

**EVALUATING OCCUPATIONAL EXPOSURES
AND WORK PRACTICES**

AT

**Agilex Flavors, Inc.
formerly KEY ESSENTIALS, INC.
Rancho Santa Margarita, CA**

A Technical Assistance Report to the
California/Occupational Safety and Health Administration

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SITE SURVEYED:

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Formerly Key Essentials, Inc.
Rancho Santa Margarita, CA

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SURVEY DATES:

November 6-8, 2006;

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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Introduction

In response to a technical assistance request from California Division of Occupational Safety and Health (Cal/OSHA) in 2006, researchers from the National Institute for Occupational Safety and Health (NIOSH) conducted a site visit of Key Essentials, Inc. (now Agilex Flavors Inc.) at their Mission Viejo, California plant on November 6-8, 2006. Key Essentials is participating in the Flavoring Industry Safety and Health Evaluation Program (FISHEP), a voluntary special emphasis program. This program was initiated by the California Department of Health Services (CDHS) and the California Division of Occupational Safety and Health (Cal/OSHA) in 2006 to identify workers with flavoring-related lung disease such as bronchiolitis obliterans (BO) and institute preventive measures in the California flavoring industry. Under FISHEP, companies must report the results of worksite industrial hygiene assessments to CDHS, and implement control measures recommended by Cal/OSHA. This site report was conducted as the result of a formal technical assistance request on occupational exposures to potentially hazardous chemicals in the manufacturing of food flavors.

Due to the scale and complexity of formulations handled, this site was selected for inclusion in this investigation at the specific request of Cal/OSHA. The objectives of the industrial hygiene surveys conducted included identifying common work tasks, plant processes, and procedures as well as characterizing potential occupational exposures within the flavoring industry. A secondary goal was to provide preliminary engineering control guidance, which has been addressed in other correspondence[1].

Process Description

Key Essentials, Inc. produces wholesale flavors, extract, syrups, as well as malt, drink mixes, sport or energy drinks in liquid or powder forms. In October 2006, the Key Essentials, Inc facility was approximately 40,000 square feet^[2] and employed at least 13 production workers in the liquid and powder production room during the first shift.

Flavors are produced by compounding ingredients identified on recipes from batch tickets. These tickets identify the order and quantity of ingredients which need to be added to make a flavor formulation. High priority chemicals, i.e. substances that may pose a respiratory hazard as designated by the Flavoring Extract and Manufacturing Association^[3], are identified on the batch ticket and appropriate respiratory protection is also highlighted.

Weighing and measuring of flavoring ingredients can occur at various locations throughout the liquid production room, usually near the mixing tank or blender that will be used to produce the final product. It was noted that, for the most part, workers were assigned to either liquid or powder flavoring processes. Each worker would frequently rotate from the production rooms to the warehouse to collect the chemical ingredients necessary for each flavor formulation.

Exposures vary dramatically depending upon the flavor formulations completed on a particular day. An employee can make numerous flavor formulations daily depending upon the size and complexity of a batch order. It was not unusual to observe multiple batches being compounded concurrently by different employees in the production areas. The majority of flavors manufactured are on an as ordered basis, with little advance notice.

Liquid Flavor Production

The facility contained one large liquid production room approximately 51 by 73 feet in dimension. The liquid production area consisted of several small, medium and large stationary and mobile open tanks for mixing liquid flavoring ingredients as well as several long work benches for mixing flavors (Figure 1). The mobile tanks were moved throughout the liquid production room according to need of the batch or formulation. Employees typically pour, weigh and mix small quantities of flavoring chemicals on top of these work benches and then transfer the ingredients to a larger mixing tank. Employees complete large pours, near the large open tanks often pouring directly into the tank. When the recipe is completed, the mixer is started and a sheet of plastic is placed over the mixing tank and secured with tape to prevent contamination. In addition, after the flavoring has been tested and cleared by QC, liquid flavorings are packaged in the room in final product containers.

During the site visit, the liquid production room was served by a general ventilation system which had supply and exhaust registers located either on the ceiling or high along the sidewall of the rooms. Given the height of these registers (approximately 20 feet above the floor) and the interference from numerous mixing tanks on the floor, airflow measurements were not able to be collected. Airflow visualization using smoke was conducted at each door between this room and adjacent areas. The room was generally under positive pressure with respect to the warehouse—this means that air from the compounding room escaped to the warehouse during normal operations. The compounding room was under negative pressure with respect to the Quality Assurance/Quality Control room.

Following the initial survey, recommendations on the design and implementation of engineering controls were provided to the company in a letter, dated February 5, 2007 [1].

Powder Flavor Production

The facility contained one large powder production room approximately 55 by 51 feet in dimension (Figure 2). Powders were typically mixed with industrial ribbon blenders in the powder production room. In these mixers, a starch or carbohydrate was combined with a liquid or paste flavoring agent. The mixing process was a source of potential exposures with visible airborne dust depending upon the work practices employed during bag dumping, blending and packaging. During the site visit, the powder compounding area consisted of 3 ribbon blenders: Blender 1 was approximately 8 feet in length and 4 feet in depth (Figure 3). Blenders 2 and 3 were each approximately 6 feet in length and 3 feet in depth. Each blender was outfitted with local exhaust ventilation (LEV) at the top of the blender where workers dumped raw materials into the blender. Some blenders also included LEV where the product powder flavorings were discharged and packaged. Not all hoods, however, were connected to the ventilation system during the site visit. The blenders were located on platforms with fixed ladders used for access. The powder production room was served by a general ventilation system which had supply and exhaust registers located on the ceiling at a height of approximately 20 feet above the floor.

Since our site visit, powder production has been removed from the facility. Accordingly, limited recommendations have been made on these operations.

Materials and Methods

Information on processes and procedures was obtained through discussions with management and by observation of the processes. Prior to the site visit, the management provided production quantities for chemicals identified as 'high priority' by FEMA[3]. This information was used to refine the sampling scheme used by investigators. Use of personal protective equipment, and work practices were also observed during site visits.

The primary objective of the survey was to comprehensively characterize worker exposures in the production areas. Characterization of the workplace environment was accomplished through the use of personal, area, and task based air sampling methods. Personal and area air samples were collected for various processes within the liquid and powder production rooms. Air samples were collected for diacetyl, acetoin, total and respirable particulates, acids (phosphoric, butyric, acetic, and propionic) and five specific aldehydes (2-furaldehyde, acetaldehyde, benzaldehyde, isovaleraldehyde, and propionaldehyde). Table 1 lists the sample type, flow rate, and standard methods utilized during the site visit. All sampling pumps were calibrated in accordance with the sampling methods utilized. Pump calibration was conducted using a Bios Drycal DC-LITE , Model DCL-M primary flow standard (BIOS, Butler, NJ). Additional air monitoring equipment used during the survey was within their calibration periods, and checked for accuracy for the contaminant of interest before being used to collect field measurements.

Personal Air Sampling

During the site visit, eight-hour time weighted average (TWA) personal air samples were collected over three consecutive days on 13 employees assigned to work in the liquid and powder production areas. Personal samples were collected for ketones, acids, and aldehydes using calibrated battery-powered personal SKC Model 210-1002 air sampling pumps (SKC Inc. , Eighty Four, PA) with appropriate sampling media for the contaminant of interest (Table 1, Figure 4). Diacetyl and acetoin samples were collected using carbon molecular sieve media at a flowrate of approximately 0.1 liters per minute and were analyzed according to NIOSH method 2557. Acid samples were collected with silica gel media (400mg/200mg) at a flowrate of approximately 0.2 liters per minutes and were analyzed according to draft NIOSH method 5048 (acetic, butyric and propionic) or NIOSH method 7903 (phosphoric acid). Aldehyde samples were collected using dinitrophenylhydrazine (DNPH) treated silica gel media at a flowrate of approximately 0.1 Liters per minute and were analyzed according to EPA TO-11 method. Employees working in the powder production room were also sampled for an eight-hour TWA for respirable dust using the model GK 2.69, personal cyclone sampler (BGI , Waltham, MA.) mated with an Airchek 2000 personal sampling pump (SKC Inc., Eighty Four, PA) at a flowrate of approximately 4.2 Liters per minute. Respirable dust samples were analyzed according to NIOSH method 0600.

Short duration task-based air sampling was also conducted for ketones, or aldehydes using appropriate sampling media and calibrated pumps to obtain measurements of exposure during selected short-term procedures. Task-based samples were collected during particular tasks (i.e

pouring or mixing) or during batch formulations which contained higher quantities of ketones, acids or aldehydes. Samples were collected for the duration of a pouring task (diacetyl, ketones or acids), or the entire duration of a mixing batch formulation depending on the overall length of the process.

Area Air Sampling

Area samples were also collected in the liquid and powder production areas to identify chemical concentrations (Figures 1, 2, 5). Eight-hour time weighted average (TWA) area air samples were collected over three consecutive days for ketones (diacetyl and acetoin), aldehydes (acetaldehyde, benzaldehyde, isovaldehyde, 2-furaldehyde, propionaldehyde) and acids (acetic, butyric, proprionic and phosphoric). Area samples for diacetyl were collected according to the NIOSH method 2557 and a modified U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) Method PV2118. This modified OSHA method used larger collection tubes (400/200 milligram silica gel tubes) which have greater capacity and minimize breakthrough of contaminant to the backup tube.

All area sample collection devices were housed inside a metal basket, which was located near employee work stations (Figure 5). Respirable dust and total dust samples were also collected in the powder production areas. Respirable dust samples were collected using a GK 2.69, personal cyclone sampler (BGI , Waltham, MA.) at a flowrate of 4.2 liters per minute (lpm). Real-time VOC concentrations were measured in selected area baskets using MiniRAE 2000 and ToxiRAE photoionization detectors (PID) (Rae Systems, Inc., Sunnyvale, CA). PIDs were programmed to log volatile organic compound (VOC) concentrations every minute. The PIDs were calibrated

for isobutylene and could detect isobutylene equivalent VOC concentrations from 1 ppm to 2000 ppm.

Thermal desorption samples were collected within the area locations for approximately two hours each day. The stainless steel thermal desorption tubes contained three beds of sorbent material: the first section contains Carbopack Y (90 mg), the second section contains Carbopack B (115 mg) and the last section contains Carboxen 1003 (150 mg). The thermal tube sorbents were run for approximately 2 hours at a flowrate of 0.1 liters per minute and were analyzed according to NIOSH method 2549. These samples provided both a qualitative and a semi-quantitative analysis of volatile organic compounds in the work environment.

After the site visit was completed, a laboratory investigation indicated that the NIOSH method for diacetyl is affected by relative humidity, resulting in an underestimation of true concentrations. A NIOSH project is currently underway to investigate the extent of this phenomenon and determine at what relative humidity levels it occurs.

Statistical Analyses

Laboratory reports provided sample results in micrograms (μg) of analyte per sample.

Analytical results were converted to an airborne concentration by dividing by the air volume associated with the sample (mg/m^3), then converting to parts per million (ppm) by volume using the gram molecular weight of the analyte at standard temperature and pressure. All calculations to determine airborne concentrations, and provide descriptive statistics were conducted using

SAS (SAS 9.1.3, SAS Institute, Cary, NC). Sampling results that were below the limit of detection for the sampling methods used were assigned a value of one-half of the airborne concentration limit of detection (LOD) for statistical analyses [4].

Applicable Occupational Exposure Limits (OELs)

In evaluating the hazards posed by workplace exposures, NIOSH investigators use both mandatory (legally enforceable) and recommended occupational exposure limits (OELs) for chemical, physical, and biological agents as a guide for making recommendations. OELs have been developed by Federal agencies and safety and health organizations to prevent the occurrence of adverse health effects from workplace exposures. Generally, OELs suggest levels of exposure to which most workers may be exposed up to 10 hours per day, 40 hours per week for a working lifetime without experiencing adverse health effects. However, not all workers will be protected from adverse health effects even if their exposures are maintained below these levels. A small percentage may experience adverse health effects because of individual susceptibility, a pre-existing medical condition, and/or a hypersensitivity (allergy). In addition, some hazardous substances may act in combination with other workplace exposures, the general environment, or with medications or personal habits of the worker to produce health effects even if the occupational exposures are controlled at the level set by the exposure limit. Also, some substances can be absorbed by direct contact with the skin and mucous membranes in addition to being inhaled, thus contributing to the overall exposure.

Most OELs are expressed as a time-weighted average (TWA) exposure. A TWA refers to the average exposure during a normal 8- to 10-hour workday. Some chemical substances and physical agents have recommended short-term exposure limits (STEL) or ceiling values where

there are health effects from higher exposures over the short-term. Unless otherwise noted, the STEL is a 15-minute TWA exposure that should not be exceeded at any time during a workday, and the ceiling limit is an exposure that should not be exceeded at any time.

In the U.S., OELs have been established by Federal agencies, professional organizations, state and local governments, and other entities. Some OELs are legally enforceable limits; others are recommendations. The U.S. Department of Labor OSHA Permissible Exposure Limits (PELs) (29 CFR 1910 (general industry); 29 CFR 1926 (construction industry); and 29 CFR 1917 (maritime industry)) are legal limits that are enforceable in workplaces covered under the Occupational Safety and Health Act. NIOSH recommended exposure limits (RELs) are recommendations that are made based on a critical review of the scientific and technical information available on the given hazard and the adequacy of methods to identify and control the hazards. NIOSH RELs can be found in the *NIOSH Pocket Guide to Chemical Hazards*[5]. NIOSH also recommends preventive measures (e.g., engineering controls, safe work practices, personal protective equipment, and environmental and medical monitoring) to minimize the risk of exposure and adverse health effects from these hazards. Other OELs that are commonly used and cited in the U.S. include the threshold limit values (TLVs)[®] recommended by the American Conference of Governmental Industrial Hygienists (ACGIH)[®], a professional organization[6] and the workplace environmental exposure levels (WEELs) recommended by the American Industrial Hygiene Association, another professional organization. ACGIH TLVs are considered voluntary guidelines for use by industrial hygienists and others trained in this discipline “to assist in the control of health hazards.” WEELs have been established for some chemicals “when no other legal or authoritative limits exist”[7].

Employers should understand that not all hazardous chemicals have specific OSHA PELs and for some agents the legally enforceable and recommended limits may not reflect current health-based information. However, an employer is still required by OSHA to protect their employees from hazards even in the absence of a specific OSHA PEL. OSHA requires an employer to furnish employees a place of employment that is free from recognized hazards that are causing or are likely to cause death or serious physical harm (Occupational Safety and Health Act of 1970, Public Law 91–596, sec. 5(a)(1)). Thus, NIOSH investigators encourage employers to make use of other OELs when making risk assessment and risk management decisions to best protect the health of their employees. NIOSH investigators also encourage the use of the traditional hierarchy of controls approach to eliminating or minimizing identified workplace hazards. This includes, in preferential order, the use of: (1) substitution or elimination of the hazardous agent, (2) engineering controls (e.g., local exhaust ventilation, process enclosure, dilution ventilation) (3) administrative controls (e.g., limiting time of exposure, employee training, work practice changes, medical surveillance), and (4) personal protective equipment (e.g., respiratory protection, gloves, eye protection, hearing protection). Table 2 contains a listing of all substances sampled during the site visit, and provides applicable OELs, where available.

Results

Descriptive statistics for all air samples are presented in Tables 3, 4, 5. The 8-hr time weighted average for both area and personal samples are shown in Table 3. Area and personal samples are presented discretely by work area in Table 4. Table 5 presents the task-based samples collected in the liquid production room with information on the formulated flavoring.

Outdoor air temperatures ranged from 55°F to 92°F while outdoor relative humidity ranged from 15% to 98% during the site visit. No indoor air temperatures or relative humidity measurements were collected.

Ketones (Diacetyl and Acetoin)

A total of 44 personal and area diacetyl/acetoin 8-hr time weighted samples were collected using NIOSH method 2557/2558 and 12 area 8-hr time weighted average samples for diacetyl were collected using modified OSHA method PV2118 during the November site visit (Tables 3 - 4). Diacetyl area samples and personal samples collected on the same day in the same production area were not significantly different than one another (p -value = 0.384). Task-based samples were collected for diacetyl during the site visit, all using the NIOSH method 2557 (Table 5). Since the facility was out of natural diacetyl during the site visit, few task based samples were collected for diacetyl and acetoin. The highest task-based exposure for diacetyl was 0.63 ppm while a worker mixed and poured ingredients for a dairy flavor.

As stated earlier, a recent laboratory investigation revealed that the NIOSH method 2557 for diacetyl is influenced by relative humidity concentrations. Although diacetyl samples analyzed using the NIOSH method have been presented in this report, it should be noted that these measurements are likely underestimates of true concentrations. Therefore, we have presented these results solely for comparison to previous investigations.

During the site visit, area diacetyl samples were collected using a modified OSHA method for diacetyl (400 mg/200 mg silica gel media). Based on the initial laboratory study, it is believed that samples analyzed with the modified OSHA analytical method provide more accurate results than samples analyzed with the NIOSH method.

In an analysis limited to samples analyzed according to the modified OSHA method, average area diacetyl concentrations were highest in the liquid production room (Arithmetic Mean(AM): 0.261 ppm, Geometric Mean(GM) : 0.206 n= 6).

Acetoin

Acetoin concentrations were higher in the powder production room for both personal and area samples than in the liquid production room, with all measurements lower than 1 ppm (Table 4).

Acetoin was always observed in lower concentrations than diacetyl during the task-based samples. The highest task-based acetoin sample concentration in the liquid production room was measured during the mixing of a vanilla wafer flavor (0.12 ppm).

Aldehydes

A total of forty-three 8hr TWA personal and air samples were collected for each of five aldehydes, specifically 2-furaldehyde, acetaldehyde, benzaldehyde, isovaleraldehyde and propionaldehyde. All 8-hr TWA were below relevant occupational exposure limits, when applicable. Eight hour TWA samples for acetaldehyde, 2-furaldehyde and isovaldehyde were higher in the liquid production room whereas benzaldehyde and propionaldehyde were higher in the powder production room. When comparing all aldehydes, acetaldehyde had the highest

arithmetic mean (0.397 ppm) and geometric mean concentration (0.201 ppm). Personal benzaldehyde concentrations varied dramatically, especially among employees working in the powder production room (GSD: 16.56).

The highest task based sample, an acetaldehyde exposure (54.7 ppm) occurred when an employee poured and mixed ingredients for fruit flavor in the liquid production room (Table 5). The next highest task based sample was also for acetaldehyde (47.7 ppm) when an employee was pouring and mixing ingredients for a berry flavor. In both cases, the monitored employees wore respiratory protection for these tasks. Both of these samples were collected for approximately 15 minutes and exceeded the ACGIH TLV ceiling limit for acetaldehyde. Although the worker being monitored during this task was wearing a respirator, nearby employees were not wearing respiratory protection. Aldehyde exposures varied considerably during the site visit depending upon batch formula, worker task and work practices.

Thermal Desorption Samples

Approximately two hundred chemical compounds were identified on the thermal desorption tubes collected at this facility. To interpret the response from the thermal tube sample analysis, these responses were categorized (using height of peak and area under peak) in each sample as 1) non-detected, 2) trace quantity present, 3) minor component of mixture, 4) significant quantity present and 5) major component of mixture. The most predominant contaminants identified are presented in Table 6, in order of decreasing abundance.

Acids

During the site visit, 8-hr TWA acetic, butyric and propionic acid samples were collected on employees and in area baskets in the liquid and powder production areas. A total of 12 8-hr TWA phosphoric acid samples were also collected in all area baskets during the site visit. All acid samples were below relevant occupational exposure limits (Table 2). Eight-hour TWA personal acetic acid samples collected in the powder production area were higher than samples collected in the liquid production room (Table 4). In contrast, 8-hr samples for butyric acid and propionic acid samples were higher in the liquid production areas compared to the powder production room. Phosphoric acid was only detected in the powder production room.

Dust Concentrations

Respirable dust concentrations were measured on employees working in the powder production room. Both total dust and respirable dust concentrations were measured in area baskets within the powder production room (Tables 3 - 4). Two 8hr TWA area total dust samples exceeded occupational exposure limits for total dust (Table 2). Employees working in this vicinity wore half face HEPA respirators or dust filtering face pieces during dusty operations while compounding the powdered flavor.

Real-time VOC samples

Real-time room area VOC concentrations are shown in Figures 6 and 7 for the liquid and powder production areas, respectively. The photoionization detectors (PIDs) used measure a wide array of volatile chemicals with ionization potentials within the response range of the instrument. It does not provide identification of specific chemicals but can be used for

comparison of exposures among a variety of tasks throughout the workday. The units were calibrated with isobutylene and thus all measurements are shown in isobutylene equivalent concentrations.

As shown in Figure 7, concentrations increased to almost 25 ppm when employees were cleaning the mixer (i.e. Shaker #1) on November 7th. During the cleaning process, dry sweeping and compressed air (80 psi) was used to clean the excess powder from the shaker and surrounding pallets.

Respiratory Protection Program

A respiratory protection program was operational in the facility. Respirator use in the liquid production room included both half-face cartridge respirators and full-face cartridge respirators with organic vapor and P100 cartridges. Respirators for employees working in the liquid production room were stored in plastic bags within black soft-sided bags which hung on racks inside the production area. Employees only wore respirators when he/she was compounding a flavor formulation that contained a “high priority” chemical. Other employees working in close proximity did not wear respiratory protection. On the powder side, employees only wore respiratory protection when completing tasks which were considered dusty. On the powder production side, respirators were stored on hooks hanging in the production area. In general, employees did not seem knowledgeable of change-out procedures.

Discussion

Two task based samples for acetaldehyde were the highest observed at the facility. Although the monitored worker wore respirator protection, other employees working in close proximity did not wear any respiratory protection. Aldehydes are volatile and will easily migrate in room air. Given the potential health effects from aldehydes including acetaldehyde, this is an inherent weakness with the observed respiratory protection program. This practice incorrectly assumes that any escaped chemicals will disappear instantaneously and it does not provide protection from vapors arising following the pours or from chemicals being used by other workers in the near vicinity.

NIOSH recommendations, OSHA regulations, and good safety and health practice dictate that respirators should be used, (1) when effective engineering controls are not feasible for preventing airborne contamination of the workplace, (2) while they are being put into place, and (3) during emergencies. Until effective engineering controls are put into place, all workers in the liquid compounding room should wear appropriate respiratory protection during the use of high priority chemicals or any other chemicals known to be respiratory hazards.

The use of engineering controls could help improve worker protection during small batch mixing and weighing of flavoring chemicals. Ventilated workstations have been shown to effectively capture contaminants and should reduce worker exposure if designed, installed, used and maintained properly[8]. Also, the implementation of ventilated mixing tank lids could allow containment of vapors during large batch mixing. The design and installation of a large enclosure such as a ventilated booth could provide a place to contain vapors from large batch

mixing as well as provide a location for packaging of liquid and powder flavorings. The implementation of any new controls requires that workers be adequately trained and that the systems be properly maintained.

It was reported that total annual diacetyl consumption in this facility was low compared to other users in the industry. During the days sampled, the facility did not have any natural diacetyl in stock and was therefore unable to compound flavor formulations which required this ingredient. Accordingly, it is unknown what typical diacetyl exposures are present in the facility when natural diacetyl is also in use. The facility should repeat diacetyl sampling on days when more typical operations are underway and when high exposure tasks are performed.

Recommendations

1. Engineering Controls:

1. Install appropriate engineering controls in the liquid and powder production rooms. These controls should address the potential sources of exposure documented in the letter from NIOSH, dated February 5, 2007[1].
 - a. Train employees on proper use and good work practices once these controls have been installed.
 - b. Engineering controls should be evaluated periodically to insure proper operation in accordance with engineering control guidance[9]. System performance checks should be added to a preventative maintenance routine.
2. Maintain negative air pressure differential for the liquid and powder compounding rooms with respect to adjacent areas. This will help reduce the escape of flavoring chemicals and

potential exposure to warehouse workers. In order to maintain a slight negative pressure, the room supply air volume should be slightly less than the exhaust air. A general rule of thumb is to set a 5%-10% flow difference between supply and exhaust flow rates but no less than 50 cubic feet per minute (cfm)[10].

2. Work Practices:

- 1) Pouring, measuring, or open transfer of high priority flavoring chemicals or ingredients should be completed in a controlled environment such as a ventilated booth using appropriate work practices and respiratory protection.
- 2) Keep containers of flavoring chemicals and/or ingredients sealed when not in use.
- 3) Utilize cold water washes and cold storage of chemicals when feasible.
- 4) Clean spills promptly to minimize emissions of chemical vapors. Include proper spill cleanup techniques in the standard operating procedures and provide worker training on these practices.
- 5) Add diacetyl and other high priority chemicals into a batch last, when possible, to minimize volatilization and exposure potential/duration.
- 6) Wear personal protective equipment including respirators and skin protection when cleaning up spills or washing empty containers of flavoring chemicals or ingredients.

7) Operate forklift machinery in a safe manner, utilizing a slow travel speed from one area to another.

3. Respiratory Protection:

1) Require mandatory respirator use for all production workers and other workers who enter the production area.

2) Re-locate the respirator storage and cartridge re-load area from inside production rooms to an alternate area with lower concentrations of flavoring chemicals.

3) In accordance with Cal/OSHA direction, "full-facepiece respirators fit-tested with an approved quantitative method are needed as minimal protection for employees exposed to flavoring ingredients in this industry. All employees entering flavor formulation areas or unprotected areas (e.g., packaging areas) must wear respirators" (FISHEP correspondence from K. Howard dated Oct. 13, 2006). Specifically, a NIOSH-certified full-face respirator with organic vapor/acid gas cartridges and particulate filters is the minimum level of respiratory protection recommended in conjunction with a fully operational respiratory protection program. Respirator cartridges should be changed out in accordance to manufacturer specifications.

Additional Information about respirators is available at the NIOSH website

(<http://www.cdc.gov/niosh/npptl/topics/respirators/> and <http://www.cdc.gov/niosh/docs/2005-100/default.html>). Details on the OSHA Respiratory Protection Standard are available on the OSHA website (<http://www.osha.gov/>).

4) Restrict access to the production rooms to only employees that need to be there, have been properly quantitatively fit-tested, and are wearing appropriate respiratory protection as identified above.

4. Medical Surveillance:

1) Follow medical surveillance guidance and recommendations as specified in communication from the CA Department of Public Health[11]. Additional information can also be found from the NIOSH topic page on flavorings located at: <http://www.cdc.gov/niosh/topics/flavorings> [12] as well as the NIOSH Alert “Preventing Lung Disease in Workers Who Use or Make Flavorings.”

5. Hazard Communication:

1) Ensure workers understand the hazards associated with flavoring chemicals and how to protect themselves. OSHA’s Hazard Communication Standard, also known as the “Right to Know Law” (29 CFR 1910.1200) requires that employees are informed and trained of potential work hazards and associated safe practices, procedures, and protective measures.

The California Code of Regulations, Title 8, Section 5194, Hazard Communication, is available at <http://www.dir.ca.gov/title8/5194b.html>.

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Table 1. Air Sampling and Analysis Methods

Type	Analysis Method	Media	Analytes	Objective	Flowrate	Sample Duration
Aldehydes	EPA TO-11	Dinitrophenylhydrazine (DNPH) treated silica (150/300 mg)	2-Furaldehyde Acetaldehyde, Benzaldehyde, Isovaleraldehyde Propionaldehyde	8-hr TWA	100cc/min	300 minutes
	EPA TO-11	Dinitrophenylhydrazine (DNPH) treated silica	2-Furaldehyde Acetaldehyde, Benzaldehyde, Isovaleraldehyde Propionaldehyde	Task Based Sample	200cc/min	15 minutes -1 hour
Acids	Draft NMAM 5048	Silica Gel (200mg/400mg)	Acetic Acid Butyric Acid Propionic Acid	8-hr TWA	200cc/min	480 minutes
	NMAM 7903	Silica Gel (200mg/400mg)	Phosphoric Acid	8-hr TWA	200cc/min	480 minutes
	Draft NMAM 5048	Silica Gel (200mg/400mg)	Acetic Acid Butyric Acid Propionic Acid	Task Based Sample	200cc/min	15 minutes -1 hour
Ketones	OSHA PV2118 (modified method)	Silica Gel (200mg/400mg)	Diacetyl	8-hr TWA	100cc/min	480 minutes
	NIOSH 2557/2558	CMS (75mg/150mg)	Diacetyl/Acetoin	8-hr TWA	100cc/min	480 minutes
	NMAM 2557/2558	CMS (75mg/150mg)	Diacetyl/Acetoin	Task Based Sample	200cc/min	15 minutes -1 hour

Table 1. (Continued) Air Sampling and Analysis Methods

Type	Analysis Method	Media	Analytes	Objective	Flowrate	Sample Duration
VOCs	NMAM 2549	Thermal Desorption Tubes	Varied based on Thermal tubes	2-hr TWA	100cc/min	60 minutes
Respirable dust	NMAM 0600	37 mm PVC filter, BGI cyclone	Respirable dust	8-hr TWA	4.2L/min	240 minutes
Total Dust	NMAM 0500	37 mm PVC filter	Total dust	8-hr TWA	1.5L/min	240 minutes

NOTES:

NMAM: NIOSH Manual of Analytical Methods

Table 2. Relevant Occupational Exposure Limits

Chemical Name	Occupational Exposure Limits								
	NIOSH REL			OSHA PEL			ACGIH TLV		
	TWA	STEL	Ceiling	TWA	STEL	Ceiling	TWA	STEL	Ceiling
2-Furaldehyde	NE	NE	NE	5 ppm ^(A)	NE	NE	2 ppm ^(A,B)	NE	NE
Acetaldehyde	NE ^(C)	NE ^(C)	NE ^(C)	200 ppm	NE	NE	NE	NE	25 ppm ^(B)
Acetic acid	10ppm	15ppm	NE	10ppm	NE	NE	10ppm	15ppm	NE
Acetoin	NE	NE	NE	NE	NE	NE	NE	NE	NE
Benzaldehyde	NE	NE	NE	NE	NE	NE	NE	NE	NE
Butyric acid	NE	NE	NE	NE	NE	NE	NE	NE	NE
Diacetyl	NE	NE	NE	NE	NE	NE	NE	NE	NE
Isovaleraldehyde	NE	NE	NE	NE	NE	NE	NE	NE	NE
Phosphoric acid	1 mg/m ³	3 mg/m ³	NE	1 mg/m ³	NE	NE	1 mg/m ³	3 mg/m ³	NE
Propionaldehyde ^D	NE	NE	NE	NE	NE	NE	20 ppm	NE	NE
Propionic acid	10 ppm	15 ppm	NE	NE	NE	NE	10 ppm	NE	NE
Respirable particulate	NE	NE	NE	5 mg/m ³	NE	NE	3 mg/m ³	NE	NE
Total particulate	NE	NE	NE	15 mg/m ³	NE	NE	10 mg/m ³ ^(E)	NE	NE
Total volatile organic compounds	NE	NE	NE	NE	NE	NE	NE	NE	NE

NOTES:

A - Skin notation

B - ACGIH confirmed animal carcinogen with unknown relevance to humans [6]

C - NIOSH potential occupational carcinogen - (See Appendix A and C in the NIOSH Pocket Guide to Chemical Hazards [5])

D - Testing has not been completed to determine the carcinogenicity of acrolein, butyraldehyde (CAS#: 123-72-8), crotonaldehyde, glutaraldehyde, glyoxal (CAS#: 107-22-2), paraformaldehyde (CAS#: 30525-89-4), propionaldehyde (CAS#: 624-67-9), propionaldehyde (CAS#: 123-38-6), and n-valeraldehyde, nine related low-molecular-weight-aldehydes. However, the limited studies to date indicate that these substances have chemical reactivity and mutagenicity similar to acetaldehyde and malonaldehyde. Therefore, NIOSH recommends that careful consideration should be given to reducing exposures to these nine related aldehydes. [13]

E - Inhalable fraction [6]

NE - Not established

Table 3 Eight-hour Time Weighted Average descriptive statistics for both area and personal samples

Analyte	units	n	AM	SD	GM	GSD	Min	Max
2-Furaldehyde	ppm	43	0.012	0.011	0.007	3.333	0.0001	0.041
Acetaldehyde	ppm	43	0.397	0.463	0.201	4.116	0.0006	1.723
Acetic Acid	ppm	47	0.828	0.893	0.397	4.351	0.0205	4.275
Acetoin	ppm	43	0.022	0.014	0.019	1.651	0.0055	0.083
Benzaldehyde	ppm	43	0.345	0.608	0.119	5.152	0.0002	2.582
Butyric Acid	ppm	47	0.356	0.423	0.138	5.586	0.0080	1.905
Diacetyl (MOSHA) ¹	ppm	12	0.166	0.172	0.112	2.444	0.0368	0.537
Diacetyl (NIOSH) ²	ppm	44	0.089	0.110	0.042	3.817	0.0059	0.485
Isovaleraldehyde	ppm	43	0.050	0.064	0.024	3.950	0.0003	0.290
Respirable Particulate	mg/m ³	16	1.489	1.146	0.849	4.11	0.037	3.37
Propionaldehyde	ppm	43	0.006	0.008	0.004	2.317	0.0004	0.050
Phosphoric Acid	mg/m ³	12	0.058	0.069	0.036	2.451	0.020	0.235
Propionic Acid	ppm	47	0.484	0.608	0.133	9.188	0.0032	2.774
Total Particulate	mg/m ³	8	5.136	5.829	1.723	7.766	0.0568	15.14

NOTES:

n: Number of samples

AM: Arithmetic Mean

SD: Standard Deviation

GM: Geometric Mean

GSD: Geometric Standard Deviation

Max: Maximum

Min: Minimum

¹ Collected/analyzed using modified OSHA method PV2118 for diacetyl

² Collected/analyzed using NIOSH method 2557 for diacetyl, which likely underestimates true exposure.

Table 4. Descriptive Statistics by Work Area
 Eight-hour Time Weighted Averages, Area and Personal Samples by Work Area

Analyte	Type	units	n	AM	SD	GM	GSD	Min	Max
Powder Production Room									
2-Furaldehyde	Area	ppm	6	0.008	0.006	0.006	2.807	0.001	0.016
	Personal	ppm	9	0.007	0.005	0.004	3.831	0.0003	0.012
Acetaldehyde	Area	ppm	6	0.072	0.015	0.071	1.230	0.054	0.091
	Personal	ppm	9	0.075	0.049	0.043	5.581	0.001	0.173
Acetic Acid	Area	ppm	6	0.394	0.478	0.130	6.547	0.020	1.222
	Personal	ppm	10	1.139	1.488	0.394	5.846	0.021	4.275
Acetoin	Area	ppm	5	0.030	0.017	0.026	1.875	0.013	0.055
	Personal	ppm	10	0.029	0.022	0.023	2.197	0.006	0.083
Benzaldehyde	Area	ppm	6	0.767	1.103	0.172	7.676	0.025	2.275
	Personal	ppm	9	0.592	0.905	0.096	16.56	0.0002	2.582
Butyric Acid	Area	ppm	6	0.016	0.014	0.013	1.877	0.008	0.044
	Personal	ppm	10	0.243	0.123	0.203	2.040	0.057	0.449
Diacetyl (MOSHA) ¹	Area	ppm	6	0.070	0.043	0.061	1.770	0.037	0.145
Diacetyl (NIOSH) ²	Area	ppm	6	0.034	0.039	0.019	3.309	0.006	0.098
	Personal	ppm	10	0.051	0.074	0.021	4.068	0.006	0.225
Isovaleraldehyde	Area	ppm	6	0.013	0.009	0.009	2.866	0.001	0.026
	Personal	ppm	9	0.011	0.011	0.007	3.842	0.0003	0.036
Respirable Particulate	Area	mg/m ³	7	1.483	1.055	1.088	2.552	0.306	2.803
	Personal	mg/m ³	7	1.908	1.125	1.589	1.996	0.522	3.37
Phosphoric Acid	Area	mg/m ³	7	0.083	0.083	0.052	2.893	0.020	0.235
Propionaldehyde	Area	ppm	6	0.005	0.003	0.004	1.816	0.002	0.012
	Personal	ppm	9	0.014	0.016	0.007	4.503	0.0004	0.050
Propionic Acid	Area	ppm	6	0.006	0.005	0.005	1.877	0.003	0.017
	Personal	ppm	10	0.336	0.144	0.297	1.825	0.068	0.583
Total Particulate	Area	mg/m ³	6	6.818	5.831	4.70	2.690	1.417	15.14

Table 4. (Continued) Descriptive Statistics by Work Area
 Eight-hour Time Weighted Averages, Area and Personal Samples by Work Area

Analyte	Type	units	n	AM	SD	GM	GSD	Min	Max
Liquid Production Room									
2-Furaldehyde	Area	ppm	6	0.018	0.014	0.014	2.258	0.005	0.041
	Personal	ppm	21	0.014	0.011	0.009	3.437	0.0001	0.041
Acetaldehyde	Area	ppm	6	0.682	0.484	0.518	2.383	0.186	1.330
	Personal	ppm	21	0.551	0.512	0.397	2.243	0.084	1.723
Acetic Acid	Area	ppm	6	0.095	0.084	0.070	2.390	0.021	0.251
	Personal	ppm	24	1.010	0.634	0.819	2.036	0.129	2.835
Acetoin	Area	ppm	6	0.015	0.005	0.014	1.587	0.006	0.019
	Personal	ppm	21	0.018	0.004	0.018	1.220	0.013	0.031
Benzaldehyde	Area	ppm	6	0.186	0.124	0.127	3.126	0.026	0.301
	Personal	ppm	21	0.179	0.135	0.121	2.725	0.030	0.423
Butyric Acid	Area	ppm	6	0.009	0.001	0.009	1.076	0.008	0.010
	Personal	ppm	24	0.587	0.474	0.437	2.299	0.057	1.905
Diacetyl (MOSHA) ¹	Area	ppm	6	0.261	0.204	0.206	2.082	0.113	0.537
Diacetyl (NIOSH) ²	Area	ppm	6	0.149	0.161	0.092	2.860	0.036	0.422
	Personal	ppm	21	0.099	0.113	0.053	3.409	0.006	0.485
Isovaleraldehyde	Area	ppm	6	0.079	0.061	0.055	2.755	0.015	0.181
	Personal	ppm	21	0.060	0.065	0.038	2.674	0.011	0.290
Respirable Particulate	Area	mg/m ³	2	0.040	0.004	0.040	1.097	0.037	0.043
Propionaldehyde	Area	ppm	6	0.002	0.001	0.002	1.334	0.002	0.003
	Personal	ppm	21	0.005	0.002	0.004	1.654	0.001	0.011
Propionic Acid	Area	ppm	6	0.003	0.0002	0.003	1.076	0.003	0.004
	Personal	ppm	24	0.802	0.699	0.549	2.669	0.067	2.774
Total Particulate	Area	mg/m ³	2	0.092	0.049	0.085	1.762	0.057	0.127

NOTES: n: Number of samples; AM: Arithmetic Mean; SD: Standard Deviation;
 GM: Geometric Mean; GSD: Geometric Standard Deviation;
 Max: Maximum; Min: Minimum

¹ Collected/analyzed using modified OSHA method PV2118 for diacetyl

² Collected/analyzed using NIOSH method 2557 for diacetyl, which likely underestimates true exposure.

Other: Per analyte, the total number of samples (n) in Table 4 may not equal the total number of samples(n) presented in Table 3. Some employees worked in multiple production areas within a day and could not be listed within one particular production area.

Phosphoric acid was not detected in the liquid production room and is therefore not listed in Table 4.

Table 5. Task based personal sampling results while pouring and mixing flavor formulations in the liquid production room

Flavoring	Analyte	Concentration (ppm)	Task Duration (min)
Berry Flavor	2-Furaldehyde	0.03	13
Artificial Nut Flavor	2-Furaldehyde	0.09	22
Fruit Flavor	2-Furaldehyde	0.17	16
Berry Flavor	2-Furaldehyde	0.03	14
Fruit Flavor	Acetaldehyde	0.25	19
Berry Flavor	Acetaldehyde	47.7	13
Artificial Nut Flavor	Acetaldehyde	0.08	22
Artificial Nut Flavor	Acetaldehyde	0.04	55
Fruit Flavor	Acetaldehyde	54.7	16
Berry Flavor	Acetaldehyde	0.57	14
Dairy Flavor	Acetoin	0.04	76
Vanilla Wafer Flavor	Acetoin	0.12	16
Fruit Flavor	Benzaldehyde	1.52	19
Berry Flavor	Benzaldehyde	0.07	13
Artificial Nut Flavor	Benzaldehyde	1.05	22
Artificial Nut Flavor	Benzaldehyde	0.21	55
Fruit Flavor	Benzaldehyde	0.67	16
Berry Flavor	Benzaldehyde	0.68	14
Confectionary Flavor	Diacetyl ¹	0.07	111
Dairy Flavor	Diacetyl ¹	0.63	76
Vanilla Wafer Flavor	Diacetyl ¹	0.01	132
Artificial Nut Flavor	Isovaleraldehyde	0.84	22
Artificial Nut Flavor	Isovaleraldehyde	0.94	55
Berry Flavor	Propionaldehyde	0.03	13
Fruit Flavor	Propionaldehyde	0.05	16

NOTES:

ppm: parts per million

min: minutes

¹ Collected/analyzed using NIOSH method 2557 for diacetyl, which likely underestimates true exposure.

Table 6. The Most Abundant Compounds Observed in Thermal Desorption Sample Results in Rank Order

Chemical Compound Observed
Limonene
Ethyl butyrate
Ethyl acetate
Benzaldehyde
Ethyl 2-methyl butyrate
p-Cymene
Isoamyl acetate (3-methyl-butyl acetate)
gamma-Terpinene
Ethyl propionate
C10H16 terpene, beta-pinene
Menthone
Ethyl isovalerate (ethyl 3-methyl butyrate)
Menthol
Propylene glycol
alpha-Terpinolene
C10H16 terpene, myrcene
Cinnamaldehyde
2-Methylbutyl acetate
Amyl acetate
Ethanol
C10H16 terpene, alpha-pinene
Dimethyl styrene isomer
C10H16 terpenes (such as thujene,sabinene,fenchene, phellandrene,etc.)
Ethyl vanillin
C10H16 terpene, camphene
Ethyl caproate (hexanoate)
Benzyl alcohol
Isoamyl alcohol (3-methyl- butanol-2-Methylbutanol
Toluene
C10H14O isomer, carvone
Amyl butyrate
Vanillin
Isovaleraldehyde (3-methylbutanal)
Methyl salicylate
Methyl cinnamate
Caffeine
Isomenthone
Hexyl acetate
Ethyl valerate

Table 6. (Continued) The Most Abundant Compounds Observed in Thermal Desorption Sample Results in Rank Order

Isoamyl butyrate
Isoamyl formate
Eugenol
C15H24 isomer, beta-caryophyllene
Ethyl lactate
C15H24 isomer, alpha-copaene
Methyl amyl ketone
Ethyl isobutyrate
cis-3-Hexenyl acetate
Isobutyl acetate
Benzene/butanol
Furfural
Piperonal
Acetic acid
Diacetyl
alpha-Terpineol
Linalool
C15H24 isomers
Maltol
cis 3-Hexen-1-ol
Triacetin
Acetyl methyl cyclohexene
Butyric acid
Propionic acid
C6 aliphatic hydrocarbons
Furfuryl alcohol
Glycolal (hydroxy acetaldehyde)
Dimethyl pyrazine
Methyl hexenoate
Menthyl acetate
Ethyl pelargonate (nonanoate)
C10H16O isomers (such as neral, geranial, citral)
Acetol
Allyl anisole
Menthofuran
Trans-anethole
Styrene
Isooctane
Ethyl ether
4-(4-Hydroxyphenyl)-2- butanone (raspberry ketone)
Isoamyl caprylate (octanoate)
Ionone

Table 6. (Continued) The Most Abundant Compounds Observed in Thermal Desorption Sample Results in Rank Order

Benzyl acetate
Limonene dioxide
Ethyl crotonate
Formaldehyde
Menthene
Dodecane
Formic acid

NOTES:

This list is not comprehensive and only lists the most predominant compounds.

Figure 1. Liquid Production Room Diagram

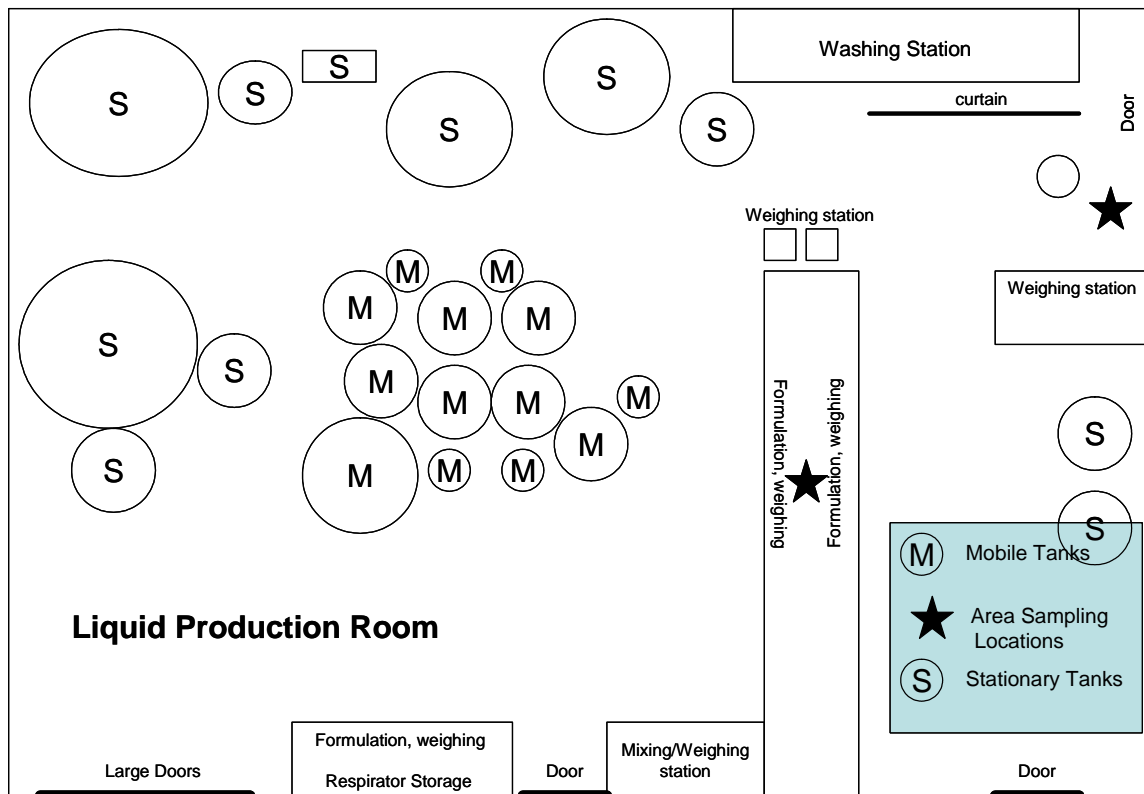


Figure 2. Powder Production Diagram

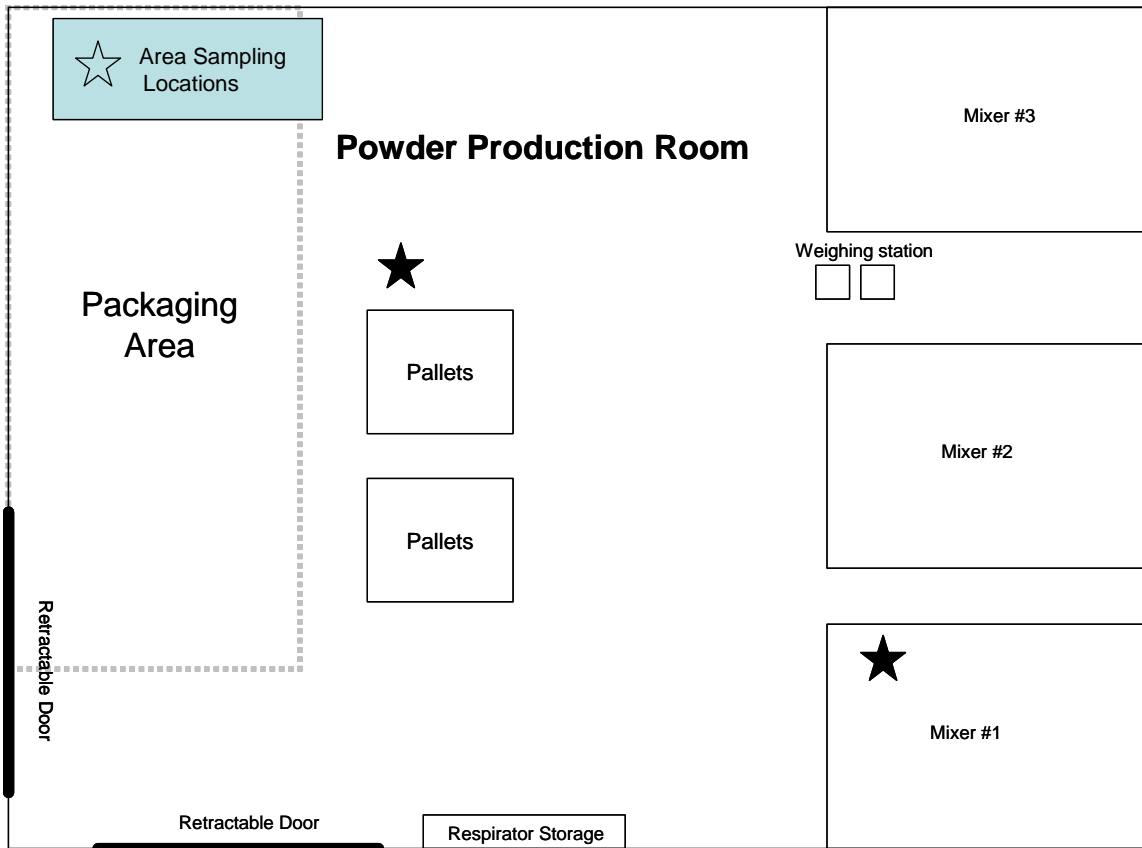


Figure 3. Photo of mixer in powder production area



Figure 4. Photo of worker with outfitted with personal samplers



Figure 5. Photograph of area sampling basket



Figure 6. Real-time VOC concentrations in liquid production area

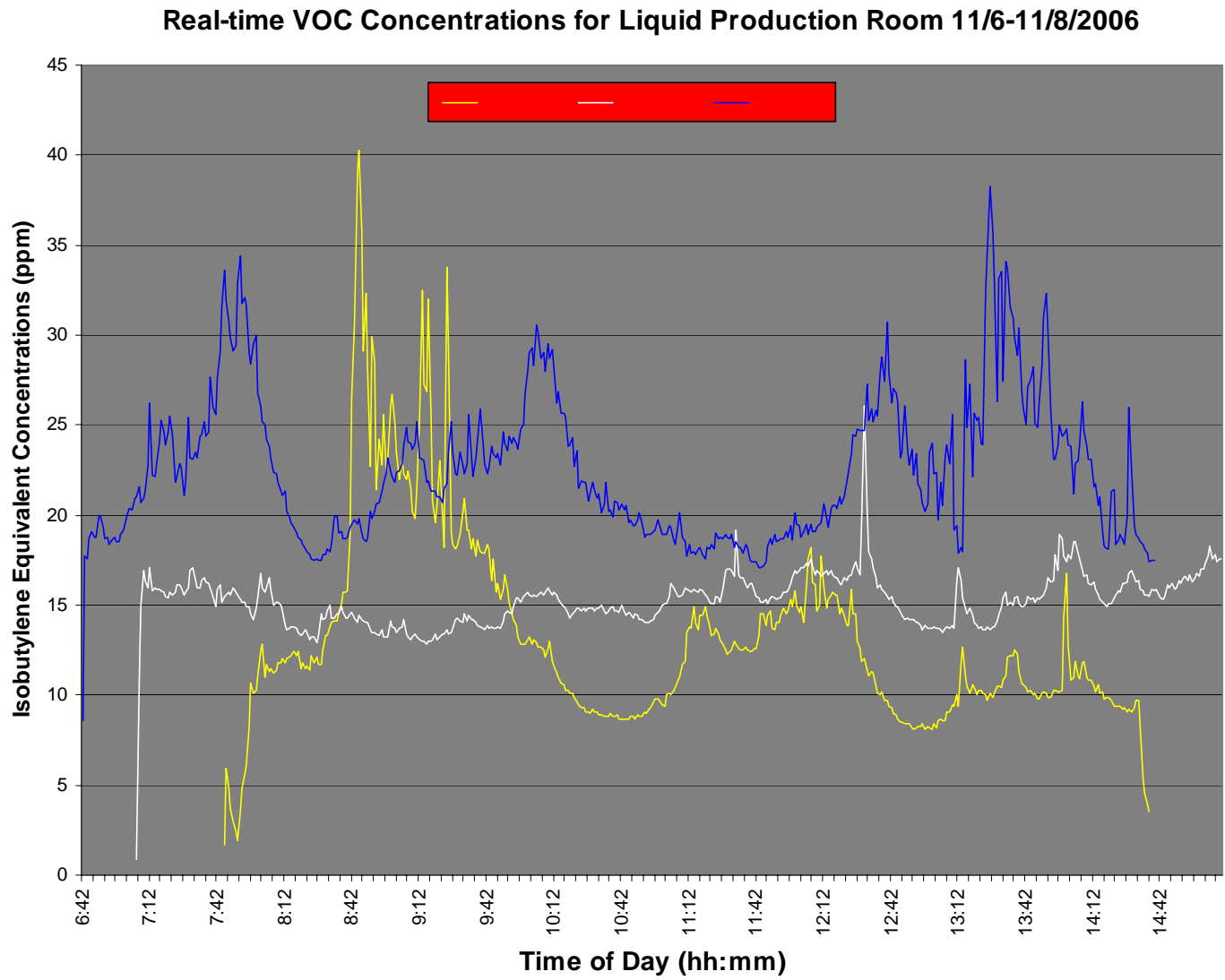


Figure 7. Real-time VOC concentrations in powder production area

