The study protocol included a timeline and the goal

[1] Thomas Verstraeten, et al., Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases (Verstraeten, et al., Pediatrics 112:5, 2003)

was to finish the analyses and submit the manuscript for publication to the New England Journal of Medicine by December 1, 2000. **The final analysis plan described analyses for the TOTAL sample and the BIRTH CERTIFICATE sample which included assessment of the RACE variable. (See pages 7 and 8 of the Final Analysis Plan). There were two primary endpoints for the study. One was using a threshold of 36 months (see Table 3a of Final Analysis Plan), and the second was a threshold of 18 months. (See Table 3b of Final Analysis Plan).** We hypothesized that if we found statistically significant effects at either the 18-month or 36-month threshold, we would conclude that vaccinating children early with the MMR vaccine could lead to autism-like characteristics or features. We never claimed or intended that if we found statistically significant effects in the TOTAL SAMPLE, we would ignore the results if they could not be confirmed in the BIRTH CERTIFICATE SAMPLE.

Timeline of Events:

1. In general, all coauthors attended the meetings I scheduled to discuss analyses with the exception of other conflicting meetings when one of us could not attend. The meetings began at least as early as March 2001.

2. On August 29, 2001, I outlined the method that would be used to code RACE for the TOTAL Sample and the Birth Certificate Sample. (See scanned notes from 2001-2002).

3. On September 5, 2001 all met finalized the study protocol and analysis plan. The goal was to not deviate from analysis to avoid the debacle that accord with the Verstraeten Thimerosal Study published in Pediatrics in 2003. At the chapter 004 5th meeting we discussed in detail how to code RACE for both the TOTAL SAMPLE and the BIRTH CERTIFICATE SAMPLE. (See Page 7 of Agendas Attachment).

4. On October 15, 2001, I ran matched and unmatched analyses for whites and blacks. I would only do this if I had found statistically significant effects by RACE. (See 2001-2002 notes dated October 15, 2001).

5. On October 24th, I wrote in my notes that we have selected the New England Journal of Medicine as the target journal for the manuscript. (See 2001-2002 notes dated October 24th, 2001).

6. On October 31, 2001, all coauthors discussed the study initial results. (See page 8 of Agendas Attachment).

7. On November 2nd, I wrote in my notebook to run analyses for whites and blacks for the early-vaccinated and late-vaccinated subjects. These analyses were run for the TOTAL sample. I would have only run those types of analyses if we had been attempting to explore why we had found significant RACE effects. (See 2001-2002 notes dated November 2, 2001)

8. On November 6, 2001, I have written notes instructing myself to run 4 group analyses and BLACK analyses. Again, I would have only been doing this if we had found concerning results for blacks. (See 2001-2002 notes dated November 6, 2001).

9. On November 8, 2001, I continued to write that the Black/White comparisons need to be continued. (See 2001-2002 notes dated November 8, 2001).

10. On February 20, 2002, all coauthors met and discussed statistical analyses for the Total Sample and the Birth Certificate Sample. (See page 14 of agendas attachment).

11. On May 22, 2002, all coauthors met and discussed analysis of the 24 month threshold for the Total Sample. We did this because there were many statistically significant effects at the 24 month threshold. (See page 16 of Agendas Attachment).

12. On June 28, 2002, all coauthors met and examined subgroup analyses by RACE for Whites and Blacks. (See page 17 in the Agendas Attachment and handout that includes Table 5).

13. In the Excel File named "describe_results_2002_0702.xls", Table 7 shows the RACE analyses that I had run using ONLY the BIRTH CERTIFICATE Sample -- the adjusted RACE effect was statistically significant (OR=1.51, [95% CI: 1.02 - 2.24]). At the bottom of Table 7, it also shows that for the NON-BIRTH Certificate Sample, the adjusted RACE effect statistically significance was HUGE. (OR=2.94 [95% CI: 1.48 - ...]. That is the main reason why we decided to report the RACE effects for ONLY the BIRTH Certificate Sample.

14. In the Excel File named "describe_results_2002_0801.xls", I split Table 7 into three different Tables (Table 7a, Table 7b, and Table 7c) to further investigate the RACE subgroup analyses.

15. All the coauthors met and decided sometime between August 2002 and September 2002 not to report any RACE effects for the paper.

16. Sometime soon after the meeting where we decided to exclude reporting any RACE effects, also between August 2002 and September 2002, the coauthors scheduled a meeting to destroy documents related to the study. Dr. Coleen Boyle was not present at the meeting even though she was involved in scheduling that meeting. The remaining 4 coauthors all met and brought a big garbage can into the meeting room and reviewed and went through all our hard copy documents that we thought we should discard and put them in the large garbage can. However, because I assumed this was illegal and would violate both FOIA laws and DOJ requests, I kept hard copies of all my documents in my office and I retained all the associated computer files. This included all the Word files (agendas and manuscript drafts), Excel files with analysis and results, and SAS files that I used to generate the statistical findings. I also kept all my written notes from meetings. All the associated MMR-Autism Study computer files have

been retained on the Immunization Safety Office computer servers since the inception of the study and they continue to reside there today.

17. On or about September 3, 2002, I informed Dr. Melinda Wharton, the Division Chief for the Branch I worked in, that we had concerning results from the MMR-Autism Study that we would like to discuss with her.

18. Dr. Melinda Wharton formally reprimanded Dr. Bob Chen, my Branch Chief, on September 18, 2002. As I stated in my e-mails to both Dr. Melinda Wharton and to Dr. Walt Orenstein, I believe this was an intimidating personnel action and threatened the credibility of the entire branch. It also put a big black cloud over our branch and demoralized many of the staff.

19. On October 9, 2002, Dr. Margarette Kolczak, an extremely reputable biostatistician, reviewed my SAS programs and made a suggestion for testing the RACE Interaction. This was a post-hoc decision and an attempt to absolve us from reporting the RACE effects.

20. On October 16, 2002, I asked Dr. Walt Orenstein to remove the formal reprimand of Dr. Chen because I said there was false information included in it. (See e-mail RE Dr. Robert Chen's Reprimand).

21. On October 20, 2002, [illegible] ibed t[illegible] renste n the [illegible]ilemma I [illegible]s in regarding the concerning MMR-Autism Study re[illegible] nd the[illegible] hand c f Dr. C[illegible] n. I tol[illegible] n I felt intimidated by the move and I linked it to them knowing the results would be problematic if they were shared outside the CDC.

22. On October 22, 2002, Dr. Boyle was assigned to brief Dr. Orenstein and Dr. Jose Cordero (the new Center Director for the National Center of Birth Defects and Developmental Disabilities).

23. Between October 22, 2002 and January 2004, there were significantly fewer hand written notes for the MMR-Autism Study because we had finalized the results and were writing the manuscript up for publication. I have many draft manuscripts that were written and are dated.

24. On January 8, 2004, I began to present draft PowerPoint presentations of the MMR-Autism Study for the Institute of Medicine meeting that I was scheduled to present on February 9, 2004 in Washington DC. I have copies of each of those PowerPoint presentations. During the next 30 days, I presented the results to the Division Director of ESD in the National Immunization Program, and the Director of the National Immunization Program. I would also present the results in the offices of Dr. Julie Gerberding.

25. On January 27, 2004, I had lunch with Dr. Marshalyn Yeargin-Allsopp. She told me that Dr. Frank DeStefano still currently reported to her.

26. On February 2, 2004, I met with Dr. Steve Cochi (the new Director of the National Immunization Program) and Dr. Melinda Wharton. During that meeting I provided Dr. Cochi with a draft of my letter to Dr. Julie Gerberding and sought his input. He requests that I remove any criticism of NIP in the letter.

27. During the February 2 meeting with Dr. Cochi and Dr. Wharton, I also requested that Dr. Walter Orenstein be brought into the meeting because he had arrived in the building that morning. Dr. Cochi suggested that Dr. Orenstein was "heading off into the sunset" and that we shouldn't bother him with these issues. Although Dr. Orenstien had announced his retirement in January 2004, he was still coming for meetings on a regular basis.

28. On this same day, Brooke Barry, a CDC public health analysis and someone I trusted very much, informed me that the "autism caucus" was meeting on February 3rd and that they were initiating or requesting a formal investigation of the National Immunization Program.

29. On February 2, 2004, after meeting with Dr. Cochi and Dr. Wharton, I delivered my letter for Dr. Julie Gerberding regarding my concerns regarding results from the MMR-Autism Study just before I had to present them to the Institute of Medicine on February 9, 2004. (See scanned letter to Dr. Gerberding dated February 2, 2004 .

30. On March 9th, I was put on administrative leave. In the Annex to the memorandum, they provided a list of my "inappropriate and unacceptable behavior in the work place" which included "you criticized the NIP/OD for doing very poor job of representing vaccine safety issues, claimed that NIP/OD had failed to be proactive in their handling of vaccine safety issues, and you requested that Dr. Gerberding reply to your letter from a congressional representative before you made your presentation to the IOM." (See scanned Memorandum dated January 9, 2004.). I stand by that statement and I do not think it was unacceptable to convey that to Dr. Gerberding.

Conclusion

I believe we intentionally withheld controversial findings from the final draft of the DeStefano et al (2004) Pediatrics paper. We failed to follow the final approved study protocol and we ran detailed in depth RACE analyses from October 2001 through August 2002 attempting to understand why we were finding large vaccine effects for blacks. The fact that we found a strong statistically significant finding among black males does not mean that there was a true association between the MMR vaccine and autism-like features in this subpopulation. This result would have probably have led to designing additional better studies if we had been willing to report the findings in the study and manuscript at the time that we found them. The significant effect of early vaccination with the MMR vaccine might have also been a proxy for the receipt of thimerosal vaccines early in life but we didn't have the appropriate data to be able to code the level of thimerosal exposure from the MADDSP school records.

In addition to significant effects for black males, we also found significant effects for "isolated autism cases" and for the threshold of 24 months of age. If we had reported the 24 month effects, our justification for ignoring the 36 month significant effects would not have been supported. In the discussion section of the final published manuscript, we took the position that service seeking was the reason we found a statistically significant effect at 36 months. This was a post-hoc hypothesis regarding the findings after we confirmed one of our primary hypotheses. Because we knew that the threshold for 24 months was also statistically significant, reporting it would have undermined the hypothesis that service seeking was the reason we found an effect at 36 months. (See published paper).

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Age at First MMR Vaccination and Autism

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N Circulatio

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May 22, 2002

Abstract

Introduction

We conducted a matched case-control study utilizing the Centers for Disease Control and Prevention (CDC) Metropolitan Atlanta Developmental Disabilities Surveillance Program. The main objective of the study was to evaluate the association between autism and age of receipt of the MMR vaccine after controlling for background characteristics. We also examined several autism subgroups to determine if the more homogenous subgroups were more likely to be associated with the age of MMR vaccine.

Methods

The CDC's Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP) was used to identify children with autism (N=647) who met the MADDSP surveillance case definition for autism and whose school records were available in one of 9 school systems in the 5 county Atlanta surveillance region. Control children (N=1,891) were selected from regular education programs and were matched to case-children based on age, sex, and school of attendance at the time of abstraction. Trained abstractors collected vaccination histories for both cases and controls from the standardized State of Georgia immunization forms that all children are required to provide to attend public schools in Georgia. The primary exposure of interest was age of receipt of the first dose of the MMR vaccine. We used conditional logistic regression models stratified by matched sets to estimate the odds ratios for the association between age at MMR vaccination and autism. Potential confounding variables were evaluated individually for their impact on the MMR-autism association.

Introduction

Autism is a serious life-long developmental disorder characterized by marked impairments in social interactions, and communication skills; and repetitive, restrictive, or stereotyped behaviors. Recent studies have suggested that the prevalence of autism is higher (30–60 per 10,000 persons) (Baird et al., 2000; Bertrand et al., 2001; Yeargin-Allsopp et al., 2002) than in studies conducted 15-20 years ago (4-5 per 10,000; Fombonne, 1999). The increase in prevalence, coupled with reports of increasing numbers of children with autism being served by schools and service agencies (California Department of Developmental Services,1999) have prompted concerns about the role of environmental factors. One of the environmental factors implicated is vaccines particularly the MMR vaccine. The recommended Advisory Committee on Immunization Practices (ACIP) schedule for the MMR vaccine coincides temporally with the age of o autis

The main support the Wakefield and colle: ~~have r~~ ~~d that~~ MMI accine r y cause autism. They ~~published a study~~ describing 12 patients with inflammatory bowel conditions and regressive developmental disorders, mostly autism (Wakefield et al, 1998). In 8 of the 12 cases, the child's parents or pediatrician suggested that MMR vaccine contributed to onset of behavioral problems. The authors hypothesized that MMR vaccine was responsible for bowel dysfunction (enterocolitis) and subsequent neurodevelopmental disorders. They ~~have~~ subsequently proposed a new syndrome consisting of certain gastrointestinal conditions, predominantly ileocolonic lymphonodular hyperplasia and mild intestinal inflammation, associated with behavioral regression (Wakefield, Anthony, et al, 2000) and reported identifying laboratory evidence of measles virus genome in the peripheral white blood cells and bowel biopsy specimens of a few such patients (Kawashimi et al, 2000; Torrente et al. 2002; Uhlmann et al., 2002). ~~Since the~~

Seems out of place here

led association between MMR and autism comes from a report by

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~~initial publication of the Wakefield report, several~~ epidemiologic studies have failed to find an association between MMR vaccination and autism (Dales et al, 2001; Farrington et al 2001; Gillberg et al, 1998; Kaye et al, 2001; Taylor et al., 1999). These studies, however, have been limited to varying degrees by incomplete case ascertainment, small sample sizes, and reliance on clinical diagnoses without standard case definitions. No studies have been published that included a concurrent comparison or control group with individual-specific vaccination histories.

We conducted a matched case-control study utilizing the Centers for Disease Control and Prevention (CDC) Metropolitan Atlanta Developmental Disabilities Surveillance Program. The main objective of the study was to compare the MMR vaccination histories of a nearly complete population-based sample of children with autism and school-matched controls who did not have autism. We also evaluated associations with MMR vaccination in subgroups of children according to different preser s with broad r category autism spectrum disorders (ASD).

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Methods

Study population

Children with autism were derived from the CDC's Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP), ~~a multiple-source~~ population based surveillance program that monitors the occurrence of selected developmental disabilities among children in the five-county metropolitan Atlanta area (Yeargin-Allsopp, M. et al., 2002). ~~MADDSP was established to ascertain all children with one or more of five developmental disabilities -- mental retardation, cerebral palsy, autism, hearing impairment, and vision impairment -- who were 3 to 10 years of age and whose parents resided in the five-county metropolitan Atlanta area.~~

Cases

In the first MADDSP autism prevalence study, they identified 987 confirmed autism cases from 1,077 children who had information available for review from the multiple-source records (Yeargin-Allsopp, M. et al., 2002). For the purpose of this study, we identified 647 confirmed autism cases that also had records available from one of the nine participating school systems used as part of the MADDSP surveillance system. The remaining case children had either moved out of state, transferred to a school in a county that is not under MADDSP's jurisdiction, transferred to a private school that is not accessible by MADDSP, or are being home schooled. We searched for school records of case children across all school systems in order to identify their school of enrollment at the time of abstraction.

Controls

We attempted to obt :1 cor case atio for thi udy. For 97% of the cases, we identified 3 controls while tl ainin ent o case ad fewe an 3 controls. Control children (N=1,891) were selected from regular education programs and were matched to case-children based on age, sex, and school of attendance at the time of abstraction. However, if a case-child was attending a school that was structured for special education students (e.g., psycho-educational school), controls were selected from the case-child's home school. A child's home school is the school in the child's neighborhood or residential area that the child would attend if the child did not have a disability. In addition, if a case-child was older than other children in their class and was in the last elementary grade level prior to middle school due to their disability, control children were selected from the middle school they would normally attend and would be matched to the case based on the established matching criteria. The names of control

children were verified in the MADDSP and special education files to assure that they were not receiving special education services **(in 1996 or ever???)**.

Vaccination history

Trained abstractors collected vaccination histories for both cases and controls from the standardized State of Georgia immunization forms that are required for all children who attend schools in Georgia. The forms are filed in each student's permanent school record ~~file that is kept at the school where the child is enrolled~~. During the period of this study, Georgia law required at least one dose of measles, mumps, and rubella vaccine in the form of either the MMR, MR, or single antigen vaccines at entry into elementary school. ~~Effective with the 1994-95 school year, for entrance into the sixth grade of school, a child needed~~ to have received at ~~least one additional dose of the MMR vaccine~~ ~~for a total of two MMR~~ vaccines administered on ~~or after the child's first birth~~ ~~d at l~~ ~~e mor th apart. D. regarding vaccination~~ ~~exemptions~~ (medical and re ;) ~~wer~~ ~~ecord d.~~

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Family Background Characteristics and Other Data Collection

Demographic information including child's date of birth, gender, birth state, and race/ethnicity was obtained from the birth certificate that is kept in the child's permanent record. Like the vaccination form, all children must provide the school of enrollment with the birth certificate for entry into elementary school; the presence of a birth certificate is not mandatory for those entering middle school. For the records that were abstracted at middle schools, a school registration form was used to obtain the necessary demographic information.

Subsequently, cases and controls born in Georgia were matched to state birth certificate records in order to derive more information on ~~child~~ and maternal characteristics. The matching criteria used were birth certificate number and child's first and last name. Of the children

identified as being born in Georgia, 57% of cases (N=359) and 56% of controls (N=1,049) were successfully matched. Variables obtained from the birth certificate included child factors of birth weight and gestational age and maternal factors of parity, age, race/ethnicity, and education.

For children with autism, additional disability related information was obtained from the MADDSP data files. This included information on the presence of other developmental disabilities, epilepsy, a major associated medical condition of autism, other co-existing medical conditions, level of cognitive functioning, as well as prenatal and perinatal conditions. In addition, we identified major congenital malformations among the case children by matching with CDC's Metropolitan Atlanta Congenital Defects Program (MACDP), a population-based surveillance program of major structural malformations that covers the same geographic area (Edmonds et al, 1981).

MMR Exposure Variable

The primary exposure of interest in this study was age of receipt of the first dose of the MMR vaccine. We examined two alternative exposure periods for age of MMR vaccination: receipt of the MMR vaccine < 18 months of age and < 24 months of age. These exposure periods were chosen because regression occurs at approximately 18 months of age and the 24-month time period is well beyond the median age of first parental concern for autistic features as well as median date for the MMR vaccine (APA, 1994; Giacomo, A. & Fombonne, E., 1998;Taylor, B., 1999). Therefore the period after 24 months would be considered an unexposed period for the causal association between the timing of receipt of the vaccine and autism.

Classification of Autism Subgroups

~~The IOM (2001) specifically recommended additional research regarding the potential susceptibility of certain subgroups of autism~~. In an effort to examine differing effects of the

MMR vaccine in various subsets of children with autism, we reviewed the records of case children to identify additional information that would help classify cases into more homogenous subgroups, particularly children with indication of delay less than one year and children with pre-existing conditions. The information that was collected included age of first parental concern, the presence of a pre-existing condition, date of concern, and verbatim description of the behaviors that led to the concern. A family history of autism and related autism spectrum conditions, and other developmental disabilities was also recorded.

Indication of developmental delay at less than one year was ~~described~~ determined by whether or not the child had developed *any* speech at appropriate ages, including cooing and babbling and whether or not the child was socially responsive in the first year of life, e.g., cuddling, appropriate eye contact, responding to parents voices. ~~Furthermore, type~~ of developmental concern was categorized as regre[illegible]or plat[illegible]au.

Statistical Analyses

We used conditional logistic regression models stratified by matched sets to estimate the odds ratios for the association between age at MMR vaccination and autism. Potential confounding variables were evaluated individually for their association with the autism case definition. Those with an odds ratio p-value < 0.20 were included as covariates in a conditional logistic regression model to estimate adjusted odds ratios for the association between age at vaccination and autism. **(should we describe referent groups and confounders ???)**

We examined two subgroups of autism cases: 1) case children with any pre-existing condition that was identified before the age of 1 year by either a medical provider or the parent and 2) case children with a regression or plateau of developmental milestones described in their records (????). Pre-existing conditions included an established cause for autism, a co-occurring

condition suggesting an early prenatal etiology (e.g., tuberous sclerosis, fragile X, or other congenital/chromosomal anomalies), parental concern before the age of one, and developmental disability ascertained by MADDSP that were diagnosed before age 1 years.

In the results, I think we should have separate tables for the ASD cases and the sub-categories

Table X: Associations c ASD

Total sample

B.C. sample (unadjusted)

B.C. sample (adjusted)

Table Y: Associations c selected ASD categories

No delay before 1 yr.

Total sample

B.C. (adj./unadj.)

No Co-occurring conditions

Total sample

B.C. (adj./unadj.)

Regression/Plateau

Total sample

B.C. sample (adj./unadj.)

CERTIFICATE OF SERVICE

This is to certify that I have on this 29th day of September, 2016 placed a true and correct copy of the:

PLAINTIFFS' NOTICE TO THE COURT OF Candyce Estave's CRIMINAL AFFIDAVIT Pursuant to 28 U.S.C. §1361 in Incorporated Case No. 2:16-cv-05224-SVW-AGR at the below address, or by depositing the same in the U.S. Mails;

To: Marine Pogosyan, Clerk to Magistrate Judge Alicia G. Rosenberg, United States District Court Central District of California, Western Division, 312 North Spring Street room G-8 Los Angeles, California 90012.

And to:

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I declare under penalty of perjury that the above is true and correct.

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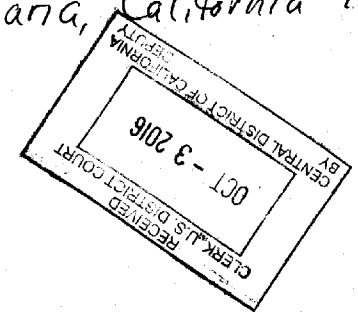

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