Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

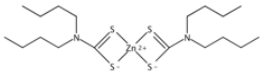
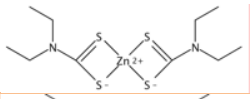
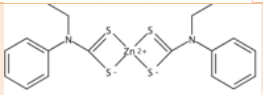
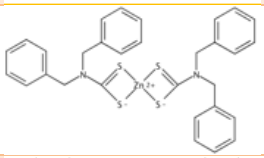
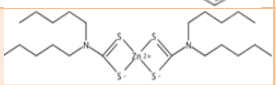
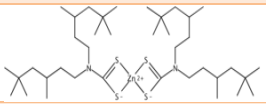
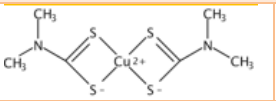
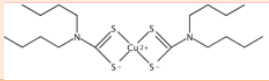
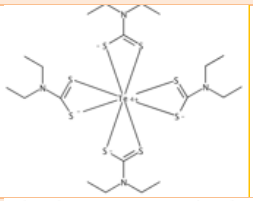
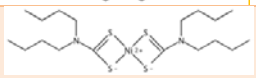
Group Name: Dithiocarbamate Complexes

General structure:

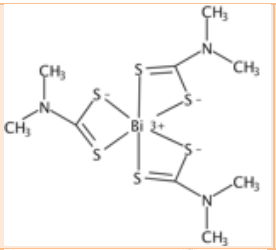
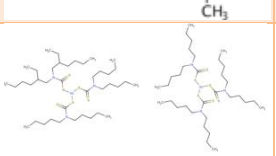
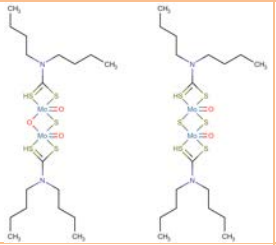
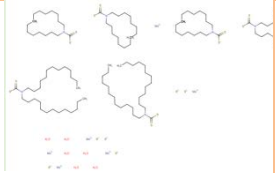
Revision history

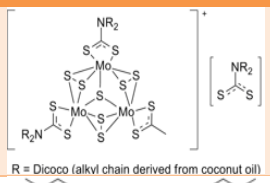
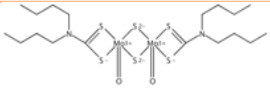
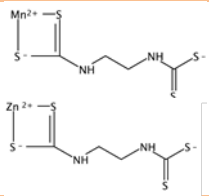
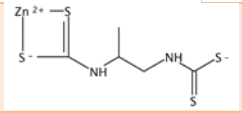
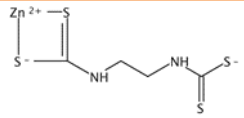
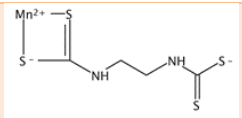
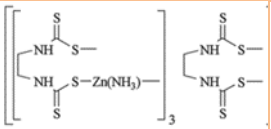
Version	*Date*	*Description*
1.0	24 September 2021	

Substances within this group:

EC / List number	CAS number	Substance name [and / or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Zinc (Zn) dithiocarbamate (DTC) complexes				
205-232-8	136-23-2	zinc bis(dibutyldithiocarbamate)	ZDBC 	Full, >1000
205-288-3	137-30-4	Ziram	-	Full, 100-1000
238-270-9	14324-55-1	zinc bis(diethyldithiocarbamate)	ZDEC 	Full, >1000
238-677-1	14634-93-6	zinc bis(N-ethyl-N-phenyldithiocarbamate)		Full, 1-10
238-778-0	14726-36-4	zinc bis(dibenzyldithiocarbamate)		Full, >1000
239-370-5	15337-18-5	zinc bis(dipentyldithiocarbamate)		Full, not (publicly) available
283-381-8	84604-96-6	bis[bis(3,5,5-trimethylhexyl)dithiocarbamate-S,S']zinc		Full, not (publicly) available
Copper (Cu) DTC complexes				
205-287-8	137-29-1	copper bis(dimethyldithiocarbamate)		Full, not (publicly) available
237-695-7	13927-71-4	bis(dibutyldithiocarbamato-S,S')copper	CDBC 	Full, not (publicly) available
Iron (Fe), tellurium (Te) and nickel (Ni) DTC complexes				
238-484-2	14484-64-1	Ferbam	-	Full, not (publicly) available
244-121-9	20941-65-5	tetrakis(diethyldithiocarbamato-S,S')tellurium		Full, not (publicly) available
237-696-2	13927-77-0	nickel bis(dibutyldithiocarbamate)		Full, not (publicly) available

[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

EC / List number	CAS number	Substance name [and / or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
Bismuth (Bi) and antimony (Sb) DTC complexes				
244-299-8	21260-46-8	bismuth tris(dimethyldithiocarbamate)		Full, not (publicly) available
948-063-1	-	Reaction mass of tris(dipentyldithiocarbamato-S,S')antimony and [bis(2-ethylhexyl) dithiocarbamato-S,S']bis(dipentyldithiocarbamato-S,S')antimony and bis[bis(2-ethylhexyl) dithiocarbamato-S,S'](dipentyldithiocarbamato-S,S')antimony and tris[bis(2-ethylhexyl)dithiocarbamato-S,S']antimony		Full, not (publicly) available
Molybdenum (Mo) DTC complexes				
270-180-5	68412-26-0	Molybdenum, bis(dibutylcarbamodithioato) di-μ-oxodioxodi-, sulfurized		Full, not (publicly) available
434-650-5	-	PDN 5203 Active Ingredient (AI)	-	NONS, not (publicly) available
441-570-4	-	Reaction mass of Di-μ-thio-[{bis(2-ethylhexyl)carbamato-S,S'}oxo molybdenum(V)], Di-μ-thio-[{(2-ethylhexyl)carbamato-S,S'}{(branched ditridecyl)carbamato-S,S'}oxo molybdenum(V)] and Di-μ-thio-[{bis(branched ditridecyl)carbamato-S,S'}oxo molybdenum(V)]		Full, not (publicly) available

EC / List number	CAS number	Substance name [and / or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t / y) [1]
457-320-2	-	long chain alkyl thio carbamide metal complex		Full, not (publicly) available
825-571-0	60428-79-7	Molybdenum, bis(N,N-dibutylcarbamodithioato-κS,κS')dioxodi-μ-thioxodi-, stereoisomer		Full, not (publicly) available
Zinc (Zn), manganese (Mn) ethylene / propylene bis DTC complexes				
616-995-5	8018-01-7	mancozeb (ISO); manganese ethylenebis (dithiocarbamate) (polymeric) complex with zinc salt		Full, not (publicly) available
620-365-5	9016-72-2	polymeric zinc propylenebis(dithiocarbamate); propineb (ISO)		C&L notification
235-180-1	12122-67-7	Zineb		C&L notification
235-654-8	12427-38-2	Maneb		C&L notification
618-430-8	9006-42-2	zinc ammoniate ethylenebis(dithiocarbamate)-poly[ethylenebis(thiuramdisulfide)]; metiram		C&L notification

This table contains also group members that are only notified under the CLP Regulation. However, the list is not necessarily exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[2].

[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the dithiocarbamate (DTC) ligands with metal ions moiety.

The group consists of 24 coordination complexes[3] of which 19 have full registrations. One substance is a notified new substances (NONS) and 4 substances are not registered but are notified under the CLP Regulation. The largest group of the dialkyl dithiocarbamate complexes are zinc complexes (7) followed by molybdenum (5) and copper (2). Other metals are bismuth, nickel, iron, tellurium, and antimony (1 complex of each). As the metal ions impact on hazard properties and uses, sub-groups were formed around different (groups) of metal ions. In addition, a further sub-group contains five ethylene/propylene bis dithiocarbamate complexes (complexed with manganese and/or zinc), from which four are not registered; these four were added to the group as their hazards are reflected by harmonised classifications available for these known active substances (fungicides). The organic part varies from simple aliphatic derivatives (methyl, ethyl, butyl), branched aliphatic (e.g. 2-ethylhexyl), fatty acid derivates (coco) through aromatic (phenyl, benzyl) to mixed ones (e.g. ethyl and phenyl). This group shows structural similarity to the group of dithiocarbamate salts and S-bridged bis(dithiocarbamates).

Dithiocarbamate (DTC) ligands show strong metal binding capacity. They may coordinate to the metals in different ways (bidentate, monodentate). These ligands can stabilize a high oxidation state of metal ions in complexes.

Metal complexes are in general thermodynamically stable, binding strengths of a DTC ligand to the metal ions seem to follow the Irving-Williams series (Mn < Fe < Ni < Cu > Zn). The oxidation state of the metal, nature of the coordinating ligand and the eventual coordination geometry affects the physicochemical properties and thus their reactivity in biological systems.

Based on information reported in the REACH registration dossiers, the majority of substances is used as vulcanisation accelerators or processing aids in the production of rubber and plastics in industrial settings and may be present in and released from articles. On the other hand, the molybdenum DTC complexes and the antimony DTC complex are exclusively used as corrosion inhibitors or lubricating agents in lubricants and greases, including uses by professional workers and consumers. Two substances (Ferbam and Mancozeb) are only used in formulation (of biocidal or plant protection products).

Three substances in the group can be used in the EU as active substances in biocidal products (BP) or plant protection products (PPP), please see table below.

Substance	REACH registration available	Approval status under PPPR	Approval status under BPR
EC 205-288-3 Ziram	yes, but use in PPP not reported	approved (until April 2022)	
List No. 618-430-8 Metiram	no	approved (until Jan 2022	
EC 235-180-1 Zineb	no		approved (until Dec 2025)

Ferbam (EC 238-484-2), Mancozeb (List No. 616-995-5), Propineb (List No. 620-365-5) and Maneb (EC 235-654-8) are known biocidal active substances (fungicides) but not approved for

[3] A coordination complex consists of a central atom or ion, which is usually metallic and is called the coordination centre, and a surrounding array of bound molecules or ions, that are in turn known as ligands or complexing agents (source: Wikipedia).

use in BP or PPP in the EU. Ferbam and Mancozeb are registered under REACH for use in the formulation of BP and/or PPP, which may then be exported and used outside the EU.

Substance evaluation is ongoing (started 2012) for Ziram (EC 205-288-3) with the initial grounds for concern being potential endocrine disruption. Substance evaluation for bis(dibutyldithiocarbamato-S,S')copper (CDBC, EC 237-695-7) was started in 2020 for initial reproductive toxicity, endocrine disruption and PBT/vPvB concerns.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management –restriction for carcinogenicity, reproductive toxicity, ED, skin sensitiser STOT RE and/or PBT/vPvB hazards due to the potential for release/ exposure of the DTC complexes of Zn, Cu, Fe, Te, Ni and Mo as well as Mancozeb.

Based on ECHA's assessment of currently available hazard information, for several substances experimental data indicate developmental toxicity and/or endocrine disrupting (ED) activity, which is currently followed-up by substance evaluation (SEv) for two substances (Ziram, EC 205-288-3 and CDBC, EC 237-695-7). Due to structural similarity these hazard findings were applied also to other dithiocarbamate (DTC) complexes with Zn and Cu metal ions. Data generation is ongoing or proposed for several substances to confirm developmental toxicity and/or ED activity. In addition, based on experimental data for some, combined with systemic availability and structural similarity (based on DTC moiety), these hazards seem to apply more widely to DTC complexes with Fe, Te and Ni metal ions. Furthermore, ten substances in the group (also including Mo DTC complexes) have likely PBT/vPvB properties and four have carcinogenic properties that may warrant a classification as Carc. 2. Most substances in the group are skin

sensitisers. Mancozeb (List No. 616-995-5) has a recently amended harmonised classification[4] including, among other endpoints, classification as Repr. 1B and Carc. 2. EFSA concluded that the substance meets the criteria for an ED.

The majority of substances are used as vulcanisation accelerators, stabilisers or antioxidants in the production of rubber (incl. latex) and plastics taking place in industrial settings. Vulcanisation accelerators usually react during rubber production but can be present in articles in residual amounts[5]; whereas stabilisers and antioxidants may be intended to be present in the plastic/rubber articles produced. However, there is uncertainty about actual concentrations of these substances in articles, which may likely be released from rubber or plastic articles. Only two of these substances (ZDBC, EC 205-232-8 and EC 239-370-5) also have professional and consumer uses in either coatings, adhesives or lubricants, greases reported. Ziram (EC 205-288-3) is an approved active substance for use in PPP in the EU. Although not reported in registration dossiers, uses in plant protection products and a related potential for exposure for professional workers and intended releases into the environment cannot be excluded**Error! Bookmark not defined.**.

The Mo DTC complexes are exclusively used in lubricants, greases or hydraulic fluids as corrosion inhibitors or lubricating agents including uses by professional workers and consumers.

Ferbam (EC 238-484-2) and Mancozeb (List No. 616-995-5) are known biocidal active substances, for which only the use in the formulation of BP and/or PPP is reported in registrations. As these substances are, however, not approved as active substances for use in BP and PPP in the EU, we assume that formulated products may be exported and used outside the EU[6]. The potential for exposure and releases into the environment is considered high for these substances, either from professional and consumer uses or from possible releases from plastic or rubber articles. For Ferbam and Mancozeb only used in industrial settings the potential for exposure and release may be limited.

We propose to wait for the outcome of SEv and the data already requested and/or to be requested under compliance check (CCH) to clarify the reproductive toxicity, ED and PBT/vPvB properties for a number of substances, which can also be used to substantiate the read across to other substances in the group.

The first step of the regulatory risk management action proposed, should the hazards exist, is the confirmation of hazard via SVHC identification as PBT or ED[7] and via harmonised classification (CLH) as carcinogenic and/or reprotoxic.

SVHC identification and CLH are highly recommended as a step prior to restriction. In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold.

CLH i) will require company level risk management measures (RMM) for workers to be in place;

[4] Commission Delegated Regulation (EU) 2021/849 of 11 March 2021: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.188.01.0027.01.ENG. Mancozeb (index number 006-076-00-1) is classified as Carc. 2, Repr. 1B, STOT RE 2, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1.

[5] There are e.g. well known cases of occupational dermatitis caused by dithiocarbamate vulcanisation accelerators present in latex gloves described in literature.

[6] Ferbam is subject to the PIC Regulation (EU) 649/2012 (Annex 1, part 1), Mancozeb is proposed to be included in Annex I (parts 1 and 2) of the PIC Regulation with the next amendment.

[7] Note that the Commission published the new hazard classes in CLP (PBT/vPvB, PMT/vPvM, ED): CLP Delegated Act (europa.eu). Therefore, if/when these hazard classes will be implemented in CLP, instead of SVHC identification under REACH, these hazards may be confirmed via CLH. It is not yet clear when to use which way for the time being.

ii) is needed or highly recommended in support of further regulatory processes under REACH; and iii) would lead to generic restriction of the substance(s) in consumer mixtures by means of restriction entries 28 and 30.

is also a prerequisite to restrict the presence of the substances in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)).

CLH will also support regulatory action under other legislations. For instance, in this specific case

- harmonised classification as CMR cat. 1 would render the substances unacceptable co-formulants in biocidal products if present above the concentration limit leading to classification of the mixture as CMR cat 1 according to the Biocidal product regulation (EU) 528/2012.
- harmonised classification as CMR cat 1 would render the substances unacceptable co-formulants in Plant protection products if present above the concentration limit leading to classification of the mixture as CMR cat 1 according to the plant protection product regulation (EC) No 1107/2009.

The professional uses in coatings, adhesives or lubricants, greases and hydraulic fluids are expected to be widespread (at many sites and by many users) and typically non-contained and non-automated leading to releases to the environment and with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration leading to potential workers' exposure. In addition, professional users may be self-employed and therefore not covered by OSH legislation.

Consumers may be co-exposed to the substances used by professionals (coatings, adhesives or lubricants).

Therefore, a **restriction of the substances as such or in mixtures** (concentration limit in mixtures) used by consumers, industrial and professional workers is suggested after SVHC identification and CLH, with the aim to minimise or control emissions to the environment and exposure to humans.

In addition, the use of the most harmful substances (e.g. PBT/vPvB, CMR) by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability**Error! Bookmark not defined.**.

Moreover, potential exposure from articles needs further investigation. The need for restricting substances in articles used by professionals or consumers (reported for substances 205-232-8, 205-288-3, 238-270-9, 238-677-1, 238-778-0, 239-370-5, 283-381-8, 205-287-8, 237-695-7, 244-121-9, 237-696-2, 244-299-8, 441-570-4) should be considered in the context of the restriction of professional and industrial uses.

It is suggested to cover possibly also industrial uses as part of the restriction. However, the need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

Ferbam and Mancozeb may be added to the proposed restriction to address possible concerns from formulation[8] and potential future uses that would not fall under the BP or PPP Regulations. The substances could potentially be used to substitute some of the other substances proposed for restriction (e.g. in the use as vulcanisation accelerators). If it is confirmed that a Repr. 1B classification is warranted for Ferbam we propose to amend the CLH for this substance

[8] This may be in line with/support an aim of the Chemical Strategy for Sustainability to ban the export of substances, for which uses in the EU have been banned.

accordingly[9]. As for the other substances, we may want to re-assess whether industrial uses may be subjected to authorisation instead of restriction once more data have been generated.

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on carcinogenicity, mutagenicity, reproductive toxicity, ED, skin sensitiser, or aquatic toxicity hazards of the Bi DTC complex (EC 244-299-8).

Due to low tonnage it is not possible to clarify the potential hazards of substance Bi DTC complex (EC 244-299-8). Therefore, it is proposed that there is currently no need for EU RRM action on these substances. If the registration status changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

Based on currently available information, there is no need for (further) EU regulatory risk management for Sb DTC complex (List No. 948-063-1) and -ethylene/ propylene bis dithiocarbamate complexes (except Mancozeb).

Sb DTC complex (List No. 948-063-1) has low human health hazards and sufficient self-classification for aquatic toxicity. Ethylene/ propylene bis dithiocarbamate complexes (except Mancozeb) have no registrations under REACH e and they are covered by BP and PPP legislation.

The Sb DTC complex has unlikely C/M/R, ED and skin sensitisation hazards. However, the substance shows aquatic toxicity and has widespread uses in lubricants or greases including uses by professional workers and consumers. For industrial and professional uses of the Sb DTC complex, self-classification requires company level risk management measures (RMM) for environment to be in place. Adequate product labelling should in principle provide consumers with sufficient information to handle mixtures containing the substance correctly. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

Furthermore, the substance fulfils the screening criteria for PBT/vPvB properties. However, as it is only registered at low tonnage (1-10 t/y) no further data can be requested to clarify the hazard. Accordingly, the hazard information is considered inconclusive but no action is possible. In case the substance will get registered at a higher tonnage band we should initiate possible actions to clarify the hazard.

The ethylene/ propylene bis dithiocarbamate complexes in this group (except Mancozeb) are known biocidal active substances, have harmonised classifications (see Annex 1), have likely ED properties and have been evaluated under biocidal product and PPP legislation. No registrations under REACH are however available for these substances. Only Zineb (EC 235-180-1) is approved in the EU for use in biocidal products and Metiram (List No. 618-430-8) for use in PPP (until Jan 2022). Potential for exposure and release from those uses cannot be excluded**Error! Bookmark not defined.**. As the substances are not registered under REACH no information on uses is available. Therefore, the harmonised classifications and actions required under the Biocidal Product (Regulation (EU) 528/2012) and PPP legislation (Regulation EC 1107/2009) sufficiently address concerns that may be caused by these substances in potential uses in biocidal or plant protection products, for the substances approved for those uses in the EU.

In case registrations under REACH will be submitted for these substances, reporting further uses not covered by BP or PPP Regulations (e.g. some substances might also be used as vulcanisation accelerators), the need for further regulatory action may be re-considered.

[9] As the approval in the EU as active substance was withdrawn for Ferbam already years ago, a CLH would normally not be initiated as part of processes under the BP or PPP Regulations.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited.

Subgroup name, EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Zn DTC complexes 205-232-8 205-288-3 238-270-9 238-677-1 238-778-0 239-370-5 283-381-8	Known or potential hazard for reproductive toxicity, ED, skin sensitisation Known or potential hazard for carcinogenicity for 205-288-3 Known or potential hazard for STOT RE for 205-232-8, 205-288-3, 238-270-9, 238-677-1 and 283-381-8	Known or potential hazard for aquatic toxicity except for 283-381-8 Known or potential hazard for PBT/vPvB for 205-232-8, 283-381-8, 238-778-0 and 239-370-5	Industrial use in production of rubber and plastic. Professional and consumer uses of 205-232-8 in coatings, adhesives and 239-370-5 in lubricants, greases. Potential for exposure for workers and consumers and release from articles (with uncertainty).	**Need for EU RRM: Restriction** <u>Justification</u>: The harmonised classification as CR 1 – would lead to generic restriction of the substance(s) in consumer mixtures by means of restriction entry 28 and 30. The harmonised classification as CR 1 – will render the substances unacceptable co-formulants in biocidal and plant protection products if present above the concentration limit leading to classification.	**First step:** CCH for 239-370-5 and 283-381-8 **Next steps (if hazard confirmed):** CLH, SVHC identification, restriction
Cu DTC complexes 205-287-8 237-695-7	Known or potential hazard for reproductive toxicity, ED, skin sensitisation	Inconclusive hazard for PBT/vPvB for 205-287-8	Industrial use in production of rubber and plastic, 205-287-8 also in coatings, adhesives, inks, toners.		**First step:** CCH for 205-287-8, 237-695-7

Subgroup name, EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
		Known or potential hazard for aquatic toxicity for 205-287-8.	Potential for exposure for industrial workers and release from articles (with uncertainty)	Releases to the environment from consumer uses cannot be avoided. The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, these uses are typically non-contained and non-automated leading to releases to the environment. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.	**Next steps (if hazard confirmed):** CLH, SVHC identification, restriction
Fe, Te, Ni DTC complexes 238-484-2 (Ferbam) 244-121-9 237-696-2	Known or potential hazard for carcinogenicity, reproductive toxicity, ED, skin sensitisation Known or potential hazard for STOT RE for 237-696-3	Known or potential hazard for aquatic toxicity Known or potential hazard for PBT/vPvB for 244-121-9 and 237-696-2	Industrial uses of 237-696-2 (Ni), 244-121-9 (Te) in production of rubber. Potential for exposure for industrial workers and release from articles (with uncertainty). 238-484-2 (Ferbam) is used in formulation of biocidal and plant protection products.		**First step:** CCH **Next steps (if hazard confirmed):** CLH, SVHC identification restriction
Mo DTC complexes 270-180-5 434-650-5 441-570-4 457-320-2	Known or potential hazard for skin sensitisation for 434-650-5 and 457-320-2	Known or potential hazard for PBT/vPvB Known or potential hazard for aquatic toxicity for 457-320-2 and 270-180-5	Industrial, professional and consumer uses in lubricants, greases or hydraulic fluids (434-650-5 only used in industrial settings). Potential for exposure for workers and consumers and release to environment.		**First step:** CCH for 270-180-5, 457-320-2 and 825-571-0 **Next steps (if hazard confirmed):** SVHC identification, restriction

Subgroup name, EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
825-571-0				Industrial uses to be considered as part of the restriction. Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses.	
Mancozeb **616-995-5**	Known or potential hazard for carcinogenicity, reproductive toxicity, ED, STOT RE, skin sensitisation	Known or potential hazard for aquatic toxicity and ED	Formulation of plant protection products		**First step:** SVHC identification, restriction
Bi DTC complex 244-299-8	Inconclusive hazard	Inconclusive hazard	Industrial uses in production of polymers. Potential for exposure for industrial workers and release from articles (with uncertainty).	**Currently no need for EU RRM** <u>Justification:</u> Due to low tonnage no data generation is possible to clarify the hazards currently. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.	**First step:** CCH
Sb DTC complex	No hazard or unlikely hazard	Known or potential hazard	Industrial, professional and consumer uses in	**Currently no need for EU RRM**	No action

Subgroup name, EC number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
948-063-1		for aquatic toxicity	lubricants, greases or hydraulic fluids. Potential for exposure for workers and consumers and release to environment.	Justification: Harmonised/self-classification (will) require company level risk management measures (RMM) for environment to be in place.	
Zn, Mn ethylene/ propylene bis DTC complexes **(except Mancozeb)** 235-180-1 235-654-8 618-430-8 620-365-5	Known or potential hazard for ED, STOT RE, skin sensitisation except for 235-654-8 Known or likely hazard for reproductive toxicity for 235-654-8	Known or potential hazard for ED, aquatic toxicity (except 235-180-1 and 618-430-8)	Not registered Use of Metiram (618-430-8) as active substance in PPP and of Zineb (235-180-1) in BP and related potential for exposure for professional workers and release to environment cannot be excluded.	**Currently no need for EU RRM** Justification: Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status changes.	No action

Annex 1: Overview of classifications

Data extracted on 4 November 2020.

EC / List No	Harmonised classification	Classification in registrations
238-778-0	-	*Aquatic Chronic 4 H413*
238-677-1	-	*"Aquatic Acute 1 H400, M-factor: 10* *Aquatic Chronic 1 H410"*
205-288-3 Ziram	*"Acute Tox. 4 H302* *Acute Tox. 2 H330* *Eye Damage 1 H318* *Skin Sens. 1 H317* *STOT Rep. Exp. 2 H373, affected organs: liver, spleen, red blood cells* *STOT Single Exp. 3 H335, affected organs: Respiratory tract* *Aquatic Acute 1 H400, M-factor: 10* *Aquatic Chronic 1 H410"*	*"Acute Tox. 3 H301* *Acute Tox. 2 H330* *Eye Damage 1 H318* *Skin Sens. 1 H317* *STOT Rep. Exp. 2 H373, affected organs: liver, spleen, red blood cells* *STOT Single Exp. 3 H335, affected organs: Respiratory tract* *Aquatic Acute 1 H400, M-factor: 10* *Aquatic Chronic 1 H410"*
238-270-9	*"Acute Tox. 4 H302* *Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Skin Sens. 1 H317* *STOT Single Exp. 3 H335, affected organs: Lungs* *Aquatic Acute 1 H400, M-factor: 10* *Aquatic Chronic 1 H410, M-factor: 10"*	*"Acute Tox. 4 H302* *Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Skin Sens. 1 H317* *STOT Rep. Exp. 2 H373, affected organs: liver, spleen* *STOT Single Exp. 3 H335, affected organs: Lungs* *Aquatic Acute 1 H400, M-factor: 10* *Aquatic Chronic 1 H410, M-factor: 10"*
205-232-8	*"Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Skin Sens. 1 H317* *STOT Single Exp. 3 H335, affected organs: lungs* *Aquatic Acute 1 H400* *Aquatic Chronic 1 H410, M-factor: 10"*	*"Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Skin Sens. 1 H317* *STOT Single Exp. 3 H335, affected organs: lungs* *Aquatic Acute 1 H400* *Aquatic Chronic 1 H410, M-factor: 10"*
239-370-5	-	*Aquatic Chronic 4 H413*
283-381-8	-	*Aquatic Chronic 4 H413*
457-320-2	-	*"Skin Irrit. 2 H315* *Skin Sens. 1 H317* *Aquatic Chronic 3 H412"*
457-320-3	-	-
457-320-3	-	-

EC/ List No	Harmonised classification	Classification in registrations
270-180-5	-	*Aquatic Chronic 4 H413*
825-571-0	-	-
434-650-5	-	-
441-570-4	-	*Skin Irrit. 2 H315*
205-287-8	-	*"Acute Tox. 2 H330 Aquatic Acute 1 H400 Aquatic Chronic 2 H411"*
237-695-7	-	-
244-299-8	-	-
238-484-2 *Ferbam*	*"Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335, affected organs: respiratory tract Aquatic Acute 1 H400, M-factor: 10 Aquatic Chronic 1 H410, M-factor: 10"*	*"Acute Tox. 2 H330 Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 STOT Single Exp. 3 H335, affected organs: respiratory tract Aquatic Acute 1 H400, M-factor: 10 Aquatic Chronic 1 H410, M-factor: 10"*
244-121-9	-	*"Aquatic Acute 1 H400, M-factor: 10 Aquatic Chronic 1 H410"*
237-696-2	-	*"Carc. 2 H351 Eye Irrit. 2 H319 Aquatic Chronic 4 H413 STOT RE - insufficient informatin"*
948-063-1	-	*Aquatic Chronic 2 H411*
235-180-1 *Zineb*	*"Skin Sens. 1 H317 STOT Single Exp. 3 H335; Respiratory irritation"*	-
235-654-8 *Maneb*	*"Eye Irrit. 2, H319 Skin Sens. 1, H317 Acute Tox. 4, H332 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Repr. 2, HH361d"*	-
616-995-5 *Mancozeb*	*"Skin Sens. 1, H317 Repr. 2, H361d*** Aquatic Acute 1, H400 Aquatic Acute 1, M-factor=10 Proposed Carc. 2 Repr. 1B STOT RE 2 Skin Sens. 1*	-

EC/ List No	Harmonised classification	Classification in registrations
	Aquatic Acute 1 *Aquatic Chronic 1"*	
618-430-8 *Metiram*	-	-
620-365-5 *Propineb*	-	-

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 4 November 2020.

Main types of applications structured by product or article types	205-232-8	205-288-3	238-270-9	238-677-1	238-778-0	239-370-5	283-381-8	205-287-8	237-695-7	244-121-9	237-696-2	244-299-8	270-180-5	434-650-5	441-570-4	457-320-2	825-571-0	948-063-1
Rubber (and latex) production	F, I, **A**	F, I, **A**	I, **A**	I, **A**	F, I, **A**	I, **A**	I, **A**	F, I, **A**	I, **A**	I, **A**	I, **A**							
Plastic production	F, I, **A**					I, **A**	I, **A**		I, **A**			F, I, **A**						
Use in coatings, adhesives	F, I, **P**, **C**, **A**							F, I, **A**										
Lubricants, greases, hydraulic fluids						F, I, **P**, **C**							F, I, **P**, **C**	I	F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**	F, I, **P**, **C**
Metal working fluids						I, **P**												I
Inks and toners								F, I, **A**										

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release.

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 5 November 2020.

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
205-288-3	Yes					PPP
238-484-2						PIC

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

There are no relevant completed or ongoing regulatory risk management activities for the other substances.