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NIH SPECIFICATION

Open Formula Rat and Mouse Ration - 18%
Crude Protein Autoclavable (NIH-31)
NIH Stock Number 63-8750

1. SCOPE

- 1.1 This specification is for an open formula autoclavable rat and mouse ration containing 18% crude protein. The ration is void of any feed additives containing antibiotics or estrogen activity.

2. APPLICABLE DOCUMENTS

- 2.1 The following documents of the issue in effect on date of invitation for bids or request for proposals form a part of this specification to the extent specified herein:

National Institutes of Health Standards

NIH STD 1 - Animal Feed Processing and Mill Sanitation
Standard

NIH STD 5 - For Nutrient and Chemical Contaminant Analyses of
laboratory Animal Diets

(Copies of NIH Specifications and Standards required by suppliers in connection with specific procurement functions should be obtained from the procuring activity or as directed by the Contracting Officer).

3. REQUIREMENTS

- 3.1 Material - Material shall be as specified herein:

3.1.1 Ingredients

<u>Ingredients</u>	<u>Percentage by Weight</u>
Fish meal (60% protein)	9.0
Soybean meal (48.5% protein)	5.0
Alfalfa meal (17% protein)	2.0
Corn gluten meal (60% protein)	2.0
Ground whole hard wheat	35.37
Ground #2 yellow corn	21.0
Ground whole oats	10.0
Wheat middlings	10.0
Brewers dried yeast	1.0
Soy oil	1.5
Salt	.5
Dicalcium phosphate	1.5
Ground limestone	.5
Premixes	.5
Choline-CL-70	.13
	<u>100.00</u>

Vitamin Fortification per ton (2,000 lbs) of Finished Product.

<u>Vitamin</u>	<u>Amount</u>	<u>Source</u>
A	22,000,000 IU	Vitamin A Palmitate or Acetate
D ₃ sterol	3,800,000 IU	D activated animal
K	20 g.	Menadione activity
dl alpha-tocopheryl Acetate	15 g.	
Choline	700 g.	Choline Chloride
Folic Acid	1 g.	
Niacin	40 g.	
d Pantothenic Acid	25 g.	d-Calcium Pantothenate
Riboflavin supplement	5 g.	
Thiamin	65 g.	Thiamin mono nitrate
B ₁₂ supplement	40,000 mcg.	
Pyridoxine	5 g.	Pyridoxine hydrochloride
Biotin	120 mg.	d-Biotin

Mineral Fortification per ton (2,000 lbs.) of Finished Product

<u>Mineral</u>	<u>Amount</u>	<u>Source</u>
Cobalt	400 mg.	Cobalt carbonate
Copper	4 g.	Copper sulfate
Iron	60 g.	Iron sulfate
Magnesium	400 g.	Magnesium oxide
Manganese	100 g.	Manganese oxide
Zinc	10 g.	Zinc oxide
Iodine	1500 mg.	Calcium iodate

These concentrations of vitamins and minerals shall be added to the ration via two separate (vitamin and mineral) premixes. The final formulation may be adjusted so the total amount of ingredients will equal 100%. In the case of the mineral fortification, the actual amount of each element required is specified. Therefore, the contractor shall adjust the amount of each compound used in the premix according to its mineral concentration.

3.1.2 Micro Analysis - The total calculated concentrations of nutrients in the ration from ingredients and from the fortifications at the time of manufacture should be as follows:

Crude protein	%	Minimum	18.0
Crude fat	%	Minimum	4.0
Crude fiber	%	Maximum	5.0
Ash	%	Maximum	8.0

Amino Acids Minimum (% of total diet)

Arginine	.90
Lysine	.85
Methionine	.35
Cystine	.25
Tryptophan	.20
Glycine	.95
Histidine	.38
Leucine	1.40
Isoleucine	.95
Phenylalanine	.85
Tyrosine	.60
Threonine	.65
Valine	.90

Minerals			Concentration
Calcium	%	Minimum	1.15
Phosphorous	%	"	.85
Potassium	%	"	.75
Sodium	%	"	.30
Magnesium	%	"	.15
Iron	PPM	"	190.00
Zinc	PPM	"	40.00
Manganese	PPM	"	140.00
Copper	PPM	"	12.00
Cobalt	PPM	"	0.70
Iodine	PPM	"	1.80
Vitamins			
Vitamins A	IU/g	"	20.0 (10)*
Vitamin D	IU/g	"	4.0
Alpha-tocopherol	PPM	"	45.0
Thiamin	PPM	"	70.0
Riboflavin	PPM	"	7.0
Niacin	PPM	"	80.0
Pantothenic Acid	PPM	"	30.0
Choline	PPM	"	1900.0
Pyridoxine	PPM	"	10.0
Folic Acid	PPM	"	2.0
Biotin	PPM	"	.2
Vitamin B ₁₂	mcg/kg	"	40.0
Vitamin K	PPM	"	20.0

* TRUE VITAMIN A ACTIVITY BY HPLC METHOD

3.1.4 Ingredients Standards - Ingredients used in the manufacture of this ration will not be contaminated with any more than 3 percent of foreign materials such as other grains, weed seeds, chaff etc. Nor will any mold, must, or insect-rodent infestation be allowed. The average minimum nutrient concentrations of ingredients used in the manufacture of this ration shall be equal to the values published in the most recent issue of the National Academy of Sciences Publication, "United States - Canadian Tables of Feed Composition". Contractors may be requested to provide a significant amount of data to show an effective ingredient quality control program is being followed.

- 3.2 Form - The finished product shall be furnished in oval shape pellets 5/8" - 3/4" wide, 3/8 - 7/16" thick, and 1/2 - 1" long.
- 3.3 Nutrient and Chemical Contamination Assays - The product covered by this specification is subject to nutrient and chemical contaminant analyses assays in accordance with the latest issue of National Institutes of Health Standard No. 5. All assays shall be conducted by an independent laboratory under a National Institutes of Health contract.
- 3.3.1 Product Sample - The feed manufacturing contractor shall be responsible for collecting representative sample (approximately 2 kg) from each production batch of product manufactured under this Specification. For the purposes of this Specification, a "batch" shall be defined as one continuous production run which may or may not consist of several small batches. In those instances where more than one batch is required to make up a production run for one shipment, samples for testing shall be made up using an equal portion of each of the small batches and one (1) sample will be sufficient for that production run or shipment. The minimum number of feed bags sampled shall be calculated by using the square root of the total number of bags of feed per production batch. The samples shall be shipped within 24 hours after the manufacturing process is completed as designated at the time the feed contract is awarded. Each sample shall be identified as to the name of manufacturer, the name of the product, the NIH Stock Number, and the date of manufacture. No coding of these items will be allowed.
- 3.3.2 Sample Analyses - A laboratory receiving the samples will be under an NIH Contract to analyze them for compliance with section 3.1.2 of this Specification. If nutrient concentrations in these samples are not consistent with the requirement specified in Section 3.1.2 of this Specification, the batch of feed from which the sample was obtained may be rejected and returned to the manufacturer at no cost to the Government. Analyses will also be made for concentrations of chlorinated hydrocarbon pesticides, polychlorinated biphenyls, organo-phosphate pesticides, lead, arsenic, cadmium, mercury, aflatoxins and nitrates.
- 3.3.3 Estrogen Content and Feed Additives - The product shall contain no antibiotics or estrogen additives of any kind. Award of the contract is contingent on an inspection by NIH personnel to determine if the contractor has established a program designed to prevent estrogen contamination of the product during manufacture and/or warehousing. Additionally, ascertain if the

program is being implemented at all times. The NIH reserves the right to assay any batch of product manufactured under this Specification for estrogen activity. If at any time the estrogen activity in a batch of product is found to exceed 4 ppb, the batch shall be taken back and replaced by the contractor at no expense to the National Institutes of Health.

- 3.4 Processing Restrictions - All milling and warehousing conditions and/or restrictions as specified in the latest issue of National Institutes of Health Standard No. 1 apply to the feed covered by this Specification.
- 3.5 Alteration of Product - The product shall not be altered in any manner without prior approval from the Contracting Officer, National Institutes of Health.
- 3.6 Certification of Processing - The successful bidder shall carry through without operational delay the milling or manufacturing process which shall be completed not more than thirty (30) days prior to delivery of the product.
- 3.7 Marking - Each bag shall contain the following information- the NIH name of the product, the name of the manufacturer, the net weight, the ingredients, the guaranteed analysis of its contents, the date (month, day, and year) the manufacturing process was completed and the batch number under which it was processed. The manufacturing date shall be printed at the top and/or bottom of the bag so that the date is visible when the bags are stacked on pallets. Codes or coding will not be acceptable for any markings specified herein.

4. QUALITY ASSURANCE PROVISIONS

- 4.1 Responsibility for Inspection - Unless otherwise specified in the contract or purchase order, the supplier is responsible for the performance of all inspection requirements as specified herein. Except as otherwise specified, the supplier may utilize his own facilities or any commercial laboratory acceptable to the Government. The Government reserves the right to perform any of the inspections set forth in the specification when such inspections are deemed necessary to assure supplies and services conform to prescribed requirements.5.

PREPARATION FOR DELIVERY

- 5.1 Packaging - The finished product shall be packaged into commercially acceptable laminated autoclavable 50 lb. capacity paper bags, 25 lbs. of product per bag. Bags shall be used with markings in accordance with 3.7 of this Specification. The paper bags shall be closed in a manner that will withstand autoclaving and insure the delivery of uncontaminated feed to the National Institutes of Health.