

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

HYPOMEN WITH ANTI-SCALE

Product type(s)

PT02: Disinfectants and algaecides not intended for direct application to humans or animals

Authorisation number: 925-1 1-3

R4BP asset number: DK-0030074-0010

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	HYPOMEN WITH ANTI-SCALE
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Sojitz SOLVADIS GmbH
	Address	Schirmerstr. 76 40211 Dusseldorf Germany
Authorisation number		925-1 1-3
<i>R4BP asset number</i>		DK-0030074-0010
Date of the authorisation		01/03/2023
Expiry date of the authorisation		17/11/2032

1.3. Manufacturer(s) of the product

Name of manufacturer	Hubei Xingrui
Address of manufacturer	29 Changjiang road, Xiaoting - Yichang China
Location of manufacturing sites	Hubei Xingrui - 29 Changjiang road, Xiaoting - Yichang China

Name of manufacturer	Haixing Eno Chemical Co., Ltd.
Address of manufacturer	Haixing Economic Development Area, Haixing County - Hebei Province China
Location of manufacturing sites	Haixing Economic Development Area, Haixing County - Hebei Province China

Name of manufacturer	Sinopec Jiangnan Salt & Chemical Complex
Address of manufacturer	No. 8, Hongqi Road, Wangchang Town, Qianjiang city - Hubei Province China
Location of manufacturing sites	No. 8, Hongqi Road, Wangchang Town, Qianjiang city - Hubei Province China

Name of manufacturer	Tohoku Tosoh Chemical Co., LTD
Address of manufacturer	1-4-16, Ohama Yamagata 998-0064 Sakata City Japan
Location of manufacturing sites	1-4-16, Ohama Yamagata 998-0064 Sakata City Japan

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

Active substance	Active chlorine released from calcium hypochlorite
Name of manufacturer	Sojitz SOLVADIS GmbH
Address of manufacturer	Schirmerstraße 76 40211 Düsseldorf Germany
Location of manufacturing sites	Hubei Xingrui Chemical Co, Ltd, 29 Changjiang road, Xiaoting and NO. 66-2 Xiating road, Xiaoting Dist, - Yichang China

Active substance	Active chlorine released from calcium hypochlorite
Name of manufacturer	REACH24H Consulting Group (Acting for Haixing Eno Chemical Co., Ltd. (Chine))
Address of manufacturer	Paramount Court, Corrig Road, Sandyford - Dublin 18 Ireland
Location of manufacturing sites	Haixing Economic Development Area 061200 Haixing County (Hebei Province) China

Active substance	Active chlorine released from calcium hypochlorite
Name of manufacturer	Sinopec Europa GmbH
Address of manufacturer	Friedrich-Ebert-Anlage 49 60308 Frankfurt am Main Germany
Location of manufacturing sites	No. 8, Hongqi Road, Wangchang Town - Qianjiang city (Hubei Province) China

Active substance	Active chlorine released from calcium hypochlorite
Name of manufacturer	TOSOH Europe BV (Acting for TOHOKU TOSOH Chemical Co Ltd)
Address of manufacturer	Amstelplein 1 1096 HA Amsterdam Netherlands (the)
Location of manufacturing sites	4-16, 1-Chome, Ohama 998-0064 Sakata City (Yamagata Prefecture) Japan

Active substance	Active chlorine released from calcium hypochlorite
Name of manufacturer	Chemofarm AG (Acting for Nankai Chemical CO., LTD. (Japan))
Address of manufacturer	Heinrich-Otto-Straße 28 73240 Wendlingen am Neckar Germany
Location of manufacturing sites	Nankai Chemical, Tosa Factory, 4-10-1, Sanbashi-dori - Kochi-city (Kochi prefecture) Japan

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Active chlorine released from calcium hypochlorite		active substance			64,3
Calcium hypochlorite		Non-active substance	7778-54-3	231-908-7	99

2.2. Type(s) of formulation

SG - Water soluble granules ST - Water soluble tablet BR - Water soluble briquette

3. HAZARD AND PRECAUTIONARY STATEMENTS

<p>Hazard statements</p>	<p>H302: Harmful if swallowed.</p> <p>H314: Causes severe skin burns and eye damage.</p> <p>H400: Very toxic to aquatic life.</p> <p>EUH031: Contact with acids liberates toxic gas.</p> <p>EUH206: Warning! Do not use together with other products. May release dangerous gases (chlorine).</p> <p>EUH071: Corrosive to the respiratory tract.</p>
<p>Precautionary statements</p>	<p>P101: If medical advice is needed, have product container or label at hand.</p> <p>P102: Keep out of reach of children.</p> <p>P103: Read carefully and follow all instructions.</p> <p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P220: Keep away from clothing or other combustible materials.</p> <p>P260: Do not breathe dust/fume/gas/mist/vapours/spray.</p> <p>P264: Wash hands thoroughly after handling.</p> <p>P270: Do not eat, drink or smoke when using this product.</p> <p>P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</p> <p>P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>P310: Immediately call a POISON CENTER/doctor/...</p> <p>P363: Wash contaminated clothing before reuse.</p> <p>P370+P378: In case of fire: Use... to extinguish.</p> <p>P391: Collect spillage.</p> <p>P405: Store locked up.</p>

P501: Dispose of {0:....:contents|container} to {1:....:}.

P273: Avoid release to the environment.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Swimming pool disinfection (private): shock treatment against micro-organisms

Product type	PT02: Disinfectants and algicides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Virus Development stage: no data
Field(s) of use	indoor use outdoor use The products are added to private swimming pool as a shock treatment against micro-organisms. Pools that are not connected to sewage system are not covered in this dossier.
Application method(s)	Method: Pouring or injection by a dosing system Detailed description: -
Application rate(s) and frequency	Application rate: 10 mg/L Dilution (%): - Number and timing of application: - Bacteria and virus: 10 mg/L of av Cl2 in water (contact time of 10 minutes).
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	- Bottle in HDPE (1-2 kg), in PP (2-3.3-4 kg). - Can in HDPE (1 kg). - Jerrican in PP (4 kg). - Bucket in PP/PE (2-5-10 kg), in PP (1-2-3-4-5-10 kg), in HDPE (10 kg). CLP regulation applies, as products are classified H314, child proof closure and a tactile warning are required for packaging of non professional users.

4.1.1. Use-specific instructions

Shock treatment without dosing system :

- Granular : pour directly into the skimmer or other reservoir or spread over the whole of pool with running filtration. In case of windy conditions, pre-dissolve the amount of granules needed for the treatment in water in a bucket at a maximal concentration of 40g/L.
- Tablets : put directly into the skimmer with filtration running.

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4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

- Treatment must be made in absence of bathers for shock treatment.
- Do not allow entrance to the pool until the concentration decreases back to 1.4 mg/L of available chlorine for swimming pools or to national chlorine limit.

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

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

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

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4.2. Use description

Table 2. Swimming pool disinfection (private) : shock treatment against algae

Product type	PT02: Disinfectants and algacides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: no data Common name: green algae Development stage: no data
Field(s) of use	indoor use

	<p>outdoor use</p> <p>The products are added to private swimming pool as a shock treatment against green algae. The application rate of the product added to the swimming pool depends on the quality of water (e.g. depending on the turbidity). Pools that are not connected to sewage system are not covered in this dossier.</p>
Application method(s)	<p>Method: Pouring or injection by a dosing system</p> <p>Detailed description: -</p>
Application rate(s) and frequency	<p>Application rate: 10 - 15 mg/L</p> <p>Dilution (%): -</p> <p>Number and timing of application: 10 - 15 mg/L of av Cl₂</p> <p>Action delay: 48H</p>
Category(ies) of users	<p>general public (non-professional)</p>
Pack sizes and packaging material	<ul style="list-style-type: none"> - Bottle in HDPE (1-2 kg), in PP (2-3.3-4 kg). - Can in HDPE (1 kg). - Jerrican in PP (4 kg). - Bucket in PP/PE (2-5-10 kg), in PP (1-2-3-4-5-10 kg), in HDPE (10 kg). <p>CLP regulation applies, as products are classified H314, child proof closure and a tactile warning are required for packaging of non professional users.</p>

4.2.1. Use-specific instructions

- Recommendation of use:

- At 10mg/L of av Cl₂ in water for moderate green water (10⁴ CFU/mL)
- At 15mg/L of av Cl₂ in water for very green water (10⁵ CFU/mL)
- If the level of contamination and/or the organic load is/are unknown, the treatment could be performed in two step: if a first dose of 10 mg/L is not sufficient to reach a visually satisfactory water within 48 h, a second dose of 5 mg/L could be added.

- Shock treatment without dosing system :

- Granular : pour directly into the skimmer or other reservoir or spread over the whole of pool with filtration running. In case of windy conditions, pre-dissolve the amount of granules needed for the treatment in water in a bucket at a maximal concentration of 40g/L.
- Tablets : put directly into the skimmer with filtration running

4.2.2. Use-specific risk mitigation measures

4.2.3. Use-specific risk mitigation measures

- Treatment must be made in absence of bathers for shock treatment.
- Do not allow entrance to the pool until the concentration decreases back to 1.4mg/L of available chlorine for swimming pools or to national chlorine limit.

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

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

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

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4.3. Use description

Table 3. Swimming pool disinfection (private): continuous dosing

Product type	PT02: Disinfectants and algaecides not intended for direct application to humans or animals
Where relevant, an exact description of the authorised use	The products are added as continuous dosing into private swimming pools which are linked to sewage treatment plant system. Pools that are not connected to sewage system are not covered in this dossier.
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Virus Development stage: no data Scientific name: no data Common name: green algae

	Development stage: no data
Field(s) of use	indoor use outdoor use -
Application method(s)	Method: Automatic dosing system or pouring or manual application Detailed description: -
Application rate(s) and frequency	Application rate: 1.4 mg/L Dilution (%): 0 Number and timing of application: - Bacteria, virus and algae at the application rate of 1.4 mg/L of av Cl2 (without stabilizing agent)
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	- Bottle in HDPE (1-2 kg), in PP (2-3.3-4 kg). - Can in HDPE (1 kg). - Jerrican in PP (4 kg). - Bucket in PP/PE (2-5-10 kg), in PP (1-2-3-4-5-10 kg), in HDPE (10 kg). CLP regulation applies, as products are classified H314, child proof closure and a tactile warning are required for packaging of non professional users.

4.3.1. Use-specific instructions

- Periodic treatment with tablet or granular feeder and dosing system :
- Permanently maintain a rate of av Cl2 of 1.4 mg / L.

- Periodic treatment without dosing system :

- Granular : pour directly into the skimmer or other reservoir or spread over the whole pool with filtration running. In case of windy conditions, pre-dissolve the amount of granules needed for the treatment in water in a bucket at a maximal concentration of 40g/L.
- Tablets: put directly into the skimmer or other reservoir with filtration running.

4.3.2. Use-specific risk mitigation measures

4.3.3. Use-specific risk mitigation measures

- Treatment must be made in absence of bathers until complete dissolution of the product for direct application for maintenance treatment.

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

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

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

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5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

- Comply with the instructions of use.
 - Respect the conditions of use of the product (concentration, contact time, temperature, pH, etc.).
 - Inform the registration holder if the treatment is ineffective.
 - Read label before use
 - The treatment should be performed at range pH 6.8-7.4
- The authorisation holder should give indications of application of the product (dilution, quantity to add to the pool, etc) on the label in order to guarantee the efficacy of the product during its application.

5.2. Risk mitigation measures

- Application of this product is exclusively allowed in swimming pools with connection to a STP. It is not allowed to directly discharge swimming pool water to the surface water.
 - Granulated product / tablets: Use of a tool with a handle (like a scoop or plier) to transfer the product. This tool must be provided with the packaging and must not be in contact with the product (must not be stored inside the packaging). Decanting has to be avoided.
 - Wait the complete dissolution of the product before working on the dosing system or the skimmer / reservoir
 - Wash hands after use
- Avoid contact with skin and eyes.
- Avoid splashes and spills during the M&L and application for product dissolved in a bucket.

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

- 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.
- 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.
- 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.
- 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 CENTER or a doctor.
- In case of impaired consciousness place in recovery position and seek medical advice immediately.
- If medical advice is needed, have product container or label at hand.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

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

- Shelf life: 20 months.
- Store below 30 °C.
- Store away from light.
- Store in a dry place.
- Keep out of reach of children and non-target animals/pets.

6. OTHER INFORMATION

Bilag 1.3 Oplysninger til etiket og brugsanvisning for Sojitz Family, BPR-reg. nr. 925-1-3-x

[1]

I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen [2].

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

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

1) I hovedfeltet:

”Desinfektionsmiddel

Må kun anvendes som desinfektionsmiddel mod bakterier, vira og grønalger i svømmebassiner (private). Kun til ikke-erhvervsmæssig brug.”

2) I advarselsfeltet:

”FARE

Kan forstærke brand, brandnærende (H272)

Farlig ved indtagelse (H302)

Forårsager svære forbrændinger af huden og øjenskader (H314)

Ætsende for luftvejene (EUH071)

Meget giftig for vandlevende organismer (H400)

Advarsel! Må ikke anvendes i forbindelse med andre produkter. Farlige luftarter (chlor) kan frigøres (EUH 206)

Vask huden grundigt efter brug.

Undgå udledning til miljøet.

Udslip opsamles.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som desinfektionsmiddel mod bakterier, vira og grønalger i svømmebassiner (private).

Kun til ikke-erhvervsmæssig brug

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

Må ikke tømmes i kloakfløb.

Shockbehandling må kun udføres uden badende.

Ved anvendelse af produktet i svømmebassiner, skal svømmebassinet have forbindelse med rensningsanlæg. Det er ikke tilladt at udlede behandlet vand fra svømmebassin til overfladevand.

Man må ikke gå ned i behandlet bassin indtil koncentrationen af tilgængelig klor er reduceret tilbage til 1 mg/L for svømmebassiner eller til den nationale tærskelværdi for klor er nået.

Holdes væk fra varme/gnister/åben ild/varme overflader. Rygning forbudt.

Opbevares under lås og utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Hylder, borde og andre flader, hvor levnedsmidler skal ligge eller opbevares, må ikke behandles og skal efter arbejdet omhyggeligt renses for eventuelle stænk og spild.”

Farepiktogrammet GHS05 og GHS09.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

VED INDÅNDING: Flyt personen til et sted med frisk luft og sørg for, at vejtrækningen lettes.

I TILFÆLDE AF INDTAGELSE: Skyl munden. Fremkald IKKE opkastning.

VED KONTAKT MED HUDEN: Skyl omgående tilsmudset tøj og hud med rigeligt vand, før tøjet fjernes.

VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning.

Ring omgående til giftlinjen eller læge.

3) I deklarationsfeltet:

a) Teksten ”Desinfektionsmiddel BPR-reg. nr. 925-1-3-x[3]. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)”.

b) Oplysning om præparattyper: ”Vandopløselige granulater, vandopløselige tabletter eller vandopløselige briketter”.

c) Indholdet af aktivstof i [vægtprocent (% w/w) og g/kg].

d) Udløbsdatoen skal anføres. Denne dato må højst være 20 måneder efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.

e) Batchnummer eller – betegnelse skal anføres.

f) Pakningsstørrelse i kg.

g) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Følgende retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med sikkerhedssætning P501: ”Rester og emballage bortskaffes som farligt affald.”

Følgende sætning skal anføres under sikkerhedssætning P501: ”Ovenstående sætning er Miljøstyrelsens vejledning om affaldshåndtering af dette produkt. Følg altid kommunens affaldsregulativ og forhør dig hos kommunen, hvis du er i tvivl.”