

Summary of product characteristics for a biocidal product

Product name: Sodium Benzoate 9%

Product type(s): PT06 - Preservatives for products during storage (Preservatives)

Authorisation number: EU-0017761-0000

R4BP 3 asset reference number: EU-0017761-0000

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Administrative information

1.1. Trade names of the product

Sodium Benzoate 9%

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Novozymes A/S
	Address	Korgshoejvej 36 2880 Bagsvaerd Denmark
Authorisation number	EU-0017761-0000	
R4BP 3 asset reference number	EU-0017761-0000	
Date of the authorisation	16/07/2020	
Expiry date of the authorisation	16/07/2030	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Finfeeds Finland Oy
Address of the manufacturer	Satamatie 2 21100 Naantali Finland
Location of manufacturing sites	Satamatie 2 21100 Naantali Finland

Name of the manufacturer	Finfeeds Oy
Address of the manufacturer	Myllykatu 20 FI-65100 Vaasa Finland
Location of manufacturing sites	Myllykatu 20 FI-65100 Vaasa Finland

Name of the manufacturer	Genencor International Oy
Address of the manufacturer	Tiilikantie 15 FI-42300 Jamsankoski Finland
Location of manufacturing sites	Myllytie 6 31600 Jokioinen Finland
	Tiilikantie 15 FI-42300 Jamsankoski Finland
	Orioninkatu 4, P.O. Box 34 FI-10960 Hanko Finland

Name of the manufacturer	Genencor International BVBA
Address of the manufacturer	Komvest 43 8000 Brugge Belgium
Location of manufacturing sites	Komvest 43 8000 Brugge Belgium

1.4. Manufacturer(s) of the active substance(s)

Active substance	1423 - Sodium benzoate
Name of the manufacturer	Wuhan Youji Industries Co
Address of the manufacturer	No. 1 2nd Chemical Road 430082 Wuhan China
Location of manufacturing sites	No. 1 2nd Chemical Road 430082 Wuhan China

Active substance	1423 - Sodium benzoate
Name of the manufacturer	Emerald Kalama Chemical B.V.
Address of the manufacturer	Fascinatio Boulevard 230 3065 WB Rotterdam Netherlands
Location of manufacturing sites	Montrealweg 15 P.O.Box 1021, Havennummer 4322 3180 AA Rozenburg 3197 KH Rotterdam-Botlek Netherlands

Active substance	1423 - Sodium benzoate
Name of the manufacturer	Eastman Chemical B.V.
Address of the manufacturer	Fascinatio Boulevard 602-614 2909 VA Capelle aan den IJssel Netherlands
Location of manufacturing sites	Eastman Specialties OÜ Uus-Tehase 8 30328 Kohtla-Järve Estonia

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Sodium benzoate		Active Substance		208-534-8	9

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	
Precautionary statements	

4. Authorised use(s)

4.1 Use description

Use 1 - Enzyme preservative

Product type	PT06 - Preservatives for products during storage (Preservatives)
Where relevant, an exact description of the authorised use	The product is used to preserve enzymes. Enzymes are proteins and they lose activity when they are biodegraded. In order to preserve enzymes, enzyme manufacturers formulate them together with sodium benzoate. The resultant enzyme products are transported and stored at ambient temperature.
Target organism(s) (including development stage)	Scientific name: <i>Pseudomonas aeruginosa</i> Common name: Bacteria, aerobic Gram-negative Development stage: Bacterial spores Scientific name: <i>Staphylococcus aureus</i> Common name: Bacteria, aerobic Gram-negative Development stage: Bacterial spores Scientific name: <i>Escherichia coli</i> Common name: Bacteria, aerobic Gram-negative Development stage: Bacterial spores Scientific name: <i>Candida albicans</i> Common name: Fungi/yeasts Development stage: Spores and spore producing structures Scientific name: <i>Aspergillus brasiliensis</i> Common name: Fungi/yeasts Development stage: Spores and spore producing structures Scientific name: <i>Aspergillus niger</i> Common name: Fungi/yeasts Development stage: Spores and spore producing structures Scientific name: <i>Talaromyces/ Rasamsonia emersonii</i> Common name: Fungi/yeasts Development stage: Spores and spore producing structures
Field(s) of use	Indoor Stored product protection (PT6).
Application method(s)	Method: Stored product protection /Food protection Detailed description: Direct application, e.g. pumping, into the enzyme product to be preserved. The biocidal product may be applied in either of the 2 steps depending of the use of the enzyme product to be preserved: 1. During the final steps of the fermentation 2. After separation of the fermentation broth from the microorganisms
Application rate(s) and frequencies	Application Rate: The product is applied directly to the batch process, normally just one time Dilution (%): The application rate of the product is such so as to get a concentration in the final product between 0.3% and 3% w/w for instance. Number and timing of application: The product is applied directly to the batch process, normally just one time.
Category(ies) of users	Industrial
Pack sizes and packaging material	>=1000 L stainless steel tanks, 1000 L IBC containers, HDPE.

4.1.1 Use-specific instructions for use

4.1.2 Use-specific risk mitigation measures

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

5. General directions for use

5.1. Instructions for use

The biocidal product may be applied in either of the 2 steps depending on the use of the final product:

1. During the final steps of the fermentation
2. After separation of the fermentation broth from the microorganisms

Handle in accordance with good industrial hygiene and safety practice.

5.2. Risk mitigation measures

Not required. The biocidal product is not classified as hazardous to human health or the environment.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

The biocidal product is not classified as hazardous to human health or the environment.

Description of first-aid measures

Inhalation: Remove person to fresh air. If signs/symptoms continue, get medical attention.

Skin contact: Remove and wash contaminated clothing before re-use. Wash off immediately with plenty of water. If symptoms persist, call a doctor.

Eye contact: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.

Ingestion: Rinse mouth with water and drink plenty of water. If symptoms persist, call a doctor. If medical advice is needed, have product container or label at hand.

Accidental release measures: No special environmental precautions required.

5.4. Instructions for safe disposal of the product and its packaging

Dispose of in accordance with local regulations. Waste water should be discharged to sewage treatment plant. Waste codes should be assigned by the user based on the application for which the product was used.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Keep container tightly closed. Store in a dry place, at ambient temperature. Protect from frost.

Shelf-life: 4 weeks at ambient temperature.

6. Other information

The following information is relevant for Markeing Area 'Denmark' only.

Oplysninger til etiket og brugsanvisning for Sodium Benzoate 9%, BPR-reg. nr. 876-1

I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen [1].

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk. Nedstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

III. Etiketten skal indeholde nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:

"Konserveringsmiddel

Må kun anvendes som konserveringsmiddel til bekæmpelse af bakterier og gær ved industriel produktion af enzymer."

2) I advarselsfeltet:

"FORSIGTIG

Vask huden efter arbejdet.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes til konserveringsmiddel til bekæmpelse af bakterier og gær ved industriel produktion af enzymer.

Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer."

Evt. oplysninger om førstehjælp.

3) I deklarationsfeltet:

a) Teksten "Konserveringsmiddel BPR-reg.nr. 876-1. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

b) Oplysning om præparattype: "væske" for dette præparat.

c) Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C.

d) Udløbsdatoen skal anføres. Denne dato må højst være 28 dage efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.

e) Batchnummer eller – betegnelse skal anføres.

f) Pakningsstørrelse i L.

g) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: "Indholdet/holderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering."

Derudover skal mærkningen ske efter retningslinjerne:

"Tom emballage og rester kan bortskaffes med dagrenovationen."