NOSB NATIONAL LIST FILE CHECKLIST

PROCESSING

MATERIAL NAME: #28 Yeast, Brewers

NOSB Database Form

References

___ MSDS (or equivalent)

FASP (FDA)

TAP Reviews from: Joe Montecalvo, Rich
Theuer

NOSB/NATIONAL LIST COMMENT FORM PROCESSING

Material Name: #28 Yeast, Brewers

| Please | use this | page to | o write | down | comments, | questions, | and your | anticipated | vote(s) |
|--------|----------|---------|---------|------|-----------|------------|----------|-------------|---------|
| | | | | | | | | | |

COMMENTS/QUESTIONS:

| 1. In my opinion, this material Synthetic Non-sy | | | |
|--|--------------|------------------------------|----------------|
| 2. Should this material be allow | wed in an "o | ganic food" (95% or higher o | organic |
| ingredients)? Yes | | | |
| (IF NO, PROCEED TO QUES | | | |
| 3. Should this substance be allo | owed in a "f | ood made with organic ingred | ients" (50% or |
| higher organic ingredients)? | | No | |

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

| This file is due back to us by: August 29, 1995 |
|---|
| Name of Material: Brewers Yeast Reviewer Name: REVIER |
| Is this substance Synthetic or non-synthetic? Explain (if appropriate) NON-MATHETIC (IF NOT BIOEXIO If synthetic, how is the material made? (please answer here if our database form is blank) |
| This material should be added to the National List as: Synthetic AllowedProhibited Natural or,Non-synthetic (Allowed as an ingredient in organic food) Non-synthetic (Allowed as a processing aid for organic food) or, this material should not be on the National List |
| Are there any use restrictions or limitations that should be placed on this material on the National List? |
| BOOD MANU FACTURING PRACTICES Please comment on the accuracy of the information in the file: OCC Any additional comments? (attachments welcomed) |
| Do you have a commercial interest in this material? Yes; No Signature Date 8/28/95 |

Please address the 7 criteria in the Organic Foods Production Act: (comment in those areas you feel are applicable)

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

NONE

(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

NONE

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

NONE

(4) the effect of the substance on human health;

POSITIVE

(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;

POSITIVE

(6) the alternatives to using the substance in terms of practices or other available materials; and

NONE

(7) its compatibility with a system of sustainable agriculture.

POSITIVE

TAP REVIEWER COMMENT FORM for USDA/NOSB

Use this page or an equivalent to write down comments and summarize your evaluation regarding the data presented in the file of this potential National List material. Complete both sides of page. Attach additional sheets if you wish.

| This file is due back to us by: August 29, 1995 | |
|--|----------------|
| Name of Material: Brewers Yeast | |
| Reviewer Name: DR. JOE Montecaluo | |
| Is this substance Synthetic or non-synthetic? Explain appropriate) Non Synthetic (That improved by DNA Recombined in Synthetic, how is the material made? (please answer here if our form is blank) | nant technique |
| This material should be added to the National List as Synthetic Allowed Prohibited Natur | |
| or, Non-synthetic (Allowed as an ingredient in organic food) Non-synthetic (Allowed as a processing aid for organic fo | o đ) |
| or, this material should not be on the Nation Are there any use restrictions or limitations that should placed on this material on the National List? | |
| Please comment on the accuracy of the information in the file: | ı |
| Any additional comments? (attachments welcomed) | |
| Do you have a commercial interest in this material? Yes; Signature \(\frac{1}{31} \frac{q_5}{31} \) | <u></u> |

Please address the 7 criteria in the Organic Foods Production Act: (comment in those areas you feel are applicable)

(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;

NORE .

(2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;

nothing in literature.

(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;

Not a Reat

(4) the effect of the substance on human health;

As with Any Yeart product > Yeart Are hish in Nuclaic Acids

- (5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
- (6) the alternatives to using the substance in terms of practices or other available materials; and

None

(7) its compatibility with a system of sustainable agriculture.

I helieve 14 is 1000pa+40le.

NOSB Materials Database

Identification

Common Name

Yeast, brewers

Chemical Name

Other Names

Saccharomyces genus

Code #: CAS

N. L. Category

Non-agricultural

Code #: Other

MSDS

Oyes no

Chemistry

Family

Composition

Selected strains of the yeast genus Saccharomyces., particularly Saccharomyces cerevisiae (ale) and

Saccharomyces uvarum (lager). Most industrial yeasts are polyploid which renders them more

genetically stable. Brewing strains are distinct from baking strains of the same species.

Properties

Rapid carbohydrate fermenting ability, appropriate flocculation and sedimentation characteristics,

ethanol tolerance and ability to produce a highly concentrated ethanol. Yeast is a eukaryote.

How Made

Can be "improved" by recombinant DNA techniques.

Use/Action

Type of Use

Processing

Specific Use(s) Action

carbonation of beverages, fermentation agent.

Yeasts produce ethanol and carbon dioxide from carbohydrates.

Combinations

<u>Status</u>

OFPA

N. L. Restriction

EPA, FDA, etc

FDA-GRAS

Directions

Safety Guidelines

State Differences

Historical status

As old as the history of man.

Internation | status

NOSB Materials Database

OFPA Criteria

2119(m)1: chemical interactions

Not Applicable

2119(m)2: toxicity & persistence

Not Applicable

2119(m)3: manufacture & disposal consequences

Beer making is the largest biotechnology industry.

2119(m)4: effect on human health

Yeasts are one of the oldest plants cultivated by man and has been consumed for thousands of years without known negative health effects. The effect of the resulting alcohol consumption is not so benign but is well documented elsewhere.

2119(m)5: agroecosystem biology

Not Applicable

2119(m)6: alternatives to substance

2119(m)7: Is it compatible?

Industrial yeasts are used extensively in genetic manipulation research and biotechnology.

References

See attached

BREWERS YEAST REFERENCES

AU: Abbott,-M.S.; Pugh,-T.A.; Pringle,-A.T.

TI: Biotechnological advances in brewing.

SO: ACS-symp-ser. Washington, D.C.: American Chemical Society, 1974-. 1993. (536) p. 150-180.

CN: DNAL QD1.A45

AB: A variety of biotechnological tools have been applied to improve the ingredients of the brewing process. Using these tools agricultural materials have been developed that are free of viruses, have improved agronomic yields, or are resistant to disease. Brewer's yeasts have been constructed with novel properties such as the ability to ferment normally unfermentable carbohydrates, chill-proof beer, or degrade beta-glucans. Although there are many advantages to biotechnologically improved agricultural materials and yeast, these advantages must be weighed against regulatory, legal and consumer concerns.

AU: Boulton,-C.A.

TI: Developments in brewery fermentation.

SO: Biotechnol-genet-eng-rev. Wimborne: Intercept. 1991. v. 9 p. 127-181.

CN: DNAL TP248.3.B46

AU: Ormrod,-I.H.L.; Lalor,-E.F.; Sharpe,-F.R.

TI: The release of yeast proteolytic enzymes into beer.

SO: J-Inst-Brew. London: The Institute. Nov/Dec 1991. v. 97 (6) p. 441-443.

CN: DNAL 390.9-IN7

AU: Walker,-M.D.; Simpson,-W.J.

TI: Production of volatile sulphur compounds by ale and lager brewing strains of Saccharomyces cerevisiae.

SO: Lett-Appl-Microbiol. Oxford: Blackwell Scientific Publications. Jan 1993. v. 16 (1) p. 40-43.

CN: DNAL QR1.L47

AU: Nielsen,-H.; Andersen,-H.B.; Jakobsen,-M.

TI: The brewers control of yeast multiplication.

SO: Tech-Q-Mast-Brew-Assoc-Am. Madison, Wis.: The Association. 1990. v. 27 (4) p. 103-105.

CN: DNAL 390.9-M39T

AU: Hinchliffe,-E.

TI: Strain improvement of brewing yeast.

SO: Symp-Ser-Br-Mycol-Soc. Cambridge: Cambridge University Press. 1991. (18) p. 129-145.

CN: DNAL QK600.B72

AU: Dziezak,-J.D.

TI: Yeasts and yeast derivatives: definitions, characteristics, and processing.

SO: Food-Technol. Chicago, Ill.: Institute of Food Technologists. Feb 1987. v. 41 (2) p. 104-121 (not consecutive). ill., charts.

CN: DNAL 389.8-F7398

AB: Abstract: A detailed, illustrated technical review focuses on the definitive characteristics of yeasts and their commercial production. The characteristics, use, and production of each of the active yeasts (Baker's yeasts, Brewer's yeasts, and yeasts for alcohol production) and inactive yeasts (dried Brewer's yeast and primary yeasts and yeast products) are individually discussed. Yeast derivatives also are covered.(wz).

AU: Russell,-I.; Jones,-R.; Stewart,-G.

TI: The genetic modification of brewers' yeast and other industrial yeast strains.

SO: Biotechnology in food processing / edited by Susan K. Harlander and Theodore P. Labuza. Park Ridge,

N.J.: Noyes Publications, c1986. p. 171-195. ill.

CN: DNAL TP248.2.B5537

CNUM=1568

U.S. FOOD AND DRUG ADMINISTRATION

| | | | FOOD ADDITIVE SAFETY PROFILE | / PROFILE | |
|---------|----------------------------------|-------|-----------------------------------|-----------|---------------------|
| /EPST | /EMST #FF-MALT SPROUT EXTRACT | EXTRA | lcT | | |
| S#: | 77011554 | | | 0.005211 | MG/KG BW/DAY/PERSON |
| SP#: 1 | 1568 | | CE: | 6150.000 | LBS/YR |
| PE: | ISP | | | 8./ | |
| | S#: 110/ MA#: | | JECFA: JECFA ADI: | | MG/KG BW/DAY/PERSON |
| AS#: | | | JECFA ESTABLISHED: | | |
| TENTIAL | . BEVERAGE | USE | TENTIAL BEVERAGE USE LAST UPDATE: | 940115 | |

RUCTURE CATEGORIES: B8

LOGP:

DENSITY:

MPONENTS:

NONYMS:

EMICAL FUNCTION:

FLAVORING AGENT OR ADJUVANT CHNICAL EFFECT:

172.590 R REG NUMBERS:

NIMUM TESTING LEVEL: 2

MMENTS:

LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE RAT OR MOUSE STUDIES X 4A:

RANKING FACTOR: 1.737E-5 LEL: 300 MG/KG BW/DAY COMPLETENESS: B 1 RAT BLOOD GLUCOSE (GLU) INCREASE

UDY: ECIES: FECTS: TES: MMENTS:

LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE DOG STUDIES X 4B:

COMPLETENESS: B RANKING FACTOR: 6.948E-7 LEL: 7500 MG/KG BW/DAY

UDY: ECIES: I FECTS: H TES: S

DOG HEMOSIDEROSIS SPLEEN EFFECT = SIDEROTIC NODULES

```
SOURCE: FAP 2A2735 1:100-102
YEAR: 1970
LEL: 15000 MG/KG BW/DAY
HNEL:
                                                                                                                                                                                                                                                                                                                                                                             : 1.737E-6
MG/KG BW/DAY
MG/KG BW/DAY
                                RANKING FACTOR: 1.737E-5
LEL: 300 MG/KG BW/DAY
                                                                                                                                                                                           MG/KG BW/DAY MG/KG BW/DAY
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  RANKING FACTOR: 1.737E-6
LEL: 3000 MG/KG BW/DAY
HNEL: 300 MG/KG BW/DAY
                                                                                                                                                                                                                     BLOOD GLUCOSE (GLU) INCREASE
MINERALIZATION
HISTOPATHOLOGY OBSERVATION(S) NOT ELSEWHERE CLASSIFIED
                                                                                                                                                          HIGHEST OBSERVED NO-EFFECT LEVEL IN SPECIES OF BOX 4C
LOWEST EFFECT LEVEL OBSERVED IN ALL AVAILABLE STUDIES
                                                                                                                                                                                                                                                                                                                                                            TE: PANCREAS
ECIES: RAT
LSTUDY: 5
ELSTUDY: 5
ELSTDY: 5
COMPLETENESS: B LEL: 3000 P
COMPLETENESS: B HNEL: 300 P
MMENTS: TEST COMPOUND IS MALT SPROUT EXTRACT
                                                                                                                                                                                          15000
5000
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      PE: SHORT TERM
ECIES: RAT
RATION: 56 DAYS
FECTS: MINERALIZATION
TES: KIDNEY
MMENTS: COMPOUND FN TESTED, COMPOSITION NOT GIVEN
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          ORAL TOXICITY STUDIES (OTHER THAN ACUTE)
                                                                                                                                                                                          COMPLETENESS: B LEL: HNEL:
                              COMPLETENESS: B
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         COMPLETENESS: C
                                                            BLOOD GLUCOSE (GLU) INCREASE
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 COMPLETENESS: B
                                                                                                                                                                                                                                                                                                                                                                                                                                                   REPRODUCTIVE ORGAN TOXICITY TESTIS
                                                                                                                                                                                                                                                                                                               HIGH CONCERN EFFECTS
                                                                                                                                                                                                                                                                                                                                            HYPERPLASIA
PANCREAS
RAT
                                                                             TES:
MMENTS: SEE BOX 4A
                                                                                                                                                                                                        RAT
                                                                                                                                                                                                                                                                                                                                                                                                                                                  FECT:
TE:
ECIES:
LSTUDY:
ELSTDY:
MMENTS:
                                                                                                                                                                                                                                                                 MMENTS:
                                            ECIES:
FECTS:
                                                                                                                                                                                       UDY:
ECIES:
FECTS:
  x 4C:
                                                                                                                                                                                                                                                                                                                                              FECT:
                                                                                                                                                          : 9
X
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         :6 X
                                                                                                                                                                                                                                                                                                                ..
8
×
                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         JDY:
```

| | | ā |
|--|--|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |