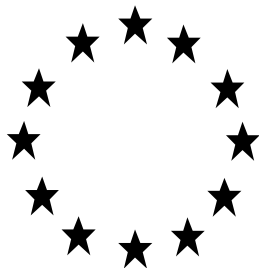
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Sodium Benzoate 9%

Product type(s) 6

Sodium Benzoate as included in Annex I under Regulation 528/2012

Case Number in R4BP: BC-WS033286-09

Evaluating Competent Authority: Denmark

Date: 16 July 2020

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1 CONCLUSION

The Danish eCA proposes the authorisation of the biocidal product 'Sodium Benzoate 9%' as an in-can preservative (PT 6) for industrial use against bacteria and yeast for the preservation of enzymes products. The biocidal product contains the active substance sodium benzoate (CAS no. 532-32-1) at a concentration of 9.0% (w/w).

Sodium Benzoate 9% is eligible for a simplified authorisation according to Article 25 of Regulation No. 528/2012 (BPR) as:

(a) the product contains only active substances listed on Annex I of Regulation No. 528/2012 and satisfies the restriction specified in that Annex (i.e. that the product does not require classification for hazards to human health or safety, or to the environment, according to Regulation No. 1272/2008 (CLP)),
(b) the product does not contain any substances of concern,
(c) the product does not contain any nanomaterials,
(d) the product is sufficiently effective, and
(e) handling of the product and its intended use do not require personal protective equipment.

Stability of the product is limited to 4 weeks at ambient temperature.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
Sodium Benzoate 9%	Denmark

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Novozymes A/S
	Address	Krogshøjvej 36 DK-2880 Bagsværd Denmark
Authorisation number	EU-0017761-0000	
Date of the authorisation	16 July 2020	
Expiry date of the authorisation	Not set	

2.1.1.3 Manufacturer(s) of the product(s)

Name of manufacturer	Novozymes A/S
Address of manufacturer	Krogshøjvej 36 DK-2880 Bagsværd Denmark
Location of manufacturing sites	Denmark

Name of manufacturer	Novozymes A/S
Address of manufacturer	Hillerødgade 42 DK-2200 Copenhagen N Denmark
Location of manufacturing sites	Denmark

Name of manufacturer	Novozymes A/S
Address of manufacturer	Hallas Alle 1 DK-4400 Kalundborg Denmark
Location of manufacturing sites	Denmark

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Sodium benzoate
Name of manufacturer	Emerald Kalama Chemicals B.V.

Address of manufacturer	Havennr 4322 Montrealweg 15 3197 KH Rotterdam Botlek The Netherlands
Location of manufacturing sites	The Netherlands

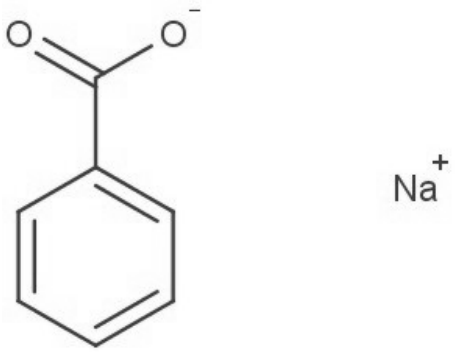
2.1.2 Product composition and formulation

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐

No ☒ N/A as the active substance is not included on the Union list of Approved active substances as the substance is, instead, included in Annex I under Regulation No. 528/2012.

2.1.2.1 Identity of the active substance

Main constituent(s)	
IUPAC or EC name	Sodium benzoate
EC number	208-534-8
CAS number	532-32-1
Index number in Annex VI of CLP	N/A
Minimum purity / content	> 99%
Structural formula	

2.1.2.2 Candidate(s) for substitution

Not applicable. Sodium benzoate is listed in Annex I under Regulation No. 528/2012 (CLP), under Category 1 – Substances authorised as food additives according til Regulation (EC) No. 1333/2008.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Refer to the Confidential Annex.

2.1.2.4 Information on technical equivalence

Not applicable.

2.1.2.5 Information on the substance(s) of concern

The biocidal product does not contain any substances of concern.

2.1.2.6 Type of formulation

AL - Any other liquid

2.1.3 Hazard and precautionary statements

Classification and labelling of the products according to the Regulation (EC) 1272/2008

Classification	
Hazard category	Not classified.
Hazard statement	No hazard statement required.
Labelling	
Signal words	No signal word required.
Hazard statements	No hazard statement required.
Precautionary statements	No precautionary statements required.
Note	No notes required.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – In-can preservative for enzyme products

Product Type	6
Where relevant, an exact description of the authorised use	The product is used as an in-can preservative for enzyme products. Enzymes are protein and they lose activity when they are biodegraded. In order to preserve enzymes, enzyme manufacturers can formulate them together with sodium benzoate. The resultant enzyme products are transported and stored at ambient temperature.
Target organism (including development stage)	Bacteria and yeasts.

Field of use	Stored product protection (PT6).
Application method(s)	Direct application, e.g. pumping, into the enzyme product to be preserved.
Application rate(s) and frequency	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 microoganisms. The biocidal product is applied directly to the batch, normally just once. The application rate of the product is beetween 116mL and 348mL per litre of enzymes slurry to get a concentration sodium benzoate in the final product beetween 1% and 3% w/w.
Category(ies) of users	Industrial.
Pack sizes and packaging material	>1000 L stainless-steel tanks; 1000 L IBC containers, HDPE.

2.1.4.2 Use-specific instructions for use

Refer to section 2.1.5.1.

2.1.4.3 Use-specific risk mitigation measures

Refer to section 2.1.5.2.

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

Refer to section 2.1.5.3.

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

Refer to section 2.1.5.4.

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

Refer to section 2.1.5.5.

2.1.5 General directions for use

2.1.5.1 Instructions for use

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 microoganisms.

Handle in accordance with good industrial hygiene and safety practice.

2.1.5.2 Risk mitigation measures

Not required.

2.1.5.3 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. Show this safety data sheet to the doctor in attendance.

Skin contact: Remove and wash contaminated clothing before re-use. Wash off immediately with plenty of water. If symptoms persist, call a doctor. Show this safety data sheet to the doctor in attendance.

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. Show this safety data sheet to the doctor in attendance.

Accidental release measures: No special environmental precautions required.

2.1.5.4 Instructions for safe disposal of the product and its packaging

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

2.1.5.5 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.

2.1.6 Other information

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2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Stainless-steel tanks	>1000 L	Stainless-steel	Stainless-steel	Industrial	Yes
IBC containers	1000 L	HDPE	HDPE	Industrial	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

See Annex 3.1 for complete references.

2.1.8.2 Access to documentation

According to Article 20(1)b of Regulation No. 528/2012 (PBR), a Letter of Access is not required for applications for authorisation under the simplified authorisation procedure. In addition, as the active substance is not included on the Union List of approved active substances, no dossier exists.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

Table 2. Intended use # 1 – enzyme preservative

Product Type(s)	PT06
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 kept on shelves at ambient temperature.
Target organism (including development stage)	*Pseudomonas aeruginosa*-Bacterial spores|Bacteria-Bacteria, aerobic Gram-negative *Staphylococcus aureus*-Bacterial spores|Bacteria-Bacteria, aerobic Gram-negative *Escherichia coli*-Bacterial spores|Bacteria-Bacteria, aerobic Gram-negative *Candida albicans*-Spores and spore producing structures-Fungi/yeasts *Aspergillus brasiliensis*-Spores and spore producing structures-Fungi/yeasts *Aspergillus niger*-Spores and spore producing structures-Fungi/yeasts *Talaromyces/ Rasamsonia emersonii*-Spores and spore producing structures-Fungi/yeasts
Field of use	Indoor
Application method(s)	Stored product protection /Food protection - The biocidal product may be applied in either of the 2 steps depending of the use of the final product: 1. During the final steps of the fermentation 2. After separation of the fermentation broth from the microoganisms
Application rate(s) and frequency	The product is applied during formulation of the final product. - The final concentration at which the active substance will be used is 9.0% in the biocidal product. - The product is applied directly to the batch process, normally just one time.
Category(ies) of user(s)	Industrial
Pack sizes and packaging material	>=1000 L stainless steel tanks, 1000 L IBC containers, HDPE.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	OPPTS 830-6302	8.86 % Na-benzoate	Liquid	LAUS GmbH (2016a)
Colour at 20 °C and 101.3 kPa	OPPTS 830-6303	8.86 % Na-benzoate	Clear colourless	LAUS GmbH (2016a)
Odour at 20 °C and 101.3 kPa	OPPTS 830-6304	8.86 % Na-benzoate	Mild, not pungent smell	LAUS GmbH (2016a)
Acidity / alkalinity	CIPAC MT 75.3	8.86 % Na-benzoate	pH=8.36	LAUS GmbH (2016a)
Relative density / bulk density		9% Na-benzoate	1.029 g/cm^2	LUNA 2018-04432-01
Storage stability test – **accelerated storage**	-	-	Not relevant for PT6 products.	-
Storage stability test – **long term storage at ambient temperature**	The test was performed for 4 weeks @ 20±2°C.	8.86 % Na-benzoate	Nominal content: 9%. Measured A.S. content prior to storage (t0): 8.86%. A.S. content after storage (t28): 8.79%. Degradation: 0,79%. Deviation between nominal and content prior to storage (t0): 1.6%. pH prior to storage: 8.36. pH after storage: 8.41. No significant changes were noted regarding odour or visuals after storage. Conclusion: the study is accepted.	LAUS GmbH (2016a)
Storage stability test – **low temperature stability test for liquids**	The product is recommended not to be stored at temperature ≤ 0°C. Therefore, no testing is necessary.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	The packaging protects the products from light. No testing is therefore necessary.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	The packaging protects the products from humidity. No testing is therefore necessary.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			The storage stability test was conducted in HDPE packaging. No reactivity was observed. The product is also intended to be stored in stainless steel tanks. A justification for non-submission was given by the applicant stating that Na-benzoate has anti-corrosive properties, therefore testing in steel containers are not relevant. This justification was accepted by the eCA.	
Wettability	Not relevant for AL formulations.			
Suspensibility, spontaneity and dispersion stability	Not relevant for AL formulations.			
Wet sieve analysis and dry sieve test	Not relevant for AL formulations.			
Emulsifiability, re-emulsifiability and emulsion stability	Not relevant for AL formulations.			
Disintegration time	Not relevant for AL formulations.			
Particle size distribution, content of dust/fines, attrition, friability	Not relevant for AL formulations.			
Persistent foaming	Not relevant as the product should not be diluted prior to use.			
Flowability/Pourability/Dustability	Not relevant for AL formulations.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning rate — smoke generators	Not relevant for the proposed use.			
Burning completeness — smoke generators	Not relevant for the proposed use.			
Composition of smoke — smoke generators	Not relevant for the proposed use.			
Spraying pattern — aerosols	Not determined. Only relevant for aerosols.			
Physical compatibility	Not relevant as the product should not be mixed with other products.			
Chemical compatibility	Not relevant as the product should not be mixed with other products.			
Degree of dissolution and dilution stability	Not relevant for water-based products.			
Surface tension	Not relevant for water-based products. The product does not contain any organic solvents.			
Viscosity	Not relevant for water-based products. The product does not contain any organic solvents.			

Conclusion on the physical, chemical and technical properties of the product
The product is considered stable during a 4 week storage period at a controlled temperature 20±2°C.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Not relevant as Na-benzoate is not classified as explosive.			
Flammable gases	Not relevant as Na-benzoate is not classified as flammable.			
Flammable aerosols	Not relevant as Na-benzoate is not classified as flammable.			
Oxidising gases	Not relevant as Na-benzoate is not classified as oxidising.			
Gases under pressure	Not relevant for AL formulations.			
Flammable liquids	Not relevant as Na-benzoate is not classified as flammable.			
Flammable solids	Not relevant for AL formulations.			
Self-reactive substances and mixtures	Not relevant as Na-benzoate is not classified as self-reactive.			
Pyrophoric liquids	Not relevant as Na-benzoate is not classified as pyrophoric.			
Pyrophoric solids	Not relevant for AL formulations.			
Self-heating substances and mixtures	Not relevant for Na-benzoate.			
Substances and mixtures which in contact with water emit flammable gases	Not relevant for water-based formulations.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Oxidising liquids	Not relevant as Na-benzoate is not classified as oxidising.			
Oxidising solids	Not relevant for liquid formulations.			
Organic peroxides	Not relevant as Na-benzoate is not classified as an organic peroxide.			
Corrosive to metals	Not relevant as the product does not contain any components classified to be corrosive to metals, and having very moderate pH value of 8.36 is neither acidic nor particularly alkaline.			
Auto-ignition temperatures of products (liquids and gases)	Not relevant as Na-benzoate is not classified for auto-ignition or self-ignition.			
Relative self-ignition temperature for solids	Not relevant for AL formulations.			
Dust explosion hazard	Not relevant for AL formulations.			

Conclusion on the physical hazards and respective characteristics of the product
No data for physical or chemical hazards has been submitted. As the product contains Na-benzoate and water only, testing is not necessary and not relevant for the simplified authorisation procedure. The product should not be classified for any physical hazards.

2.2.4 Methods for detection and identification

The tested product was 2015-31330 with a composition of 9% Na benzoate, 91% water.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**		**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean		
Active substance	HPLC-UV	Solutions of the concentrations 5 / 10 / 15 / 20 / 25 / 30 / 35 mg/L	R^2=0.99934 Slope=0.3406	No interference	97.9 – 102.9 %	100.2 % RSD 0.66 %	5 mg/L	LAUS GmbH (2016)

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substanc	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

e)									
Not relevant under the simplified authorisation procedure.									

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not relevant under the simplified authorisation procedure.									

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not relevant under the simplified authorisation procedure.									

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not relevant under the simplified authorisation procedure.									

Analytical methods for animal and human body fluids and tisues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not relevant for the use.									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Not relevant for the use.									

Conclusion on the methods for detection and identificationof the product
A HPLC-UV-method was successfully validated for the determination of benzoic acid. The product used for the validation of the analytical methode was 2015-31330 with a composition of 9% Na benzoate and 91% water. This is the same components as Sodium Benzoate 9% and is acceptable. The validated method is regarded as suitable to determine benzoic acid. The study shows acceptable precision, specificity, recovery rate and linearity. The study is acceptable.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Stored product protection. Enzyme preservation. Industrial use only.

2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected

The biocidal product has a claimed bactericidal, fungicidal and yeasticidal function to prevent biodegradation of enzymes in the final products.

2.2.5.3 Effects on target organisms, including unacceptable suffering

The biocidal product has a claimed bactericidal, fungicidal and yeasticidal effect.

No unacceptable suffering is forseen as a result of the use of the product.

2.2.5.4 Mode of action, including time delay

Slow acting toxin. Time to product effect > 0 - ≤ 28 days.

The activity of sodium benzoate increases with decreasing pH and diminishes above pH 7. Sodium benzoate is converted to free undissociated benxoic acid when pH decreases. If intracellular pH drops to 5 or below, anaerobic fermentation of glucose decreases and the growth of bacteria and fungi is inhibited.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Bactericide, Fungicide, Yeasticide.	Enzyme preservative	Sodium Benzoate (control)	*Bacteria: Pseudomonas aeruginosa Staphylococcus aureus Escherichia coli Yeast: Candida albicans Fungi: Aspergillus brasiliensis*	ISO 11930 2012	Test matrix: Enzymes (glycoamylase suspension) Concentration: 0 % (control) Contact time: 0 days, 7 days, 14 days and 28 days Temperature: 22.5 ° ± 2.5 °C	Results: Fail, pass criteria not met. Growth established for all test organisms at day 28. Validation criteria met.	Woodall (2016a) Report No. BT-CEH-02-01
Bactericide, Fungicide, Yeasticide.	Enzyme preservative	Sodium Benzoate	*Bacteria: Pseudomonas aeruginosa* *Staphylococcus aureus* *Escherichia coli Yeast: Candida albicans Fungi: Aspergillus brasiliensis*	ISO 11930 2012	Test matrix: Enzymes (glycoamylase suspension) Concentration: 1 % Na-benzoate Contact time: 0 days, 7 days, 14 days and 28 days Temperature: 22.5 ° ± 2.5 °C	Pass, ≥3 log reduction achieved for all test organisms. Validation criteria met.	Woodall (2016b) Report No. BT-CEH-02-02
Bactericide, Fungicide, Yeasticide.	Enzyme preservative	Sodium Benzoate	*Bacteria: Pseudomonas aeruginosa* *Staphylococcus aureus* *Escherichia coli Yeast: Candida albicans Fungi: Aspergillus brasiliensis*	ISO 11930 2012	Test matrix: Enzymes (glycoamylase suspension) Concentration: 2 % Na-benzoate Contact time: 0 days, 7 days, 14 days and 28 days Temperature: 22.5 ° ± 2.5 °C	Pass, ≥3 log reduction achieved for all test organisms. Validation criteria met.	Woodall (2016c) Report No. BT-CEH-02-03

Bactericide, Fungicide, Yeasticide.	Enzyme preservative	Sodium Benzoate	*Bacteria: Pseudomonas aeruginosa* *Staphylococcus aureus* *Escherichia coli* *Yeast: Candida albicans* *Fungi: Aspergillus brasiliensis*	ISO 11930 2012	Test matrix: Enzymes (glycoamylase suspension) Concentration: 3 % Na-benzoate Contact time: 0 days, 7 days, 14 days and 28 days Temperature: 22.5 ° ± 2.5 °C	Pass, ≥3 log reduction achieved for all test organisms. Validation criteria met.	Woodall (2016d) Report No. BT-CEH-02-04-A1
Bactericide, Fungicide, Yeasticide.	Enzyme preservative	Sodium Benzoate, potassium sorbate	*Bacteria: Pseudomonas aeruginosa* *Staphylococcus aureus* *Escherichia coli* *Yeast: Candida albicans* *Fungi: Aspergillus brasiliensis*	ISO 11930 2012	Test matrix: Enzymes (glycoamylase suspension) Concentration: 3 % Na-benzoate + 1 % K-sorbate Contact time: 0 days, 7 days, 14 days and 28 days Temperature: 22.5 ° ± 2.5 °C	Pass, ≥3 log reduction achieved for all test organisms. Validation criteria met.	Woodall (2016e) Report No. BT-CEH-02-05-A1
Bactericide, Fungicide, Yeasticide.	Enzyme preservative	Sodium Benzoate, potassium sorbate	*Bacteria: Pseudomonas aeruginosa* *Staphylococcus aureus* *Escherichia coli* *Yeast: Candida albicans* *Fungi: Aspergillus brasiliensis*	ISO 11930 2012	Test matrix: Enzymes (glycoamylase suspension) Concentration: 1 % Na-benzoate + 3 % K-sorbate Contact time: 0 days, 7 days, 14 days and 28 days Temperature: 22.5 ° ± 2.5 °C	Pass, ≥3 log reduction achieved for all test organisms. Validation criteria met.	Woodall (2016f) Report No. BT-CEH-02-06-A1

Fungicide	Enzyme preservative	Sodium Benzoate, Potassium sorbate	*Fungi: Geotrichum candidum NCPF 8632*	IBRG PDG 16-007.02	Test matrix: Enzymes (glycoamylase suspension) Concentrations: Sample 1:0% Sample 2:1% Sample 3:2% Sample 4: 3% Na-benzoate, Sample 5: 3% Na-benzoate + 1% K-sorbate, Sample 6: 1% Na-benzoate + 3% K-sorbate, Sample 7: 3% Na-benzoate + 3% K-sorbate,	TVC was 0 (cfu/mL) for all test concentrations immediately after and 7 days after inoculation for all 4 challenges (days 7, 14, 21 and 28). Significant growth in the control samples was established after the first inoculation. **Validation criteria not met:** it was not possible to validate the neutraliser as insufficient information was given in the test report.	Woodall (2019), Report No. BT-CEH-03-A2

Conclusion on the efficacy of the product
The product Sodium Benzoate 9% may be approved for use as an enzyme preservative against bacteria and yeasts in use concentrations equivalent of 1-3% sodium benzoate in the preserved product. Despite a ≥3 log reduction for fungi was achieved in the ISO 11930 tests, this was not considered sufficient to prove a fungicidal activity as CFU is not a suitable method for determination of growth of *A. brasiliensis*. The IBRG test method study could not be validated, therefore neither this study could be used to proof the fungicidal action of the product.

2.2.5.6 Occurrence of resistance and resistance management

Occurance of resistance not observed during history of use.

The DK eCA accepts that there is no significant risk of development of resistance for the active substance and the product, however, if the applicant becomes aware of any reports of resistance of the active substance, sodium benzoate, and/or the product these should be reported to appropriate bodies (e.g. the efficacy working group and/or concerned member states) so that it can be determined if further action is needed.

2.2.5.7 Known limitations

The efficacy of Sodium Benzoate decreases at pH values above 7.

2.2.5.8 Evaluation of the label claims

The biocidal product is not marketed. It is manufactured and added to the end-use product at the same site (site of manufacture). Efficacy of Sodium Benzoate 9% as an in-can preservative to preserve enzymes against degradation bacteria and yeasts at in-use concentrations equivalent to 1 – 3% sodium benzoate in the preserved product was successfully demonstatred.

2.2.6 Risk assessment for human health

The active substance sodium benzoate is included in Annex 1 (category 1) of Regulation No. 528/2012 (BPR). According to the SDS for Sodium benzoate 9%, Na-benzoate is classified for severe eye irritation, cat. 2 (H319). The concentration of sodium benzoate in the biocidal product is 9.0%, which is below the concentration limit (≥ 10%) triggering classification for H319. Consequently, the product does not require classification concerning human health according to Regulation No. 1272/2008 (CLP). The biocidal product does not pose a risk to human health when following the described intended use and does not require the use of personal protection equipment.

The eCA concludes that the risk assessment for human health does not preclude approval of the biocidal product according to the simplified procedure.

2.2.7 Risk assessment for the environment

Overall conclusion on the risk assessment for the environment of the product
A risk assessment for the environment is not required by the conditions of article 25. 1. Na-benzoate is authorised as a food additive under Regulation (EC) 1333/2008 and is listed in Annex I under Regulation 528/2012 (BPR). 2. Based on the SDS for the active substance provided by the applicant, neither Na-benzoate nor the biocidal product Sodium Benzoate 9% should be classified as hazardous to the environment. The eCA DK therefore conclude that the biocidal product Sodium Benzoate 9% does not pose a risk to the environment.

2.2.8 Measures to protect man, animals and the environment

Please refer to the summary of product assessment, section 2.1.

2.2.9 Assessment of a combination of biocidal products

Not relevant. The biocidal product is not intended to be used with other biocidal products.

3 ANNEXES

3.1 List of studies for the biocidal product

Author	Year	Title	Owner
Brinkmann, A	2016a	LAUS GmbH (2016a) Determination of the storage stability of 2015-31330 at room temperature (Report No. 16031604G001).	The Sodium Benzoate Consortium
Brinkmann, A	2016b	LAUS GmbH (2016b) Validation of an analytical method using HPLC for the determination of 2015-31330 (Report No. 16031604G926).	The Sodium Benzoate Consortium
Woodall C	2016a	Test Report: ISO 11930 2012 Cosmetics-Microbiology- Evaluation of the antimicrobial protection of a cosmetic product (Report No. BT-CEH-02-01).	The Sodium Benzoate Consortium
Woodall C	2016b	Test Report: ISO 11930 2012 Cosmetics-Microbiology- Evaluation of the antimicrobial protection of a cosmetic product (Report No. BT-CEH-02-02).	The Sodium Benzoate Consortium
Woodall C	2016c	Test Report: ISO 11930 2012 Cosmetics-Microbiology- Evaluation of the antimicrobial protection of a cosmetic product (Report No. BT-CEH-02-03).	The Sodium Benzoate Consortium
Woodall C	2016d	Test Report: ISO 11930 2012 Cosmetics-Microbiology- Evaluation of the antimicrobial protection of a cosmetic product (Report No. BT-CEH-02-04).	The Sodium Benzoate Consortium
Woodall C	2016e	Test Report: ISO 11930 2012 Cosmetics-Microbiology- Evaluation of the antimicrobial protection of a cosmetic product (Report No. BT-CEH-02-05).	The Sodium Benzoate Consortium
Woodall C	2016f	Test Report: ISO 11930 2012 Cosmetics-Microbiology- Evaluation of the antimicrobial protection of a cosmetic product (Report No. BT-CEH-02-06).	The Sodium Benzoate Consortium
Woodall C	2019	Test Report: IBRG Test Method IBRG PDG 16-007.02 Tier 1 Method for Determining the Basic Efficacy of Biocidal Active Substances used to Preserve Aqueous-Based Products. (Report no. BT-CEH-03-A2)	The Sodium Benzoate Consortium

3.2 Output tables from exposure assessment tools

Not applicable to a simplified authorisation.

3.3 New information on the active substance

Not applicable to a simplified authorisation.

3.4 Residue behaviour

Not applicable to a simplified authorisation.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)

Please refer to the IUCLID file, section 6.7, Efficacy data to support these claims.

3.6 Confidential annex

Please see separate confidential document.

3.7 Other

Not relevant.