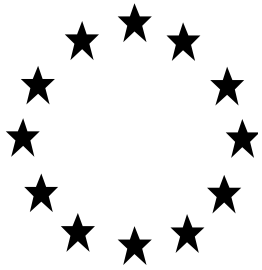
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report



Potassium sorbate

Product-type 08
(wood preservative)

February 2015

Germany

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of the active substance potassium sorbate as product-type 08(wood preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 89 of Regulation (EU) No 528/2012, with a view to the possible approval of this substance.

Potassium sorbate (CAS no. 24634-61-5) was notified as an existing active substance, by Sorbic acid task force, hereafter referred to as the applicant, in product-type 08.

Commission Regulation (EC) No 1451/2007 of 4 December 2007[1] lays down the detailed rules for the evaluation of dossiers and for the decision-making process.

In accordance with the provisions of Article 7(1) of that Regulation, Germany was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for potassium sorbate as an active substance in Product Type 08 was 28th of March 2004, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 28th of March 2004, German competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 28th of June 2004

On 12th of June 2006, the Rapporteur Member State submitted to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Agency. Revisions agreed upon were presented at the Biocidal Products Committee and its Working Groups meetings and the competent authority report was amended accordingly.

1.2. Purpose of the assessment report

The aim of the assessment report is to support the opinion of the Biocidal Products Committee and a decision on the approval of potassium sorbate for product-type 08, and, should it be approved, to facilitate the authorisation of individual biocidal products. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available from the Agency web-site shall be taken into account.

[1] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data for that purpose has been granted to that applicant.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

The identity of potassium sorbate (CAS-No.: 24634-61-5) is given in detail in the confidential part of the dossier (see confidential section of the CA-Report). The evaluation has established that for the active substance notified by the applicant, none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

Potassium sorbate is a white, crystalline, odourless powder. Potassium sorbate is well soluble, readily dissociates in water and thus displays a low logPow at neutral pH. It has a correspondingly low vapour pressure, and can safely be assumed to be essential non-volatile from water based on its Henry's Law constant.

The active substance and the impurities have been analysed by potentiometric titration.

Potassium sorbate is neither flammable, explosive nor has oxidising properties. In conclusion, no hazard indication is required for potassium sorbate.

Polyethylene has been used as lining material for potassium sorbate for decades. Polyethylene is inert to potassium sorbate and vice versa.

2.1.2. Intended Uses and Efficacy

Potassium sorbate has been evaluated for its use as a wood preservative belonging to product type 8 according to Annex V of Directive 98/8/EC.

The effectiveness of potassium sorbate for short-term preservation of wood has been shown in test conducted according to an in-house method by Holzforschung Austria. It has been shown that an aqueous solution of 5% to 10 % potassium sorbate effectively protects freshly cut wood for 2 to 4 weeks against staining fungi.

From the test results it cannot be differentiated whether there is a fungicidal and/or fungistatic effect. The test results support fungicidal/fungistatic activity of Potassium sorbate against staining fungi and surface moulds.

Target organisms for this product are primarily wood staining fungi.

Mode of action:

Potassium sorbate acts as fungicide/ fungistatic agent.

The antimicrobial effect of sorbates rests on a wide spectrum of different and relatively unspecific mechanisms:

To cause its biocidal effect, sorbate resp. sorbic acid must penetrate the cell wall, which is only possible in its undissociated form as free acid. Due to the equilibrium between the sorbate and the free acid, both substances are available within the solution depending on the pH - independent of the nature of the compound applied (in the present case potassium sorbate). With respect to wood protection, the slightly acidic matrix that wood represents ensures the presence of free acid in sufficient amounts.

Sorbic acid forms covalent bonds with SH groups, thereby inactivating a broad range of enzymes, such as enolases or lactate dehydrogenases involved in the carbohydrate metabolism, catalases and peroxidases, and interferes with several enzymes of the citrate cycle. Sorbic acid also inhibits absorption of amino acids and may partially destruct the cell membrane, thus leading to osmotic disturbance.

The antimicrobial action of sorbic acid probably is a consequence of a combination of the above factors which may differ among various types of microorganisms, with some details remaining unexplained.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

A literature research conducted in order to retrieve corresponding information on resistance gave no evidence for resistance.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Up to now, there is no legal classification, because potassium sorbate has not been inserted into Annex I of Directive 67/548/EEC, yet. Evaluation of the submitted data under Directive 98/8/EC resulted in the following proposal for classification and labelling. This proposal is in accordance with the proposal submitted by the applicant:

Table 2-1 Proposed classification of potassium sorbate based on Directive 67/548/EEC

Classification		
Class of danger	Xi	Irritating
R phrases	36	Irritant to eyes
	38	Irritant to skin
S-phrases	24/25	Avoid contact with skin and eyes
	26	*In case of contact with eyes, rinse immediately with plenty of water and seek medical advice*
	35	*This material and its container must be disposed of in a safe way*

Remark: S-Phrases in italics are optional.

Table 2-2 Proposed classification of potassium sorbate based on Regulation (EU) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	[1] Eye Irrit. 2	
Hazard statements	[1] H319	Causes serious eye irritation

Table 2-3 Proposed labelling of potassium sorbate on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS07	
Signal Word	Warning	
Hazard statements	[1] H319	Causes serious eye irritation
Precautionary statements		

[1] For the risk assessment originally skin irritation 2 was considered (RAC-opinion of March 2013)

The applicant submitted a biocidal product which was not on the market at the time of the dossier submission.
The classification and labelling of the representative biocidal product was done in compliance with the requirements of Directive 1999/45/EC.
As potassium sorbate is the only hazardous substance in this product and has a concentration of 50%, the classification is the same as for the active substance.

Table 2-4 Proposed classification of TC 3 based on Directive 67/548/EEC

Classification		
Class of danger	Xi	Irritating
R phrases	36	Irritant to eyes
	38	Irritant to skin
S-phrases	24/25	Avoid contact with skin and eyes
	26	*In case of contact with eyes, rinse immediately with plenty of water and seek medical advice*
	35	*This material and its container must be disposed of in a safe way*

Remark: S-Phrases in italics are optional.

Table 2-5 Proposed classification of TC 3 based on Regulation (EU) No 1272/2008

	Classification	Wording
Hazard classes, Hazard categories	[1] Eye Irrit. 2	
Hazard statements	[1] H319	Causes serious eye irritation

Table 2-6 Proposed labelling of TC 3 on Regulation (EC) No 1272/2008

	Labelling	Wording
Pictograms	GHS07	
Signal Word	Warning	
Hazard statements	[1] H319	Causes serious eye irritation
Precautionary statements		

[1] For the risk assessment originally skin irritation 2 was considered (RAC-opinion of March 2013)

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Hazard identification

Absorption, distribution, excretion, and metabolism

Potassium sorbate is almost completely absorbed after oral application and is subsequently well distributed in the body. It is mainly oxidised to CO_2 and H_2O. Therefore excretion proceeds with 80-86 % via the lung as CO_2. 2-10% of the excreted radioactivity was found in the urine as urea and in minor concentration as sorbic acid and muconic acid. Excretion via the lung was completed 10 h after application. Radioactivity of labelled material was detected in intestines, muscles and carcass.
In the absence of experimental data on dermal absorption, a value of 25 % was derived as a reasonable worst case estimate, based on read across of dermal absorption data for a related fatty acid available from the published literature. Before granting an authorisation for a biocidal product submission of experimental data on dermal absorption for the biocidal product in question is recommended. Otherwise, exposure assessment will be performed on the basis of default values for dermal absorption according to EFSA (2012) guidance.

Acute toxicity
Potassium sorbate is not acutely toxic or harmful when administered orally (LD50 > 10000 mg/kg bw) or dermally (LD50 > 2000 mg/kg bw).
A valid inhalation toxicity study using crystalline potassium sorbate was not provided. Instead, the applicant proposed (and that was agreed on) to use a study of the biocidal product, i. e. a 50 % (w/w) aqueous solution of potassium sorbate based on the potassium sorbate content of the test aerosol, the 4 h-LC50 was > 5.15 mg/L air.
Irritation studies revealed that potassium sorbate is not irritating to the skin but to the eyes

of rabbits. However, in medical surveillance studies (see below) irritating effects to the skin are observed.
According to the criteria of Directive 67/548/EEC, potassium sorbate displayed no skin-sensitising potential in a modified guinea pig maximisation test.

Medium-term toxicity
No substance-related adverse effects could be observed in the repeated oral administration tests in rats and dogs.

Oral short-term NOAEL (rats) = 100000 ppm in the diet, equivalent to ca. 7000 mg/kg bw (the highest dose tested).

Oral short-term NOAEL (dogs) = 40000 ppm in the diet, equivalent to ca. 1000 mg/kg bw (the highest dose tested).

Genotoxicity

Potassium sorbate did not display a genotoxic potential either in vitro or in vivo.

Chronic toxicity/ Carcinogenicity

Only weak, borderline effects on body and organ weights were seen after treatment of rats and mice for 24 and 18 months, respectively. Focal fatty changes in the liver of female rats were the only effect observed upon histopathological examination.

Oral NOAEL (24-mo. study, rat) = 750 mg/kg bw/d, based on reduced body weight (gain), increased organ weights (liver, kidney, thyroid) and focal fatty changes in livers of female animals at 5000 mg/kg bw/d.

Oral NOAEL (18-mo. study, mouse) = 1400 mg/kg bw/d, based on reduced terminal body weight and increased organ weights (liver, kidney) at 7000 mg/kg bw/d.

No evidence was found for a carcinogenic potential of potassium sorbate.

Taking into account the large dose spacing used in the 24-month rat study as well as the marginal nature of the effects observed at the high-dose level, it was decided that the limit dose level of 1000 mg/kg bw/d which proved safe in the 90-d study in dogs as well as the multi-generation studies in rats and was also exceeded by the NOAEL in the 18-month mouse study, should be used as the starting point for deriving any toxicological limit values for long-term exposure in humans.

Reproduction toxicity

Developmental toxicity

The teratogenicity studies did not indicate any specific embryo/foetotoxic potential of potassium sorbate. Foetal growth retardation and embryo-foetal death and/or reduced viability were present in rabbits at a dose of 1000 mg/kg bw/d, which also induced slight maternal toxicity (increased respiration rate, decreased food consumption and body weight gain, coarse spleen surface). A dose of 3000 mg/kg bw/d resulted in maternal lethality and increased morphologic abnormalities (brain, limbs) in the foetuses of surviving dose. The following NOAELs were established from the developmental studies:

Rats:

NOAEL (maternal toxicity/embryotoxicity, teratogenicity) = 340 mg/kg bw/d (the highest

dose testes)

Rabbits:

NOAEL (maternal toxicity) = 300 mg/kg bw/d, based on reduced food consumption and body weight gain, clinical signs, coarse spleen surface, mortality, abortions at 1000 mg/kg bw/d

NOAEL (embryotoxicity) = 300 mg/kg bw/d, based on decreased body weight, fetal survival, embryo lethality, and morphological abnormalities at 1000 mg/kg bw/d

NOAEL (teratogenicity) = 1000 mg/kg bw/d (the highest dose tested)

The severe effects on offspring and maternal animals observed in this study were most likely attributable to damage of the rabbit gastro-intestinal tract, which was caused by high local concentrations of sorbic acid after bolus gavage administration, and to which this species seemed especially amenable (as in the rat multigeneration gavage study comparable findings were not observed). As a consequence, both the design (unusually high gavage dose levels at and above the limit dose level) and the results obtained from this study were seen as bearing little relevance to exposure scenarios to be expected for humans in the context of this dossier, where oral bolus ingestion is highly unlikely.

Reproductive toxicity

In the multi-generation study in rats, there were no treatment-related adverse effects on P-generation animals and reproduction in rats up to a dose of 3000 mg/kg bw/day. Adverse effects on growth, attainment of developmental landmarks and behavioural changes were observed in the offspring at 3000 mg/kg bw/d. The dose of 1000 mg/kg bw/d is considered the relevant NOAEL for offspring toxicity.

NOAEL (parental and reproductive toxicity): 3000 mg/kg bw/d (the highest dose tested)

NOAEL (offspring toxicity): 1000 mg/kg bw/d) reduced postnatal body weight gain, development, and behaviour at 3000 mg/kg bw/d

Medical data

Three reports from production plants were submitted concerning the regular medical surveillance of production staff handling potassium sorbate. No negative impact on workers was observed in two of these examinations. However, one report (Astvad 2004) states that 'Irritation from eyes, skin and respiratory passages were seen when working with sorbic acid.' at a potassium sorbate production plant.

A multitude of publications was submitted regarding medical experience with topical applications/exposure of human skin and eyes to sorbic acid and its salts. Four main ways of toxic action were identified:

Non-immunological contact urticaria (NICU)

Transient, but nevertheless intense erythema and oedema are regularly evoked by sorbic acid when applied to human skin in various parts of the body. While not proven in a narrow sense, some mechanistic evidence was presented, that these skin reactions are mediated by release of vasoactive substances (mainly prostaglandin D2). An immunological, T-cell mediated mechanism is ruled out, also because no systemic reaction has been observed in the respective patients.

Immunological contact urticaria

In rare cases, also true allergic eczematous reactions to sorbic acid were observed. Even in large collectives of some thousands of patients, the number of positive patch test results rarely exceeded 1 %. Given the almost ubiquitous pre-exposure with sorbic acid via food or cosmetics, these findings indicate at most a very weak sensitising potential of sorbic acid.

Burning mouth syndrome

From the data submitted with this dossier, it appears that the etiology of this syndrome is, at present, not completely understood. Some of the patients displaying this syndrome tested positive for sorbic acid in epicutaneous patch tests. Dietary avoidance of sorbic acid brought relief in some cases. Other confounding factors seem to contribute to the syndrome (e.g. women after the menopause are affected more often). In any case, due to the oral exposure route involved in this effect, this is not seen as being especially relevant in the context of the current dossier.

Ocular effects

In accordance with the irritating properties of sorbic acid to the eye which were reported in the corresponding animal experiment, conjunctival contact sensitivity was observed in individuals applying contact lens care solutions containing sorbic acid as a preservative.

2.2.1.2. Effects assessment

Acute toxic effects of sorbic acid in repeated dose studies were not observed in any of the tested species (rats, mice, dogs) up to the limit dose level of 1000 mg/kg bw. An acute relevant NOAEL for AEL/MOE derivation is not allocated, since no acute toxic effects have been identified.

The 90-day study in dogs is considered the most suitable study for deriving reference doses, and the NOAEL of 1000 mg/kg bw/d (limit dose level) is supported by the multi-generation studies in rats. Applying an Assessment Factor of 100, **a value of 10 mg/kg bw/d (sorbic acid) (equal to 13.4 mg/kg bw/d potassium sorbate)** is derived for both the **medium-term and long-term systemic acceptable exposure level (AEL)**. Adjustment for oral absorption is not necessary.

Taking into account the large dose spacing used in the long-term study in rats as well as the marginal nature of the effects observed at the high-dose level (5000 mg/kg bw/d), the NOAEL of 750 mg/kg bw/d from this study is not considered adequate for the derivation of the medium- and long-term reference doses.

Nevertheless, the above AEL medium-/long-term of 10 mg/kg bw is proposed as a highly conservative starting point for risk characterisation of acute exposure scenarios and refinement should take place before any exposure scenario is considered unsafe based on a moderate exceedance of this value.

For sorbic acid, it is not expected that residues in food or feeding stuffs will occur in relevant amounts for the applied uses. Therefore, an ADI as well as an ARfD are not considered necessary. If residues may arise from further applications under other PTs the ADI would be in the same order than the AEL medium-term and long-term (10 mg/kg bw/d (sorbic acid); 13.4 mg/kg bw/d (potassium sorbate).

In 1973, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an ADI of 0 – 25 mg/kg bw/d for humans on the basis of a long-term study in rats and

maintained this ADI in 2003. The Scientific Committee for Food (SCF) of the European Commission confirmed this value in 1994. In its evaluation, SCF additionally considered the 2-year rat study (Gaunt et al. 1975), which is also considered in this CAR, but concluded that the observed effects at 5000 mg/kg bw were not sufficiently severe to establish a lower ADI. In this CAR, a lower reference value was derived, because of a different, in part more recent, database. As explained above, the $AEL_{medium-/long-term}$ in this CAR is based on a 90-day dog study (Deuel et al. 1954) and a two generation toxicity study in rats, which was performed more recently (Cordts 2004). In addition, findings in a 2-year rat study (Gaunt et al. 1975) and in a teratogenicity study in rabbits (Cordts 2004) support the NOAEL of 1000 mg/kg bw/d. Particularly the studies performed in 2004 were not considered by JECFA and SCF. The difference between the $AEL_{medium-/long-term}$ in this CAR and the JECFA ADI is therefore justified, because they were both established from smaller databases.

A dermal absorption of 25 % was derived based on expert judgement but should be refined by a dermal absorption study before granting authorisations for biocidal products. Otherwise, exposure assessment will be performed on the basis of default values for dermal absorption according to EFSA (2012) guidance.

In the absence of data, an inhalative absorption of 100 % is assumed.

The wood protection product TC 3 containing 50 % potassium sorbate is considered virtually non-toxic if swallowed or applied to the skin. An acute inhalation study clearly revealed that the biocidal product is not toxic by inhalation but it is considered irritating to eyes and skin. Furthermore, there is no evidence for skin-sensitising potential of TC 3.

2.2.1.3. Exposure assessment

Occupational Exposure

Potassium sorbate is produced within the EU as a 50 % aqueous solution. The biocidal product ("TC 3") is used as a 10% aqueous solution of potassium sorbate and applied in preventive treatment of wood only. Due to the low vapour pressure of potassium sorbate ($< 10^{-5}$ Pa, 25°C, 50 °C), inhalative exposure to vapour is of minor relevance. The inhalation and dermal exposure is assessed to potassium sorbate in this report. 1 g potassium sorbate corresponds to 0.7 g sorbate. The following scenarios are covered by the exposure assessment:

- Production of the active substance/biocidal product (a clear distinction between production and formulation is not possible),
- Automated bathing or dipping (5 cycles per day, for application the biocidal product is diluted to an aqueous solution containing 10 % of the active substance),
- Mechanical processing of treated wood (secondary exposure due to sawing of treated wood and pilling of treated pellets).

Potential exposure estimates concerning formulation and use of the biocidal product TC3 are performed which do not take account of safety measures (Tier 1). In all scenarios, skin contact significantly contributes to the total internal dose.

Wood is treated for 30 min per cycle (max. 5 cycles per day are reasonable) using a highly automated bathing or dipping procedure. After the treatment, the wood is transferred to a drying oven and stored. Due to the low vapour pressure of potassium sorbate inhalative exposure to vapour is negligible, even for the drying process at 65-80°C. In the *TNsG Human Exposure to Biocidal Products,* there is no exposure model, which sufficiently fits the task of interest. However, the tasks during a vacuum pressure process are thought to be similar and the degree of automation appears comparable. Therefore, the assessment concerning potential body exposure by skin contact was performed using Model 1 (Handling) of the *TNsG Human Exposure to Biocidal Products* (Part 2, p. 160-162), which

applies to vacuum pressure processes. Assessment of potential hand and feet exposure relies on the CEB method, which is based on immersion of the hands in liquids of varying viscosity and partially wiping (Versar 1984; SAIC, 1996). In combination the potential dermal exposure for workers towards potassium sorbate during bathing or dipping is estimated to **7298 mg/person/day**, a significant contribution comes from the application phase with **5055 mg/person/day**.

Non-occupational exposure

Non-professional use of the temporary wood protection product TC 3 is not intended, application is restricted to professional operators in specialised plants. Therefore, primary exposure of non-professionals will not occur.

No acute secondary non-professional exposure to TC 3 or its active substance potassium sorbate has to be expected since admission to the industrial plant during production, formulation or wood treatment is forbidden for bystanders. Subsequent working steps will be performed in the wood-working company as well and no further processing outside the manufacturing plant entailing the risk of secondary exposure of bystanders is foreseen.

A possible chronic secondary exposure of non-professionals/bystanders or the general public to TC 3 can be excluded since the treated wood is predominantly intended to be used as pallets for the transportation of goods where uninvolved people or food will not get into direct contact with. Since potassium sorbate‘s volatility is very low exposure of bystanders via inhalation can be neglected.

The use of TC 3 will bear no undue risk for non-professionals/bystanders for intended uses applied if above mentioned regular prerequisites, e. g. bystanders are not allowed to enter the industrial plant during production, formulation or application, are fulfilled. The general public will not be exposed to potassium sorbate in its regular use as a temporary wood preservative.

2.2.1.4. Risk characterisation

Professional Risk characterization
The most relevant exposure scenario in this risk characterisation is the application of the biocidal product during bathing and dipping of wood. The biocidal product contains 50 % (w/w) potassium sorbate in water. For the dipping or bathing process, potassium sorbate concentrations between 3 % and 10 % are used.

For risk characterisation, the total internal body burden resulting from the relevant exposure scenarios is compared to the AEL long-term of 600 mg/person/d (10 mg/kg bw /d x 60 kg/person).
The AEL (as internal reference value) is based upon the oral long-term NOAEL of 1000 mg/kg bw /d, a 10 x 10 assessment factor for inter- and intraspecies differences and on results from toxicokinetic studies revealing a 100 % oral absorption. There are no relevant inhalation toxicity studies or dermal toxicity studies.

The risk characterisation for potassium sorbate, especially for the relevant bathing/dipping scenario, is exclusively triggered by dermal contact. The actual dermal exposure estimate for potassium sorbate accounts for some kind of personal protective equipment (standard work clothing and footwear, chemical protection gloves for connecting transfer lines and maintenance, leather gloves for other tasks) to reduce potential dermal exposure.

Based on the exposure-to-AEL ratio of 2.3 the bathing/dipping scenario without personal protective measures (potential exposure) is decided to be of concern.

Based on the exposure-to-AEL ratio of 0.7, taking into account the low toxic potency of

sorbic acid, the bathing/dipping scenario with the personal protective measures described (actual exposure) is not considered to result in unacceptable health risks (no concern).

Table 2-7 Refined Risk Characterisation/AEL (professionals, sorbic acid, actual exposure)

Exposure scenario	Total internal body burden (mg/person/d)	AEL Long-term[1] (mg/person/d)	Total internal body burden divided by AEL	Concern	
				Yes	No
2 Bathing or dipping (application of biocidal product)	400	600	0.7		X
3 Processing of treated wood: Sawing of treated wood or pilling of pallets	1.4	600	0.002		X

So far, the risk calculated is expressed as total internal body burden divided by the AEL. This risk characterisation may be additionally presented as "margin of exposure". In the MOE approach the scenario-specific MOE (the relationship between the internal NOAEL and the scenario-specific total internal body burden) is compared with a reference MOE (the product of assessment factors). There is only the difference in form, not in content.

Table 2-8 Refined Risk Characterisation/MOE (professionals, sorbic acid, actual exposure)

Exposure scenario	Reference MOE[1]	Scenario-specific MOE[2]	Reference MOE divided by scen.-spec. MOE	Concern	
				Yes	No
2 Bathing or dipping (application of biocidal product)	100	150	0.7		X
3 Processing of treated wood: Sawing of treated wood or pilling of pallets	100	45752	0.002		X

[1] Product of assessment factors used (10 * 10)
[2] Internal NOAEL of 1000 mg/kg/d * 60 kg/sc.-sp. total internal body burden

This risk characterisation is considered to be sufficiently comprehensive and reliable for the purposes of annex I inclusion of potassium sorbate. It is essential to indicate, that the conclusions only apply to the active substance in the biocidal product (and not to other ingredients).

Conclusion:
Results of the Tier 2 are given in table 2.4. After detailed analysis all exposure scenarios appear to be acceptable. The above described skin protection is sufficient for professional bathing or dipping.

2.2.2. Environmental Risk Assessment

2.2.2.1. Fate and distribution in the environment

Biodegradation
Potassium sorbate is dissociated by a reversible reaction with water under environmental conditions. The sorbate anion is the relevant part for the degradation of the active substance in water. Therefore, tests with sorbic acid can be used to determine the biodegradability of potassium sorbate. The biodegradation rate for sorbic acid mounts up to > 60 % within the 28 day period and the 10-day window. Sorbic acid and consequently potassium sorbate can be classified as "readily biodegradable".

In view of the ready biodegradability, no further biodegradation tests are considered necessary.
For PEC-calculation a default half-life for biodegradation in bulk soil of 30 days may be derived according to the approach suggested by TGD 2.3.6.5, Table 8.

Abiotic degradation
Selecting sorbic acid for testing purposes is acceptable and the results can be extrapolated to the active substance potassium sorbate, because both are dissociated in water and only the sorbate ion could be degraded. Sorbic acid is stable in sterile buffer solutions at pH 4, 7 and 9. Thus no considerable hydrolytic degradation will occur under environmental conditions. Sorbic acid is slowly transformed in water by photolysis, which is reflected in the environmental half-life under normal climatic conditions. The estimated environmental half-life in 52° Northern latitude ranges from 17.3 days in June to 2440 days in December. For the two main metabolites (max. 9 and 22 % of the initial concentration, probably cis- and trans-isomers of sorbic acid), formed after 12 hours, no significant photo transformation in water was observed. Based on these results, direct photo transformation of sorbic acid in water is of minor importance. The ecological relevance of the two metabolites was not further investigated.

Due to its very low vapour pressure, sorbic acid has a low tendency to volatilize. Based on the half-life of potassium sorbate in air (7.73 h) an accumulation to this compartment is not to be expected. Therefore, air has not been considered as a compartment of concern.

Distribution
Results of the adsorption screening test, plausible but not valid, indicate that sorbic acid is highly mobile in soil. Furthermore, potassium sorbate is preferentially distributed to the hydrosphere. The distribution into other environmental compartments is of small importance.

Mobility
No studies, regarding the mobility of the active substance in soil have been performed, which is comprehensible related to the evaluation regarding to the performed adsorption-/desorption screening test and with relation to the section above (Distribution).

Bioaccumulation
The potential of potassium sorbate to bioaccumulate in aquatic and terrestrial organisms is considered to be negligible. The calculated BCF-values are based on the physico-chemical properties of sorbic acid. Both bioconcentration factors, for the aquatic (BCF_{fish} = 0.007) and terrestrial compartment ($BCF_{earthworm}$ = 0.84), are exhibiting very small values.

2.2.2.2. Effects assessment

Aquatic compartment

In an acute toxicity study with fish, up to the highest tested concentration of 1000 mg/l no adverse effects were observed.

The available data for the short term toxicity to invertebrates indicate that potassium sorbate exhibits a low acute toxicity to invertebrates (48h-EC50 = 982 mg/l).

The algae growth inhibition study (48 h) results in a 48h-E_rC_{50} of 480 mg/l and 48h-NOEC of 97 mg/l

No data on the long-term toxicity to fish and invertebrates have been performed, which is acceptable as the acute effect values were clearly > 100 mg/l.

No inhibitory effects on aquatic microbial activity were found in a limit test up to a nominal concentration of 100 mg/l. Instead, slightly stimulating effects on the metabolism could be observed.

A $PNEC_{aqua}$ of 480 µg/l has been derived from the lowest effect value obtained for algae.

As the biocidal product is simply a 3-10 % aqueous solution of potassium sorbate and contains no other active substance or substance of concern, the effect values described for the active substance potassium sorbate can be transferred to the biocidal product.

Sediment
As no tests with bentic organisms are available, the $PNEC_{sed}$ is derived from the $PNEC_{aqua}$ using the equilibrium partitioning method, resulting in a $PNEC_{sed}$ of 375 µg/kg ww.

Terrestrial compartment
Short-term tests with earthworms and terrestrial plants and a test with soil microorganisms have been performed. For earthworms a 14d-LC50 of 864 mg/kg dw was observed and sorbic acid is not expected to have a long term influence on the C- and N-cycle of soil microorganisms up to 500 mg/kg dw. The lowest effect value was determined for terrestrial plants (21d-EC_{50} = 83.6 mg/kg dw). Additionally a long term test on terrestrial plants has been performed. The no observed effect concentration has been determined for Avena sativa (NOEC ≥ 100mg/kg dw (44d)) and Brassica rapa (NOEC = 50 mg/kg dw (14d)).

A PNECsoil of 1 mg/kg dw was derived from the long-term effect value for plants using an assessment factor of 50. This PNECsoil corresponds to 0.88 mg/kg ww.

As the biocidal product is simply a 10% or 3% aqueous solution of potassium sorbate and contains no other active substance or substance of concern, the effect values described for the active substance potassium sorbate can be transferred to the biocidal product.

2.2.2.3. PBT and POP assessment

The PBT- and vPvB-Assessment for Potassium sorbate is performed according to the guidance given in the TGD (2003) as described in part II, chapter 4.4 as well as in the new REACH legislation:

- P criterion: Half-life > 40 d in freshwater (> 60 d in marine water) or
  > 120 d in freshwater sediment (> 180 d in marine sediment) or
  > 120 d in soil (according to the new REACH legislation)
- B criterion: BCF > 2000
- T criterion: Chronic NOEC < 0.01 mg/L or CMR or endocrine disrupting effect

Potassium sorbate is considered to be readily biodegradable, its potential to bioaccumulate in aquatic and terrestrial organisms is considered to be negligible and according to the data available it does not fulfil the T criterion. Therefore potassium sorbate does not fulfil the PBT- or vPvB criteria.

2.2.2.4. Exposure assessment

For the life cycle stage "Production", only general issues on environmental exposure during production of the active substance and no further data for a specific consideration of release have been provided. Information about the waste disposal of the active substance and release into waste water and treatment of liquid/solid waste in an incineration plant are not available. A generic environmental exposure assessment for the life cycle stage "Production" was performed according to the EU TGD on Risk Assessment (2003).

Furthermore, no exposure related data on the life cycle stage "Formulation of the biocidal product" was provided. The active substance is marked as a 50% preparation, which is diluted to a 3% - 10% aqueous solution for industrial use. A generic environmental exposure assessment for the life cycle stage "Formulation of the biocidal product" was performed according to the EU TGD on Risk Assessment (2003) as a release into the environment for this life cycle stage can be expected.

Two different scenarios have to be assessed for the life cycle stage "Industrial use" including the application of the biocidal product, post treatment conditioning and storage of the treated wood. The intended use of the biocidal product is a temporary (2 – 4 weeks) protection of wood against staining fungi after application of the biocidal product by a dipping process.

For the life cycle stage "Service life" the use of treated wood for pallets for food transportation and storage was specified by the applicant. In this case, releases to the environment caused by weathering and leaching of the active substance are rather limited. In the case of leaving the intended application ("pallets for food transportation and storage"), a release of the active substance from the pallets into the environment cannot be excluded. As this specific use of the biocidal product is not introduced in the OECD Emission Scenario Documents for wood preservatives (2003), a new scenario had to be created to estimate the release of active substance for "Outside storage of pallets" as a reasonable worst case scenario.

2.2.2.5. Risk characterisation

<u>Aquatic compartment</u>

For the aquatic compartment, incl. sediment there is no unacceptable risk within the different life cycle stages. For production, formulation, industrial application and storage as well as wood in service all estimated PEC/PNEC ratios are lower than 1. For the sewage treatment plant the PEC/PNEC ratios also are lower than 1.

<u>Terrestrial compartment including groundwater</u>

For the terrestrial compartment including groundwater, the estimated PEC/PNEC ratios for soil pose no unacceptable risk concerning the life cycle stage "Production". However, the production processes of Company B result in a concern for the groundwater at the basis of the limit value for active substances or substances of concern. Therefore, it was concluded that appropriate risk mitigation measures must be applied during the production process of

the b.p.

The formulation process of the biocidal product considering a concentration of 3% - 10% active substance results for the soil in PEC/PNEC ratios lower than 1. Applying a worst case estimation by choosing a generic Method of PEC estimation for groundwater results in a PEC/PNEC ratio higher than 1. Therefore, it was concluded that appropriate risk mitigation measures must be adopted during the formulation process of the biocidal product. In addition feasible waste treatment options have to be proven when recycling within the process is not practicable.

For the application process (dipping/immersion) PEC/PNEC ratios for soil poses no unacceptable risk to the terrestrial compartment, whereas the estimated PEC for the groundwater exceeds the limit value of 0.1 µg/l. This indicates an unacceptable risk that has to be reduced by the risk mitigation measures proposed to prevent releases to the soil compartment.

For treated wood in temporary storage after dipping, the PEC/PNEC ratios for soil and groundwater indicate an unacceptable risk. Risk mitigation measures, effective to both environmental compartments soil and groundwater, have to be applied. As proposed and accepted by the applicant, the treated wood has to be stored covered by roof and on impermeable hard standing, protected from weathering, preventing penetration of the leachate run-off to soil. Before authorisation of biocidal products, the applicant has to take care for labelling the storage conditions under the use instructions of the biocidal product to confirm that the potassium sorbate is not released into soil during storage. Under these conditions, the temporary storage of treated wood is acceptable.

The estimated PEC/PNEC ratios for the life cycle stage "Wood in service" do not result in a risk for both the soil as well as the groundwater compartment assuming the storage of 1% of treated pallets outside the intended use of food transportation and storage.

2.2.2.6. Assessment of endocrine disruptor properties

Potassium sorbate is not considered to have endocrine disrupting properties.

2.3. Overall conclusions

The outcome of the assessment for potassium sorbate in product-type 08 is specified in the BPC opinion following discussions at the meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA web-site.

2.4. List of endpoints

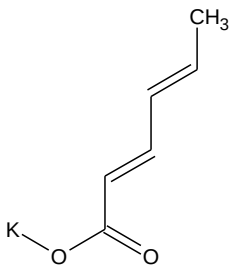
The most important endpoints, as identified during the evaluation process, are listed in Appendix I.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling

Active substance (ISO Common Name)	Potassium sorbate
Product-type	Wood preservartive

Identity

Chemical name (IUPAC)	Potassium (E,E)-hexa-2,4-dienoate
Chemical name (CA)	2,4-Hexadienoic acid, potassium salt, (1:1) (2E, 4E)-
CAS No	24634-61-5
EC No	246-376-1
Other substance No.	Registered as food additive. Substance identification: E 202
Minimum purity of the active substance as manufactured (g/kg or g/l)	990g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	No impurities of toxicological, ecotoxicological or environmental concern
Molecular formula	$C_6H_7KO_2$
Molecular mass	150.22 g/mol
Structural formula	

Physical and chemical properties

Melting point (state purity)	n.a. (decomposition above 200 °C) (Purity: 100 %)
Boiling point (state purity)	n.a. (decomposition above 200 °C) (Purity: 100 %)
Temperature of decomposition	Above 200°C
Appearance (state purity)	Solid, white, crystalline powder, odourless (100%)
Relative density (state purity)	1.36 at 23.5 °C (Purity: 100 %)

Surface tension	σ = 72.6 mN/m at 20°C (c = 1 g/l)
Vapour pressure (in Pa, state temperature)	< 10^{-5} Pa at 25 °C
Henry's law constant (Pa m^3 mol^{-1})	H < 2.77 ×10^{-9} Pa × m^3/mol at 20 °C (calculated from experimentally determined values for water solubility and vapour pressure)
Solubility in water (g/l or mg/l, state temperature)	pH 4: 1.96 g/l at 20°C
	pH 7: 543 g/l at 20°C
	pH 9: 563 g/l at 20°C
Solubility in organic solvents (in g/l or mg/l, state temperature)	79 g/l at 10, 20 or 30 °C in methanol 30 g/l at 10, 20 or 30 °C in p-xylene
Stability in organic solvents used in biocidal products including relevant breakdown products	Data not considered to be required, since the biocidal product is an aqueous solution containing no further (organic) solvents.
Partition coefficient (log P_{OW}) (state temperature)	pH 2.5: 1.32 at 20°C
	pH 6.5: -1.72 at 20°C
	(data referring on sorbic acid)
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH_____:
	pH_____:
	pH_____:
Dissociation constant	pKa = 4.69 ± 0.03 (SD)
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	
Photostability (DT_{50}) (aqueous, sunlight, state pH)	
Quantum yield of direct phototransformation in water at □ > 290 nm	
Flammability	Not highly flammable
Explosive properties	Not explosive
Oxidizing properties	Not oxidizing

Classification and proposed labelling

with regard to physical/chemical data	
with regard to toxicological data	**X_i; R36/38** ('Irritating to eyes and skin')

with regard to fate and behaviour data	
with regard to ecotoxicological data	

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	Potentiometric titration
Impurities in technical active substance (principle of method)	Potentiometric titration

Analytical methods for residues

Soil (principle of method and LOQ)	parent GC-MS/MS, LOQ: 0.05 mg/kg
Air (principle of method and LOQ)	not required
Water (principle of method and LOQ)	parent GC-MS/MS, LOQ: 0.1 µg/L
Body fluids and tissues (principle of method and LOQ)	not required
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	not required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	not required

Chapter 3:Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals

Rate and extent of oral absorption:	Almost completely absorbed
Rate and extent of dermal absorption:	25 % (derived by expert judgment in the absence of experimental data)
Distribution:	Widely distributed in the body
Potential for accumulation:	No potential for accumulation
Rate and extent of excretion:	Rapid excretion of 80-86 % via the lung as CO_2 after oxidation. Excretion via the lung is completed within 10 h after application. 2-10 % renal excretion as urea and in low concentrations as sorbic acid (0.7 %) and muconic acid (0.4 %).
Toxicologically significant metabolite(s)	None

Acute toxicity

Rat LD_{50} oral	> 10000 mg/kg bw
Rat LD_{50} dermal	> 2000 mg/kg bw
Rat LC_{50} inhalation	> 5.15 mg/L air (4 hrs) (aerosol: aqueous solution of potassium sorbate; nose-only)
Skin irritation	Not irritating in animal tests (cf. medical data section)
Eye irritation	Irritating
Skin sensitization (test method used and result)	Not sensitising (modified M & K with intradermal challenge)

Repeated dose toxicity

Species/ target / critical effect	No relevant effestc
Lowest relevant oral NOAEL / LOAEL	90 day, rat: NOAEL = 6800 mg/kg bw/d 90 day, dog: NOAEL = 1000 mg/kg bw/d
Lowest relevant dermal NOAEL / LOAEL	No data
Lowest relevant inhalation NOAEL / LOAEL	No data

Genotoxicity	No genotoxic potential

Carcinogenicity

Species/type of tumour	Liver changes, increased organ weight, reduced body weight (gain)

lowest dose with tumours	2 year, rat: NOAEL = 750 mg/kg bw/d

Reproductive toxicity

Species/ Reproduction target / critical effect	Rat: Reduced postnatal body weight gain, delayed postnatal development, behavioural changes
Lowest relevant reproductive NOAEL / LOAEL	NOAEL (parental): 3000 mg/kg bw/d NOAEL (reproduction): 3000 mg/kg bw/d) NOAEL (offspring): 1000 mg/kg bw/d
Species/Developmental target / critical effect	Rat: No adverse effects Rabbit: <u>Mid- and high-dose</u>: reduced foetal body weight, increased post-partal mortality, <u>High dose only:</u> decreased no. of live foetuses, increased no. of resorptions, abortions, malformations (head, forepaws), All effects at or above limit dose with severe maternal toxicity
Developmental toxicity	
Lowest relevant developmental NOAEL / LOAEL	Rat: NOAEL = 340 mg/kg bw/d (highest dose level tested) Rabbit: NOAEL(embryotoxicity): 300 mg/kg bw/d NOAEL(teratogenicity): 1000 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	No data, no concern from other studies
Lowest relevant developmental NOAEL / LOAEL.	

Other toxicological studies

....	No data

Medical data

....	Report of irritation to skin and eyes in manufacturing personnel Causes non-immunological urticaria

Summary	Value	Study	Safety factor

Non-professional user			
AEL_{acute}[$] / medium-term / long-term [$] For risk characterisation of acute exposure scenarios, this value constitutes a highly conservative starting point and refinement should take place in case of only moderate exceedance.	10 mg/kg bw/d (sorbic acid) 13.4 mg/kg bw/d (potassium sorbate)	90-d dog/ multi-gen. rat, supported by rat and mouse long-term studies	100
ARfD (acute reference dose)	Not allocated – no residues in food or feed expected to arise from intended use in biocidal product		
ADI	Not allocated – no residues in food or feed expected to arise from intended use in biocidal product		

Acceptable exposure scenarios (including method of calculation

Professional users	**Method of calculation:** For lack of measurement data, exposure models are applied, namely those listed in the *TNsG Human Exposure to Biocidal Products* and the EASE model.	
Production of active substance / Formulation of biocidal product (In general, assessment of exposure during production and formulation is not required under the BPD)		
Removal of the filter cakes (50 % potassium sorbate, duration: 60 min., frequency: 2-3 / week) Sampling for laboratory analysis (50 % potassium sorbate duration: 1 min, frequency: 4/day) Filling of the 50 % potassium sorbate solution (frequency: 10/day) Model: EASE	Potential inhalation exposure	negligible
	Potential dermal exposure	2541 mg/person/day
Intended uses: automated bathing or dipping		
Mixing and loading: connecting lines (conc. 50 % active substance), frequency: daily; duration: 15 min. Application: loading and unloading treated wood (conc. 10 % active substance), frequency: 5 dipping/bathing cycles per day, daily; duration 30 min. per cycle	Potential inhalation exposure	negligible
	Potential dermal exposure	7298 mg/person/day
	Actual dermal exposure	2142 mg/person/day

Post application: cleaning and maintenance work, frequency: daily, duration: 30 min. standard work clothing and footwear, chemical protection gloves for connecting transfer lines and maintenance, leather gloves for other tasks Model: Model 1 Handling TNsG Human Exposure (Part 2, p. 160-162)		
Secondary exposure		
sanding and sawing of treated wood, duration: 8h/day, frequency: daily	Potential inhalation exposure	0.017 mg/m^3
pilling up treated wood pallets with a contact of 4 h per day, frequency: daily Model: Expert judgement	Potential dermal exposure	7.4 mg/person/day

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	Sorbic acid is hydrolytically stable at pH values 4, 7, and 9 and at a temperature of 50° C. Results can be extrapolated to a.s. potassium sorbate.
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Results can be extrapolated to a.s. potassium sorbate. Photolysis rate constant: 9.75×10^{-6} s^{-1} $\pm$ 0.91×10^{-6} s^{-1} (mean and standard deviation; n=3) at pH 7 and 20 °C DT 50: 17.3 (June) – 2440 (December) (estimated by Abiwas; normal climatic conditions, 52° Northern altitude)) Two metabolites formed: 9 % and 22 % of the initial concentration; probably cis- and trans-isomers of sorbic acid
Readily biodegradable (yes/no)	Yes (Sorbic acid: 75 % after 28 days), result can be extrapolated to potassium sorbate
Biodegradation in surface water (according to TGD on risk assessment, table 7)	DT_{50} = 15 days (default value)
Biodegradation in seawater	Not relevant for intended use
Non-extractable residues	No data required (in view of ready biodegradability, no further biodegradation tests are considered to be necessary)
Distribution in water / sediment systems	No data required (in view of ready biodegradability and low adsorption

(active substance)	coefficient K_{oc}, no water/sediment degradation study is considered to be necessary)
Distribution in water / sediment systems (metabolites)	No data required (in view of ready biodegradability and low adsorption coefficient K_{oc}, no water / sediment degradation study is considered to be necessary)

Route and rate of degradation in soil

Mineralization (aerobic)	No data required (in view of ready biodegradability and low adsorption coefficient K_{oc}, no soil degradation study is considered to be necessary)
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): Based on ready biodegradability and low solid-water partition coefficient $K_{p\ soil}$ a soil half-life of **30 days** may be allocated by default .
	degradation in the saturated zone:
Field studies (state location, range or median with number of measurements)	DT_{50f}: No data required
	DT_{90f}:
Anaerobic degradation	No data required
Soil photolysis	
Non-extractable residues	No data required
Relevant metabolites - name and/or code, % of applied active ingredient (range and maximum)	No data required
Soil accumulation and plateau concentration	No data required

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	Log Koc: -1.82 (study plausible, but not valid) Koc: 0.015 l/kg

Fate and behaviour in air

Phototransformation in air	Estimation method (AOPWIN) with 24-hours-mean-day concentration of $0.5x10^6$ OH radical cm^{-3}: DT 50: 7.73 hrs
Quantum yield of direct phototransformation in water at □ > 290	0.191 ± 0.018 (mean and standard

nm	deviation; n=3)
Volatilization	Not relevant (refer to chapter 1, Henry's law constant)

Monitoring data, if available

Soil (indicate location and type of study)	
Surface water (indicate location and type of study)	
Ground water (indicate location and type of study)	
Air (indicate location and type of study)	

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity
Fish			
Oncorhynchus mykiss	96 h	mortality	LC50 > 1000 mg/l
Invertebrates			
Daphnia magna	48 h	immobilization	EC50 = 982 mg/l
Algae			
Desmodesmus subspicatus	48 h	growth inhibition	ErC50 = 480 mg/l NOEC = 97 mg/l
Microorganisms			
Activated sludge from municipal sewage treatment plant	3 h (static)	Respiration inhibition	EC50 > 100 mg/l NOEC ≥ 100 mg/l

Effects on earthworms or other soil non-target organisms

Acute toxicity to …….. (Annex IIIA, point XIII.3.2)	Eisenia fetida : LC50 (14 d) = 864 mg/kg dw
Reproductive toxicity to …… (Annex IIIA, point XIII.3.2)	n.a.

Effects on soil micro-organisms

Nitrogen mineralization	EC50 (28 d) > 5000 mg/kg dry soil weight
Carbon mineralization	NOEC (28d) = 500 mg/kg dry soil weight EC 50 = approximately. 5000 mg/kg dry soil weight (57 % inhibition)

Effects on terrestrial vertebrates

Acute toxicity to mammals	See Chapter 3
Acute toxicity to birds	n.a.
Dietary toxicity to birds	n.a.
Reproductive toxicity to birds	n.a.

Effects on terrestrial plants

Acute toxicity to terrestrial plants	*Allium cepa*: EC50 (21 d) = 83.6 mg/kd dw (seedling emergence, growth, health) *Pisum sativum*: EC50 (21 d) = 113.7 mg/kg dw (seedling emergence, growth, health)
Long term test on terrestrial plants	*Avena sative* NOEC (44d) ≥ 100 mg/kg dw *Brassica rapa* NOEC (14d) = 50 mg/kg dw

Effects on honeybees

Acute oral toxicity	n.a.
Acute contact toxicity	n.a

Effects on other beneficial arthropods

Acute oral toxicity	n.a
Acute contact toxicity	n.a
Acute toxicity to ……..	n.a

Bioconcentration

Bioconcentration factor (BCF)	BCF_{fish} = 0.007 (calc.) at pH 6.5 BCF_{fish} = 2.6 (calc.) at pH 2.5 $BCF_{earthworm}$ = 0.84 (calc.) at pH 6.5
Depuration time (DT_{50}) (DT_{90})	n.a.
Level of metabolites (%) in organisms accounting for > 10 % of residues	n.a.

Chapter 6:Other End Points

Appendix II: List of Intended Uses

The intended uses of the representative wood preservative (PT 08) are only for professional application. An aqueous solution of potassium sorbate is used for automated bathing or dipping (for application the biocidal product is diluted to an aqueous solution containing 10 % of the active substance).
The submitted studies indicate efficacy of potassium sorbate for 2 to 4 weeks against staining fungi and surface mould for the protection of freshly cut wood.

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount per treatment			Remarks:
				Type	Conc. of as	method kind	number	interval between applications (min)	g as/L	water L/m^2	g as/m^2	
Wood preservative	Germany	TC3 Not yet on the market	staining fungi and surface mould	Aqueous souluti on	50 %	Bathing and dipping	one	once	16 g a.s./m² aqueous solution containing 10 % of the active substance			Only protection for freshly cut wood for 2 – 4 weeks is envisaged

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 60 of Regulation (EU) No 528/2012.

Section No / Reference No[2]	**Author(s)**[3]	**Year**	**Title**[4] **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
Doc II B 9	EU	2003	Technical Guidance Document on Risk Assessment		Public
Doc II B 9	EU	2003	OECD Emission Scenario Document for Wood Preservatives		Public
Doc II B9	EU	2004	Human Exposure to Biocidal Products (TNsG June 2002), User Guidance Document		Public
Doc II B9	SAIC, Science Applications International Corporation	1996	Occupational dermal exposure assessment, A review of methodologies and field data		Public
Doc II B9	EU	June 2002a	Technical Notes for Guidance: Human Exposure to Biocidal Products - Guidance on Exposure Estimation [„Report 2002" http://ecb.jrc.it/biocides]		Public
Doc II B9	US EPA	1995	Exposure Factors Handbook		Public
Doc II B9	R. Guiver, H. Chambers, R. Foster, P. Johnson, D. Rimmer	1999	A report of 16 visits addressing occupational exposure arising from dipping activities with biocides and non agricultural pesticides. 3830/R51.169		Public
Doc II B9	SAIC,	1996	Occupational dermal exposure		Public

[2] ***Section Number/Reference Number*** should refer to the section number in Doc III-A or III-B. If the study is non-key, and hence not summarised in Doc III but mentioned in Doc II, it should be included in the reference list alongside related references and its location in Doc II indicated in brackets. (If there is a need to include a cross-reference to PPP references then an additional column can be inserted).

[3] ***Author's Name*** should include the author's surname before initial (s) to enable the column to be sorted alphabetically. If the Human Rights Charter prevents author's surnames on unpublished references being included in non-confidential documents, then it will be necessary to consider including 'Unpublished [number/year & letter] ' in Doc II, and both ' Unpublished [number/year & letter]' and the 'Authors Name' in the reference list'. This may necessitate the need for an additional column to state whether a reference is unpublished which can then be sorted.

[4] ***Title, Source (where different from company), Company, Report No., GLP (where relevant), (Un)Published*** should contain information relevant to each item (ideally on separate lines within the table cell for clarity). If useful, the name of the electronic file containing the specific study/reference could be added in brackets.

Section No / Reference No[2]	Author(s)[3]	Year	Title[4] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
	Science Applications International Corporation		assessment, A review of methodologies and field data		
Doc II B9	EU	June 2002a	Technical Notes for Guidance: Human Exposure to Biocidal Products - Guidance on Exposure Estimation [„Report 2002" http://ecb.jrc.it/biocides]		Public
Doc II-A 4, Doc II-B 7, Doc II-B 10		1999	Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.	No	Public
Doc II-B 10		1991	Council Directive 91/414/EEC concerning the placing of plant protection products on the market	No	Public
Doc II-B 9 Doc II-C 13		2002	European Chemicals Bureau (ECB 2002): Technical Notes for Guidance in Support of Directive 98/8/EC of the European Parliament and the Council Concerning the Placing of Biocidal Products on the Market. Human Exposure to Biocidal Products, Guidance on Exposure Estimation, Part 3, Final draft.	No	Public
Doc II-B 9 Doc II-C 13	Versar, Inc.	1984	Exposure Assessment for Retention of Chemical Liquids on Hands, Washington D.C., Exposure Evaluation Division, U.S. Environmental Protection Agency, Contract No. 68-01-6271	No	Public
Doc II-C 13		2001	International Programme on Chemical Safety (IPCS) of the World Health Organisation (2001): Guidance Document for	No	Public

Section No / Reference No[2]	Author(s)[3]	Year	Title[4] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			the Use of Data in Development of Chemical-Specific Adjustment Factors (CSAFs) for Interspecies Differences and Human Variability in Dose/Concentration–Response Assessment.		
Doc II-C 13	Renwick, AG	1993	Data-derived safety factors for the evaluation of food additives and environmental contaminants. Food Addit Contam (10), 275–305, 1993	No	Public
A3.7/01	Wilfinger, W.	2003	Solubility of potassium sorbate in two organic solvents GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20031274/01-PSBO GLP, Not Published	Y (New/First)	Nutrinova
A3.9/01	Heintze, A.	2002	Partition coefficient of Sorbic acid (HPLC method) GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20011364/01-PCPC GLP, Not Published	Y (New/First)	Nutrinova
A3.11/01	Franke, J.	2003	Potassium sorbate - Flammability (solids) and auto-flammability (solids - determination of relative self-ignition temperature) Siemens Axiva, Frankfurt, Germany, Report-No.: 20030852.01 GLP, Not Published	Y (New/First)	Nutrinova
A3.13/01	Wilfinger, W.	2003	Surface tension of potassium sorbate GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20031475/01-PCST GLP, Not Published	Y (New/First)	Nutrinova
A3.15/01	Battersby, R.V.	2004	Explosivity of Sorbic acid technical EBRC Consulting GmbH, Hannover, Germany, Report-No.: NUT-040112-01 Not GLP, Not Published	Y (New/First)	Nutrinova
A3.16/01	Battersby,	2004	Oxidising properties of Sorbic	Y	Nutrinova

Section No / Reference No[2]	Author(s)[3]	Year	Title[4] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
	R.V.		acid technica EBRC Consulting GmbH, Hannover, Germany, Report-No.: NUT-040112-02 Not GLP, Not Published	(New/First)	
A4.1/01	Anonymous	2000	Prüfanweisung QS/Betriebslabor, Gehalt (titrimetrisch), Nutrinova GmbH, Frankfurt, Germany, Report-No.: PA300-010 Not GLP, Not Published	Y (New/First)	Nutrinova
A4.1/02	Anonymous	2000	Prüfanweisung QS/Betriebslabor, Wassergehalt (Karl Fischer), Nutrinova GmbH, Frankfurt, Germany, Report-No.: PA300-020 Not GLP, Not Published	Y (New/First)	Nutrinova
A4.1/03	Gnädinger, Liebl, Michalke	2000	Prüfanweisung QS/Betriebslabor – Aldehydtest, Nutrinova GmbH, Frankfurt, Germany, Report-No.: PA300-020 Not GLP, Not Published	Y (New/First)	Nutrinova
A4.1/04	Gnädinger, Liebl, Michalke	2000	Prüfanweisung QS/Betriebslabor – Alkalinität, Nutrinova GmbH, Frankfurt, Germany, Report-No.: PA300-020 Not GLP, Not Published	Y (New/First)	Nutrinova
A4.1/05	Gnädinger, Liebl, Michalke	2000	Prüfanweisung QS/Betriebslabor – Schwermetalle (ber. als Pb) (Limit-Test). Nutrinova GmbH, Frankfurt, Germany, Report-No.: PA300-020 Not GLP, Not Published	Y (New/First)	Nutrinova
A4.1/06	Schmitt M, Bähr A, Schneider B	2004	Bestimmung von Elementen mit der ICP-MS und ICP-OES, Clariant GmbH, Division LSE, Analytical Services, Griesheim, Germany, Report No. AA 1020-137, July 15, 2004 Not GLP, Not Published	Y (New/First)	Nutrinova
A4.2/01	Thom, M.	2003	Validation of an analytica method for the determination of Sorbic acid in soi	Y (New/First)	Nutrinova

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			GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20021004/01-RVS GLP, Not Published		
A4.2/02	Thom, M.	2003	Validation of an analytical method for the determination of Sorbic acid in surface water GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20021004/01-RVW GLP, Not Published	Y (New/First)	Nutrinova
A5.4.1/01	Lück, E., Jager, M.	1995	Sorbic acid Antimicrobial Food Additives, 2nd Ed., Springer Verlag, Chapter 19 Not GLP, Published	N	
A5.4.1/02	Lück, E., Jager, M., Raczek, N.	1998	Sorbic acid Ullmann's Encyclopedia of Industrial Chemistry, 6th Ed., 10pp. Not GLP, Published	N	
A5.5/01	Hoferer, D.	2004	Statement concerning the use of potassium sorbate as biocidal product Written communication, Treyer Holzverarbeitungs GmbH, Bad Peterstal, Germany, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
A5.5/02	Metlich, T.	2004	Statement of the UIC on use of TC 3 at the production of EUR-pallets Written communication, Union Internationale des Chemins de Fer, Vienna, Austria, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
A6.1.1/01	Deuel, H.J., et al.	1954	Sorbic acid as a fungistatic agent for foods. I. Harmlessness of sorbic acid as a dietary component Food Res. 19, 1-12 Not GLP, Published	N	
A6.1.1/02	Uchida, O., et al.	1985	Studies on the acute oral toxicity of dehydroacetic acid, sorbic acid and their combination compound in rats Bull. Natl. Inst. Hyg. Sci. 103, 166-171	N	

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A6.1.1/03	Smyth, H.F., Carpenter, C.P.	1948	Further experience with the range finding test in the industrial laboratory J. Ind. Hyg. Toxicol. 30, 63-68 Not GLP, Published	N	
A6.1.1/04	Kobayashi, H. et al.	1976	The results on acute toxicities of food additives Ann. Rep. Tokyo Metr. Res. Lab. 27, 159-160 Not GLP, Published	N	
A6.1.2/01	XXX	2002	Acute toxicity study of sorbic acid in sprague-dawley rats by dermal administration XXX GLP, Not Published	Y (New/First)	Nutrinova
A6.1.3/01	XXX	1971	Vergleichende Prüfung im akuten Inhalationsversuch und Untersuchung auf Haut- und Schleimhautverträglichkeit XXX Not GLP, Not Published	Y (New/First)	Nutrinova
A6.1.4.1/01	XXX	1987	Kaliumsorbat - Prüfung auf Hautreizung am Kaninchen XXX Not GLP, Not Published	Y (New/First)	Nutrinova
A6.1.4.2/01	XXX	1987	Kaliumsorbat - Prüfung auf Augenreizung am Kaninchen XXX Not GLP, Not Published	Y (New/First)	Nutrinova
A6.1.5/01	Maurer, T.H.; et al.	1979	Predictive evaluation in animals of the contact allergenic potential of medically important substances Contact Dermatitis 5, 1-10 Not GLP, Published	N	
A6.1.5/02	Marzulli, F.N., Maibach, H.I.	1974	The use of graded concentrations in studying skin sensitizers: experimental contact sensitization in man Food Cosmet. Toxicol. 12, 219-227 Not GLP, Published	N	
A6.1.5/03	Marzulli, F.N.,	1973	Antimicrobials: Experimental contact sensitization in man	N	

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	Maibach, H.I.		J. Soc. Cosmet. Chem. 24, 399-421 Not GLP, Published		
A6.1.5/04	Klaschka, F.	1968	Sensibilisierungs- und Testergebnisse mit niedrigmolekularen Konservantien in Körperpflegemitteln Fette Seifen Anstrichmittel 70, 887-893 Not GLP, Published	N	
A6.1.5/05	Schorr, W.F.	1971	Cosmetic allergy Arch. Derm. 104, 459-466 Not GLP, Published	N	
A6.2.1/01	Westöö, G.	1964	On the metabolism of Sorbic acid in the mouse Acta Chem. Scand. 18, 1373-1378 Not GLP, Published	N	
A6.2.1/02	Fingerhut, M., et al.	1962	Über den Stoffwechsel der 1-14C-Sorbinsäure Biochemische Zeitschrift 336, 118-125 Not GLP, Published	N	
A6.2.1/03	Deuel, H.J., et al.	1954	Sorbic acid as a fungistatic agent for foods. II. Metabolism of alpha, beta-unsaturated fatty acids with emphasis on Sorbic acid Food Res. 19, 13-19 Not GLP, Published	N	
A6.3.1/01	Ehling, G.	2003	Rat 28-day dietary dose range finding study, + 15-day recovery Aventis Pharma Deutschland, Hattersheim, Germany, Report-No.: PT02-0039 GLP, Not Published	Y (New/First)	Nutrinova
A6.3.1/02	Ehling, G.	2005	Amendment no. 1 to toxicology study report PT02-0039, Rat 28-day dietary dose range finding study, + 15-day recovery Aventis Pharma Deutschland, Hattersheim, Germany, Report no.: PT02-0039 GLP, Not Published	Y (New/First)	Nutrinova
A6.4.1/01	Ehling, G.	2004	Sorbic acid - rodent 90-day	Y	Nutrinova

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			dietary toxicity (feeding) study Aventis Pharma Deutschland, Hattersheim, Germany, Report-No.: PT02-0040 GLP, Not Published	(New/First)	
A6.4.1/02	Lang, K.	1960	Die Verträglichkeit der Sorbinsäure Arzneimittel Forschung 10, 997-999 Not GLP, Published	N	
A6.5/01	Gaunt, I.F., et al.	1975	Long-term toxicity of sorbic acid in the rat Food Cosmet. Toxicol. 13, 31-45 Not GLP, Published	N	
A6.6.1/01	Engelbart, K.	1979	Test for mutagenicity in bacteria strains in the absence and presence of a liver preparation Hoechst AG, Frankfurt, Germany, Report-No.: 417/79 A Not GLP, Not Published	Y (New/First)	Nutrinova
A6.6.1/02	Fujita, H., Sasaki, M.	1986	Mutagenicity test of food additives with Salmonella thyphimurium TA97a and TA102 Ann. Rep. Tokyo Metr. Res. Lab. 37, 447-452 Not GLP, Published	N	
A6.6.1/03	Anonymous	1976	Microbiological mutagenicity evaluation of sorbic acid/sodium nitrite reaction products Litton Bionetics, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
A6.6.1/04	Brusick, D.J.	1977	Mutagenic evaluation of calcium sorbat Litton Bionetics, NTIS, PB-266894, Report-No.: 2672 Not GLP, Published	N	
A6.6.1/05	Brusick, D.J.	1974	Mutagenic evaluation of compound FDA 73-4, potassium sorbate Litton Bionetics, NTIS, PB-245434, Report-No.: 2468 Not GLP, Published	N	
A6.6.1/06	Ishidate, M., Sofuni, T., Yoshikawa,	1984	Primary mutagenicity screening of food additives currently used in Japan Food Chem. Toxicol. 22, 623-636	N	

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	K., Hayshi, M., Nomhi, T., Sawada, M., Matsuoka, A.		Not GLP, Published		
A6.6.2/01	Ishidate, M., Odashima, S.	1977	Chromosome tests with 134 compounds on Chinese hamster cells in vitro - a screening for chemical carcinogens Mutat. Res. 478, 337-354 Not GLP, Published	N	
A6.6.2/02	Ishidate, M.	1988	Sorbic acid Data Book of Chromosoma Aberration Test in Vitro, Life-Science Information Center Not GLP, Published	N	
A6.6.2/03	Hasegawa, M.M., et al.	1984	Effects of sorbic acid and its salts on chromosome aberrations, sister chromatid exchanges and gene mutations inculture chinese hamster cells Food Chem. Toxicol. 22, 501-507 Not GLP, Published	N	
A6.6.2/04	Abe, S., Sasaki, M.	1977	Chromosome aberrations and sister chromatid exchanges in Chinese hamster cells exposed to various chemicals J. Natl. Cancer Inst. 58, 1635-1641 Not GLP, Published	N	
A6.6.2/05	Schlatter, J., et al.	1992	The potential genotoxicity of sorbates effects on cell cycle in vitro in V79 cells and somatic mutations in drosophila Food Chem. Toxicol. 30, 843-851 Not GLP, Published	N	
A6.6.2/06	Schiffmann, D., Schlatter, J.	1992	Genotoxicity and cel transformation studies with sorbates in Syrian hamster emryo fibroblasts Food Chem. Toxicol. 30, 669-672 Not GLP, Published	N	
A6.6.2/07	Ishidate, M. et al.	1988	A comparative analysis of data on the clastogenicity of 951 chemical substances tested in	N	

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			mammalian cell cultures Mutat. Res. 951, 151-213 Not GLP, Published		
A6.6.3/01	XXX	1989	Evaluation of Sorbinsäure in the unscheduled DNA synthesis test in mammalian cells in vitro XXX Not GLP, Not Published	Y (New/First)	Nutrinova
A6.6.3/02	Münzner, R., et al.	1990	Re-examination of potassium sorbate and sodium sorbate for possible genotoxic potential Food Chem. Toxicol. 28, 397-401 Not GLP, Published	N	
A6.6.3/03	Cojocel, C., Knauf, B.	1989	Untersuchung des genotoxischen Potentials von Sorbinsäure (Kaliumsorbat) mit Hilfe der alkalischen Elutionstechnik Hoechst AG, Frankfurt, Germany, Report-No.: 89.1188 Not GLP, Not Published	Y (New/First)	Nutrinova
A6.6.4/01	XXX	1989	Micronucleus test in male and female NMRI mice after oral administration XXX Not GLP, Not Published	Y (New/First)	Nutrinova
A6.6.4/02	XXX	1998	Sister chromatid exchange assay in bone marrow cells of the mouse XXX Not GLP, Not Published	Y (New/First)	Nutrinova
A6.6.4/03	Banerjee, T.S., Giri, A.K.	1986	Effects of sorbic acid and sorbic acid-nitrite in vivo on bone marrow chromosomes of mice Toxicology Letters 31, 101-106 Not GLP, Published	N	
A6.6.4/04	Jung, R., et al.	1992	Evalution of the genotoxic potential of sorbic acid and potassium sorbate Food Chem. Toxicol. 30, 1-7 Not GLP, Published	N	
A6.7/01	Hendy, R.J., et al.	1976	Long-term toxicity studies of sorbic acid in mice Food Cosmet. Toxicol. 14, 381-386 Not GLP, Published	N	

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A6.7/02	Odashima, S.	1979	Cooperative programme on long-term assays for carcinogenicity in Japar Montesano, R., et al. (Eds.): Molecular and cellular aspects of carcinogen screening tests, 315-322 Not GLP, Published	N	
A6.8.1/01	Bailey, D.E., Morgareidge, K.	1975	Teratologic evaluation of FDA 73-4, potassium sorbate; sorbistat in mice and rats FDRL, NTIS, PB-245520, Report-No.: 2123(18) Not GLP, Published	N	
A6.8.1/02	Cordts, R.	2004	Prenatal developmental toxicity study in rabbits with sorbic acid by oral administration XXX, Hamburg, Germany, Report-No.: 16972/03 GLP, Not Published	Y (New/First)	Nutrinova
A6.8.1/03	XXX	2004	Statement on the embryotoxicity of sorbic acid XXX Not GLP, Not Published	Y (New/First)	Nutrinova
A6.8.1/04	Verrett, M.J., et al.	1980	Toxicity and teratogenicity of food additive chemicals in the developing chicken embryo Toxicol. Appl. Pharmacol. 56, 265-273 Not GLP, Published	N	
A6.8.1/05	Wilfinger, W.	2004	Report amendment no. 1 to study 20021004/01-PCVS: Dose verification of Sorbic acid from application matrix GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: Am 20021004/01-PCVS GLP, Not Published	Y (New/First)	Nutrinova
A6.8.2/01	XXX	2004	Two-generation reproduction toxicity study of Sorbic acid following oral administration to the rats of the F0 and F1-generation XXX GLP, Not Published	Y (New/First)	Nutrinova
A6.8.2/02	Demaree,	1955	Preliminary studies on the effect	N	

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	G.E., et al.		of feeding sorbic acid upon the growth, reproduction, and cellular metabolism of albino rats J. Am. Pharm. Assoc. 44, 619-621 Not GLP, Published		
A6.8.2/03	Wilfinger, W.	2004	Report Amendment No. 1 to Study 20021004/01-PCRT - Dose Verification of Sorbic Acid from Application Matrix [XXX project no. 16645/03] GAB & IFU, Niefern-Öschelbronn, Germany, Report No. 20021004/01-PCRT GLP, Not Published	Y (New/First)	Nutrinova
A6.12.1/01	Dosch, E.	2004	Declaration of medical surveillance procedures for manufacturing plant personnel Nutrinova GmbH, Frankfurt, Germany, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
A6.12.1/02	Astvad, K.	2004	Declaration of medical surveillance procedures for manufacturing plant personnel Cheminova A/S, Lemvig, Denmark, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
A6.12.1/03	Terakawa, T.	2004	Declaration of medical surveillance procedures for manufacturing plant personnel Daicel Europe GmbH, Düsseldorf, Germany, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
A6.12.6/01	Soschin, D., et al.	1986	Sorbic acid-induced erythema and edema J. Am. Acad. Dermatol. 14, 234-241 Not GLP, Published	N	
A6.12.6/02	Lahti, A., Maibach, H.I.	1987	Immediate contact reactions: contact urticaria syndrome Seminars Dermatology 6, 313-320 Not GLP, Published	N	
A6.12.6/03	Morrow, J.D., et al.	1994	Release of markedly increased quantities of prostaglandin D2 from the skin in vivo in humans	N	

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			following the application of sorbic acid Arch. Derm. 130, 1408-1412 Not GLP, Published		
A6.12.6/04	Roberts, L.J., Morrow, J.D.	1997	Prostaglandin D2 mediates contact urticaria caused by sorbic acid, benzoic acid, and esters of nicotinic acid Contact Urticaria Syndrome, 77-88 Not GLP, Published	N	
A6.12.6/05	Lahti, A.	1980	Non-immunologic contact urticaria Acta Derm. Venereol. 60, 1-49 Not GLP, Published	N	
A6.12.6/06	Gollhausen, R., Kligman, A.M.	1985	Human assay for identifying substances which induce non-allergic contact urticaria: the NICU-test Contact Dermatitis 13, 98-106 Not GLP, Published	N	
A6.12.6/07	Fisher, A.A. et al.	1971	Allergic contact dermatitis due to ingredients of vehicles Arch. Derm. 104, 286-290 Not GLP, Published	N	
A6.12.6/08	Klaschka, F.	1966	Kontaktallergie gegen Konservierungsmittel in Salben und Cremes Fette Seifen Anstrichmittel 68, 756-760 Not GLP, Published	N	
A6.12.6/09	Klaschka, F., Beiersdorff, H.U.	1965	Crux medicurum: Allergie gegen nicht deklarierte Salbenkonservantien MMW 4, 185-188 Not GLP, Published	N	
A6.12.6/10	Schnuch, A., et al.	1998	Patch testing with preservatives, antimicrobials and industrial biocides. Results from a multicentre study Brit. J. Dermatol. 138, 467-476 Not GLP, Published	N	
A6.12.6/11	de Groot, A.C., et al.	1986	Contact allergy to preservatives - (I) Contact Dermatitis 14, 120-122 Not GLP, Published	N	

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A6.12.6/12	Shehade, S.A., et al.	1991	Epidemiological survey of standard series patch test results and observations on day 2 and day 4 readings Contact Dermatitis 24, 119-122 Not GLP, Published	N	
A6.12.6/13	Ramsing, D.W., Menné, T.	1993	Contact sensitivity to sorbic acid Contact Dermatitis 28, 124-125 Not GLP, Published	N	
A6.12.6/14	Hjorth, N., Trolle-Lassen, C.	1962	Skin reactions to preservatives in creams Am. Perfum. 77, 43-46 Not GLP, Published	N	
A6.12.6/15	Brasch, J., et al.	1993	Patch test reactions to a preliminary preservative series Dermatosen 41, 71-76 Not GLP, Published	N	
A6.12.6/16	Hannuksela, M., et al.	1976	Allergy to ingredients of vehicles Contact Dermatitis 2, 105-110 Not GLP, Published	N	
A6.12.6/17	Brun, R.	1975	Epidemiology of contact dermatitis in Geneva (1000 cases) Contact Dermatitis 1, 214-217 Not GLP, Published	N	
A6.12.6/18	Iden, D.L., Schroeter, A.L.	1977	The vehicle tray revisited: The use of the vehicle tray in assessing allergic contact dermatitis by a 24-hour application method Contact Dermatitis 3, 122-126 Not GLP, Published	N	
A6.12.6/19	Huang, W., et al.	1996	The burning mouth syndrome J. Am. Acad. Dermatol. 34, 91-98 Not GLP, Published	N	
A6.12.6/20	Tourne, L.P.M., Fricton, J.R.	1992	Burning mouth syndrome Oral Surg. Oral Med. Oral Pathol. 74, 158-167 Not GLP, Published	N	
A6.12.6/21	Lamey, P.-J., et al.	1994	Type 3 burning mouth syndrome: psychological and allergic aspects J. Oral Pathol. Med. 23, 216-219 Not GLP, Published	N	

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A6.12.6/22	Lamey, P.-J., et al.	1987	Atypical burning mouth syndrome Contact Dermatitis 17, 242-243 Not GLP, Published	N	
A6.12.6/23	Haustein, U.F.	1988	Burning mouth syndrome due to nicotinic acid esters and sorbic acid Contact Dermatitis 19, 225-226 Not GLP, Published	N	
A6.12.6/24	Clemmensen, O.J., Schiodt, M.	1982	Patch test of the buccal mucosa to sorbic acid Contact Dermatitis 8, 341-342 Not GLP, Published	N	
A6.12.6/25	Veien, N.K., et al.	1987	Oral challenge with food additives Contact Dermatitis 17, 100-103 Not GLP, Published	N	
A6.12.6/26	Clemmensen, O., Hjorth, N.	1982	Perioral contact urticaria from sorbic acid and benzoic acid in a salad dressing Contact Dermatitis 8, 1-6 Not GLP, Published	N	
A6.12.6/27	Maucher, O.M.	1974	Periorbitalekzem als iatrogene Erkrankung Klin. Mbl. Augenheilk. 164, 350-365 Not GLP, Published	N	
A6.12.6/28	Herbst, R.A., Maibach, H.I.	1991	Contact dermatitis caused by allergy to ophthalimic drugs and contact lens solutions Contact Dermatitis 25, 305-312 Not GLP, Published	N	
A6.12.6/29	Herbst, R.A., Maibach, H.I.	1992	Allergische Kontaktdetermatitiden durch ophthalmologische Externa und Kontaktlinsenlösungen Akt. Dermatol. 18, 36-40 Not GLP, Published	N	
A6.12.6/30	Riedl, B., et al.	1991	Typ-IV-Allergie gegen Inhaltsstoffe von Augentherapeutika Klin. Mbl. Augenheilk. 198, 251-254 Not GLP, Published	N	
A6.12.6/31	Podmore,	1989	Contact lens intolerance; allergic	N	

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	P., Storrs, F.J.		conjunctivitis? Contact Dermatitis 20, 98-103 Not GLP, Published		
A6.12.6/32	Fisher, A.A.	1985	Allergic reactions to contact lens solutions CUTIS 85, 209-211 Not GLP, Published	N	
A6.12.6/33	Rudzki, E., et al.	1995	Frequency of contact sensitivity to drugs and preservatives in patients with conjunctivities Contact Dermatitis 33, 270 Not GLP, Published	N	
A6.12.6/34	Josephson, J.E., Caffery, B.	1986	Sorbic acid revisited J. Am. Optometric Association 57, 188-189 Not GLP, Published	N	
A6.12.6/35	Fisher, A.A.	1980	Cosmetic dermatitis, part II - Reactions to some commonly used preservatives Cutis 26, 136-148 Not GLP, Published	N	
A7.1.1.1.1/01	Heintze, A.	2002	Abiotic degradation of Sorbic acid. Hydrolysis of a function of pH GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20011364/01-PCHY GLP, Not Published	Y (New/First)	Nutrinova
A7.1.1.1.2/01	Hennecke, D.	2004	Aquatic photodegradation and quantum yield of Sorbic acid Fraunhofer Institut für Molekularbiologie und Angewandte Ökologie, Schmallenberg, Germany, Report-No.: ERB-001/7-05 GLP, Not Published	Y (New/First)	Nutrinova
A7.1.1.2.1/01	Dengler, D.	2002	Assessment of the ready biodegradability of Sorbic acid with the closed bottle test GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20011364/01-AACB GLP, Not Published	Y (New/First)	Nutrinova
A7.1.3/01	Heintze, A.	2002	Adsorption-coefficient on soil of Sorbic acid (CAS No. 110-44-1) Screening test by HPLC	Y (New/First)	Nutrinova

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			GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20011364/01-PCAD GLP, Not Published		
A7.3.1/01	Sendor, T.	2003	Estimation of the photochemical oxidative degradation rate in the atmosphere of potassium sorbate EBRC Consulting GmbH, Hannover, Germany, Report-No.: NUT-031015-01 Not GLP, Not Published	Y (New/First)	Nutrinova
A7.3.1/02	Battersby, R.V.	2002	AOP Sorbic acid, calculation by EBRC EBRC Consulting GmbH, Hannover, Germany, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
A7.4.1.1/01	XXX	2004	Acute toxicity testing of potassium sorbate in rainbow trout (Oncorhynchus mykiss) (Teleostei, Salmonidae) XXX GLP, Not Published	Y (New/First)	Nutrinova
A7.4.1.1/02	XXX	1988	Kaliumsorbat: Prüfung der akuten Toxizität am Fisch Zebrabärbling (Brachydanio rerio) über 96 Stunden XXX Not GLP, Not Published	Y (New/First)	Nutrinova
A7.4.1.2/01	XXX	2004	Assessment of Toxic Effects of potassium sorbate on Daphnia magna using the Assessment of toxic effects of potassium sorbate on Daphnia magna using the 48 h acute immobilisation test XXX GLP, Not Published	Y (New/First)	Nutrinova
A7.4.1.2/02	XXX	1995	Prüfung der toxischen Wirkung von Kaliumsorbat - Granulat (701N57029) auf Kleinkrebse ("Daphnientoxizität") XXX Not GLP, Not Published	Y (New/First)	Nutrinova
A7.4.1.2/03	XXX	1995	Prüfung der toxischen Wirkung von Sorbinsäure - Panosorb	Y (New/First	Nutrinova

Section No / Reference No[2]	Author(s)[3]	Year	Title[4] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			(701N53022) auf Kleinkrebse ("Daphnientoxizität") XXX Not GLP, Not Published	)	
A7.4.1.3/01	Heusel, R.	1993	Sorbic acid. Effect to Scenedesmus subspicatus (Green alga) in a growth inhibitation test (method OECD) Hoechst AG, Frankfurt, Germany, Report-No.: CE92/129 Not GLP, Not Published	Y (New/First)	Nutrinova
A7.4.1.3/02	Dengler, D.	2005	Testing of toxic effects of potassium sorbate on the single cell green alga *Desmodesmus subspicatus* (formerly *Scenedesmus subspicatus*) GAB Biotechnologie, Niefern-Öschelbronn, Germany, June 10, 2005 Not GLP, Not Published	Y (New/First)	Nutrinova
A7.4.1.4/01	Dengler, D.	2002	Acute toxicity testing of Sorbic acid on activated sludge with respiration inhibition test GAB & IFU, Niefern-Öschelbronn, Germany, Report no.: 20011364/01-AAHT GLP, Not Published	Y (New/First)	Nutrinova
A7.4.2/01	Sendor, T.	2003	Estimation of the bioconcentration factor (BCF) of sorbic acid, potassium sorbate and Calcium sorbate EBRC Consulting GmbH, Hannover, Germany, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
A7.5.1.1/01	Kölzer, U.	2004	Assessment of the side effects of Sorbic acid on the activity of the soil microflora GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20021001/01-ABMF GLP, Not Published	Y (New/First)	Nutrinova
A7.5.1.2/01	Stäbler, D.	2003	Acute toxicity of Sorbic acid to earthworms, Eisenia fetida, using an artificial soil test GAB & IFU, Niefern-Öschelbronn, Germany, Report no.: 20021004/01-NLEf	Y (New/First)	Nutrinova

Section No / Reference No[2]	Author(s)[3]	Year	Title[4] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			GLP, Not Published		
A7.5.1.3/01	Balluff, M.	2004	Seedling emergence limit test for non target plants following a single rate application with soi incorporation of sorbic acid GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20031330/S1-FGSE GLP, Not Published	Y (New/First)	Nutrinova
A7.5.1.3/02	Balluff, M.	2004	Seedling emergence dose-response test for non target plants following multiple dose applications with soi incorporation of Sorbic acid GAB & IFU, Niefern-Öschelbronn, Germany, Report no.: 20031330/S2-FGSE GLP, Not Published	Y (New/First)	Nutrinova
A7.5.2.2/01	Förster, B.	2010	Potassium sorbate: Chronic toxicity to higher plants. ECT Oekotoxikologie GmbH, Flörsheim, Germany, report no. 09BX1PC, February 09, 2010 (unpublished)	Y	Nutrinova
A7.5.5.1/01	Sendor, T.	2003	Estimation of the terrestria bioconcentration factor (BCF) of potassium sorbate EBRC Consulting GmbH, Hannover, Germany, Report-No.: NUT-20031110-01 Not GLP, Not Published	Y (New/First)	Nutrinova
A9/01	von Rymon Lipinski, G.-W.	2004	Rationale for R 38 "Irritating to skin" for potassium sorbate Written communication, Nutrinova GmbH, Frankfurt, Germany, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
A9/02			Label for the active substance (potassium sorbate granules) Nutrinova GmbH, Frankfurt, Germany, Report-No.: Not GLP, Not Published	N	Nutrinova
A9/03	Michalke, A.	2001	Packmittelspezifikationen Faltschachtel (including English translation) Nutrinova GmbH, Frankfurt,	Y (New/First)	Nutrinova

Section No / Reference No[2]	Author(s)[3]	Year	Title[4] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Germany, Report-No.: Not GLP, Not Published		
A9/04	Michalke, A.	2003	Packmittelspezifikationen PE-Seitenfaltsack (including English translation) Nutrinova GmbH, Frankfurt, Germany, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
A9/05	Anonymous	2000	Packmittelspezifikationen Big Bag Nutrinova GmbH, Frankfurt, Germany, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
B3.5/01	Wilfinger, W.	2003	pH of "Kaliumsorbat Lösung 50 %" GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20031279/01-PCPH GLP, Not Published	Y (New/First)	Nutrinova
B3.6/01	Wilfinger, W.	2003	Relative density of "Kaliumsorbat Lösung 50 %" GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20031279/01-PCRD GLP, Not Published	Y (New/First)	Nutrinova
B3.7/01	Michalke, A.	2004	Lagerstabilität von 50 %iger Kaliumsorbat-Lösung Nutrinova GmbH, QS-Labor, Frankfurt, Germany, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova
B3.10.1/01	Wilfinger, W.	2003	Surface tension of "Kaliumsorbat Lösung 50 %" GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20031279/01-PCST GLP, Not Published	Y (New/First)	Nutrinova
B3.10.2/01	Wilfinger, W.	2003	Viscosity of "Kaliumsorbat Lösung 50 %" GAB & IFU, Niefern-Öschelbronn, Germany, Report-No.: 20031279/01-PCVC GLP, Not Published	Y (New/First)	Nutrinova
B5.10.2/01	Gründlinger, R., Pfabigan, N.	2003	Labormethode zur Prüfung der Wirksamkeit von Holzschutzmitteln für den temprären Bläueschutz von	Y (New/First)	Nutrinova

Section No / Reference No[2]	Author(s)[3]	Year	Title[4] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Schnittholz Holzforschung Austria, Wien, Austria, Report-No.: 720/2003/1-HS Not GLP, Not Published		
B5.10.2/02	Gründlinger, R., Pfabigan, N.	2004	Biological test of potassium sorbate for the temporary protection in the field test Holzforschung Austria, Wien, Austria, Report-No.: 394/2004/1-HS Not GLP, Not Published	Y (New/First)	Nutrinova
B5.10.2/03	Gründlinger, R., Pfabigan, N.	2004	Biological test of potassium sorbate for the temporary protection in the field test Holzforschung Austria, Wien, Austria, Report-No.: 394/2004/2-HS Not GLP, Not Published	Y (New/First)	Nutrinova
B6.1.3/01	XXX	2004	Acute inhalation toxicity study of 50 % Potasium sorbate in water in rats XXX, Report-No.: 16706/03 GLP, Not Published	Y (New/First)	Nutrinova
B6.6/01	Sendor, T.	2004	Estimation of human exposure to potassium sorbate from application of TC 3 EBRC Consulting GmbH, Hannover, Germany, Report-No.: NUT-040316-01 Not GLP, Not Published	Y (New/First)	Nutrinova
B7.1/01	Sendor, T.	2004	Estimation of environmental exposure to potassium sorbate following application as a wood preservative by dipping/immersion - environmental emission scenario - EBRC Consulting GmbH, Hannover, Germany, Report-No.: NUT-040317-02 Not GLP, Not Published	Y (New/First)	Nutrinova
B7.1/02	Sendor, T.	2004	Estimation of predicted environmental concentrations of potassium sorbate following application as a wood preservative by	Y (New/First)	Nutrinova

Section No / Reference No[2]	Author(s)[3]	Year	Title[4] Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			dipping/immersion - EUSES report EBRC Consulting GmbH, Hannover, Germany, Report-No.: NUT-040317-01 Not GLP, Not Published		
B7.1/03	Schuhmacher, P., Wegner, R.	2010	Test report No. 31/09/1300/01, Materialprüfungsamt Brandenburg GmbH, Eberswalde, Germany, report no. 31/09/1300/01, February 17, 2010 (unpublished).	Y	Nutrinova
B9/01			Label for the biocidal product (50 % potassium sorbate solution) Nutrinova GmbH, Frankfurt, Germany, Report-No.: Not GLP, Not Published	N	Nutrinova
B9/02			Label for the biocidal product (TC-3) Timberclean GmbH, Bad Peterstal Germany, Report-No.: Not GLP, Not Published	N	Nutrinova
B9/03	Michalke, A.	2002	Packmittelspezifikationen Palettentank (including English translation) Nutrinova GmbH, Frankfurt, Germany, Report-No.: Not GLP, Not Published	Y (New/First)	Nutrinova

Appendix IV – Human Health Tables for Risk Characterisation

Table 1: Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		Estimated Internal Exposure *(unit in CAR documents I and II, specified as mg/person/day)*				Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)[3]	AF MOE_{ref}	MOE	Exposure /AEL
		estimated oral uptake [mg/kg b.w/day]	estimated inhalation uptake [mg/kg b.w/day]	estimated dermal uptake [mg/kg b.w/day][2]	estimated total uptake [mg/kg b.w/day]				
Tier 1 (no PPE)	Production of active substance (scenario 1)	-	negligible	7.9	7.9	NOAEL= 1000 mg/kg/d $AEL_{med/long\ term}$= 10 mg/kg/d	100	127	0.8
Tier 2 (refinement)	not required								
Tier 1 (no PPE) **Tier 2** (refinement)	Production of active substance	Risk characterisation for this scenario not performed							
Tier 1 (no PPE)	Bathing or dipping (application of the biocidal product; scenario 2)	-	negligible	22.7	22.7	NOAEL= 1000 mg/kg/d $AEL_{med-/long\ term}$= 10 mg/kg/d	100	44	2.3
Tier 2 (dermal PPE and standard working clothing)		-	negligible	6.7	6.7			150	0.7

[1] Based on the assumption of 100% absorption by inhalation, body weight 60 kg
[2] Based on the assumption of 25% dermal absorption
[3] Based on an experimental oral NOAEL of 1000 mg/kg/d. The default AF of 100 and an oral absorption of 100% was applied

Table 2: Non Professional Users – Primary Exposure

Exposure Scenario (indicate duration)		**Estimated Internal Exposure**				**Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)**	**AF MOE_{ref}**	**MOE**	**Exposure /AEL**
		estimated oral uptake [mg/kg b.w/day]	**estimated inhalation uptake [mg/kg b.w/day]**	**estimated dermal uptake [mg/kg b.w/day]**	**estimated total uptake [mg/kg b.w/day]**				
Tier 1 (no PPE)									
Tier 2 Refinement or other risk mitigation measures – Specify)									

Exposure Scenario (indicate duration)		**Estimated Internal Exposure**				**Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)**	**AF MOE_{ref}**	**MOE**	**Exposure /AEL**
		estimated inhalation uptake [mg/kg b.w/day]	**estimated dermal uptake [mg/kg b.w/day]**	**estimated oral uptake [mg/kg b.w/day]**	**estimated total uptake [mg/kg b.w/day]**				
Tier 1 (Worst Case) Short term Scenario									
Exposure Scenario (indicate duration)		**Estimated Internal Exposure**				**Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)**	**AF MOE_{ref}**	**MOE**	**Exposure /AEL**
		estimated inhalation uptake [mg/kg b.w/day]	**estimated dermal uptake [mg/kg b.w/day]**	**estimated oral uptake [mg/kg b.w/day]**	**estimated total uptake [mg/kg b.w/day]**				
Tier 2 (Refinement Short Term Scenario									

Table 3: Indirect Exposure as a result of use – Secondary Exposure

Table 4: Indirect Exposure as a result of use – Secondary Exposure

Exposure Scenario (indicate duration)		**Estimated Internal Exposure** *(unit in CAR documents I and II, specified as mg/person/day)*				**Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium or chronic)**[3]	**AF MOE_{ref}**	**MOE**	**Exposure /AEL**
		estimated inhalation uptake [mg/kg b.w/day][1]	**estimated dermal uptake [mg/kg b.w/day]**[2]	**estimated oral uptake [mg/kg b.w/day]**	**estimated total uptake [mg/kg b.w/day]**				
Tier 1 (Worst Case) Chronic Scenario	Professional user: Processing of treated wood	0.002	0.02	-	0.02	NOAEL= 1000 mg/kg/d $AEL_{med-/long\ term}$= 10 mg/kg/d	100	50000	0.002
Exposure Scenario (indicate duration)		**Estimated Internal Exposure**				**Relevant NOAEL/ LOAEL [mg/kg b.w/day] & Reference Value e.g: AEL (acute or medium**	**AF MOE_{ref}**	**MOE**	**Exposure /AEL**
		estimated inhalation uptake [mg/kg b.w/day]	**estimated dermal uptake [mg/kg b.w/day]**	**estimated oral uptake [mg/kg b.w/day]**	**estimated total uptake [mg/kg b.w/day]**				

					or chronic)			
Tier 2 (Refinement-Specify) Chronic Scenario	not required							

(1) Based on the assumption of 100% absorption by inhalation, body weight 60 kg and an breathing volume of 10 m^3 per shift
(2) Based on the assumption of 25% dermal absorption
(3) Based on an experimental oral NOAEL of 1000 mg/kg/d. The default AF of 100 and an oral absorption of 100% was applied