SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

2-(2*H*-Benzotriazol-2-yl)-p-cresol

EC No 219-470-5

CAS No 2440-22-4

Evaluating Member State(s): Czech Republic

Dated: 01 March 2017

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2016

Member State concluded the evaluation without any further need to ask more information from the registrants under Article 46(1) decision.

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Contents

Part A. Conclusion

1. CONCERN(S) SUBJECT TO EVALUATION

2-(2H-Benzotriazol-2-yl)-p-cresol was originally selected for substance evaluation in order to clarify concerns about:

- skin sensitizer,
- exposure assessment.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

The competent authority of Czech Republic notes that similar type of benzotriazoles used as UV-absorbers have been included in the candidate list of substances of very high concern due to PBT/vPvB and endocrine disrupting properties. However, those properties were not in the focus of this particular substance evaluation of EC 219-470-5. Czech Republic finds that it would be more appropriate to consider such substances together with other Member States in a larger group than individually. In this evaluation only screening assessment of these features has been made.

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarised in the table below.

Table 1

CONCLUSION OF SUBSTANCE EVALUATION Conclusions	Tick box
Need for follow-up regulatory action at EU level	
Harmonised Classification and Labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action at EU level	x

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

4.1.1. Harmonised Classification and Labelling

Self-classified as Skin Sens. 1B; no further action needed

4.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not applicable.

4.1.3. Restriction

Not applicable.

4.1.4. Other EU-wide regulatory risk management measures

Not applicable.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Table 2

REASON FOR REMOVED CONCERN The concern could be removed because	Tick box
Clarification of hazard properties/exposure	x
Actions by the registrants to ensure safety, as reflected in the registration dossiers (e.g. change in supported uses, applied risk management measures, etc.)	

All available information (registration dossier, Chemical Safety Report and literature data and review) was used to clarify the concerns. The available information is sufficient and reliable to conclude the substance evaluation.

The following conclusions were reached:

Skin sensitization

Self-classification of 2-(2H-Benzotriazol-2-yl)-p-cresol as Skin Sens. 1B is considered by the eMSCA to be appropriate and therefore no further action at EU level is proposed.

Exposure assessment

Exposure scenarios were processed using CHESAR software. The structure of exposure scenarios including descriptors was taken from the registration dossier and the CSR for 2-(2H-Benzotriazol-2-yl)-p-cresol.

Estimated exposure to the substance seems to be under control. Based on the available data it appears that all the exposure values are below the derived DNEL(s) and all the RCRs (including those for combined exposures) are below 1. Therefore the eMSCA considers that the risks are controlled.

5.2. Other actions

Not applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not applicable, see section 5.

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

2-(2H-Benzotriazol-2-yl)-p-cresol was originally selected for substance evaluation in order to clarify concerns about:

- skin sensitizer,
- exposure assessment.

Table 3

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Skin sensitization	Self-classified as Skin Sens. 1B; no further action needed
Exposure and RMM	concern not substantiated

7.2. Procedure

2-(2H-Benzotriazol-2-yl)-p-cresol was included (22 March 2016) in the Community rolling action plan (CoRAP) for substance evaluation. Czech Republic (evaluating Member State) started the evaluation in March 2016.

Relevant data available in the CSR and the registration dossier were evaluated in relation to specified concerns. For further information the eMSCA conducted also a literature search.

Based on the gathered information, it was concluded that data are sufficient for the purpose of this substance evaluation.

Skin sensitization data collected in the registration dossier were assessed with respect to their reliability (GLP, human × animal, guideline). After consideration of all available data the eMSCA concluded that self-classification Skin Sens. 1B, referred in the registration dossier, is appropriate.

The exposure of industrial and professional workers and consumers was estimated using CHESAR software in connection with the IUCLID dataset. The structure of exposure scenarios including descriptors and main conditions of use was taken from the registration dossier and the CSR for 2-(2H-Benzotriazol-2-yl)-p-cresol.

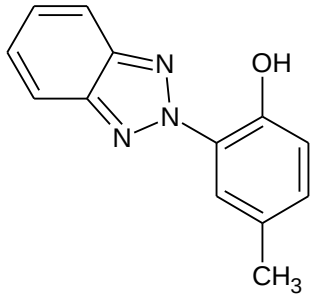
7.3. Identity of the substance

Table 4

SUBSTANCE IDENTITY	
Public name:	2-(2H-Benzotriazol-2-yl)-p-cresol
EC number:	219-470-5
CAS number:	2440-22-4
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	$C_{13}H_{11}N_3O$
Molecular weight range:	225.25
Synonyms:	ADK Stab LA 32, Drometrizole, Tinuvin P, Benazol P, Benazol II, Mark LA 32, Seikalizer AZ, Sumisorb 200, Viosorb 520, Uvinul 3033P, Lowilite 55, Arelite BT10, Evesorb 71, Cyasorb UV5365, Uvasorb SV

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



7.4. Physico-chemical properties

Table 5

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	yellowish powder
Vapour pressure	1.46×10^{-5} Pa (20°C)
Water solubility	0.173 mg/l (20°C)
Partition coefficient n-octanol/water (Log Kow)	4.20 (25°C, pH=6.3)
Flammability	not flammable
Explosive properties	not explosive
Oxidising properties	not oxidising

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Granulometry	median: 449 µm
Melting point	130°C
pH	6 (1 % water suspension)
Thermal stability	stable

7.5. Manufacture and uses

7.5.1. Quantities

Table 6

AGGREGATED TONNAGE (PER YEAR)				
☐ 1 – 10 t	☐ 10 – 100 t	☐ 100 – 1000 t	☒ 1000- 10,000 t	☐ 10,000-50,000 t
☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☐ Confidential

7.5.2. Overview of uses

2-(2H-Benzotriazol-2-yl)-p-cresol is an ultraviolet light absorber. It is used for ultraviolet protection in a wide variety of polymers, plastics, elastomers, adhesives, polycarbonates, polyurethanes, and some cellulose esters and epoxy.

The list of exposure scenarios is given in the Table 7 in Part C – Confidential Annex.

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

2-(2H-Benzotriazol-2-yl)-p-cresol is not harmonized classified.

7.6.2. Self-classification

Self-classification was based on the test results presented in registration dossier.

Classification: Skin Sens. 1B; H317
Aquatic Chronic 1; H410

According to Regulation 1272/2008 and pursuant to Daphnia magna Reproduction test result, the multiplication factor M = 1 should be used for environmental classification of this substance.

7.7. Environmental fate properties

Not relevant for this evaluation.

7.8. Environmental hazard assessment

Not relevant for this evaluation.

7.9. Human Health hazard assessment

7.9.1. Toxicokinetics

Two toxicokinetic studies are available[31,32] in the registration dossier. Both of them follow the OECD TG 417 principles. On basis of these assays it was found that a considerable part of the evaluated substance is absorbed from the gastrointestinal tract into the organism.

A large part of the administered dose (64 – 69 % according to radioactivity) was presented in the gastrointestinal tract at 6 hours after administration to rats. Nearly the complete amount of the administered substance (94 %) was excreted after 168 hours (69 % in urine, 25 % in faeces), but cca 90 % of the substance was excreted already during the first 48 hours after administration. Maximal concentrations of the evaluated substance (according to radioactivity) was determined in kidney and liver (except gastrointestinal tract).

Metabolites are not assessed in the reports but due to the low degradability of 2-(2H-Benzotriazol-2-yl)-p-cresol (0 – 2 % during 28 days according to carbon dioxide evolution test[13]) it can be expected that the larger part of the substance passes through the organism in unchanged form.

Based on results of the two toxicokinetic tests in rats, it can be concluded that tendency to accumulate in organism of the evaluated substance is negligible.

7.9.2. Acute toxicity and Corrosion/Irritation

Not relevant for this evaluation.

7.9.3. Sensitisation

There are a number of studies on skin sensitisation for 2-(2H-Benzotriazol-2-yl)-p-cresol in the registration dossier. The key study in this dossier is based on Guinea Pig Maximisation Test[4] (GPMT), it was carried out under GLP according to OECD TG 406 (Skin Sensitisation). The treated group had 80 % positive responses after 24 hours and 90 % positive responses after 48 hours, unfortunately, the intensity of allergic reactions of individual animals was not provided. The incidence of positive responses in negative control group (1/10 after 24 h; 2/10 after 48 h) is not clarified. Frequency of positive responses would be affected by relative high dose level (20 %) of the test substance which was used in challenge part of this test.

The positive result was also recorded in another study using the GPMT assay[5] with reliability 4. In this paper several potential skin sensitizers are compared. 2-(2H-Benzotriazol-2-yl)-p-cresol, by comparison with other sensitizing substances, is a compound having a relatively weak sensitizing effect but a low elicitation threshold.

Skin sensitisation test results, performed by the LLNA method, were published in the public literature (reliability 3). According to one of these articles the result of the LLNA assay was negative[6]. The second assay[7] had a positive result, but this LLNA study was not performed in accordance with standard procedures – before performing the test the experimental animals were treated by subcutaneous injection of the test substance, which could substantially affect the test result.

Besides assays on animals, there are clinical studies carried out on human volunteers[10,11]. Several tens of volunteers were treated using the epicutaneous patch test with repeated

challenge exposure. In both of these studies the results were negative. Reliability of both of these studies is questionable because both studies are rather old (the beginning of 1960s), but the basic test conditions are listed (reliability 2).

There are also some case studies published of allergic reactions to various components of clothing, in which the test substance was contained[8,9].

The registrants have classified the 2-(2H-Benzotriazol-2-yl)-p-cresol, pursuant to Regulation No. 1272/2008 (CLP), as **Skin Sens. 1B**. Based on the available information, the eMSCA can support this classification.

7.9.4. Repeated dose toxicity

The key study for long-term toxicity assessment appears to be the chronic toxicity assay in rodents as this study covers almost whole of the life-span of tested animals. The study[1] was carried out similar to OECD 452 (Chronic Toxicity Studies) and it is marked as key study with reliability 1. Used concentrations (dosed in diet) 100, 300, 1000 and 3000 ppm cover doses approximately from 4 to 169 mg/kg/day. The NOEL = 1000 ppm (corresponding dose is 47 mg/kg/day for male and 58 mg/kg/day for female rats) in this assay is based on reduction of body weight gain. Besides this effect some other specificity was found using more accurate statistic method. There were found increase in kidney and thyroid gland weight for female rats – both without dose-response relationship.

In an earlier test[2] (90-day sub-chronic oral test in rats) were found increase in weight of liver and kidneys for both sexes. Specifically for male rats was recorded slight reduction in weight of testes; for female rats slight decrease in weight of adrenal gland. All of these effects were without histopathological changes. Recorded NOEL = 0.2 % (increase in liver weight), corresponds to dose cca 100 mg/kg/day. This study is considered as key study too (reliability 2).

A similar test of sub-chronic oral toxicity in dogs (key study, reliability 1) was carried out later. This test[3] was extended by the recovery period (28 days) after the treatment period (90 days). The NOEL = 1000 ppm (in diet) was established on the base increased liver weight and clinical chemistry changes at middle dose (3000 ppm). Moreover, reduced food consumption for both sexes and decreased relative thyroid weight for male dogs were reported at the highest dose (10 000 ppm). Increased liver weight was not observed for dogs at the end of recovery period.

Similar results were obtained at an older sub-chronic study[12] with dogs which is marked as supporting study (reliability 3). In this assay no reversibility of observed effects is reported. A NOEL = 1000 ppm (cca 33 mg/kg/day) was established based on increased liver weight and clinical chemistry changes.

The most frequent observed effect is increased weight of liver, usually without histopathologic findings. Considering that this feature was not associated with any specific adverse effect and these changes were reported as reversible[3,14,27] (if recovery phase was a part of the test), it can be regarded as a common reaction of the organism to increased uptake of the evaluated substance.

There was no evidence of any unambiguous specific adverse effects in relation to the evaluated substance, 2-(2H-Benzotriazol-2-yl)-p-cresol. Based on the available information the eMSCA concludes that there is no reason to classify it as specific target organ toxicant following repeated exposure.

7.9.5. Mutagenicity

There are six *in vitro* and five *in vivo* assays of mutagenicity tests of 2-(2H-Benzotriazol-2-yl)-p-cresol in this registration dossier. These studies have different reliability.

Results of Ames' test reverse gene mutation in bacteria (*in vitro*) were negative in all studies, with and without metabolic activation[20,21,22,23]. Although these assays are of

different quality and reliability, the key study result is negative (reliability 2) and results of the other studies (supporting studies, reliability 3 and 4) are negative too. The results of all tests are consistent and do not contradict.

Another two *in vitro* assays are cited in the Action Memorandum US EPA[26] about reassessment of two inert substances. In an *in vitro* assay of rat primary hepatocyte cultures a dose-related increase in unscheduled DNA synthesis was reported. Positive mutagenicity result were reported in *in vitro* mouse lymphoma assays with metabolic activation, but not without metabolic activation. Further details are not available.

In the registration dossier two *in vivo* mammalian bone marrow chromosomal aberration assays[15,20] (according to OECD TG 475) are listed, one of which is regarded as key study[15] (reliability 1). The second study[20] is poorly described in public literature (reliability 4). Results of these two *in vivo* tests were negative.

Another *in vivo* key study[24] was performed according to OECD TG 474 (Mammalian Erythrocyte Micronucleus Test). Some minor deviations from the standard procedure were noted (number of bone marrow cells is given instead number of erythroblasts, lower number of animals per dose). This assay with reliability 2 gave negative result.

A dominant lethal assay[25], carried out according to OECD TG 478, is listed as supporting study with reliability 2. The positive control test was not a part of this assay, but the reference to the positive control tests, performed in the same laboratory at the same time by the same people, is cited in the endpoint study record. The result of this assay is negative too.

For the *in vivo* assays it is not explicitly confirmed that the test substance reaches the bone marrow cells. However, based on the results of the toxicokinetic assays (excretion via urine) and long-term toxicity (increased liver weight) it can be assumed that the test substance (at least partially) is absorbed by the organism, it is present in the blood stream and effects on the bone marrow can be assumed.

No evidence of carcinogenicity was recorded, which may indicate non-mutagenic character of the evaluated substance.

In summary: All key studies gave negative results. The results of other supporting studies are generally consistent with the results of key studies.

Based on the available data the eMSCA does not see any specific concern for mutagenicity.

7.9.6. Carcinogenicity

Carcinogenicity of 2-(2H-Benzotriazol-2-yl)-p-cresol was assessed[16] by OECD Guideline 451: Carcinogenicity studies (mouse, oral (food)). Administered doses that corresponded intake 0.8, 6.6 and 63 mg/kg/day caused no deaths, nor increased incidence proliferative or neoplastic lesions was observed, neither inflammatory nor degenerative changes were reported.

Similar results were observed during chronic oral toxicity test in rats[1] (according to OECD Guideline 452: Chronic Toxicity Study). In this assay doses corresponding to an intake of cca 5, 15, 52 and 155 mg/kg/day were administered. No death was observed, nor significant clinical changes, neither other signs of the increased incidence cancer or precancerous neoplasms.

A supportive study[17] was conducted in 1961 when 2-(2H-Benzotriazol-2-yl)-p-cresol was administered to 50 female mice via a single subcutaneous dose and subsequently the experimental animals were fed on tested substance in diet (0.5 mg/animal/day) until the natural death of animals. Some of the animals were autopsied after death – no increased incidence of tumors was found.

On the basis of available information, there is no indication that 2-(2H-Benzotriazol-2-yl)-p-cresol would be a carcinogen.

7.9.7. Toxicity to reproduction (effects on fertility and developmental toxicity)

The screening study, conducted according to OECD TG 422 (Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test), is reported in the submitted CSR[14]. As the whole study is in Japan language, information included in the registration dossier are based on an English abstract. However, conclusion of the study is formulated: no effect of the compound was observed on the reproductive performances.

Fertility

In a sub-chronic assay in rodents[2] (similar to OECD TG 408: Repeated Dose 90-day Oral Toxicity in Rodents), reported in the registration dossier, a slight reduction in relative testes weight at doses 500 and 2500 mg/kg/day was observed (without histopathology findings).

The chronic assay in rodents[16] was performed according to OECD TG 452 (Chronic Toxicity Studies). Gross pathology and organ weight findings was a part of this test. During this assay no significant effect on reproductive organs was reported.

Another sub-chronic test noted in the registration dossier was conducted in dogs (similar to OECD TG 409 - Repeated Dose 90-Day Oral Toxicity in Non-Rodents). There was no effect detected on reproductive organs.

Despite a slight decrease in relative weight of testes observed in the sub-chronic assay in rodents, the eMSCA concludes that based on the available information there is no specific concern related to fertility.

Developmental toxicity

Besides the screening assay (OECD TG 422) listed above, two studies of developmental toxicity are presented in the registration dossier. Both of them were performed similar to OECD TG 414 (Prenatal Developmental Toxicity Study).

The first study[18] was performed in rats (oral exposure) and a NOEL ≥ 1000 mg/kg/day (teratogenicity) was determined. Negligible increase in the number of complete ossification of sternebrae and phalangeal bones compared to the control group were noted exclusively at the middle dose group.

The second study[19] was performed in mice (oral exposure as well). Increased incidence of the completed ossification of sternebrae and phalangeal bones at the lowest dose group was observed in this assay too. As this effect was recorded only at the lowest dose group and has no associate with any developmental disorder, it was not considered an irregularity in fetal development. NOEL ≥ 1000 mg/kg/day (developmental toxicity) was determined in this assay.

In both of these assays was reported earlier ossification of sternebrae and bones of fingers of limbs. These effects were observed at lowest or middle dose but it was not observed at the highest dose. Earlier ossification presumably has not a negative influence on subsequent development of fetuses. In neither assay the dose-response relationship for these effects could be demonstrated, so that they have rather the character of accidental variation.

Significant influence on the course of pregnancy (death of the developing organism, structural abnormality, growth disorders, or functional deficiency) was not observed in any assay.

According these findings the eMSCA concludes that there is no concern for developmental toxicity.

7.9.8. Hazard assessment of physico-chemical properties

Not relevant for this evaluation.

7.9.9. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptors for critical health effects

Not relevant for this evaluation.

7.9.10. Conclusions of the human health hazard assessment and related classification and labelling

The eMSCA supports classification as **Skin Sens. 1B**.

7.10. Assessment of endocrine disrupting (ED) properties

Not in the scope of this evaluation.

7.11. PBT and vPvB assessment

Not in the scope of this evaluation.

7.12. Exposure assessment

The eMSCA has carried out an exposure assessment based on the information provided in the registration dossier and agrees with the Registrants' assessment and concludes that there is no concern for occupational exposure or consumer health.

Exposure scenarios were processed using CHESAR software (version 3.0.0). The structure of exposure scenarios including descriptors was taken from registration dossier and CSR for 2-(2H-Benzotriazol-2-yl)-p-cresol.

The evaluated substance is slightly volatile solid with a melting point higher than 100°C, negligibly soluble in water.

More detailed information are stated in Part C – Confidential Annex.

7.12.1. Human health

The evaluated substance is not harmonised classified in Annex VI of CLP but the registrants self-classified this substance, on the basis of the information gathered in the registration dossier, as skin sensitizing (Skin Sens 1B). Exposure, according to the presented exposure scenarios, is expected for both workers and consumers.

Workers

Industrial workers only come into contact with 2-(2H-Benzotriazol-2-yl)-p-cresol as such in the manufacture and formulation of the mixtures (master batches). Dermal and inhalation exposure is anticipated. Workers exposure can be effectively reduced via operational conditions (ventilation, closed processes, etc.) or using personal protection equipment (goggles, gloves, etc.).

Consumers

Consumers mostly come into contact with products in which the evaluated substance is firmly incorporated in low concentrations. Thus, prevailing exposure for consumers may be expected via dermal route.

Human exposure estimates are based on ECETOC TRA3 included in the CHESAR software.

7.12.2. Environment

2-(2H-Benzotriazol-2-yl)-p-cresol is a widely used substance which gets into the environment mainly through products in which it is included as UV-absorber. This substance is not readily degradable and because of this persists a long time in the environment.

According to information gathered in the registration dossier, the potential to bioaccumulation of the evaluated substance is not high, so that its accumulation through the food chain or secondary poisoning is unlikely.

The data that have been published in literature[37,38,39] suggests that real concentrations of the evaluated substance in the environment are in the range of units to tens nanograms per litre.

Significant reduction of the incidence in the environment may take place through incineration of the STP sludge that is declared in several ES.

Environmental exposure estimates are based on EUSES (version 2.1.2) included in the CHESAR software.

7.13. Risk characterisation

7.13.1. Human health

Some risks for human health, arising from the use of 2-(2H-Benzotriazol-2-yl)-p-cresol, have been identified. This substance is classified as Skin Sensitizing (category 1B). Due to the wide use of the evaluated substance, exposure is expected.

The structure of exposure scenarios including descriptors was taken from the registration dossier and the CSR for 2-(2H-Benzotriazol-2-yl)-p-cresol. Required RMMs are noted for each scenario (see Part C – Confidential Annex). Under circumstances which are specified in these scenarios all risks resulting from the use of the evaluated substance are under control (relevant RCRs are below 1), therefore the eMSCA concludes that there is no concern for occupational exposure nor consumer health.

7.13.1.1. Workers

For all exposure scenarios and for all eligible routes of exposure, including combined exposure, RCRs appear well below 1. eMSCA in the calculation took into account conditions (including RMM) specified by registrants. Where necessary, needful RMMs have been supplemented. These conditions are listed below (see Part C – Confidential Annex).

For all exposure scenarios and for all eligible routes of exposure, including combined exposure, RCRs are below 1.

7.13.1.2. Consumers

For all exposure scenarios and for all eligible routes of exposure, including combined exposure, RCRs are below 1.

7.13.1.3. Indirect exposure of humans via the environment

For all exposure scenarios and for all eligible routes of exposure including combined exposure, RCRs are below 1.

7.13.2. Environment

With respect to the environment, 2-(2H-Benzotriazol-2-yl)-p-cresol is self-classified as Aquatic Chronic (category 1). The total quantity of the manufactured substance is in the range 1 000 to 10 000 tonnes per year. Due to high annual production volume and main use (UV-stabilizer), wide dispersive use of the evaluated substance with a high potential for environmental exposure can be expected.

As the evaluated substance, according to screening test, is not readily biodegradable, adverse effect on the environment can be expected. However, it can be assumed that actual concentrations in the environment should be less than the estimated concentrations in the table No. 8, as 2-(2H-Benzotriazol-2-yl)-p-cresol is most of its life-cycle bound in materials of which it is released gradually during their degradation. This corresponds to the results reported in the literature[37,38,39] as measured concentrations in seawater, sewage treatment plant or soil are in the range of units to tens ng/l.

The comparison of PECs to the relevant PNECs, calculated by the eMSCA, leads to the conclusion that risk for the environment posed by 2-(2H-Benzotriazol-2-yl)-p-cresol is controlled (see table 205 in Part C - Confidential Annex).

7.14. References

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(The full list of references is given in Part C – Confidential Annex)

7.15. Abbreviations

CAS	Chemical Abstract Services
CoRAP	Community Rolling Action Plan
CLP	Regulation (EC) No. 1272/2008
CSR	chemical safety report
DNEL	derived no effect level
ECHA	European Chemicals Agency
eMSCA	evaluating Member State Competent Authorities
ES	exposure scenario
GLP	good laboratory practice
GPMT	guinea pig maximisation test
NO(A)EL	no observed (adverse) effect level
OECD (TG)	Organisation for Economic Co-Operation and Development (Testing Guideline)
PBT/vPvB	persistent, bioaccumulative and toxic / very persistent and very bioaccumulative substances
PNEC	predicted no effect concentration
REACH	Regulation (EC) No. 1907/2006
RMM	risk management measuring
UV	ultraviolet
UVA	ultraviolet absorber
US EPA	United States Environmental Protection Agency

Part C. Confidential Annex has been removed from the published report