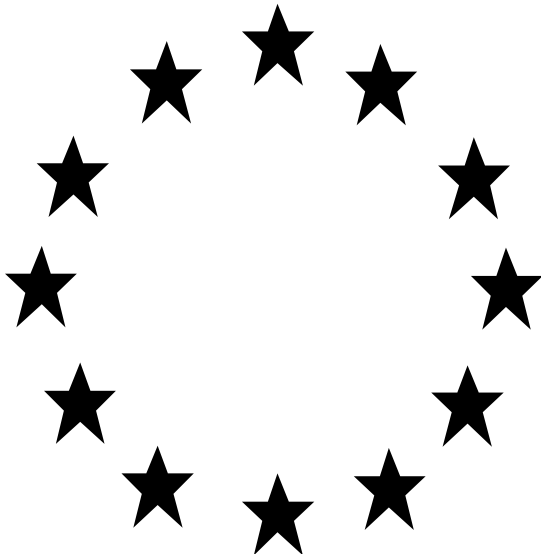

Draft Assessment Report (DAR)

- public version -

Initial risk assessment provided by the rapporteur Member State the Netherlands for the existing active substance

SODIUM HYPOCHLORITE

of the fourth stage of the review programme referred to in Article 8(2) of Council Directive 91/414/EEC

Volume 3, Annex B, part 3, B7

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B.7 Residues data

Sodium hypochlorite is an inorganic salt, which is applied in aqueous solution to mushroom casing layers. The sodium hypochlorite solution might also reach the underlying compost containing the fungal mycelium.

The chemical acid-base equilibrium between the different anionic species as well as the resulting reactions in aqueous solution is pH dependent. The different compartments within the cultivation of the mushrooms will have different pH's: around 7-7.5 for the compost and the casing layer, pH 4 for vacuoles and extra cellular matrix and about pH 7-7.5 for cytoplasm.

Taking this pH range into account and the material it will contact, different chlorine species can be expected. On contact with organic material, hypochlorite is rapidly degraded and will result in HCl, HClO, ClO_2^- and ClO_3^- and finally Cl^-. Cl_2 is not expected at pHs > 4. It is generally assumed that the reactions will end with Cl^- as the terminal residue.

In addition, some of the reactive species will react with hydrocarbon molecules by chlorination, especially carbon atoms containing amine groups. These halogenated hydrocarbon molecules are potential carcinogens.

However, since the reactivity and volatility of the different chlorine species, most of them will have been reacting in the casing layer and compost or might have been evaporated before they reach the mycelium. In B9 a study was summarised showing that DT_{50} in water < 1h. DT_{50} in water containing organic material or soil will even be much lower (<<1h).

For the intended use, application will take place in an early growth stage of the fruit bodies, up to pea size. So, all reactive chlorine species might have been reacted at the moment fruit bodies will expand and reach their final size (3-7DAT). Furthermore, residues reaching the mycelium or fruiting bodies of the mushrooms are expected to damage the mushroom cultivation. Therefore, significant amounts of chlorate and chlorite are not expected to occur or to be maintained in healthy mycelia and fruit bodies. Finally, since gross of the hypochlorite will have been reacted with the organic material in the compost or casing layer, the possible occurrence of carcinogenic chlorinated organic molecules is expected outside the mushrooms.

B.7.1 Metabolism, distribution and expression of residues in plants (IIA 6.1, IIIA 8.1)

Given the nature of the active substance, it is not practical to conduct studies with sodium hypochlorite. Radio-labelled ^{36}Cl is a relatively stable isotope, however, metabolites of sodium hypochlorite are not stable (see B. 4). Therefore, metabolites will be difficult or impossible to quantify relevant metabolites.

In a metabolism study total radioactive residues (TRR) might well be determined and this would be the only possibility to 100% exclude that residues of ClO^- reach the fruit bodies of the fungi, leaving residues of active chlorine species of chlorinated organic molecules.

However, based on data from B9 showing that DT50 will be <<1h, the rapporteur member state is of the opinion that residues are unlikely to occur in mushroom fruit bodies. Therefore, a metabolism study is not needed.

B.7.2 Metabolism, distribution and expression of the residues in livestock (AII 6.2, IIIA 8.1)

Although mushroom stalks can be fed to livestock, the amounts are of minor relevance and therefore no evaluation of metabolism in livestock is proposed.

B.7.2.1 Summary/assessment

No studies are submitted. Based on the DT_{50} <<1h, for mushroom fruit bodies, possible residues of sodium hypochlorite are not expected

In view of the nature of the active substance and the notified use, livestock metabolism data are considered not necessary.

B.7.3 Definition of the residue (IIA 6.7, IIIA 8.6)

Based on the behaviour of hypochlorite in soils rich in organic material, residues of hypochlorite in mushroom fruit bodies are not expected to occur. Therefore, it is not necessary to propose a residue definition. It is proposed to take up sodium hypochlorite in Annex IV of Regulation 396/2005/EEC.

B.7.4 Use pattern

Sodium hypochlorite is applied in aqueous solution using a concentration of 315 ppm sodium hypochlorite. It is added to the water used to irrigate the mushroom crop by diluting the commercial product (100-120 g/L hypochlorite). Mushroom crops are watered quite heavily during the pre-crop period as the mushroom mycelium colonises the casing layer. The intended use is maximal 4 applications of 1L/m2 with interval 1d and PHI 1d between the first and second flush of each growth cycle.

Four consecutive applications per cultivation period result in maximal 1,26 g hypochlorite/m^2 for one cultivation period, respectively.

These volumes would be applied to a 40 – 50 mm depth of casing layer, (80% peat and 20% $CaCO_3$, limestone) which lies on top of mushroom compost.

B.7.5 Identification of critical GAPs

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)	Remarks
(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number (max) (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)	(m)	
Mushrooms	EU	Sodium hypo-chlorite	I	Bacterial blotch caused by Pseudomonas tolaasii	SL	10 – 12% available chlorine	In irrigation water applied by watering tree	From appearance of mushrooms on beds until mushrooms are pea size	40[A]	1 day	31.5 NaClO ≈ 30 g available Cl_2	10,000	3150 NaClO ≈ 3000 g available Cl_2	1[B]	[A] 40 applications per year (assuming 10 cultivation cycles per year and 3-4 applications per cycle) [B] A PHI of 1 day was proposed by the notifier. However, in practice the PHI will be longer.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant-type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

B.7.6 Residues arising from supervised trials (IIA 6.3; IIIA 8.2)

No data from supervised field trials were submitted. See B.7.2.4 for conclusions.

Stability of residues prior to analysis

Since no residue definition and no MRLs are proposed, no storage stability studies are needed.

B.7.7 Effects of industrial processing and/or household processing (IIA 6.5, IIIA 8.4)

Since no residues are expected, processing information is not needed.

B.7.8 Livestock feeding studies (IIA 6.4, IIIA 8.3)

Although mushroom stalks can be fed to livestock, no relevant amounts of residue are expected to occur in animal feed and therefore no evaluation of metabolism in livestock is proposed.

B.7.9 Residues in succeeding or rotational crops (IIA 6.6, IIIA 8.5)

Although there will be increased levels of Cl^--salts in spent mushroom compost, this will not result in residues of concern in other crops subsequently grown in the compost.

B.7.9.1 Summary/assessment

No data were submitted on residues in crops or in food products of animal origin. It is proposed that the nature of sodium hypochlorite and the notified use mean that residues in treated crops probably will not be of concern from a consumer risk perspective.

B.7.10 Proposed pre-harvest intervals for envisaged uses or withholding periods, in the case of post harvest uses (Annex IIA 6.8, Annex IIIA 8.7)

Farmers do not water mushrooms any larger than pea size i.e. they water in between flushes and may apply up to 4 treatments with hypochlorite on consecutive days and then go without watering for 7/8 days until the flush has been picked off. Since residues are not expected to occur > 1DAT, a PHI is not required. A PHI of 1d is sufficient to get rid of hypochlorite residues in order to reach a safe worker exposure situation.

B.7.11 Community MRL's and MRL's in EU Member States (IIIA 12.2)

No residue definition nor MRLs need to be set for sodium hypochlorite, it is proposed to be taken up in Annex IV of Regulation 396/2005/EEC.

B.7.12 Proposed EU MRLs and justification for the acceptability of those MRL's (IIA 6.7, IIIA 8.6)

Since no residues are expected at the time of harvest, no MRLs are proposed for sodium hypochlorite.

B.7.13 Proposed EU Import tolerances and justification for the acceptability of those residues

None proposed.

B.7.14 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRL's

Not applicable as there are no CAC MRLs in place.

B.7.15 Estimates of potential and actual dietary exposure through diet and other means (IIA 6.9, IIIA 8.8)

The ADI is set at 0.15 mg/kg bw/d, which is in the same order as other moderately toxic active substances. As the notified use of sodium hypochlorite on mushrooms will not result in residues on treated crops or on food products of animal origin, it is not necessary to calculate estimates of dietary exposure. No risk is expected for consumers.

B.7.16 Summary and evaluation of residue behaviour (Annex II 6.9, Annex IIIA 8.6)

Although no data were submitted on residues in crops or in food products of animal origin, the nature of sodium hypochlorite and the notified use mean that residues in treated crops will not be of concern from a consumer risk perspective.

B.7.17 References relied on

Annex point/ reference no.	Author(s)	Year	Title Company, report no. Source (where different from company) GLP or GEP status (where relevant) Published or not	Data Protection Claimed Y/N	Owner
IIA 6	RAR (unknown)	2007	RISK ASSESSMENT REPORT FOR SODIUM HYPOCHLORITE, DRAFT November 2007 Italy non GLP Published (via ECB website)	N	ECB