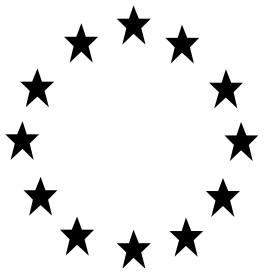
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	Purin NN
Product type(s):	04
Active ingredient(s):	Active chlorine released from sodium hypochlorite
Case No. in R4BP	BC-XF045802-34
Asset No. in R4BP	DE-0026697-0000
Evaluating Competent Authority	DE (BAuA)
Internal registration/file no	710-05-04-00002-00-00-00-0000
Date	03.02.2023

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1 Conclusion

The assessment presented in this report has shown the efficacy but no unacceptable risks, if the product, Purin NN with the active substance active chlorine released from sodium hypochlorite (7.5 % w/w) is used as a disinfectant in food and feed area (product-type 04) for disinfection by “cleaning in place with circulation“ of milking machines and milk cooling tanks.

The conditions for granting an authorisation according to Article 19 of Regulation (EU) No 528/2012[1] are fulfilled.

Please find detailed information on the uses appropriate for authorisation in chapter 2.4.
General directions for use of the product are summarised in chapter 2.5.

A classification according to Regulation (EC) No 1272/2008[2] is necessary. Detailed information on classification and labelling is provided in chapter 2.3.

The assessment of the intended use(s) as applied for by the applicant (see chapter 3.1) has taken the following into consideration:

1. The conclusions and recommendations of the Italian Assessment Report for the approval of the active substance active chlorine released from sodium hypochlorite including the “elements to be taken into account by Member States when authorising products” as requested by the Italian CA.
2. The specific provisions from Inclusion Directive for the active substance active chlorine released from sodium hypochlorite (Commission Implementnig Regulation (EU) 2017/1273).

Approval of the active substance
The active substance active chlorine released from sodium hypochlorite is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any use covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance.

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[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

- In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.
- For products that may lead to residues in food or feed, the need to set new or to amend existing MRLs in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

Composition and formulation

The soluble concentrate Purin NN contains the active substance active chlorine released from sodium hypochlorite.
Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.
The substances sodium hydroxide and potassium hydroxide have been identified as substances of concern. Please refer to chapter 2.2 (Composition and formulation) and the confidential annex for detailed information.

Physical, chemical and technical properties

The physical, chemical and technical properties have been determined and deemed acceptable (please find more information in chapter 3.2).

Physical hazards and respective characteristics

The product has to be classified because of identified physical-chemical hazard(s) (see chapter 2.3). However, this does not lead to an unacceptable risk for end users (please find more information in chapter 3.3).

Methods for detection and identification

Information on the analytical methods for the active substance and its residues is provided in chapter 3.4. The evaluation is based on the residue definitions and action levels derived from the Assessment Report or Competent Authority Report.

Efficacy against target organisms

The product has been shown to be efficacious for the uses appropriate for authorisation listed in chapter 2.4. Please find more information on efficacy of the product in chapter 3.5.

Risk assessment for human health

The substances sodium hydroxide and potassium hydroxide have been identified as substances of concern.

The human health risk assessment for this product is based on the active substance and identified substances of concern.

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3).

A human health risk assessment has been carried out for professional use of the product (see chapter 3.6) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to professional users, bystanders and residents. Regarding professional users health protection, there are no objections against the intended uses if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

Risk assessment for the environment

Since no relevant substance of concern has been identified for the environment, the risk assessment for the environment for this product is based on the active substance.

There are no indications for endocrine disrupting properties of the biocidal product (please find more information in chapter 2.2.3).

A qualitative risk assessment for the environment has been carried out for the product (see chapter 3.8) for all intended uses (see chapter 3.1).

Based on the risk assessment it is unlikely that the intended use cause any unacceptable risk for the environment if the directions for use according to chapter 2.5 and if applicable to 2.4 are followed.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Purin NN

2.1.2 Manufacturer(s) of the product

Name of manufacturer	DeLaval Operations Sp. z.o.o
Address of manufacturer	Ul. Robotnicza 72 53-608 Wroclaw Poland
Location of manufacturing sites	Ul. Robotnicza 72 53-608 Wroclaw Poland

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

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	PCC Rokita SA
Address of manufacturer	Ul. Sienkiewicza 4 56-120 Brzeg Dolny Poland
Location of manufacturing sites	Ul. Sienkiewicza 4 56-120 Brzeg Dolny Poland

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	Nobian Industrial Chemicals BV
Address of manufacturer	Van Asch van Wijckstraat 53, 3811 LP Amersfoort, The Netherlands
Location of manufacturing sites	Elektrolysestraße 1 06749 Bitterfeld Germany
	Hauptstraße 47 49479 Ibbenbüren Germany

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from sodium hypochlorite	Sodium hypochlorite	Active substance	7681-52-9	231-668-3	7.5
Sodium hydroxide	Sodium hydroxide	Non-active substance	1310-73-2	215-185-5	5.5
Potassium hydroxide	Potassium hydroxide	Non-active substance	1310-58-3	215-181-3	2

- Information on the full composition is provided in the confidential[3] annex (see chapter 5.1).

- 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 ☒

- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012.

2.2.2 Information on technical equivalence

- Is the source of the active substance(s) the same as the one 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 ☐

2.2.3 Information on endocrine disrupting properties

Based on the submitted information and according to the SVHC-candidate list there are no indications for endocrine disrupting properties of the biocidal product. Therefore no corresponding regulatory measures are required.

[3] Access level: “Restricted” to applicant and authority

Further information available in section 5.1.2 in the Confidential annex.

2.2.4 Information on the substance(s) of concern

The following substance(s) of concern was/were identified:

- Potassium hydroxide (CAS No. 1310-58-3)
- Sodium hydroxide (CAS No. 1310-73-2)

➢ (Further) information on the substance(s) of concern is provided in the confidential annex (chapter 5.1).

2.2.5 Candidate(s) for substitution

No candidate for substitution was identified.

2.2.6 Type of formulation

SL – soluble concentrate

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[4]

Besides the active substance “Active chlorine released from sodium hypochlorite” (CAS-Nr. 7681-52-9) and the substances of concern “Potassium hydroxide” (CAS No. 1310-58-3) and “Sodium hydroxide” (CAS No. 1310-73-2), the other components do not affect the classification of the biocidal product with regard to human health.
Besides the releaser of the active substance sodium hypochlorite, the other components do not affect the environmental classification of the biocidal product.

The current harmonised classification of the active substance releaser sodium hypochlorite is based Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation):
Aquatic acute 1, M=10
Aquatic chronic 1, M=1

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Classification of the biocidal product pursuant to the Regulation (EC) 1272/2008 is required.

For labelling according to Article 69 of Regulation (EU) 528/2012, in particular precautionary and risk mitigation measures as well as categories of users to which the use is restricted, please refer to chapter 2.5 and if applicable to chapter 2.4.

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Metal Corr.	H290
Skin Corr. 1B	H314
Eye Dam. 1	(H318)*
Aquatic acute 1	H400
Aquatic chronic 2	H411

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS05	
	GHS09	
Signal word	-	Danger
Hazard statements	H290	May be corrosive to metals.
	H314	Causes severe skin burns and eye damage..
	H410	Very toxic to aquatic life with long-lasting effects.
Supplemental hazard information	EUH031	Contact with acids liberates toxic gas.
	EUH071	Corrosive to the respiratory tract.
Supplemental label elements		
Precautionary statements	P234	Keep only in original packaging.
	P260	Do not breathe mist/vapours.
	P264	Wash hands and face thoroughly after handling.
	P273	Avoid release to the environment.

Labelling	Code	Pictogram / Wording
	P280	Wear protective gloves/ protective clothing/eye protection/face protection.
	P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
	P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower.
	P363	Wash contaminated clothing before reuse.
	P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P310	Immediately call a POISON CENTER or doctor
	P321	Specific treatment (see **risk mitigation measures and additional first aid measures** on this label).
	P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P390	Absorb spillage to prevent material damage.
	P391	Collect spillage.
	P405	Store locked up.
	P501	Dispose of contents/container in accordance with local regulation.

For labelling according to Article 69 of Regulation 528/2012, in particular precautionary and risk mitigation measures (RMM), please refer to chapter 2.5 and 2.4.

Labelling has to be in accordance with article 69 of Regulation (EU) No. 528/2012 and with Regulation (EU) No. 1272/2008.
It is within the responsibility of the authorisation holder to comply with the legal provisions for classification and labelling.

2.4 Use(s) appropriate for authorisation[5]

2.4.1 Use 1 appropriate for authorisation – Disinfection of milk tanks/milking machines by CIP

Product Type(s)	PT 04
Where relevant, an exact description of the use	Food and feed area (Disinfectants)
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor Disinfection by “cleaning in place with circulation“ of milking machines and milk cooling tanks on dairy farms
Application method(s)	Method: Closed system Detailed description: Cleaning in place (CIP) with circulation.
Application rate(s) and frequency	Application Rate: 250 ml per 10L water Dilution (%): 2.5% v/v product in tap water (60 to 85°C) Number and timing of application: The time between applications will depend on the frequency of cleaning of the milking machines and cooling tanks (maximal 2x/day, after each milking). Contact time: 10 min for bacteria and yeast
Category(ies) of users	Professional
Pack sizes and packaging material	Can 20L, 25L Drum 60L, 200L IBC 1000L Material of the packaging and of closure(s): HDPE

2.4.1.1 Use-specific instructions for use

See chapter 2.5

5 Member States might refuse to grant an authorisation or adjust the terms and conditions of the authorisation to be granted according to Article 37 BPR.

2.4.1.2 Use-specific risk mitigation measures

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

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

See chapter 2.5

2.5 General directions for use

2.5.1 Instructions for use

1) Pre-rinse installation with water (40 - 45°C) until all residual milk traces are removed.
2) Dose 2.5 % v/v product in warm water between 60 and 85°C.
3) Circulate solution 10 minutes. Always keep water temperature above 40°C. Check clusters and water flow.
4) Remove disinfection solution and rinse the equipment with clean cold water.
5) Allow the installation to dry.

2.5.2 Risk mitigation measures

1) Animals and the general public (bystanders) must not be present during the use of the product.
2) Keep out of reach of children and non-target animals/pets.

3) Rinse treated equipment, pipes and machinery with drinking water before and after application.
4) For food commodities, make sure that the concentration of chlorate present in food does not exceed the MRL values set by EU Commission (Reg. (EU) 2020/749).
5) The following personal risk mitigation measures can be considered **for mixing, loading and maintenance:**

The wearing of protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) is required during product handling phase.

Wear a protective coverall (at least type 6, EN 13034).

The use of eye protection during handling of the product is mandatory.

Wear suitable protective footwear against chemicals (EN 13832) when applying the product.

This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

6) For repair or maintenance of dosing pumps: Prior to intervention in the pumps, existing product residues must be largely removed by flushing the pumps.
7) The following personal protection equipment shall be worn by professional bystanders working in the vicinity of the mixing and loading process:

The use of eye protection during handling of the product is mandatory. This is without prejudice to the application by employers of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work.

8) During CIP application, no PPE is considered necessary as long as the application solution is within the closed system.
9) The use of a dosing pump for manual loading is required.

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

1) IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

2) IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

3) IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.
4) IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid

5) Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.
6) Take up mechanically and collect in suitable container for disposal. Dispose of in an incinerator approved for chemicals.

2.5.4 Instructions for safe disposal of the product and its packaging

1) Residues of the biocidal product must be disposed of in accordance with the Waste Framework Directive (2008/98/EG) and the European Waste Catalogue (EWC) as well as national and regional regulations.
2) Leave biocidal products in original containers. Do not mix with other wastes. Containers containing residues of the product have to be handled accordingly.
3) Waste entry on pesticides: 20 01 19*
4) Waste entry on packaging containing residues of or contaminated by dangerous substances: 15 01 10*

*specific to Germany

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

1) Shelf-life: 9 months.
2) Store at temperatures not exceeding 30°C.
3) Protect from frost.
4) Store away from light.

2.5.6 Other information

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2.6 Packaging

Table 4

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of the closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials
Can	20L	HDPE	sealed screw caps (HDPE)	professional	Yes
Can	25L	HDPE	sealed screw caps (HDPE)	professional	Yes
Drum	60L	HDPE	sealed screw caps (HDPE)	professional	Yes
Drum	200L	HDPE	sealed screw caps (HDPE)	professional	Yes
IBC	1000L	HDPE	sealed screw caps (HDPE)	professional	Yes

3 Assessment of the product

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

3.1.1 Intended use 1 – Disinfection of milk tanks/milking machines by CIP

Product Type(s)	PT04
Where relevant, an exact description of the use	Disinfection by “cleaning in place with circulation” of milking machines and milk cooling tanks
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor Disinfection by “cleaning in place with circulation” of milking machines and milk cooling tanks
Application method(s)	Method: Closed system Cleaning in place (CIP) with circulation
Application rate(s) and frequency	250 ml / 10 L Dosing: 2.5 % v/v Frequency: The time between applications will depend on the frequency of cleaning of the milking machines and cooling tanks (maximal 2x/day, after each milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Type Material Size Can Plastic: HDPE 20L Can Plastic: HDPE 25L Drum Plastic: HDPE 60L Drum Plastic: HDPE 200L IBC Plastic: HDPE 1000L

3.2 Physical, chemical and technical properties

Table 5: Physical, chemical and technical properties of the Biocidal product

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	Purin NN (13.5 % active chlorine)	Clear liquid.	No study, part of product specification. Appearance after storage addressed in stability study (see below).
Colour at 20 °C and 101.3 kPa	Visual		Slightly yellow.	
Odour at 20 °C and 101.3 kPa	Organoleptic		Slight chorine-like odour.	
Acidity / alkalinity	similar to CIPAC MT 75.3 similar to CIPAC MT 191 (Endpoint of titration: pH 8.5)	Purin NN (7.65 % w/w available chlorine) Batch No. CT624-1	1 % solution at 25 °C: pH = 12.21 Alkalinity (undiluted product): 6.84 % w/w as NaOH 5.30 % w/w as Na_2O	Study No. 2016-PC-001 (2016)
Relative density / bulk density	USP method 841 modified according to EC method A.3	Purin NN Batch No. CT624-1	Realtive density at 20 °C: 1.228 g/cm^3.	Study No.2016-PC-009 (2016)
Storage stability test – **accelerated storage**	Data waiving. The label indicates that the product should be protected from temperatures above 30 °C.	-	-	Waiving
Storage stability test – **long term storage at ambient temperature**	Purin NN stored in 10L HDPE cans for 9 months at 25 °C / 60 % R.H. **pH**	Purin NN batches (available chlorine): CT624-1 (7.65 % w/w) CT624-2 (7.81 % w/w) CT624-3 (7.89 % w/w)	Appearance of the product and packaging is described as conform in all cases troughout the study. No changes have been observed.	Report No. RA180262 (2018) Report No. V1JYT111 (2018)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	similar to CIPAC MT 75.3 **Alkalinity:** similar to CIPAC MT 191 **Relative density:** USP method 841 modified according to EC method A.3	For tracking of chlorate: 723-09 (7.9 % w/w)	**Batch CT624-1:** Available chlorine (% w/w) Before storage: 7.65 After 9 months: 2.53 (-67 %) pH (1 % solution): Before storage: 12.2 After 9 months: 12.1 Alkalinity (% w/w as Na_2O): Before storage: 5.3 After 9 months: 4.9 Relative density (g/cm^3): Before storage: 1.234 After 9 months: 1.227 **Batch CT624-2:** Available chlorine (% w/w) Before storage: 7.81 After 9 months: 2.56 (-67 %) pH (1 % solution): Before storage: 12.3 After 9 months: 12.2	Report No. V1JAR641 (2018)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Alkalinity (% w/w as Na_2O): Before storage: 5.5 After 9 months: 4.9 Relative density (g/cm^3): Before storage: 1.232 After 9 months: 1.225 **Batch CT624-3:** Available chlorine (% w/w) Before storage: 7.89 After 9 months: 2.60 (-67 %) pH (1 % solution): Before storage: 12.3 After 9 months: 12.2 Alkalinity (% w/w as Na_2O): Before storage: 5.4 After 9 months: 4.7 Relative density (g/cm^3): Before storage: 1.236 After 9 months: 1.227 **Batch 723-09:**	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Available chlorine (% w/w): Before storage: 7.9 After 9 months: 2.0 (-75 %) Chlorate (% w/w): Before storage: 0.58 After 9 months: 2.30 (+297 %)	
Storage stability test – **low temperature stability test for liquids**	Data waiving. The label indicates that the product should be protected from frost.	-	-	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Data waiving. It is indicated on the label that the container should be protected from direct light. Additionally, the product is protected from UV-light by HDPE packaging	-	-	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Data waiving. The label indicates that the product should be protected from temperatures above 30 °C. The product is an aqueous solution, so protection from humidity is not necessary.	-	-	-
Effects on content of the active substance and technical characteristics of	-	-	After a plausibility check of the submitted documents: long-term storage studies and	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
the biocidal product - **reactivity towards container material**			IUCLID data, the material (HDPE) biocidal active substance combination in the biocidal product "Purin NN" can be assessed as suitable if the biocidal active substance "Sodium hypochlorite" is transported and stored as intended (the temperature of 30°C must not be exceeded).	
Wettability	Not applicable.	-	-	-
Suspensibility, spontaneity and dispersion stability	Not applicable.	-	-	-
Wet sieve analysis and dry sieve test	Not applicable.	-	-	-
Emulsifiability, re-emulsifiability and emulsion stability	Not applicable.	-	-	-
Disintegration time	Not applicable.	-	-	-
Particle size distribution, content of dust/fines, attrition, friability	Not applicable.	-	-	-
Persistent foaming	CIPAC MT 47	Purin NN Batch-No. 723-09 2.5 % v/v dilution	No foam observed after 0, 1, 3 and 12 minutes at 20 °C.	Report No. NB 708:55 (2018)
Flowability/Pourability/Dustability	Not applicable.	-	-	-
Burning rate — smoke generators	Not applicable.	-	-	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Burning completeness — smoke generators	Not applicable.	-	-	-
Composition of smoke — smoke generators	Not applicable.	-	-	-
Spraying pattern — aerosols	Not applicable.	-	-	-
Physical compatibility	Not applicable. Purin NN is not intended to be used with other substances or mixtures.	-	-	-
Chemical compatibility	Not applicable. Purin NN is not intended to be used with other substances or mixtures.	-	-	-
Degree of dissolution and dilution stability	CIPAC MT 41	Purin NN Batch-No. 723-09 (before and after 9 months after storage) 2.5 % v/v dilution	A 2.5 % v/v dilution of Purin NN remains sligthly cloudy, with no separation or precipitation after 18 hours. The result does not change after 9 months of storage.	Report No. NB 708:55 (2018) Report No. NB 740:75 (2018)
Surface tension	EU method A.5 (ring method)	Purin NN Batch-No. G180330200 2.5 % v/v dilution	67.7 mN/m at 20 °C Purin NN is not surface-active.	Report No. 1801161 (2018)
Viscosity	similar to OECD 114	Purin NN (7.65 % w/w available chlorine) Batch No. CT624-1	Viscosity at 20 °C (30 rpm): 3.44 cP = $3.44 \cdot 10^{-3}$ Pa·s Viscosity at 40 °C (30 rpm): 2.94 cP = $2.94 \cdot 10^{-3}$ Pa·s	Study No. 2016-PC-001 (2016)

Table 6

Conclusion on the physical, chemical and technical properties
Purin NN is a clear, slightly yellow liquid with a slight chlorine odour. It is a basic solution with a pH of 12.21 at 1 % dilution and an alkalinity of 6.84 % w/w as NaOH (undiluted product). The relative density is 1.228 g/cm³. During 9 months storage at ambient temperature, appearance, pH, alkalinity and relative density of the product remain stable. The active substance content decreases by 67 % while there is a significant increase of chlorate. The high decrease of active substance content and increase in chlorate is well known for products containing active chlorine released from sodium hypochlorite. Efficacy of the aged product was confirmed. No persistent foaming was observed for the only in-use-concentration of 2.5 % v/v. The degree of dissolution and dilution stability of Purin NN at 2.5 % v/v is high and does not change after 9 months of storage. Purin NN is not surface-active. The viscosity is $3.44 \cdot 10^{-3}$ Pa·s at 20°C and $2.94 \cdot 10^{-3}$ Pa·s at 40 °C. The data provided by the applicant was acceptable. Purin NN has a shelf-life of 9 months and should be stored below 30 °C, protected from frost and light.

3.3 Physical hazards and respective characteristics

Table 7: Physical hazards and respective characteristics of the product

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Explosives	-	-	-	Data waiving. The product does not contain any chemical groups that are associated with explosive properties.	
Flammable gases	-	-	-	Not applicable. Product is a liquid.	
Flammable aerosols	-	-	-	Not applicable. Product is a liquid.	
Oxidising gases	-	-	-	Not applicable. Product is a liquid.	
Gases under pressure	-	-	-	Not applicable. Product is a liquid.	
Flammable liquids	EU method A.9 (closed cup equilibrium)	Purin NN (7.65 % w/w available chlorine) Batch No. CT624-1	-	No Flash Point below boiling point (< 131 °C) Not classified as flammable liquid based on GHS/CLP criteria.	Study No. YW21WC (2017)
Flammable solids	-	-	-	Not applicable. Product is a liquid.	
Self-reactive substances and mixtures	-	-	-	Data waiving. The product does not contain any chemical groups that are associated with self-reactive properties.	
Pyrophoric liquids	-	-	-	Data waiving. Based on experience in production and handling of the product, it does not exhibit pyrophoric properties.	

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
Pyrophoric solids	-	-	-	Not applicable. Product is a liquid.	
Self-heating substances and mixtures	-	-	-	Not applicable. This hazard class only applies to solid mixtures exposing a large surface area. Purin NN is an aqueous solution and therefore a liquid.	
Substances and mixtures which in contact with water emit flammable gases	-	-	-	Data waiving. Based on experience in production and handling of the product, it does not react with water. Also Purin NN is placed on the market as an aqueous solution.	
Oxidising liquids	-	-	-	Data Waiving. None of the constituents of Purin NN is classified as oxidising. Therefore, it can be excluded that the product, which is an aqueous solution, shows oxidising properties.	
Oxidising solids	-	-	-	Not applicable. Product is a liquid.	
Organic peroxides	-	-	-	Not applicable. Product does not fall under the definition of organic peroxides.	
Corrosive to metals	UN Test in Part III of the UN-MTC, 37.4	Purin NN (undiluted)	Test conducted with Aluminium for 7 days. Steel: not conducted	Aluminium (after 7 days): 99.99 % mass loss (fully submerged); 62.91 % mass loss (50 % liquid / 50 % vapour); No mass loss (vapour phase) Due to total desintegration of the metal in contact with the liquid, localised/pitting corrosion was not investigated.	Report-No. 12/001zd (2012)

Hazard class / characteristics	Guideline and Method	Purity of the test substance (% (w/w)	Parameter	Results	Reference
				Substance or mixture corrosive to metals, Category 1 based on GHS/CLP criteria H290: May be corrosive to metals.	
eCA remark:	The guidance generally requests testing of aluminium and steel. In this case, testing corrosiveness only with Aluminium is acceptable as the classification criteria are already fulfilled and Purin NN will be classified.				
Auto-ignition temperature (liquids and gases)	EN 14522 DIN 51794 ASTM E 659	-	-	Data waiving. Testing not necessary for liquids that are non flammable in air.	
Relative self-ignition temperature for solids	Regulation (EC) No 440/2008, Method A.16	-	-	Not applicable. Product is a liquid.	
Dust explosion hazard	-	-	-	Not applicable. Product is a liquid.	

Table 8

Conclusion on the physical hazards and respective characteristics
The data provided by the applicant was acceptable. Purin NN is a non-flammable liquid without explosive, self-reactive and oxidising properties. The corrosivity testing was positive and therefore Purin NN is classified as „Corrosive to metals, Category 1" with the Hazard statement „H290: May be corrosive to metals".

3.4 Methods for detection and identification

Table 9

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Available Chlorine	Redox titration with $Na_2S_2O_3$ after addition of KI	Specifity was established by application of the method procedure to 1) solvent only 2) a product placebo containing all ingredients except the active substance. No reaction with KI was observed.	0.15 – 0.60 g of sample Purin NN (50 – 200 % of normal amount), n=7 y = 21.002x + 0.066 R^2 = 0.9999	4.1, 8.4 and 15.0 % w/w available chlorine / one measurement each	99.4 – 101.3	100.3 (n=3)	0.77 (n=3)	n/a	Validation Report - WM 004 (2018)

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**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
Chlorate (ClO_3^-)	Ion Chromatography (IC)	Specifity was established by comparative analysis of Chlorate standard, NaOCl solution, blank formula of Purin NN, and the full formula of Purin NN. The specifity for chlorate in the sample matrix was demonstrated.	1.03 – 10.25 ppm (n=5), y = 0.12387x - 0.03238 R^2 = 0.9994	Spike level 101% n = 4	88 – 93	91	2.59%	LOQ = 1.03 ppm LOD (theoretical) = 0.31 ppm	Test Report V1JYT111 (2021) Test report V1MKN399 (2021)

Table 10

Relevant residue definitions for monitoring and levels for which compliance is required			
Matrix	**Residue definition**	**Limit / MRL**	**Reference / Remarks**
Soil	not relevant; Active chlorine (HClO/ClO^-) reacts rapidly with organic matter	-	AR “Active chlorine released from sodium hypochlorite” PT1, 2, 3, 4, 5 LoEP, 01/2017
Drinking water	Active chlorine* (HClO/ClO^-) and relevant metabolite chlorate $ClO3^-$	0.7 mg/L (chlorate) 0.2 - 5 mg/L (chlorine)	AR “Active chlorine released from sodium hypochlorite” PT1, 2, 3, 4, 5 LoEP, 01/2017 WHO Guidelines for Drinking-water Quality, 4th edition (2011)
Surface water	not relevant; Active chlorine (HClO/ClO^-) reacts rapidly with organic matter	-	AR “Active chlorine released from sodium hypochlorite” PT1, 2, 3, 4, 5 LoEP, 01/2017
Air	not relevant	-	AR “Active chlorine released from sodium hypochlorite” PT1, 2, 3 ,4, 5 LoEP, 01/2017
Animal and human body fluids and tissues	not relevant; Active chlorine (HClO/ClO^-) reacts rapidly with organic matter	-	AR “Active chlorine released from sodium hypochlorite” PT1, 2, 3 ,4, 5 LoEP, 01/2017
Food of plant origin	chlorate ClO_3^-	0.05 mg/kg	AR “Active chlorine released from sodium hypochlorite” PT3, 4, 5; LoEP, 01/2017 Regulation (EU) No 2020/749, Annex III A
Food of animal origin	chlorate ClO_3^-	fat, milk: 0.1 mg/kg others: 0.05 mg/kg	AR “Active chlorine released from sodium hypochlorite” PT3, 4, 5; LoEP, 01/2017 Regulation (EU) No 2020/749, Annex III A

* The active substance is "active chlorine released from sodium hypochlorite", which is thought to consist of chlorine (Cl_2), hypochlorous acid (HClO) and hypochlorite anion (ClO^-) in equilibrium. The predominant species will depend on pH value (chlorine is available only at pH<4, hypochlorous acid is

predominant in the range 4 to 5.5, whereas only the hypochlorite anion is present at pH>10). At the in use pH values in PT1, 2, 3, 4, 5 chlorine is virtually non-present at the equilibrium, whereas the predominant species are the hypochlorous acid and the hypochlorite anion or (at higher pH values) the hypochlorite anion only (AR “Active chlorine released from sodium hypochlorite” PT1, 2; 3, 4, 5 01/2017).

Table 11

Analytical methods for drinking water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
chlorate	LC-MS/MS, IonPac AS11 HC column, ESI-, m/z 83→67; m/z 85→69	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Report No. 18C11060-01-VMWA; Post-approval data, Doc IIIA; A4.2c; 11/2018
chlorine	Photometric detection at 510 nm	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Report No. IF-18/04521040; Post-approval data, Doc IIIA; A4.2c; 11/2018

Table 12:

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analyte (type of analyte e.g. active substance)**	**Analyte (type of analyte e.g. active substance)**	**Analyte (type of analyte e.g. active substance)**	**Analyte (type of analyte e.g. active substance)**	**Analyte (type of analyte e.g. active substance)**			**Analyte (type of analyte e.g. active substance)**	**Analyte (type of analyte e.g. active substance)**
					Range	**Mean**	**RSD**		
NaOH	Ion chromatography	specific, chromatographic separation	not reported	Range 0.05...4 mg/m³ / N=5	**102…107.6**	**103.5**	**2.1**	LOQ = 0.041 mg/m³	IFA Arbeitsmappe 7638
KOH	Ion chromatography	specific, chromatographic separation	not reported	Range 0.05...4.3 mg/m³ / N=5	**98.1…102.3**	**98.6**	**2.5**	LOQ = 0.032 mg/m³	IFA Arbeitsmappe 7638

Residue definition: Cl_2/HClO/ClO^-

In the assessment report for Active chlorine released from sodium hypochlorite (PT04, Italy, 2017), no residues of HClO/OCl^- are expected as no aerosol forming spraying applications are envisaged and the in-use pH is higher than 10.

Two analytical methods are available for monitoring active chlorine (Cl_2/HClO/ClO^-) in air in the case of accidential release:

1) Reference: OSHA Method «Chlorine in Work place Atmosphere» 05.01.83; Smith & Cochran Spectrophotometric determination of Free Chlorine in Air using Sulphamic acid/Tri-iodide procedure - Anal Chem 1986 Vol 58 pp 1591-1592.

2) Reference: OSHA Method «Chlorine in Work place Atmosphere» 05.01.83; NIOSH free chlorine in air 01.01.75; ISO 7392/2 Water quality – Determination of free and total chlorine Part 2 Colorimetric method using DPD for routine control purposes 15.10.85.

Although the methods are not validated, the monitoring range is considered to be 0.3 to 7.0 mg Cl_2/m^3.

The methods are based on the oxidative properties of active chlorine species (Cl_2/HClO/ClO^-), which produce a marker which can be quantified.

Table 13

Analytical methods for monitoring of active substances and residues in food and feeding stuff of plant origin									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
chlorate	LC-MS/MS, IonPac AS11 HC column, ESI-, m/z 83→67; m/z 85→69	No interfering substances were detected.	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Report No. 18C11060-01-VMPL; Post-approval data, Doc IIIA; A4.3; 11/2018

Table 14

Analytical methods for monitoring of active substances and residues in food and feeding stuff of animal origin									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
chlorate	LC-MS/MS, IonPac AS11 HC column, ESI-, m/z 83→67; m/z 85→69	No interfering substances were detected.	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Report No. 18C1106-01-VMAT; Post-approval data, Doc IIIA; A4.3; 11/2018

Analytical methods for monitoring of active substances and residues in food and feeding stuff of animal origin									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Specificity**	**Linearity (range, R^2)**	**Fortification range / Number of measurements**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	**Mean**	**RSD**		
				[redacted]	[redacted]	[redacted]	[redacted]		

Table 15

Data waiving was acceptable for the following information requirements	
Information requirement	Regarding analytical methods for monitoring in soil, in surface water and in body fluids and tissues data waiving was accepted at EU level.
Justification	-

Table 16

Conclusion on the methods for detection and identification
Methods for the detection of residues of active chlorine in drinking water and in food of plant and animal origin were provided and deemed acceptable at EU level. Methods regarding residues of substances of concern were not necessary. The method(s) provided regarding the active substance(s), residues and substances of concern was/were acceptable.

3.5 Efficacy against target organisms

3.5.1 Function and field of use

The biocidal product is a concentrate based on the active substance active chlorine, released from sodium hypochlorite, which is diluted prior to use.
In PT4 (food and feed area) the disinfectant is intended to be used for the disinfection of milking machines and cooling tanks in milk industry facilities by cleaning-in-place (CIP) with circulation. The product is dosed into water of 60 – 85 °C and circulated for 10 min during which the temperature does not fall below 40 °C.

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

The product is intended to have bactericidal and yeasticidal efficacy to avoid contamination in the milk-processing equipment to protect humans.

3.5.3 Effects on target organisms, including unacceptable suffering

Application of the product leads to irreversible inactivation of bacterial cells and yeasts.

3.5.4 Mode of action, including time delay

When diluted in water, sodium hypochlorite releases active chlorine, which „consist[s] of chlorine (Cl_2), hypochlorous acid (HClO) and hypochlorite anion (ClO^-) in equilibrium. The predominant species will depend on pH value (chlorine is available only at pH < 4, hypochlorous acid is predominant in the pH range 4 to 5.5, whereas only hypochlorite anion is present at pH >10)“.[6]
Active chlorine leads to oxidative disruption of cell membranes, inactivation of enzymes and modifications of nucleic acids.

[6] Assessment Report for Active chlorine releases from sodium hypochlorite, product-type 4 (01/2017)

3.5.5 Efficacy data

As the product is intended to be applied for disinfection by cleaning-in-place (CIP) with circulation, the efficacy was tested with quantitative suspension tests (phase 2, step 1 tests) according to the Transitional Guidance on the Biocidal Products Regulation, Transitional Guidance on Efficacy Assessment for Product Types 1-5, Disinfectants, May 2016, chapter 5.3. All efficacy studies have been performed based on available EN standards for 10 minutes with 10 g/l skimmed milk soiling representing dirty conditions for the milk industry. The active substance concentration decreases (> 10 %) over time. Therefore, quantitative suspension studies were performed with product at the time of manufacturing (unstored product) and with product which has been stored for 9 months at 25 °C prior to the tests or which was stored at 50 °C for 9 days to reconstitute the long term storage (stored product).

As the product is dosed into water between 60 and 85 °C and the solution is then kept above 40 °C throughout circulation, efficacy tests were performed at 40 °C and 85 °C to cover the whole temperature range of the use.
At 40 °C bactericidal efficacy tests of the unstored product were carried out according to EN 1276 with the standard test organisms *Staphylococcus aureus*, *Enterococcus hirae*, *Escherichia coli* and *Pseudomonas aeruginosa*. The stored product was in addition to the standard test organisms also tested with the thermotolerant bacterium *Enterococcus faecium*. Yeasticidal efficacy tests were performed according to EN 1650 at 40°C with the standard test organism *Candida albicans*.

Additional efficacy tests with unstored and stored product were provided with *E. faecium* at 85 °C. According to the applicable efficacy guideline, chapter 1.4.4.4, there is no standardized thermotolerant test organism among yeasts. Therefore, no additional tests at temperatures above 40°C (highest, validated temperature according to EN 1650) were performed with yeast.
Due to the fact that control A and the water control were thermally inactivated for *E. faecium* at this high temperature, additional controls at 40 °C were performed to confirm the validity. To account for the possibility that the active substance might be thermally instable at 85 °C leading to a possibly inefficacious active substance concentration when the product dilution cools down during the use, stability of the active substance was determined by incubation of unstored and stored product at 85 °C. Active substance concentrations were measured at different time points and no decrease in the active substance content was observed over up to 75 minutes, which ensures the thermal stability of the active substance during the 10 min application.

The product Purin NN contains sodium hydroxide and potassium hydroxide (see product composition, chapter 2.2.1). Both bases were identified as active substances in accordance with the Regulation (EC) No. 1451/2007. In order to prove that sodium hydroxide and potassium hydroxide are not acting as active substances, the applicant provided a phase 2, step 1 test against the bacterium *E. faecium* (EN 1276)

(Study number TSR 2021-11-127) in accordance with the Technical Agreements for Biocides (TAB)-EFF confirming that both co-formulants are not acting as active substances in the product.

Taken all data together, bactericidal and yeasticidal efficacy has been sufficiently demonstrated for the intended use as presented in the conclusion on the efficacy.

Table 17

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**
PT 4 Bactericidal	CIP in milking machines and milk cooling tanks	Purin NN (F-2336), Batch-Nr.: CT 624-16 at time of manufacturing (TOM) AS: active chlorine, released from sodium hypochlorite; concentration in unstored product: not tested for this batch; nominal value 7,5 % (w/w)	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Escherichia coli* ATCC 10536 *Pseudomonas aeruginosa* ATCC 15442	EN 1276 (2009)	Quantitative suspension test 40 °C, Dirty conditions (10 g/l skimmed milk) 0,1 %, 0,3 %, 0,4 %, 0,5 % (v/v) product concentration 10 min contact time	Results showed a > 5 lg reduction for bacteria with 0,3 % (v/v) Purin NN within 10 min at 40 °C under dirty conditions (milk soiling). N0 and Nv0 were slightly too high (Nv0=200 cfu/ml; N0 = 6,2*10^7 cfu/ml) for *S. aureus*. All other controls were valid.	*WEST AGRO, Inc. (2016a)* Study number TSR 2016-04-085* raw data provided in laboratory protocol (*TSR 2016-04-085 Raw Data NB 636 p52-53, 60-73*) readable test protocol provided (*REP PROT TSR 2016-04-085 - Purin NN - EN1276 - 40C - 10min - milk (signed) 13-May-2016*)
PT 4 Yeasticidal	CIP in milking machines and milk cooling tanks	Purin NN (F-2336), Batch Nr.: CT 624-1 at time of manufacturing (TOM) AS: active chlorine, released from sodium hypochlorite; concentration in unstored product: 7,65 % (w/w)	*Candida albicans* ATCC 10231	EN 1650 (2013)	Quantitative suspension test 40 °C, Dirty conditions (10 g/l skimmed milk) 0,1 %, 0,3 %, 0,4 %, 0,5 % (v/v) product concentration 10 min contact time	Results showed a > 4 lg reduction for yeast with 0,3 % (v/v) Purin NN within 10 min at 40 °C under dirty conditions (milk soiling). All controls were valid.	*WEST AGRO, Inc. (2016b)* Study number TSR 2016-03-058* raw data provided in laboratory protocol (*TSR 2016-03-058 Raw Data NB 604 p59-62, 73-75*) readable test protocol

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**
							provided (*REP PROT TSR 2016-03-058 - Purin NN - EN1650 - 40C - milk10-Mar-2016 (signed)*))
PT 4 Bactericidal	CIP in milking machines and milk cooling tanks	Purin NN (F-2336), Batch-Nr.: CT 624-16, after 9 months storage (9MO) AS: active chlorine, released from sodium hypochlorite; concentration in stored product: not tested for this batch	*Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541 *Escherichia coli* ATCC 10536 *Pseudomonas aeruginosa* ATCC 15442 *E. faecium* ATCC 6057	EN 1276 (2009)	Quantitative suspension test 40 °C, Dirty conditions (10 g/l skimmed milk) 1,75 %, 2,0 %, 2,25 %, 2,5 % (v/v) product concentration 10 min contact time	Results showed a > 5 lg reduction for bacteria with 2,5 % (v/v) stored Purin NN within 10 min at 40 °C under dirty conditions (milk soiling). All controls were valid.	*WEST AGRO, Inc. (2017a)* Study number TSR 2017-02-056* raw data provided in laboratory protocol (*TSR 2017-02-056 Raw Data NB 686 p13-14, 22-24, 51-60*)
PT 4 Yeasticidal	CIP in milking machines and milk cooling tanks	Purin NN (F-2336), Batch Nr.: CT 624-1 after 9 months storage (9MO) AS: active chlorine, released from sodium hypochlorite; concentration in stored product: see chapter 3.2, table 5	*Candida albicans* ATCC 10231	EN 1650 (2013)	Quantitative suspension test 40 °C, Dirty conditions (10 g/l skimmed milk) 0,5 %, 0,75 %, 1,0 %, 1,25 % (v/v) product concentration 10 min contact time	Results showed a > 4 lg reduction for yeast with 0,75 % (v/v) stored Purin NN within 10 min at 40 °C under dirty conditions (milk soiling). All controls were valid.	*WEST AGRO, Inc. (2017b)* Study number TSR 2016-12-299* raw data provided in laboratory protocol (*TSR 2016-12-299 Raw Data NB 663 p62-63, 66-67, 72-73*) readable test protocol provided (REP PROT TSR 2016-12-299v1.0 - Purin NN - EN1650 - milk - 9mo)
PT 4 Bactericidal	CIP in milking machines and milk cooling tanks	Purin NN, Batch Nr.: G113620200 at time of manufacturing (TOM); AS: active chlorine, released from sodium	*E. faecium* ATCC 6057	EN 1276 (2019)	40 °C, 85 °C Dirty conditions (10 g/l skimmed milk) 0,1 %, 0,3 %, 0,4 %, 0,5 % (v/v) product concentration	Results showed a > 5 lg reduction for *E. faecium* with 0,5 % (v/v) Purin NN within 10 min at 40 °C under dirty	*WEST AGRO, Inc. (2021a) Study number TSR 2021-09-114*

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**
		hypochlorite; concentration in unstored product: not tested for this batch; nominal value 7,5 % (w/w)			10 min contact time Controls were performed at 40 °C. Additional water control at 40 °C and 85 °C.	conditions (milk soiling). All controls were valid. Testing performed at 85 °C showed a complete inactivation of *E. faecium* under dirty conditions (milk soiling) within 10 min at 85 °C with or without the addition of Purin NN.	
PT 4 Bactericidal	CIP in milking machines and milk cooling tanks	Purin NN, Batch Nr.: G113620200 aged by storage at 50 °C for 9 days; AS: active chlorine, released from sodium hypochlorite	*E. faecium* ATCC 6057	EN 1276 (2019)	40 °C, 85 °C Dirty conditions (10 g/l skimmed milk) 1,75 %, 2 %, 2,25 %, 2,5 % (v/v) product concentration 10 min contact time Controls were performed at 40 °C. Additional water control at 40 °C and 85 °C.	Results showed a > 5 lg reduction for *E. faecium* with 2,5 % (v/v) aged Purin NN within 10 min at 40 °C under dirty conditions (milk soiling). N was slightly too low (N=1,1*10^8 cfu/ml); lgR was nevertheless achieved. All other controls were valid. Testing performed at 85 °C showed a complete inactivation of *E. faecium* under dirty conditions (milk soiling) within 10 min at 85 °C, with or	*WEST AGRO, Inc. (2021b) Study number TSR 2021-09-113*

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**
						without the addition of Purin NN.	
PT 4 Bactericidal Product without active substance (testing for secondary active substances)	CIP in milking machines and milk cooling tanks	Purin NN, Batch Nr.: G113620200 ; AS: active chlorine, released from sodium hypochlorite; concentration in unstored product: not tested for this batch, nominal value 7,5 % (w/w) Purin NN without sodium hypochlorite, Batch Nr.: MH735-99A	*E. faecium* ATCC 6057	EN 1276 (2019)	40 °C Dirty conditions (10 g/l skimmed milk) 0,5 % (v/v) Purin NN 2,5 % (v/v) Purin NN w/o NaOCl 10 min contact time	Results showed a > 5 lg reduction for *E. faecium* with 0,5 % (v/v) Purin NN within 10 min at 40 °C under dirty conditions (milk soiling). All controls were valid. Tests perfomed with 2,5 % (v/v) Purin NN without sodium hypochlorite did not demonstrate any efficacy against *E. faecium* within 10 min at 40 °C under dirty conditions (milk soiling). All controls were valid.	*WEST AGRO, Inc. (2021c) Study number TSR 2021-11-127*
Determination of active substance concentration throughout 75 min incubation at 85 °C (testing for stability of active substance during the contact time)	CIP in milking machines and milk cooling tanks	Purin NN at time of manufacturing (TOM); AS: active chlorine, released from sodium hypochlorite Purin NN aged by storage at 50 °C for 9 days; AS: active chlorine, released from sodium hypochlorite	*Not applicable*	DeLaval method WM 4 (iodometric titration; corresponding to validated method WM 004, see chapter 3.4, table 14)	Dilution: 2.5 % (v/v) in tap water Temperature: 85 °C: maintained throughout the test Determination of active substance concentration at 0, 15, 30 and 75 min	The active substance concentration did not decrease for Purin NN and aged Purin NN throughout 75 min incubation at 85 °C.	*DeLaval (2022) Study Number NB 860: 1, 23 Purin NN dilute chlorine stability 20220427*

3.5.6 Occurrence of resistance and resistance management

According to the CAR, “no management strategies are necessary as acquired resistance to active chlorine [neither has developed nor is likely to] develop due to its reactive nature and unspecific mode of action”[7]. Only rare information is available about resistance occurrence to chlorine-releasing agents in the literature. It is therefore unlikely that resistance develops for this product.

3.5.7 Known limitations

No known limitations.

3.5.8 Evaluation of the label claims

The label claims have to reflect the use conditions as specified in the SPC

3.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The product is not intended to be authorized for use in combination with other biocidal products.

3.5.10 Data waiving and conclusion

Table 18

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving.
Justification	-

Table 19

Conclusion on the efficacy
The biocidal product Purin NN demonstrated bactericidal and yeasticidal efficacy according to EN 1276 and EN 1650 under test conditions suitable for disinfection by cleaning-in-place (CIP) in the dairy

[7] Assessment Report for Active chlorine releases from sodium hypochlorite, product-type 4 (01/2017)

Conclusion on the efficacy
industry under high soiling conditions (soiling: 10 g/l reconstituted milk). The efficacy was demonstrated for the product at a dilution to 2,5 % (v/v) product concentration with a contact time of 10 minutes and a minimum temperature of 40 °C. Active substance measurements indicated thermal stability of the active substance at 85 °C for the intended contact time of 10 min so that efficacy is demonstrated for the whole temperature range from 40 °C up to 85 °C. The product is expected to be effective against bacteria and yeast if used in accordance with the use instructions given in the SPC.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Table 20

Active chlorine released from sodium hypochlorite	Value	Study
$AEC_{inhalation}$ (NaOCl)	0.5 mg/m³ available chlorine Based on chlorine data	Assessment-Report (RMS Italy (2017))
$AEC_{inhalation}$ (HClO)	0.5 mg/m³ available chlorine Based on chlorine data	Assessment-Report (RMS Italy (2017)
$NOAEC_{dermal}$	1 % avCL	Assessment-Report (RMS Italy (2017)
ARfD (Chlorate)	36 µg chlorate/kg bw	Assessment-Report (RMS Italy (2017))
ADI (Chlorate)	3 µg chlorate/kg bw	Assessment-Report (RMS Italy (2017))
Inhalative absorption	Not relevant because chlorine-related toxicity is based on local effects only.	Assessment-Report (RMS Italy (2017))
Oral absorption	The BPC TOX-WGIII-2016 agreed that human health effects are primarily due to the local mode of action of hypochlorite and potential systemic effects are secondary to its direct irritating reactivity. Consequently, oral absorption of sodium hypochlorite is not relevant.	Assessment-Report (RMS Italy (2017))
Dermal absorption	see 3.6.2.7 Information on dermal absorption	

3.6.2 Assessment of effects of the product on human health

3.6.2.1 Skin corrosion and irritation

Table 21

Summary table of in vitro studies on skin corrosion/irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks (e.g. major deviations)**	**Reference**
OECD guideline No. 404 (2002), GLP, 1	rabbit , New Zealand albino, female, 1	Purin NN (100 %), Batch no: 1248307, 0.5 ml under semi-occlusive dressing for 1h	Skin Corr. 1 B (Draize scores: 24 h Erythema 4, Oedema 3 48 h Erythema 4, Oedema 3)	Animal was euthanized after 2 days due to necrotic lesions of the skin for ethical reasons.	Report No. IC-OCDE-PH-12/0660

Table 22

Data waiving was acceptable for the following information requirements	
Information requirement	No data waiving. 8.1. Skin corrosion or skin irritation
Justification	-

Table 23

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Causes severe skin burns and eye damage.
Justification for the value/conclusion	Based on the results of an animal study the biocidal product is corrosive to the eyes and the skin. The pH of the product is ≥ 11.5. The product contains the active substance Active chlorine from sodium hypochlorite (CAS No. 7681-52-9), as well as two co-formulants, classified for skin corrosion in relevant concentrations. For additional information please see section 5.1.4.1 in the Confidential annex.
Classification of the product according to CLP	Skin Corr. 1B, H314

3.6.2.2 **Eye irritation**

Table 24

Data waiving was acceptable for the following information requirements	
Information requirement	8.2. Eye irritation
Justification	No studies on eye irritation were submitted by the applicant. Non-submission is acceptable. Classification of the biocidal product can be derived from a skin corrosion study (please see Table 31 section 3.6.2.1 Skin corrosion and irritation).

Table 25

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye damage.
Justification for the value/conclusion	Based on the results of an animal study the biocidal product is corrosive to the eye and the skin. The pH of the product is ≥ 11.5. The product contains the active substance Active chlorine from sodium hypochlorite (CAS No. 7681-52-9), as well as two co-formulants classified for skin corrosion in relevant concentrations. For additional information please see section 5.1.4.2 in the Confidential annex.
Classification of the product according to CLP	Eye Dam. 1

3.6.2.3 **Respiratory tract irritation**

Table 26

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Corrosive to the respiratory tract.
Justification for the value/conclusion	The biocidal product has a pH > 11.5 and is therefore classified for skin corrosivity. A study on acute inhalation was not submitted. Inhalation exposure to the classified product must be expected. According to Annex II section 1.2.6 the product needs to be labeled with EUH071.
Classification of the product according to CLP	Labelling with EUH071 „Corrosive to the respiratory tract." is required.

Table 27

Data waiving was acceptable for the following information requirements	
Information requirement	8.10. Other test(s) related to the exposure to humans
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory tract irritation.

Data waiving was acceptable for the following information requirements	
	Classification of the biocidal product has to be made according to the rules of the Regulation (EC) No 1272/2008.

3.6.2.4 Skin sensitisation

Table 28

Data waiving was acceptable for the following information requirements	
Information requirement	8.3. Skin sensitisation
Justification	Studies on potential skin sensitising properties of the biocidal product are not required. According to Annex III, Title 1 of the BPR (Regulation (EU) 528/2012) and section 3.1.3 “Skin sensitisation” of the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (Version 1.2, May 2018), “*testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.*” Furthermore the high pH of the product does not allow to perform skin sensitisation studies. The composition of the biocidal product is known. Sufficient information on skin sensitising properties of the components of the biocidal product is available. Information or indications on synergistic effects are not available. According to the Regulation (EC) No 1272/2008 and Regulation (EU) No 528/2012 further testing of the components and/or of the biocidal products is considered not necessary.

Table 29

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising to the skin
Justification for the value/conclusion	The biocidal product does not contain any components, which are known to have sensitising properties. Hence, classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Not classified for skin sensitisation.

3.6.2.5 Respiratory sensitization (ADS)

Table 30

Data waiving was acceptable for the following information requirements	
Information requirement	8.4. Respiratory sensitisation

Data waiving was acceptable for the following information requirements	
Justification	There are currently no standard tests and no OECD test guidelines available for respiratory sensitisation. Data on respiratory sensitisation for the biocidal product or their components are not available.

Table 31

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising to the respiratory tract.
Justification for the value/conclusion	The biocidal product does not contain any components, which are known to have sensitising properties. Hence classification according to Regulation (EC) No 1272/2008 is not required.
Classification of the product according to CLP	Not classified for respiratory sensitisation.

3.6.2.6 **Acute toxicity**

3.6.2.6.1 Acute toxicity by oral route

Table 32

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration *(gavage, in diet, other)***	**Signs of toxicity *(nature, onset, duration, severity, reversibility)***	**Value LD50**	**Remarks *(e.g. major deviations)***	**Reference**
OECD No. 423, GLP, 1	Rat, Sprague Dawley, 6 females	Purin NN (100 %), 2000 mg/kg (1.64 ml/kg bw) by gavage, once	No classification required. No mortility occured.	> 2000 mg/kg bw	Decrease in spontaneous activity (5/6), piloerection (2/6), salivation (1/6), vocalisation (3/6) and myosis (5/6) with recovery until 24 h post-dose. Decrease in spontaneous activity (2/2), piloerection (2/2), swollen abdomen (1/2) and hollow flanks (1/2) were noted from day 13 on and remained.Low body weight gain in treated animals.Hollow flanks were noted in 1/6 animals before necropsy. Macroscopic examination	Report No. TAO423-PH-12/0660

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration *(gavage, in diet, other)***	**Signs of toxicity *(nature, onset, duration, severity, reversibility)***	**Value LD50**	**Remarks *(e.g. major deviations)***	**Reference**
					of animals revealed thickening of the forestomach (3/6) or thinning of the forestomach (1/6) associated with a red coloration of the stomach (1/6), and swollen stomach, adherent to the intestines (3/6).	

Table 33

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD50(oral) > 2000 mg/kg bw
Justification for the selected value	Based on an animal study on acute oral toxicity in accordance with Regulation (EC) No 1272/2008. The biocidal product contains potassium hydroxide (CAS No. 1310-58-3) classified for Acute Tox. 4, H302, LD50 oral: 333 mg/kg bw. For additional information please see section 5.1.4.3 in the Confidential Annex.
Classification of the product according to CLP	Not classified.

3.6.2.6.2 Acute toxicity by inhalation

Table 34

Data waiving was acceptable for the following information requirements	
Information requirement	8.5.2. By inhalation
Justification	Studies on potential acute toxicity by inhalation route of the biocidal product are not available and are not required. According to Annex III of the BPR (Regulation (EU) 528/2012) and the Guidance on the Biocidal Products Regulation, Part A, Volume III, Human Health (2018), “testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.”

Data waiving was acceptable for the following information requirements	
	The composition of the biocidal product is known. Based on safety data sheets and other information for each of the individual components in the biocidal product sufficient data on the intrinsic properties are available. There is no information or indication on synergistic effects between any of the components (e.g. surfactants. The active substance releaser sodium hypochlorite reacts with acids to release chlorine (CAS 7782-50-5). Chlorine is classified with Acute Tox. 3 According to Annex II section 1.2.2 of the Regulation (EC) No 1272/2008 (CLP) the product needs to be labelled with EUH031: Contact with acids liberates toxic gas. The SCL for EUH031 is C ≥ 5 %. Consequently, classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 and testing of the components and/or of the biocidal products is not required.

Table 35

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Product: LC_{50} (inhalation) > 5 mg/L air (aerosol) Chlorine: LC50 ATE 0.5 mg/ml, Acute Tox. 3
Justification for the selected value	Based on the evaluation of the single components and the criteria for classification as acute toxic by inhalation according to Regulation (EC) No 1272/2008 (Section 3.4. Criteria for classification of mixtures).
Classification of the product according to CLP	Not classified. Labeling with 'EUH031: Contact with acids liberates toxic gas' is required.

3.6.2.6.3 Acute toxicity by dermal route

Table 36

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area,**	**Signs of toxicity (nature, onset, duration, severity, reversibility)**	**LD50**	**Remarks (e.g. major deviations)**	**Reference**
OECD guidance No. 402, GLP, 1	Rat, Spague Dawley rat (SPF Caw), 5 males	Purin NN (100 %), 2000 mg/kg bw (1.64 ml/kg bw), once, 10 % of body	No mortality occured.	> 2000 mg/kg bw	Coutaneous reactions (erythema, scrab, dryness) were noted from 24 h	Report No. TAD-PH-12/0660

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area,**	**Signs of toxicity (nature, onset, duration, severity, reversibility)**	**LD50**	**Remarks (e.g. major deviations)**	**Reference**
	and 5 females	surface area of where covered with porous gauze dressing for 24 h			post-dose, reversible on day 5 in males and 14 days in females. Yellow coloration was noted in all animals at 24 h post-dose, reversible on day 2 in females and remained on day 14 in males.	

Table 37

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD50(dermal) > 2000 mg/kg bw
Justification for the selected value	Based on an animal study on acute dermal toxicity in accordance with Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified.

3.6.2.7 Information on dermal absorption

Table 38

Value(s) used in the Risk Assessment – Dermal absorption		
Substance exposure scenario(s) (e.g. undiluted formulation or 1:100 in-use dilution, etc.)	Concentrate	In-use dilution (2.5 % v/v)
Value(s)	100 %	100 %
Justification for the selected value(s)	Default for corrosive formulations However, dermal absorption is considered not relevant for the risk assessment since the toxicity of the active substance Active chlorine from sodium hypochlorite is based on local effects only (CAR, Italy 2017 Doc. IIB and BPC TOX-WGIII_2016).	Default for corrosive formulations According to section 3.2 table 10 the pH of a 1% aqueous dilution is >11,5. Hence, it must be assumed that in accordance to Regulation (EC) No 1272/2008 also the in-use dilution is corrosive. However, dermal absorption is considered not relevant since the toxicity of the active substance Active chlorine from sodium hypochlorite is based on local effects only (CAR, Italy 2017 Doc. IIB and BPC TOX-WGIII_2016).

3.6.2.8 Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)

Please refer to section 5.1.3 in the Confidential annex.

3.6.2.9 Available toxicological data relating to a mixture

Not available.

3.6.2.10 Other

Not relevant.

3.6.2.11 Summary of effects assessment

Table 39

Endpoint	Brief description
Skin corrosion and irritation	Skin Corr. 1B, H314

Endpoint	Brief description
	Based on an animal study according to OECD Guideline 404.
Eye irritation	Eye Dam. 1 Based on an animal study on skin corrsion according to OECD Guideline 404.
Respiratory tract irritation	Corrosive to the respiratory tract. Labelling with EUH071 „Corrosive to the respiratory tract." is necessary.
Skin sensitisation	Not sensitising to the skin. Based on the available information on the intrinsic properties of the single components classification for skin sensitisation is not required.
Respiratory sensitization (ADS)	Not sensitising to the respiatory tract. Based on the available information on the intrinsic properties of the single components classification for respiratory sensitisation is not required.
Acute toxicity by oral route	Not toxic by oral route. Based on an animal study according to OECD Guideline 423.
Acute toxicity by inhalation	Based on the available information on the intrinsic properties of the single components classification for acute toxicity by inhalation is not required. The product needs to be labelled with EUH031: Contact with acids liberates toxic gas.
Acute toxicity by dermal route	Not toxic by dermal route. Based on an animal study according to OECD Guideline 402.
Information on dermal absorption	100 % for the concentrated product and the in-use-dilution(default for corrosive substances) Due to local effects not relevant for the human health risk assessment.
Available toxicological data relating to non-active substance(s)	For relevant information on substances of concern, refer to the Confidential Annex.
Available toxicological data relating to a mixture	Not relevant.
Other relevant information	Not relevant.

3.6.3 Exposure assessment

3.6.3.1 Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Table 40

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	Not applicable	Yes	n.a.	Not applicable	Yes	No	n.a.
Dermal	Not applicable	Yes	n.a	Not applicable	Yes	No	n.a.
Oral	Not applicable	Not applicable	n.a	Not applicable	Not applicable	No	Yes

The biocidal product Purin NN is intended to disinfect milking machines and corresponding tanks by cleaning-in-place (CIP). It is used by professional users within PT04. Purin NN is applied as a 2.5% (v/v biocidal product) solution. The active substance is active chlorine released from sodium hypochlorite. Sodium hydroxide (CAS No.: 1310-73-2) and Potassium hydroxide (CAS No.: 1310-58-3) are identified as substances of concern based on classification according to Annex VI of Regulation (EC) No 1272/2008 with H314 (causes severe skin burns and eye damage).

The use CIP was already assessed in the corresponding CAR for active chlorine released from sodium hypochlorite (IT, 2014).

During the mixing and loading operations, dermal and inhalation exposure is expected.

In the application phase, no exposure is expected, as the CIP process happens in a closed system.

The post-application phase contains several processes:

During the maintenance, dermal and inhalation exposure is expected (contact to concentrate or in-use solution).

Exposure from empty biocidal product containers is considered negligible, as only minor amounts remain in the containers.

As the pH value of the biocidal product is > 12, no HClO formation is expected during the mixing and loading phase. As the application solution has a pH of > 10 no significant HClO formation is expected as well.

List of scenarios

Purin NN is intended for the use “Cleaning-in-Place (CIP) disinfection of milking tanks/systems”. This application includes only one use (“Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)”). Only this use was assessed in the corresponding exposure scenarios.

This use was also described as representative use in the assessment report for the active substance “Active chlorine released from sodium hypochlorite” (PT04, Italy, 2017).
Professional users make the in-use dilution in hot water manually or connect the lines of an automatic dosing system to the product containers.

During the mixing and loading operation, the users (professional users) might be exposed to chlorine species contained in the undiluted biocidal product by dermal contact or inhalation. The exposure during the manual mixing and loading step is considered to represent a worst-case for automated mixing and loading (Scenario 1).

The exposure during the CIP process is considered to be negligible, as it is a closed process. Corresponding to the assessment report of the active substance, a separate post-application scenario is not considered.

Table 41

Summary table: scenarios			
Scenario number	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure** **Description of scenario**	**Exposed group (e.g. professionals, non-professionals, bystanders)**
Scenario 1	Mixing and loading (manual dosing)	Primary exposure: „Manually prepare an in-use dilution in hot water“ also covers automated mixing and loading „Coupling of the containers to an automated dosing system“.	Professionals, bystanders (see Scenario 5)
Scenario 2	Application: Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)	Primary exposure: Closed system: The treatment solution is circulated through the pipework and storage tanks of the installations. Exposure is not expected	Professionals

Summary table: scenarios			
Scenario number	**Scenario (e.g. mixing/ loading)**	**Primary or secondary exposure Description of scenario**	**Exposed group (e.g. professionals, non-professionals, bystanders)**
Scenario 3	Post-application: Maintenance of machines (Repair of broken dosing system; contact to concentrate)	Primary exposure: Regular maintenance; the worker comes into contact with concentrate (biocidal product concentrate).	Professionals
Scenario 4	Post-application: Maintenance of machines (repair of broken dosing system; contact to in-use solution)	Primary exposure: Regular maintenance; the worker comes into contact with in-use solution (diluted, application solution).	Professionals
Scenario 5	Bystander during mixing and loading	A professional stands aside the worker who is conducting a mixing and loading operation.	Professionals

3.6.3.1.1 Professional exposure

For the active substance sodium hypochlorite a quantitative exposure assessment of dermal and inhalation exposure is conducted.

- **<u>Scenario 1:</u> Mixing and loading (manual dosing)**

Table 42

Description of Scenario 1: Mixing and loading (manual dosing)		
The in-use solution is prepared by diluting the biocidal product which is supplied in form of a concentrate. This includes coupling of containers to an automated dosing system (automated M&L) or manually preparing the in-use solution by mixing the concentrate with hot water within the reservoir. *Process description for manual loading:* The product is dosed from the container into a measuring beaker by using a dosing pump to reduce spills and the formation of aerosol. Then the product is transferred into the milking machinery. The estimated inhalation update covers also the process of rinsing the measuring beaker. A task duration of 10 minutes per event and a frequency of one event per day is assumed. Incidental contact to eyes is possible through spills or hand to eyes transfer. *Process description for automated mixing and loading:* Containers are coupled to the automatic dosing system. A task duration of 1 minute per event and a frequency of 50 events per year is assumed. Incidental contact to eyes is possible through spills or hand to eyes transfer. The potential inhalation exposure is calculated with the TNsG M&L model 7 (pouring liquids) according to HEAdhoc recommendation 6 for 1 event/day The dermal exposure is assessed semi-quantitatively by comparing the concentration of the active substance and the substances of concern to the corresponding NOAEC (see chapter 3.6.4.6). Scenario 1 (manual dosing) also covers exposure during automated dosing. Please refer to chapter 3.6.4.6 for local risk assessment.		
	Parameters	Value
Tier 1	Indicative inhalation exposure (potential) 1)	0.94 mg/m³
	Active chlorine concentration (NaOCl)	7.5%
	SoC: Sodium hydroxide concentration	5.5%
	SoC: Potassium hydroxide concentration	2.0%

1) TNsG M&L model 7 (pouring liquids)

Calculations for Scenario 1

Example calculation:

Estimated inhalation exposure = Indicative inhalation exposure (bp, potential) x Active chlorine concentration

0.0705 mg/m³ = 0.94 mg/m³ x 7.5% = 0.94 mg/m³ x 0.0705

Further details can be found in chapter 4.3 Output tables from exposure assessment.

- **<u>Scenario 2:</u> Application: Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)**

Table 43

Description of Scenario 2: Application: Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)		
The disinfection of milking machines, related pipework and tanks is conducted as cleaning in place (CIP) procedure. As the technical facilities described above are closed systems when operating regularly, no inhalation, dermal exposure or eye contact is expected.		
	Parameters	Value
Tier 1	Active chlorine concentration (NaOCl)	0.19%
	SoC: Sodium hydroxide concentration	0.14%
	SoC: Potassium hydroxide concentration	0.05%

- **<u>Scenario 3:</u> Post-application: Maintenance of machines (Repair of broken dosing system; contact to concentrate)**

Table 44

Description of Scenario 3: Post-application: Maintenance of machines (Repair of broken dosing system; contact to concentrate)		
The product is directly pumped out of the container into the system. There are no separate tank or containers at the milking system to be used for storing disinfecting agents. It might be possible that a technician is accidentially exposed to remains of the concentrate when dealing with the dosing pump or the corresponding lines. Dermal or inhalation exposure may occur during maintenance operations, such as exchanging parts, testing or repairing of the system. The dermal exposure is assessed semi-quantitatively by comparing the concentration of the active substance and the substances of concern to the corresponding NOAEC (see chapter 3.6.4.6). Contact to concentrate is considered as a worst-case scenario as the system shall be carefully rinsed after each disinfection. The task duration and frequency depends on the technical requirements related to maintenance. Incidental contact to eyes is possible through spills or hand to eyes transfer.The potential inhalation exposure is calculated with the TNsG M&L model 7 (pouring liquids) according to HEAdhoc recommendation 6 for one event/day as worst case assumption. Please refer to chapter 3.6.4.6 for local risk assessment.		
	Parameters	Value
Tier 1	Indicative inhalation exposure (potential) 1)	0.94 mg/m^3
	Active chlorine concentration (NaOCl)	7.5%
	SoC: Sodium hydroxide concentration	5.5%
	SoC: Potassium hydroxide concentration	2.0%

1) TNsG M&L model 7 (pouring liquids)

Further details can be found in chapter 4.3 Output tables from exposure assessment

- **Scenario 4: Post-application: Maintenance of machines (repair of broken dosing system; contact to in-use solution)**

Table 45

Description of Scenario 4: Post-application: Maintenance of machines (repair of broken dosing system; contact to in-use solution)		
The product is directly pumped out of the container into the system. There are no separate tank or containers at the milking system to be used for storing disinfecting agents. It might be possible that a technician is accidentially exposed to remains of the in-use solution when dealing with the pipelines of the milking system. Dermal or inhalation exposure may occur during maintenance operations, such as exchanging parts, testing or repairing of the system. As the system shall be carefully rinsed after each disinfection, contact to in-use solution should be a rare case. According to the applicant the milk storage tanks are not intended to be entered by persons during maintenance. Incidental contact to eyes is possible through spills or hand to eyes transfer. Task duration and frequency: As required. The potential inhalation exposure is calculated with the TNsG M&L model 7 (pouring liquids) according to HEAdhoc recommendation 6. The dermal exposure is assessed semi-quantitatively by comparing the concentration of the active substance and the substances of concern to the corresponding NOAEC (see chapter 3.6.4.6). Please refer to chapter 3.6.4.6 for local risk assessment.		
	Parameters	Value
Tier 1	Indicative inhalation exposure (potential)	0.94 mg/m^3
	Active chlorine concentration (NaOCl)	0.19%
	SoC: Sodium hydroxide concentration	0.14%
	SoC: Potassium hydroxide concentration	0.05%

1) TNsG M&L model 7 (pouring liquids)

Further details can be found in chapter 4.3 Output tables from exposure assessment.

- **<u>Scenario 5:</u> Secondary exposure: Bystander during mixing and loading**

Table 46

Description of Scenario 5: Secondary exposure: Bystander during mixing and loading		
During mixing and loading operations, a professional may be present as a bystander. As a worst-case assumption, the exposure of a bystander is assessed as the exposure of the worker who is performing the M&L task. Incidental contact to eyes is possible through spills or hand to eyes transfer. The potential inhalation exposure is calculated with the TNsG M&L model 7 (pouring liquids) according to HEAdhoc recommendation 6. The dermal exposure is assessed semi-quantitatively. Please refer to chapter 3.6.4.6 for local risk assessment.		
	Parameters	Value
Tier 1	Indicative inhalation exposure (potential)	0.94 mg/m³
	Active chlorine concentration (NaOCl)	7.5%
	SoC: Sodium hydroxide concentration	5.5%
	SoC: Potassium hydroxide concentration	2.0%

1) TNsG M&L model 7 (pouring liquids)

Further details can be found in chapter 4.3 Output tables from exposure assessment.

Table 47

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation exposure**	**Estimated dermal exposure**	**Estimated oral exposure**	**Estimated total uptake**
Scenario 1	1	7.05E-02 mg/m³	n. a.	n. a.	n.a (no systemic effects)
Scenario 2	1	Not expected	Not expected	Not expected	Not expected
Scenario 3	1	7.05E-02 mg/m³	n. a.	n. a.	n.a (no systemic effects)
Scenario 4	1	1.76E-03 mg/m³	n. a.	n. a.	n.a (no systemic effects)
Scenario 5	1	7.05E-02 mg/m³	n. a.	n. a.	n.a (no systemic effects)

- **Combined scenarios**

Not applicable as only local effects are expected.

3.6.3.1.2 Non-professional exposure

Primary exposure of non-professional users is not expected. The product is for professional use only.

3.6.3.1.3 Secondary exposure of the general public

According to the applicant, secondary exposure of the general public is not expected. For most animal housing, this is acceptable. However, particularly for small farms, it cannot be generally excluded that uninvolved bystanders (general public) may enter an area, where treatment takes place. Therefore, an appropriate advice on the label is required (e.g. Animals and the general public (bystanders) must not be present during the use of the product.). Furthermore the risk assessment is based on the assumption that animals and children do not have access to the product. Therefore labelling with “Keep out of reach of children and non-target animals/pets. N-316 is obligatory.

3.6.3.2 **Dietary exposure**

Table 48

Intended use(s) (critical application with regard to dietary exposure)	
Active substance(s)	Active chlorine released from sodium hypochlorite
Type of formulation	SL - Soluble concentrate
Substance(s) of concern	Potassium hydroxide (CAS 1310-58-3) Sodium hydroxide (CAS 1310-73-2)
Field(s) of use	Indoor Disinfection by “cleaning in place (CIP) with circulation“ of milking machines and milk cooling tanks on dairy farms
Target organism(s)	Bacteria and Yeasts
Application rate(s) and frequency	Application Rate: 250 mL biocidal product per 10 L water Dilution (%): 2.5 % v/v Frequency: maximal 2x/day, after each milking
Category(ies) of users	Professional
Waiting periods after treatment	/
Further information	Before treatment all machines and equipment are rinsed with water to remove residues of milk. After treatment the disinfection solution is removed and machines and equipment are rinsed with clean cold drinking water and allowed to dry.

Representative dietary exposure scenarios

The biocidal product Purin NN is intended to be used for the CIP disinfection of milking machines and milk cooling tanks on dairy farms. Therefore, a potential transfer of residues from treated surfaces into milk and a subsequent consumer dietary exposure cannot be excluded.

Critical scenarios with respect to consumer dietary intake for the biocidal product Purin NN are presented in the following table.

Table 49

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
Transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)			
1.	Food industry	Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)	Milk

3.6.3.2.1 Information of non-biocidal use of the active substance

- Information on the residue definitions is provided in chapter 3.6.4.2 (Maximum residue limits or equivalent).

Table 50

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection product (PPP)	Not approved as a PPP active substance.	Different MRLs for the DBP chlorate are set for various food commodities according to Reg. (EU) 2020/749 MRL values between 0.05 - 0.7 mg/kg MRL in milk*: 0.1 mg/kg
2.	Household products	Cleaning of surfaces, bleaching of fabrics	None identified

**Includes raw milk, heat-treated milk and milk for the manufacture of milk-based products. The MRL applies to milk ready for use (marketed as such or reconstituted as instructed by the manufacturer.*

3.6.3.2.2 Nature of residues

Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly. Potential residues of sodium hypochlorite are ubiquitously available elements such as sodium and chloride, which are not considered of toxicological concern (CAR PT4, 2017, IT). However, sodium chlorate residues might be formed during storage and as disinfection by-product (DBP) during and after application of the biocidal products. The BPC APCP-WGII-2016 concluded that chlorate residues are relevant for dietary risk assessment as chlorate is considered a stable metabolite.

3.6.3.2.3 Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant, as the biocidal product Purin NN is only used for the disinfection of milking machines and milk cooling tanks but not for the treatment of animals (e.g. teat disinfection), feed or surfaces that come in contact with livestock. Direct contact of animals with disinfected parts of machinery is not foreseen.

3.6.3.2.4 Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

The biocidal product Purin NN is intended to be used for the CIP disinfection of milking machines and milk cooling tanks on dairy farms. Before the treatment all machines and equipment are emptied and rinsed with water to remove residual milk. After a circulation time of 10 minutes the disinfection solution is removed, machines and equipment are rinsed with clean cold drinking water and allowed to dry.
The active substance active chlorine and the precursor sodium hypochlorite are highly reactive and react immediately with organic matter at the site of first contact. However, DBPs such as chlorate, which is considered the most stable metabolite (BPC APCP-WGII-2016), may be formed and an additional dietary exposure of the general public to chlorate residues in milk is possible.

The current guidance document on DBPs (Guidance on the Biocidal Products Regulation - Volume V, Version 1.0, January 2017) does not include a PT4 scenario to estimate the level of potential residues of DBPs in milk after the professional use of active chlorine containing products for CIP. Therefore, the applicant performed a literature search which is presented in the annex under 4.4 Residue behaviour. According to that search, the applicant identified chloroform as a representative marker for DBPs in milk. Moreover, pre- and post-rinsing as well as the correct use of the disinfection solution (e.g. correct dosing) were identified as major factors to reduce the level of DBPs like chloroform in milk.

Based on the literature search and the BPC APCP-WGII-2016 decision the applicant performed a field trial using Purin NN for the disinfection of milking equipment (ME) and a bulk tank (BT) according to the

label instructions. Subsequently, the level of chlorate and chloroform were measured in three consecutive milk pick-ups (PU1-3) and in waste water resulting from the disinfection of ME and BT.
As sodium chlorate residues might not only be formed as DBPs but also during storage of the biocidal product, the field trial was performed with a fresh (TOM) and a 9 months old batch (LOP) of Purin NN.
As a negative control, an additional trial was performed with a chlorine free detergent CFD100 to determine which residues are formed due to the chlorine present in the product.
A trial summary, graphs as well as information about the analytical method used to measure chlorate levels in milk are included in the confidential annex under 5.2. Residual trial.

- **Chloroform**

In most of the milk samples (4 of 6) no chloroform could be measured above the LOQ of 10 µg/kg. The highest chloroform level measured in milk was 60 µg chloroform/kg milk. The average value for all milk samples was 20 µg chloroform/kg milk (note that in 4 of 6 samples no chloroform was measured above the LOQ, for determining the average level the LOQ of 10 µg/kg was used for these 4 samples).

- **Chlorate**

The highest chlorate level measured in milk was 85 µg chlorate/kg milk. The average value for all milk pick-ups was 22 µg chlorate/kg milk (6 samples, including PU 1-3 for TOM and LOP samples).

Conclusion

Consumer exposure to residues of chlorate and chloroform in milk from the intended uses cannot be excluded. For calculation of consumer exposure please refer to section 3.6.4.9 Risk for consumers via residues in food.

3.6.3.2.5 Estimating transfer of biocidal active substances into foods as a result of non-professional use

Not relevant, as the biocidal product Purin NN is only used by professional users.

3.6.3.2.6 Dietary exposure to substances of concern

Two substances of concern have been identified for the biocidal product Purin NN:

- Potassium hydroxide (CAS 1310-58-3)
- Sodium hydroxide (CAS 1310-73-2)

Detailed information on the assessment of both SoCs can be found in the confidential annex under 5.1.3 and 5.1.4. Both SoCs show only local effects (classification of biocidal product due to classified SoC: Skin Corr. 1B (H314), Eye Dam. 1) and no systemic oral toxicity can be expected from the use of

both substances in the biocidal product Purin NN. Any potential residues transferred into milk are not considered to be of toxicological concern.

3.6.3.3 Exposure associated with production, formulation and disposal of the biocidal product

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR.

3.6.3.4 Aggregated exposure

Not applicable.

3.6.3.5 Summary of exposure assessment

Table 51

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
Scenario 1 Mixing and loading (manual dosing)	Professional user	Protective gloves, protective coverall, eye protection, boots	n.a. (no systemic effects)
Scenario 2 Application: Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)	Professional user	Not applicable, no exposure expected	n.a. (no systemic effects)
Scenario 3 Post-application: Maintenance of machines	Professional user	Protective gloves, protective coverall, eye protection, boots	n.a. (no systemic effects)

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
(Repair of broken dosing system; contact to concentrate)			
Scenario 4 Post-application: Maintenance of machines (repair of broken dosing system; contact to in-use solution)	Professional user	Protective gloves, protective coverall, eye protection, boots	n.a. (no systemic effects)
Scenario 5 Primary exposure: Bystander during mixing and loading	Professional user	Eye protection	n.a. (no systemic effects)

3.6.4 Risk characterisation for human health

3.6.4.1 Reference values to be used in Risk Characterisation

Reference values have been derived during assessment of the active substance(s) for the purpose of approval and are reported in the respective Assessment Report(s) as in Chapter 3.6.1 Assessment of effects of the active substance on human health.

3.6.4.2 Maximum residue limits or equivalent

Residue definitions

Chlorates (incl. Mg, Na, K chlorates)

Chloroform (marker residue: not applicable)

Table 52

MRLs or other relevant reference values	Reference	Relevant commodities	Value
MRL (Chlorate)	Reg. (EU) 2020/749	Various	0.05 - 0.7 mg/kg Milk*: 0.1 mg/kg
MRL (Chloroform)	Reg. (EU) 37/2010	Food of animal origin origin, target tissues: not applicable	No MRL required**

** Includes raw milk, heat-treated milk and milk for the manufacture of milk-based products. The MRL applies to milk ready for use (marketed as such or reconstituted as instructed by the manufacturer.*

*** Other provisions: Only to be used as an excipient in vaccines and only at concentrations not exceeding 1 % w/v and total doses not exceeding 20 mg per animal.*

3.6.4.3 Specific reference value for groundwater

No specific reference values for groundwater were derived.

3.6.4.4 Endocrine disrupting properties

Based on the information available from ECHA databases (e.g. SVHC-candidate list) there are no indications for endocrine disrupting properties for any of the single components of the biocidal product. For details see section 5.1.2 in the Confidential annex.

3.6.4.5 Risk for industrial users

No industrial applications are intended.

3.6.4.6 Risk for professional users

The occupational risk assessment for the biocidal product (BP) Purin NN takes into account local effects of the active substance (a.s.) active chlorine released from sodium hypochlorite and local effects of the substances of concern (SoC) sodium hydroxide and potassium hydroxide. Potential systemic effects of the a.s. active chlorine released from sodium hypochlorite are secondary to its direct irritating activity.

The occupational risk assessment for local effects of the active substance active chlorine from sodium hypochlorite is based on the external reference value (AEC). For the substances of concern sodium hydroxide and potassium hydroxide there are no occupational exposure limit (OEL) (no national or EU OEL) values which could be the basis for risk characterisation. Therefore for the substances of concern a qualitative risk assessment was performed.
In the biocidal product Purin NN sodium hydroxide (CAS No.: 1310-73-2) and potassium hydroxide (CAS No.: 1310-58-3) are identified as substances of concern based on classification according to Annex VI of Regulation (EC) No 1272/2008 with H314 (causes severe skin burns and eye damage).

Systemic effects – quantitative

Systemic effects of the a.s. and the SoC are not expected due to the mode of action

Local effects - quantitative

The local toxicity profile of the a.s. active chlorine released from sodium hypochlorite is considered. The primary toxic effect of the a.s. active chlorine released from sodium hypochlorite is a treatment-related response confined to ocular and respiratory tract irritation (seen in subchronic study in Rhesus monkeys) with respect to inhalation exposure. There is an AEC available so that a quantitative risk characterisation for professional users is carried out regarding the inhalation route.

Details of risk characterisation

Reference values

For the purpose of risk characterisation resulting from inhalation exposure of professional users to active chlorine released from sodium hypochlorite from the biocidal product Purin NN, inhalation exposure to active chlorine released from sodium hypochlorite is assessed. For this, the local reference value $AEC_{inhalation}$ (0.5 mg/m^3) of active chlorine is used as external inhalation reference value and directly compared with airborne concentrations of active chlorine released from sodium hypochlorite.

Calculation of AEC exhaustion (%)
The exposure-to-AEC ratio (%) referring to the active substance active chlorine released from sodium hypochlorite resulting from use of the biocidal product Purin NN is determined according to the equation:

Exposure-to-AEC ratio (%) = inhalation exposure to active chlorine released from sodium hypochlorite (in mg/m³) / $AEC_{inhalation}$ of active chlorine released from sodium hypochlorite (in mg/m³) x 100 %.

A risk for professional users referring to the a.s. active chlorine released from sodium hypochlorite resulting from the use of the biocidal product Purin NN or resulting from the secondary exposure is unlikely if the AEC exhaustion (%) is below the value of 100 %.

Results

Table 53 gives a detailed overview of the risk characterisation results referring to the a.s. active chlorine released from sodium hypochlorite in the biocidal product Purin NN. It is noted that for clarity reasons all values are rounded to two decimal places in Table 53. However, the underlying calculations are based on unrounded values.

As shown in Table 53, for all scenarios except the scenario “Application: Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)” a risk for the professional user is unlikely already in Tier 1. As also shown in Table 53, for the scenario “Application: Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)” there is no exposure expected.

Combined scenarios

Not necessary, see chapter 3.6.4.10.

Table 53: Overview of detailed local risk assessment results for inhalation route referring to the active substance active chlorine in the biocidal product Purin NN

Scenario-No.	**Scenario**		**Reference value inhalative $AEC_{long-term}$** mg/m³	**Estimated inhalation exposure** mg/m³	**Estimated inhalation exposure / AEC** AEC exhaustion %	**Acceptable** (yes/no)
Scenario 1	Mixing and loading	Tier 1	0.5	7.05E-02	14.10	**yes**
Scenario 2	Application: Disinfection of milk tanks/milking	Tier 1	0.5	not expected	-	**yes**

Scenario-No.	Scenario		Reference value inhalative $AEC_{long-term}$	Estimated inhalation exposure	Estimated inhalation exposure / AEC AEC exhaustion	Acceptable
	machines by Cleaning in Place (CIP)					
Scenario 3	Post-Application: Maintenance of machines (repair of broken dosing system; contact to concentrate)	Tier 1	0.5	7.05E-02	14.10	**yes**
Scenario 4	Post-Application: Maintenance of machines (repair of broken dosing system; contact to in-use solution)	Tier 1	0.5	1.76E-03	0.35	**yes**

Conclusion

Based on the risk assessment of the active substance active chlorine released from sodium hypochlorite via the inhalation route, a risk for professional users resulting from all uses and secondary exposure with the biocidal product Purin NN is unlikely at the latest after Tier 1 consideration. Regarding occupational safety, there are no objections taking into account the provisions described in chapter 2.5.2 of this PAR.

Local effects – semi-quantitative

Active substance active chlorine

The a.s. active chlorine released from sodium hypochlorite causes local irritation/corrosion and oxidation at the site of first contact; thus effects triggered by NaOCl are rather concentration than time-dependent. The semi-quantitative risk characterisation for professional users takes into account the dermal exposure concentration of active chlorine released from sodium hypochlorite resulting from use of the biocidal product Purin NN. For the assessment, the dermal 'No observed adverse effect concentration' (NOAEC) of 1 % active chlorine is used.

Details of risk characterisation

Dermal effect concentration

For the purpose of risk characterisation for professional users the dermal exposure concentration of active chlorine released from sodium hypochlorite is compared with the dermal NOAEC of 1 % active chlorine.

If the dermal exposure concentration exceeds the NOAEC, appropriate RMM have to be applied to avoid skin contact with the biocidal product Purin NN.

Table 54 gives a detailed overview of the semi-quantitative risk assessment results referring to the a.s. active chlorine released from sodium hypochlorite in the biocidal product Purin NN. It is noted that for clarity reasons all values are rounded to two decimal places in Table 54. However, the underlying calculations are based on unrounded values.

As shown in Table 54, for all scenarios except the scenario “Post-application: Maintenance of machines (repair of broken dosing system; contact to in-use solution)” the dermal exposure concentration is above the NOAEC. RMMs (skin protection) are considered necessary regarding the a.s active chlorine released from sodium hypochlorite in the biocidal product Purin NN.

Table 54: Overview of semi-quantitative risk assessment results for dermal route and the active substance active chlorine in the biocidal product Purin NN based on dermal NOAEC 1 %

Scenario-No.	Task/scenario	Dermal NOAEC	Concentration active chlorine (max.) in application solution	Concentration active chlorine higher/lower than dermal NOAEC?	RMM
1	Mixing & Loading	1%	7.50%	higher	Skin protection needed, see section Local risks
2	Application: Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)	1%	Not expected	-/-	Not necessary (closed system)
3	Post-application: Maintenance of machines (Repair of broken dosing system; contact to concentrate)	1%	7.50%	higher	Skin protection needed, see section Local risks
4	Post-application: Maintenance of machines (repair of broken dosing system; contact to in-use solution)	1%	0.19%	lower	Not neccessary
5	Secondary exposure (Bystander during mixing and loading)	1%	7.50%	higher	Skin protection needed, see section Local risks

Conclusion

Based on the semi-quantitative risk assessment of the local effects of the a.s. active chlorine via the dermal route for professional users for all scenarios except the scenario “Post-application: Maintenance

of machines (repair of broken dosing system; contact to in-use solution)" RMMs are considered necessary (see LRA). Please take into account the provisions described in chapter 2.5.2 of this PAR.

Substances of concern

The SoC sodium hydroxide exerts toxic effects as it contributes to the classification of the biocidal product as Skin Corr. 1B, H314.

The SoC potassium hydroxide exerts toxic effects as it contributes to the classification of the biocidal product as Skin Corr. 1B, H314.

In Table 55 the classification and assigned band according to the banding evaluation scheme of the SoC Guidance (Annex A to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)) are shown.

Table 55: Overview of the relevant classification and assigned band from the banding evaluation scheme according to the SoC-Guidance for the SoCs sodium hydroxide and potassium hydroxide

Substance	Resulting classification according to Regulation (EC) No. 1272/2008	Relevant band from Banding evaluation scheme	Associated evaluation/risk management requirements	Implementation
Sodium hydroxide	Contributes to: Skin Corr. 1B, H314	B	b)	See section 2.5.2
Potassium hydroxide	Contributes to: Skin Corr. 1B, H314	B	b)	See section 2.5.2

a) Application of P-statements normally associated with concerned H statements

b) Qualitative exposure and risk assessment to determine whether P-statements normally associated with concerned H-statements are sufficient or whether other risk mitigation measures should be applied

c) Fully quantitative risk assessment by using EU IOELVs (when available), DNELs or other reference values (e.g. AELs, AECs)

Local effects – qualitative

The active substance active chlorine released from sodium hypochlorite and the substances of concern sodium hydroxide and potassium hydroxide trigger the classification and labelling of the biocidal product Purin NN.

The concentrated product and the in-use solution are classified as Skin Corr. 1B, H314 (Causes severe skin burns and eye damage).

Therefore a qualitative risk assessment for local effects regarding contact with the eyes, skin and respiratory tract is conducted. The qualitative risk assessment for local effects takes into account the

concentrated biocidal product and the in-use solution as well as the proposed technical and organizational RMMs (dosing pump and rinsing of the system/pumps before opening). The Table 56 gives an overview of the relevant classifications for the qualitative risk assessment for local effects of biocidal product Purin NN. Furthermore, the allocated hazard categories according to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) are plotted against the respective classification.

Table 56: Relevant classification and resulting hazard categories of biocidal product Purin NN

b.p. concentration in application solution [%]	Resulting classification according to Regulation (EC) No. 1272/2008	Resulting hazard category according to Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017)
100%	Skin Corr. 1B, H314	high
2.5%	Skin Corr. 1B, H314	high

Concluding qualitatively on the acceptability of risk, the frequency and duration of potential exposure as well as potential degree of exposure for the particular hazard category is taken into account. According to the Guidance on the Biocidal Products Regulation Volume III Human Health – Part B Risk Assessment (December 2017) the following tables are prepared to carry out the qualitative risk assessment for local effects regarding contact with the skin, eye and respiratory tract of the biocidal product Purin NN for the intended uses. With the proposed risk mitigation measures the reduction of dermal, eye and respiratory tract contact minimises the anticipated health risk to an acceptable level for the intended use and for secondary exposure.

Table 57: Summary of qualitative conclusions for local risk assessment for "use 1 "Disinfection of milking parlour and cooling tanks by CIP"" of the biocidal product Purin NN

No.	Task, uses, processes	Concentration b.p. (max.)	Concentration a. s. (%)	Local effects in terms of C&L	Hazard category	Potential degree of exposure	Necessary RMM & PPE for acceptable risk	Acceptability
1	„Mixing and loading (manual dosing)": „Manually prepare an in-use dilution in hot water" and "couing of the containers to an automated dosing system"	100.00%	7.50%	Skin Corr. 1B, H314 EUH071	high	SKIN Contact of body and hands possible (splashes, drops) EYES: Incidental contact to eyes possible (hand to eyes transfer) RESPIRATORY SYSTEM: Vapour pressure of a. s. and SoCs is very low, so no inhalation exposure expected	**Technical measures:** Use of a dosing pump for manual M&L **Organisation:** Good standard* **PPE:** Wear protective gloves (EN374), eye protection (EN166), coverall (type 6, EN 13034) and protective footwear (EN 13832).	**Acceptable** with using appropriate PPE and used for short duration
2	Disinfection of milk tanks/milking machines by Cleaning in Place (CIP)	2.50%	0.19%	Skin Corr. 1B, H314	high	SKIN: No contact of hands and body expected EYES: No incidental contact to eyes expected RESPIRATORY SYSTEM: No inhalation exposure expected	**Technical Measure:** Closed system (CIP application) **Organisation:** Good standard* **PPE:** -/-	**Acceptable** because of closed system

No.	Task, uses, processes	Concentration b.p. (max.)	Concentration a. s. (%)	Local effects in terms of C&L	Hazard category	Potential degree of exposure	Necessary RMM & PPE for acceptable risk	Acceptability
3	Post-application: Maintenance of machines (Repair of broken dosing system; contact to concentrate)	100.00%	7.50%	Skin Corr. 1B, H314 EUH071	high	SKIN: Contact of body and hands possible (splashes, drops) EYES: Incidental contact to eyes possible (hand to eyes transfer) RESPIRATORY SYSTEM: Vapour pressure of a. s. and SoCs is very low, so no inhalation exposure expected	**Organisation:** Flushing prior intervention in the pumps Good standard* **PPE:** Wear protective gloves (EN374), eye protection (EN166), coverall (type 6, EN 13034) and protective footwear (EN 13832).	**Acceptable** with using appropriate PPE
4	Post-application: Maintenance of machines (repair of broken dosing system; contact to in-use solution)	2.50%	0.19%	Skin Corr. 1B, H314 EUH071	high	SKIN: Contact of body and hands possible (splashes, drops) EYES: Incidental contact to eyes possible (hand to eyes transfer) RESPIRATORY SYSTEM: Vapour pressure of a. s. and SoCs is very low, so no inhalation exposure expected	**Organisation:** Flushing prior intervention in the pumps Good standard* **PPE:** Wear protective gloves (EN374), eye protection (EN166), coverall (type 6, EN 13034) and protective footwear (EN 13832).	**Acceptable** with using appropriate PPE and used for short duration

No.	Task, uses, processes	Concentration b.p. (max.)	Concentration a. s. (%)	Local effects in terms of C&L	Hazard category	Potential degree of exposure	Necessary RMM & PPE for acceptable risk	Acceptability
5	Secondary exposure (Bystander during mixing and loading)	100.00%	7.50%	Skin Corr. 1B, H314 EUH071	high	SKIN: No contact expected EYES: Contact to eyes unlikely, but possible by accident RESPIRATORY SYSTEM: Vapour pressure of a. s. and SoCs is very low, so no inhalation exposure expected	**Organisation:** Good standard* **PPE:** Wear eye protection (EN166).	**Acceptable** with using appropriate PPE

* At the workplace a good standard of occupational hygiene is assumed including:

- Training for staff on good practice
- Procedures and training for emergency decontamination and disposal
- Good standard of personal hygiene

Conclusion

Concerning the corrosive properties of the biocidal product Purin NN, exposure should be minimised with risk mitigation measures. If the proposed risk mitigation measures are implemented, the intended uses as well as secondary exposure do not lead to concern for professional users.

Overall Conclusion

In summary, a risk for professional users resulting from the use of the biocidal product Purin NN is unlikely for the intended uses as well as from secondary exposure (see Table 53 to Table 57). Risk mitigation measures described in chapter 2.5.2 have to be taken into account in order to ensure safe use of the biocidal product Purin NN.
The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

3.6.4.7 Risk for non-professional users

Not relevant the biocidal product is for professional use only.

3.6.4.8 Risk for the general public

According to the applicant, secondary exposure of the general public is not expected. For most animal housing, this is acceptable. However, particularly for small farms, it cannot be generally excluded that uninvolved bystanders (general public) may enter an area, where treatment takes place. Therefore, an appropriate advice on the label is required (e.g. Animals and bystanders must not be present during the use of the product.). Furthermore the product should be stored out of reach of children, therefore a labelling (e.g. Keep out of reach of children and non-target animals/pets.) is necessary.

3.6.4.9 Risk for consumers via residues in food

The biocidal product Purin NN is intended to be used for the CIP disinfection of milking machines and milk cooling tanks on dairy farms. Therefore, a potential transfer of residues from treated surfaces into milk and a subsequent consumer exposure via residues in milk is possible. According to the CAR of active chlorine released from sodium hypochlorite (PT4, 2017, IT) chlorate represents the worst-case for sodium hypochlorite residues. Additionally, the applicant determined chloroform as a relevant DBP in milk based on a literature search (see 4.4 Residue behaviour). Consequently, a worst case consumer estimate (WCCE) to chlorate and chloroform residues in milk is calculated according to EMA guideline

on risk characterisation and assessment of maximum residue limits (MRL) for biocides (EMA/CVMP/SWP/90250/2010).
The applicant performed a field trial measuring chlorate and chloroform residues in milk after disinfection of the milking equipment and the bulk tank with Purin NN (see confidential annex under 5.2. Residual trial).
The highest chlorate level measured in milk was 85 µg chlorate/kg milk, the average value for all milk samples was 22 µg chlorate/kg milk.
The highest chloroform level measured in milk was 60 µg chlorate/kg milk, the average value for all milk samples was 20 µg chloroform/kg milk (note that in 4 of 6 samples no chloroform was measured above the LOQ, for determining the average level the LOQ of 10 µg/kg was used for these 4 samples).

WCCE calculations are performed with consumption values for milk from the EMA food basket (milk: 1500 g) for adults (60 kg) and the highest milk consumption values from PRIMO v3.1.

Calculation

$$WCCE_{milk} = R_{milk} \times I_{milk}$$

- $WCCE_{milk}$: worst case consumer exposure for milk (mg/kg bw/d)
- R_{milk}: residues in in milk
    - Chlorate: acute exposure: 0.085 mg/kg, chronic exposure: 0.022 mg/kg
    - Chloroform: acute exposure: 0.06 mg/kg, chronic exposure: 0.02 mg/kg
- I_{milk}: consumer intake of milk per body weight and day
    - EMA food basket 25 g/kg bw/d
    - PRIMO v3.1 chronic: DE women 14-50 yr 12.39 g/kg bw/d, NL toddler 59.73 g/kg bw/d
    - PRIMO v3.1 acute: NL general 38.56 g/kg bw/d, UK infant 124.22 g/kg bw/d

- **Chlorate**

Reference value for chlorate

ADI* = 0.003 mg/kg bw/day

ARfD* = 0.036 mg/kg bw

**according to the CAR of active chlorine released from sodium hypochlorite (PT4, 2017, IT)*

Worst-Case Consumer Exposure (WCCE) via chlorate residues in milk						
	EMA Food Basket		**PRIMO v3.1 Adults**		**PRIMO v3.1 Child**	
	WCCE	**% ADI /ARfD**	**WCCE**	**% ADI /ARfD**	**WCCE**	**% ADI /ARfD**
Chronic [mg a.s./kg bw/d]	0.00057	19	0.00028	9	0.00135	45

Worst-Case Consumer Exposure (WCCE) via chlorate residues in milk						
	EMA Food Basket		PRIMO v3.1 Adults		PRIMO v3.1 Child	
	WCCE	% ADI /ARfD	WCCE	% ADI /ARfD	WCCE	% ADI /ARfD
Acute [mg a.s./kg bw]	/	/	0.00328	9	0.01056	29

- **Chloroform**

Reference value for chloroform

ADI* = 0.010 mg/kg bw/day

**toxicological ADI according to EMA/CVMP/350579/2013. No acute reference dose has been set, therefore the ADI will also be used to estimate the acute exposure.*

Worst-Case Consumer Exposure (WCCE) via chloroform residues in milk						
	EMA Food Basket		PRIMO v3.1 Adults		PRIMO v3.1 Child	
	WCCE	% ADI /ARfD	WCCE	% ADI /ARfD	WCCE	% ADI /ARfD
Chronic [mg a.s./kg bw/d]	0.0005	5	0.00025	2	0.00119	12
Acute [mg a.s./kg bw]	/	/	0.00231	23	0.00745	75

Conclusion

Conclusion on dietary risk

The WCCE for chlorate and chloroform residues in milk is below the toxicological reference values for both substances for adults and children.

Thus, a chronic and acute risk for consumers via consumption of chlorate and chloroform residues in milk from the intended use of Purin NN is not expected.

The following risk mitigation measures (RMM) are proposed:

- Rinse treated equipment, pipes and machinery with drinking water before and after application.

Conclusion on MRLs

MRL values for chlorate in milk have been set at 0.1 mg/kg (Reg. (EU) 2020/749). All measured chlorate levels in milk in the Purin NN field trial are below that limit. An exceedance of existing MRLs for chlorate from the intended uses is not expected. Nevertheless, professional users of the biocidal product should be informed of the existence of MRLs for chlorates. They may be held liable if these

MRLs are exceeded during controls carried out on foodstuffs that have been in contact with surfaces treated with a Purin NN. The following RMM should be added:

- For food commodities, make sure that the concentration of chlorate present in food does not exceed the MRL values set by EU Commission (Reg. (EU) 2020/749).

According to the opinion of the committee for medicinal products for veterinary use (EMA/CVMP/317099/2013) no MRL is required for chloroform residues in all food producing species. This conclusion was derived under the provision that in the veterinary framework chloroform should only be used as an excipient in vaccines and should not exceeding 1 % w/v and total doses not exceeding 20 mg per animal. Moreover in "*its evaluation the CVMP also noted that the feasibility of control of residues in tissues and commodities of animal origin is minimal. This is because the volatility of the substance is such that substantial losses would occur during sample preparation, storage and analysis. This limits both the possibility and the potential value of establishing numerical MRL values.*" (EMA/CVMP/350579/2013, 21.02.2014).
As no consumer risk has been identified for the consumption of chloroform residues in milk from the intended uses of Purin NN, an MRL evaluation for chloroform is not considered necessary.

3.6.4.10 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

Professional user

The risk characterisation from combined exposure to several active substances or substances of concern within the biocidal product Purin NN is not necessary because no systemically acting substance is contained in the biocidal product.

3.6.4.11 Summary of risk characterisation

3.6.4.11.1 Summary of risk characterisation for industrial user

No industrial uses are intended.

3.6.4.11.2 Summary of risk characterisation for professional user

In summary, a risk for professional users resulting from the use of the biocidal product Purin NN is unlikely for the intended uses as well as from secondary exposure. Risk mitigation measures described in chapter 2.5.2 have to be taken into account in order to ensure safe use of the biocidal product Purin NN. For details see Table 58.

The risk assessment is considered to be sufficiently comprehensive and reliable for the purposes of product authorisation.

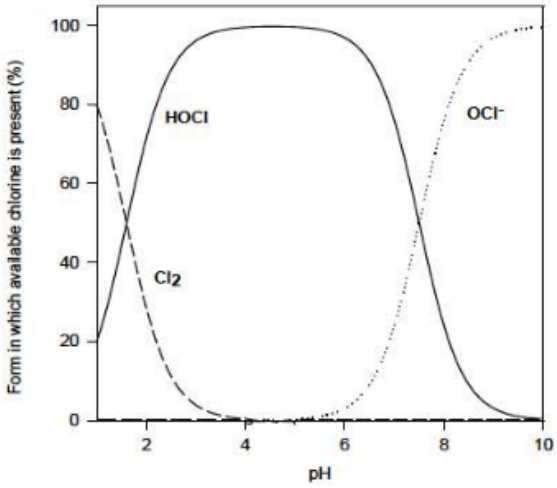
3.7 Risk assessment for animal health

According to the applicant exposure of domestic animals and pets is not relevant This is generally supported since the product is used for disinfection by “cleaning in place with circulation“ of milking machines and milk cooling tanks and also for professional users normally no exposure is expected. However, it is reported in the CAR that under specific circumstances leakages may occur. Such leakages were not assessed by the applicant in the PAR. Since the biocidal product is used in pipes for milk parlours, the absence of animals during the use of the product has to be ensured to avoid such an exposure. In conclusion, labelling with an appropriate advice is required (e.g. Animals and the general public (bystanders) must not be present during application).
Furthermore the product should be stored out of reach of animals, therefore a labelling (e.g. Keep out of reach of children and non-target animals/pets.) is necessary.

3.8 Risk assessment for the environment

3.8.1 General information

The biocidal product Purin NN is a soluble concentrate containing sodium hypochlorite, releasing the active substance active chlorine, and is intended to be used as disinfectant by cleaning in place with circulation of milking machines and milk cooling tanks. The product is formulated to contain 7.5% w/w active chlorine. No substances of concern for the environment have been identified. Hypochlorite is in equilibrium with hypochlorous acid (HClO), hypochlorite ion (ClO^-) and chlorine (Cl_2). The equilibrium depends on the pH value: chlorine is available below pH 4, in the neutral pH range hypochlorous acid is predominant, and at pH values higher than 10, the only species present is the hypochlorite ion, see figure below. The sum of these species [hypochlorite ion + hypochlorous acid + chlorine] is defined as active chlorine or (free) available chlorine (FAC).



During the ENV WG-I-2020 several conclusions were taken regarding the harmonisation of the assessment of the products containing chlorine substances:

Assessment of active chlorine:

"*It was agreed that for releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter. Uses resulting in a direct release to surface water however should be assessed quantitatively.*"

➔ In case of Purin NN, active chlorine is released via STP pathway and via manure application on agricultural soil. Since a rapid reaction of active chlorine with organic material is to be expected for both routes, only a qualitative assessment is carried out. Direct releases to surface water are not expected.

Assessment of the Disinfection by-products (DBPs):

"*It was agreed that for the time being the information provided by the applicants in their dossiers on DBPs of all ongoing authorisation applications should be only summarized and no conclusion should be drawn referring to the current lack of guidance. In fact, all the participants agreed that the current 'guidance' covering PT2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment.*"

➔ For chlorate, as DBP from the reaction of active chlorine with organic matter, no environmental assessment is performed.

Assessment of Chlorate as relevant impurity formed during the storage:

"*Chlorate is a by-product of the manufacturing process and can be formed during storage. It is also a disinfection by-product (DBP). Chlorate is considered as a relevant metabolite in drinking water. The discussion concerned only chlorate as an impurity (i.e., formed only during the storage) of products containing sodium/calcium hypochlorite. Generation of chlorate as a DBP was not considered under this discussion. The WG agreed that chlorate can be assessed qualitatively for all the environmental compartments […] [including] for groundwater."*

For chlorate, as impurity of the product Purin NN, only a qualitative assessment is performed.

3.8.2 Effects assessment

Active chlorine released from sodium hypochlorite

As no new data was provided in the course of application for authorisation of the product Purin NN, data from the active substance CAR (PT4; SK, February 2018) is taken into account for the assessment.

There, the PNEC was derived from the NOEC for algae, given as free available chlorine (FAC) per liter, with an AF of 50, resulting in

$PNEC_{aquatic}$ = 0.042 µg FAC/L.

$PNEC_{sediment}$ was derived via equilibrium partitioning method (EPM) as **0.045 µg FAC/kg wwt.**

The **$PNEC_{STP}$** was derived from the lowest NOEC value for micro-organisms with an AF of 10, resulting in **4.11 mg available chlorine/L**.

The **$PNEC_{soil}$** was derived by EPM and resulted in **0.015 µg FAC/kg wwt**.

Chlorate

No valid effect data are available for the relevant impurity chlorate from the assessment report of active chlorine released from sodium hypochlorite.

However, effect data can be retrieved from a REACH registration dossier[8] for sodium chlorate. For aquatic toxicity acute and long term data are presented with the lowest determined NOEC being 10 mg/L in a test with *Lemna minor*. No data are available for sediment toxicity.
A NOEC for the terrestrial compartment was determined for an acceptable test with soil microorganisms with 333 mg/kg. Test with earthworms showed low toxicity, while the data from tests with terrestrial plants are not suitable for the risk assessment of biocides.
Overall, the toxicity of chlorate towards non target organisms is considered to be low.
Based on this information and as indicated above, a qualitative assessment is considered acceptable and consequently, derivation of PNEC values is not necessary. As the applicant provided monitoring data on disinfection by-products, including chlorate, information is presented in the annex (see 5.2.1) for information.

3.8.2.1 Mixture toxicity

Screening step

- **Screening Step 1:**

Exposure to the environment is expected to occur via the STP path and via manure application on agricultural soil. Relevant compartments for the STP path are STP (directly), air (indirectly by potential volatilization), surface water and sediment (indirectly), as well as soil and groundwater (indirectly). Via manure application the relevant compartments are soil (directly), surface water and sediment (indirectly) and groundwater (indirectly).

- **Screening Step 2:**

Besides the active substance, no other relevant substances were identified in the composition of the product.

- **Screening Step 3: Screen on synergistic interactions**

Synergistic interactions between the components of the product are not expected.

Table 59

Screening step	
Y	Significant exposure of environmental compartments? (Y/N)
N	Number of relevant substances >1? (Y/N)
N	Indication for synergistic effects for the product or its constituents in the literature? (Y/N)

[8] https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14688

Conclusion: Mixture toxicity assessment is not required.

3.8.2.2 **Atmosphere**

No effect data for atmosphere are available. According to the active substance CAR (PT 4; SK, February 2018), the volatilisation of chlorine, hypochlorous acid and hypochlorite from water into air is very low. The adsorption of chlorine, hypochlorous acid and hypochlorite to aerosol particles and to soil particles is also very low. Thus, active chlorine (an equilibrium mixture of these three components) remains in the aqueous phase where it degrades very rapidly in the environment.

3.8.2.3 **Non-compartment specific effects**

3.8.2.3.1 Further ecotoxicological studies

No additional data was provided in the frame of the application for product authorisation.

3.8.3 Fate and behaviour

Active chlorine released from sodium hypochlorite

Active chlorine is highly reactive: it reacts rapidly with organic matter in the sewer, STP, surface water and soil. According to the AR of active chlorine released from sodium hypochlorite PT 4 (Nov. 2020, IT) the half-life of active chlorine in the sewer system and the STP is 20 s at 25 °C (converted by Arrhenius equation a DT_{50} of 54 s at 12 °C and 42.6 s at 15 °C can be obtained). The high content of organic matter in a soil will allow a quick (order of seconds) reduction of HClO, too. Active chlorine does not bioaccumulate or bioconcentrate due to its high solubility in water and high reactivity.

Chlorate

Sodium chlorate is highly soluble in water (REACH dossier: 95.7 g/100 ml at 20°C). From these finding, the environmental compartment in which sodium chlorate is expected to be present is water. The high tendency of sodium chlorate to ionise and the very low log Kow (<-2.9) suggest that no significant bioaccumulation would occur. A valid ready biodegradability test is not available since sodium chlorate is inorganic and acts as an electron acceptor like molecular oxygen. Nevertheless, reduction of chlorate has been detected in terrestrial ecosystems, fresh water, marine environment, compost, and aquifers. These findings demonstrate the wide distribution of chlorate-reducing microorganisms and that chlorate can be rapidly transformed to chloride.

3.8.3.1 Leaching behaviour (ADS)

Information on leaching behaviour is not required for the biocidal product.

Data waiving	
Information requirement	Not relevant
Justification	Information on leaching behaviour of the active substance active chlorine and the impurity chlorate is not required for the intended used of the biocidal product.

3.8.3.2 Testing for distribution and dissipation

- **Testing for distribution and dissipation in soil (ADS)**

No new data are available for the product Purin NN.

Data waiving	
Information requirement	Not relevant
Justification	No further studies are required because sufficient data on distribution and degradation in soil are available to conduct a qualitative assessment of the active substance active chlorine and the impurity chlorate.

- **Testing for distribution and dissipation in water and sediment (ADS)**

No new data are available for the product Purin NN.

Data waiving	
Information requirement	Not relevant
Justification	No further studies are required because sufficient data on distribution and degradation in water and sediment are available to conduct a qualitative assessment of the active substance active chlorine and the impurity chlorate.

- **Testing for distribution and dissipation in air (ADS)**

No new data are available for the product Purin NN.

Data waiving	
Information requirement	Not relevant

Justification	No further studies are required because sufficient data on distribution and degradation in air are available to conduct a qualitative assessment of the active substance active chlorine and the impurity chlorate.

3.8.3.3 Bioconcentration

The low log Kow values of active chlorine (-0.85 to -0.87) and chlorate (<-2.9), indicate no potential for bioconcentration.

3.8.4 Exposure assessment

3.8.4.1 General information

The biocidal product Purin NN contains active chlorine released from sodium hypochlorite as active substance and is used within PT4 for disinfection of milking machines and cooling tanks by professional users. No substances of concern for the environment have been identified.

The application of the product is described by the applicant as follows:
“Disinfection of milking installations is performed by CIP: the disinfectant is added to the circulating water and pumped through the equipment (including milking machine, pipe work) after each milking event. The milk cooling tanks are disinfected after each milk pick-up. The system is flushed with clean water after disinfection to remove any residues of the product. The emission pathway depends on the size of the farm. In bigger farms, cows are milked in so-called milking carrousels which are usually located next to the stable and which are connected to the sewer system. In small farms, cows are milked in the stable using transportable milking equipment. In this case, emission occurs in modern farms to the sewer system, in older farms, without connection to the sewer system, to the manure. The tendency is definitely to separate the waste water stream coming from the milking parlours from the manure storage system since a substantial amount of water is used for cleaning, disinfection and subsequent flushing of the milking equipment which would lead to a high water contribution to the manure storage tank. Based on this information, it is assumed that the waste water from the milking parlour system is mainly released to the sewer system.”

For the assessment of products which are based on active chlorine, the ENV WG-I-2020 decided that a qualitative assessment of the release pathway via STP and direct releases to soil is sufficient, due to the high reactivity of active chlorine with organic matter. A quantitative assessment is required for direct releases to surface water. As the biocidal product is intended to be used for disinfection of milking parlour

systems, releases to the environment are expected to occur via STP and manure application on soil. Consequently, only a qualitative assessment is performed for the biocidal product Purin NN.

According to the ENV WG-I-2020, a qualitative assessment is also acceptable for the relevant impurity chlorate, which is a by-product of the manufacturing process and also formed during storage of the product. Data on disinfection by-products (DBP) shall be presented if available, but a conclusion should not be drawn for ongoing product authorisations, as long as an updated guidance on the assessment of DBPs is not available. The applicant provided monitoring data on disinfection by-products, including chlorate, which are presented in the confidential annex for information.

Table 60

Assessed PT	PT 4
Assessed scenarios	Scenario 1: Disinfection of milking parlour systems
ESD used	Emission Scenario Document for Product Type 4: Disinfectants used in food and feed areas, JRC, 2011 Technical Agreements for Biocides, Environment (ENV), ECHA, November 2021
Approach	Qualitative assessment
Confidential Annexes	yes
Life cycle steps assessed	Scenario 1 Production: No Formulation No Use: Yes Service life: No

Emission estimation – scenario 1: milking parlour system

Not relevant, due to the conclusion at the WG ENV I 2020, that a qualitative assessment is sufficient for the assumed release pathways of active chlorine as active substance and chlorate as impurity in the biocidal product Purin NN.

3.8.4.2 Fate and distribution in exposed environmental compartments

According to ESD PT4, for the disinfection of milking parlour systems, emissions via STP and, according to TAB ENV 196, additionally the emission via manure need to be assessed. For the application of Purin NN the relevant receiving compartments are shown in Table 61.

Table 61

Identification of relevant receiving compartments based on the exposure pathway								
	Fresh-water	**Freshwater sediment**	**Sea-water**	**Seawater sediment**	**STP**	**Soil**	**Ground-water**	**Air**
Scenario 1 via STP	yes (+)	yes (+)	no	no	yes (++)	yes (+)	yes (+)	no
Scenario 1 via manure	yes (+)	yes (+)	no	no	no	yes (+)	yes (+)	no

(++) compartment directly exposed; (+) compartment indirectly exposed

The distribution and degree of removal of active chlorine in the STP is determined by oxidization of organic compounds. Biodegradation, adsorption onto sludge, removal due to sludge withdrawal and volatilization, on the contrary, do not play a role in the decomposition and distribution of the inorganic compound hypochlorite. The distribution of active chlorine in the STP is shown in Table 62.

Table 62

Calculated fate and distribution in the STP of active chlorine (Simple Treat 4.0, method 1)*	
Compartment	**Percentage [%]**
Air	0.0175
Water	0.174
Sludge	0.1195
Degraded in STP	99.7

* based on a Henry's Law constant of 0.11 Pa m³ mol^{-1} at 20 °C, an organic carbon/water partition coefficient of 13.22 L kg^{-1} and a degradation rate in the STP of 124.8 h^{-1} at 25 °C (data from LoEPs of AR of active chlorine released from sodium hypochlorite PT 4, Nov. 2020, IT)

3.8.4.3 Non-compartment specific effects

- **Primary poisoning**

Primary poisoning is not expected to occur due to the intended use of the product Purin NN.

- **Secondary poisoning**

Substances with a log Kow less than 3 like chlorine and hypochlorous acid have a low potential to bioaccumulate.
The high tendency of sodium chlorate to ionise and the very low log Kow (<-2.9) suggest that no significant bioaccumulation would occur.
Consequently, secondary poisoning is considered negligible for Purin NN.

3.8.4.4 Resulting local emission to relevant environmental compartments

Not relevant.

3.8.4.5 Calculated PEC values

As indicated above, the product is evaluated qualitatively. In consequence, no calculation of the predicted environmental concentrations is required. See section 3.8.5 for further details on the qualitative assessment.

3.8.4.6 Aggregated exposure (combined for relevant emission sources)

Aggregated exposure is not relevant for Purin NN because only one PT is intended and during the use as disinfectant in milking machines and milk cooling tanks there is no overlap in time and space assumed.

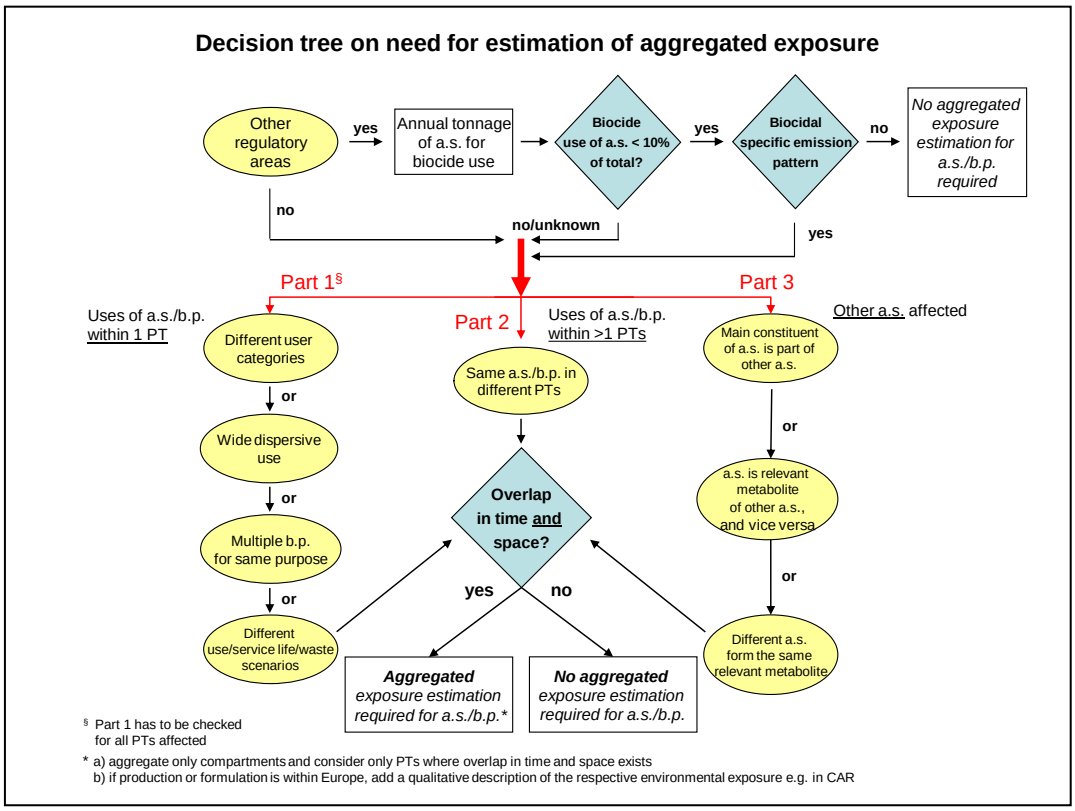


Figure 1: Decision tree on the need for estimation of aggregated exposure

3.8.5 Risk characterisation

As indicated above, a qualitative risk characterisation was conducted for the relevant substances in the biocidal product.

3.8.5.1 Aquatic compartment (sediment and STP)

- **STP**

Active chlorine released from sodium hypochlorite:

The concentration of the active substance in the effluent to which microorganisms are exposed in the STP is expected to be very low due to the following reasons: the active substance is rapidly degrading, caused by the high reactivity of the active substance with organic matter and the high amount of organic matter in the sewer. According to the sodium hypochlorite CAR (doc IIB) the residence time of the product in the sewer before entering the sewage treatment plant is considered to be 1 hour. Environmental modelling in the sodium hypochlorite CAR (doc IIB) demonstrated a rapid and almost total drop of concentration of hypochlorite within minutes after release to the sewer system.

Chlorate:

Considering the low emissions of chlorate to the environment (c_{ClO3-} < 3 % w/w of Purin NN) and the low toxicity of sodium chlorate to microorganisms, no unacceptable risks are expected for the microorganisms of the STP.

- **Aquatic compartment**

Active chlorine released from sodium hypochlorite:

The release path to the aquatic compartment after use of the biocidal product is via the STP and via manure application on soil. As discussed above, the concentration of active substance entering the STP is expected to be very low and will be rapidly further reduced in the treatment process due to the high amount of organic matter and the residence time (see sodium hypochlorite CAR DocIIB for details). Consequently, the concentration of active substance reaching the surface water compartment is expected to be even lower.

Even if degradation was only considered in the sewer, no unacceptable risks were identified for the aquatic compartment, including sediment, in the sodium hypochlorite AR.

Active chlorine might also be indirectly released to surface water due to run-off from soil after manure application. However, it is expected to react rapidly with organic material in manure and soil, making releases to further environmental compartments negligible.

Chlorate:

Considering the low emissions of chlorate to the environment (c_{ClO3-} < 3 % w/w of Purin NN), the low toxicity of sodium chlorate to aquatic organisms, and the possibility for reduction in several environmental compartments, no unacceptable risks due to chlorate are expected for the aquatic environment.

Conclusion

No unacceptable risks to the aquatic compartment are expected to originate from the use of the product.

3.8.5.2 Terrestrial compartment (Soil/Groundwater)

Active chlorine released from sodium hypochlorite:

The main release path of the active substance due to the use of the biocidal product is via the STP. Given the fact that the concentration of active substance in the STP sludge is assumed to be near-zero (nearly no sorption to sludge, reaction with organic matter in sludge), the exposure of terrestrial compartment via sludge application is expected to be negligible. Additionally, the DT50 of the active substance in soil is equal to 52 seconds. Therefore, there is no concern that unacceptable risk to the terrestrial compartment will occur due to the use of the biocidal product. Active chlorine indirectly released to soil via manure

application is also expected to react rapidly with organic material, making releases to soil and groundwater negligible.

Chlorate:
Considering the low emissions of chlorate to the environment (c_{ClO3-} < 3 % w/w of Purin NN), the low toxicity of sodium chlorate to terrestrial organisms, and the possibility for reduction in several environmental compartments, no unacceptable risks are expected for the microorganisms of the terrestrial environment.

- **Groundwater**

Active chlorine released from sodium hypochlorite:
Under real life conditions, it is very unlikely that any hypochlorite will reach the groundwater because active chlorine rapidly degrades in sewage sludge, manure and soil.

Chlorate:
Considering the low emissions of chlorate to the environment (c_{ClO3-} < 3 % w/w of Purin NN), and the possibility for reduction in several environmental compartments no exceedance of the trigger value for pesticides in groundwater is expected.

Conclusion
No unacceptable risks to the terrestrial compartment are expected to originate from the use of the product.

3.8.5.3 Atmosphere

Active chlorine released from sodium hypochlorite
According to the active substance CAR, sodium hypochlorite has a low potential for volatilisation and will remain in the water phase, were it reacts rapidly with organic matter. Exposure to air is thus not expected. There are no indications that active chlorine contributes to depletion of the ozone layer as it is not listed as ‘controlled substance’ in Annex I of Regulation (EC) No 1005/2009 of the European Parliament.

Chlorate
Due to its high solubility in water (> 696 to < 736 g/L at 20 °C; pH 4.49 to 8.70) and its low vapour pressure (< 3.5E-07 Pa at 20°C), volatilisation of sodium chlorate is also considered to be negligible.

Conclusion

The emission to air due to the use of the product is generally expected to be negligible and atmosphere is not a compartment of concern.

3.8.5.4 Non-compartment specific

- **Primary and Secondary poisoning**

As indicated above, primary and secondary poisoning are considered not to be relevant for the use of the product Purin NN.

3.8.5.5 PBT assessment

The criteria for PBT and vPvB assessment are specified in the Annex XIII of Regulation (EC) No 1907/2006 (REACH), but it is stated there, that they do not apply to inorganic substances. This is particularly the case for the P criterion, while the B and T criterion could theoretically be applied to an inorganic substance and the T criterion would then be fulfilled for active chlorine. However, altogether active chlorine and chlorate would not meet the PBT criteria.

3.8.5.6 Endocrine disrupting properties

Active chlorine

In the active substance CAR it was specified, that according to available information in provided tests and current valid legislation there is no indication of active chlorine being an endocrine disruptor.

Coformulants

The full composition of the product is listed in the Confidential annex (chapter 5)". There are no indications that a non-active substance of the product may have endocrine disrupting properties on environmental non-target organisms based on the data provided by the applicant. Nonetheless, the eCA considered in its evaluation further information available on the non-active substances: None of the co-formulants is contained in the candidate list for substances of very high concern for authorisation (SVHC), the community rolling action plan (CoRAP) or the public activities coordination tool (PACT) according to Regulation (EU) 1907/2006 for potential environmental ED-hazards or ECHA's endocrine disruptor assessment list.

3.8.5.7 **Summary of risk characterisation**

Based on the properties of the active substance and the impurity chlorate no unacceptable risks to the environment are expected to originate from the use of the biocidal product.

Mixture toxicity

Not relevant for this product since it contains only one active substance and no other substances of concern.

Assessment of disinfection-by-products (DBPs)

As explained at the beginning of the environmental assessment section, the assessment of DPBs is not performed due to the lack of guidance and agreed parameters. However, information as provided by the applicant is included for information in section 5.2.1 (confidential annex).

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

No candidate for substitution was identified (see chapter 2.2.5), hence a comparative assessment is not necessary.

4 Annexes

4.1 List of studies for the biocidal product

Table 63

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
1	3.2 Acidity, alkalinity	Determination of physical/chemical properties of Purin NN (F-2336) Study report Report No.: 2016-PC-001 WEST AGRO Inc	[redacted]	2016	DeLaval NV
2	3.3 Relative density (liquids) and bulk, tap density (solids) (relative density)	Relative density of Purin NN (F-2336) Study report Report No.: 2016-PC-009 WEST AGRO Inc	[redacted]	2016	DeLaval NV
3	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Purin NN Stability Study report Report No.: RA180262b DeLaval Manufacturing	[redacted]	2018	DeLaval NV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
4	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Test report: Quantitation of Chlorate Study report Report No.: V1JYT111 EAG Laboratories	[redacted]	2021	DeLaval
5	3.4.1 Storage stability tests (storage stability and reactivity towards container material)	Test report: Quantitation of chlorate Study report Report No.: V1JAR641 EAG Laboratories	[redacted]	2021	DeLaval
6	3.5 Technical characteristics of the biocidal product (persistent of foaming)	Persistent Foaming test - Purin NN (Lot Number 723-09) diluted 2.5% v/v Study report Report No.: NB 708:55 DeLaval MQAH R&D	[redacted]	2018	DeLaval
7	3.7 Degree of dissolution and dilution stability (dilution stability)	Dilution stability test - Purin NN (Lot number 723-09) diluted 2.5% v/v Study report Report No.: NB 708:55 DeLaval MQAH R&D	[redacted]	2018	DeLaval
8	3.7 Degree of dissolution and	Dilution stability test - Purin NN (Lot number 723-09) diluted 2.5% v/v - 9 months	[redacted]	2018	DeLaval

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
	dilution stability (dilution stability)	Study report Report No.: NB 740:75 DeLaval MQAH R&D			
9	3.8 Surface tension (surface tension)	Determination of Surface Tension on the Sample Purin NN (F-2336) Study report Report No.: 1801161 Innovhub – Stazioni Sperimentali per l'Industria	[redacted]	2018	DeLaval NV
10	3.9 Viscosity (viscosity)	Determination of physical/chemical properties of Purin NN (F-2336) Study report Report No.: 2016-PC-001 WEST AGRO Inc	[redacted]	2016	DeLaval NV
11	4.16 Corrosive to metals (corrosive to metals)	Corrosion testing CLP Purin NN Study report Report No.: 12/001zd Belgian Welding Institute NPO	[redacted]	2012	DeLaval NV
12	4.2 Flammability (flammability, other)	Purin NN - Determination of Flash Point Study report	[redacted]	2017	DeLaval NV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
		Report No.: YW21WC Envigo Research Limited			
13	5 Methods of detection and identification (analytical methods)	Validation of Titration Method WM004: Determination of Available Chlorine in Purin NN by Titration Study report *Report and Study No. not provided* DeLaval Manufacturing	[redacted]	2018	DeLaval
14	6.7 Efficacy data to support these claims (efficacy data)	Antimicrobial Efficacy of Purin NN (F-2336) as per EN1276 (2009) Study report Report No.: TSR 2016-04-085 West Agro Inc	[redacted]	2016	DeLaval NV
15	6.7 Efficacy data to support these claims (efficacy data)	Antimicrobial Efficacy of Purin NN (F-2336) as per EN1276 (2009) Study report Report No.: TSR 2017-02-056 West Agro Inc	[redacted]	2017	DeLaval NV
16	6.7 Efficacy data to support these claims (efficacy data)	Antimicrobial Efficacy of Purin NN (F-2336) as per EN1650 (2013) Study report Report No.: TSR 2016-03-058	[redacted]	2016	DeLaval NV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
		West Agro Inc			
17	6.7 Efficacy data to support these claims (efficacy data)	Antimicrobial Efficacy of Purin NN (F-2336) as per EN1650 (2013) Study report Report No.: TSR 2016-12-299 West Agro Inc	[redacted]	2017	Delaval NV
18	8.1.1 Skin irritation / corrosion (skin irritation: in vivo)	Purin NN - Assessment of acute dermal irritation Study report Report No.: IC-OCDE-PH-12/0660	[redacted]	2013	DeLaval NV
19	8.5.1 Acute toxicity: oral (acute toxicity: oral)	Purin NN - Evaluation of Acture Oral Toxicity in Rats - Acute Toxic Class Method Study report Report No.: TAO423-PH-12/0660	[redacted]	2013	DeLaval NV
20	8.5.3 Acute toxicity: dermal (acute toxicity: dermal)	Purin NN - Evaluation of acute dermal toxicity in rats Study report Report No.: TAD-PH-12/0660	[redacted]	2013	DeLaval NV
21	8.10 Other test(s) related to the	BPR chlorinated products residue trial - Purin NN	[redacted]	2018	DeLaval NV

No	Data set according to Annex III Regulation (EU) No 528/2012	Title	Author(s)	Year	Owner company
	exposure to humans (expected exposure and proposed acceptable residues)	Study report Report No.: 2017-038-Purin NN Eurofins Food Testing			

4.2 List of studies for the active substance(s)

4.2.1 Active chlorine released from sodium hypochlorite

- The applicant has access to the data from the active substance approval (see chapter 4.2.1.1 for details).

4.2.1.1 Access to data from active substance approval

The applicant provided a letter of access to the dossier assessed for the approval of the active substance “Active chlorine, released from sodium hypochlorite” for use in food and feed area (product-type 04). Please, refer to the corresponding Assessment Report for a reference list.

4.2.1.2 New information on the active substance

No new data on the active substance has been provided by the applicant.

4.2.1.3 List of studies 3rd party dossier

No 3rd party dossier has been submitted by the applicant.

4.2.1.4 Values from list of endpoints and 3rd party dossier

No 3rd party dossier has been submitted by the applicant.

4.3 Output tables from exposure assessment tools

Output tables from human health exposure assessment tools

4.3.1 Safety for professional users


parameters for exposure and risk ass

4.4 Residue behaviour

- **Literature search by the applicant regarding residues of DBP in milk from the use of active chlorine containing products for CIP**

"When active chlorine comes into contact with organic material such as milk, cream or butter, it binds to organic compounds to form so-called total organic chlorine (TOX). Total organic chlorine consists of volatile (VOX) and non-volatile organic chlorine. The formation of VOX occurs through the haloform reaction. This is the reaction of a halogenic compound, e.g. chlorine, and a methylketone to form a haloform. Milk contains a number of known and well-studied precursors for this haloform reaction. The most important VOX is trichlorohalomethane (TCM) or chloroform, which also belongs to the group of haloforms. Chloroform is highly lipophilic and accumulates in fat-rich products, amongst which dairy products like cream and butter. Given the above, it seemed justified to consider chloroform (TCM) as a good marker DBP to measure in milk.

Several factors can influence the contamination of milk with chloroform. First, the amount of milk residues in the milking installation and milk tank will determine the amount of chloroform formed. The more milk residues remain in the installations, the more active chlorine is consumed and the more chloroform is formed in the disinfection solution indicating that active chlorine comes into contact with organic matter (Nassl and Guthy, 1995). Pre- and post rinsing the milking installation with water before and after circulating the disinfection solution does prevent transfer of chloroform to milk, even if this does not prevent the formation of chloroform as soil still does accumulate (Resch and Guthy, 2000). Not rinsing the installation with water, also resulted in the formation of chloroform, but most importantly, this resulted in transfer of chloroform to the milk. This underlines the importance of rinsing to reduce the formation of chloroform (pre-rinse) and the transfer of chloroform to milk (post-rinse). Additionally, rinsing should be done with sufficient water as reducing the volume of rinse water can increase chloroform residues in milk (independently of the chlorine concentration in the disinfecting solution) (Ryan et al., 2012).

Another factor influencing the formation of chloroform in the disinfection solution is the active chlorine concentration. Higher amounts of active chlorine will lead to higher chloroform concentrations, but it only has minor influence on the transfer rate of chloroform to milk (Resch and Guthy, 2000). This is probably because chloroform first needs to accumulate in the disinfection solution, which depends on the level of soiling and alkalinity in the disinfection solution, before it can transfer to the milk. Indeed, high chloroform concentrations in the disinfection solution lead to high transfer of chloroform to milk (Resch and Guthy, 2000). On the other hand, active chlorine that is transferred to milk as such is not likely to cause high chloroform formation in milk (Resch and Guthy, 2000). The correct use of disinfection solutions, i.e. dosing correctly and not re-using disinfecting solutions to avoid build-up of soil in the disinfecting solution, is therefore important.

In conclusion, the use of chlorine-based disinfectants according to the recommended use instructions should not lead to chloroform residues in milk and dairy products. Applying the products at the correct dose and performing good pre- and post-rinsing with water can reduce chloroform formation and avoid chloroform transfer to milk. Good and continuous education of farmers is therefore important to avoid misuse of chlorine-based disinfection products (Ryan et al., 2013).”

References:

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