Environmental Protection Authority
Te Mana Rauhī Taiao

APPLICATION FORM
REASSESSMENT

Application Form: HS8 Application for whether there are Grounds for a Reassessment of a Hazardous Substance

under section 62 of the Hazardous Substances and New Organisms Act 1996

Send by post to: Environmental Protection Authority, Private Bag 63002, Wellington 6140
OR email to: HSApplications@epa.govt.nz
Payment must accompany application; see our fees and charges schedule for details.

Applicant:

Environmental Protection Authority

Date:

08 April 2020

APPLICANT CHECKLIST

Mandatory sections filled out

Appendices enclosed

Fees enclosed

Signed and dated

OFFICE USE ONLY

Application code	**Date received**
EPA contact	**Fees paid $**
Application version no.	

Important

1. Before you fill in this application form, please talk to the EPA. We can help you scope and prepare your request.
2. We need all relevant information early on in the process. Quality information up front will speed up the process.
3. Any extra material that does not fit in the form should be clearly labelled and cross-referenced. If there is commercially sensitive information, it should be collated in a separate document.
4. All applicants must sign the form at the end of Part A and enclose the correct application fee. Please check the EPA's current pricing policy: https://www.epa.govt.nz/applications-and-permits/fees-and-charges/. We are unable to process applications that do not contain the correct fee.
5. Copies of all our application forms are available on our website: http://www.epa.govt.nz.
6. If you have any suggestions for improvements to this form, please contact our operations staff at the address below.
7. You can get more information at any time by telephoning, writing to, or calling in at our Wellington office. One of our staff members will be able to help you.

   Environmental Protection Authority
   Private Bag 63002
   Wellington
   New Zealand
   Telephone: 64 4 916 2426
   Facsimile: 64 4 914 0433
   Email: HSApplications@epa.govt.nz
   http://www.epa.govt.nz

1. Applicant details

This should be the organisation or person formally responsible for this application, and be located within New Zealand.

Name: Dr Allan L Freeth, Chief Executive

Address: Environmental Protection Authority, Private Bag 63002, Waterloo Quay, Wellington 6140

Phone: 04 916 2426

Fax:

Email: reassessments@epa.govt.nz

Service Address (if different from above):

1.2. Contact's details (if different from above).

Name: Miriam Robertson, Acting Group Manager – Hazardous Substances Applications and Reassessments

Address: Environmental Protection Authority, Private Bag 63002, Waterloo Quay, Wellington 6140

Phone: 04 916 2426

Fax:

Email: reassessments@epa.govt.nz

2. Hazardous substance details

2.1. Name of substance (identify the substance as fully as possible).

If more than one substance is involved – for example, the active ingredient and the products – they should all be listed.

This application is to seek grounds to reassess substances for which the EPA has found or received new information.

The substances listed in Schedule 1 are identified as requiring changes to their classifications. Mixtures containing these substances will also require changes to their classifications ("affected mixtures"). The affected mixtures are included in Schedule 1 under the column headed "other approvals potentially affected" for information purposes only.

Any future reassessment application will detail which mixtures are included. The reassessment may cover all or some of the mixtures listed in Schedule 1, as well as any mixtures containing any of the active ingredients listed in Schedule 1 that are approved in the interim period between this grounds application and receipt of the reassessment application.

2.2. If the substance has been assessed by the authority, list the reference number(s) of the existing approval (from the authority's register).

If more than one substance is involved, for example, the active ingredient and the products, they should all be listed.

See Schedule 1.

2.3. If the substance is covered by Parts XI to XV, list any reference numbers of registrations, licenses etc under the Explosives Act, Pesticides Act, Toxic Substances Act, Dangerous Goods Act or Animal Remedies Act.

Not applicable as Parts 11 to 15 of the Hazardous Substances and New Organisms Act have expired.

3. Grounds for reassessment

3.1. Please indicate which category applies.

More than one may be relevant.

Has significant new information relating to the effects of the substance become available?

☒ Yes (go to question 3.2)

Has another substance with similar or improved beneficial effects and reduced adverse effects become available?

☐ Yes (go to question 3.3)

Has information showing a significant change of use of the substance become available?

☐ Yes (go to question 3.4)

Has information showing a significant change in the quantity of the substance manufactured or imported become available?

☐ Yes (go to question 3.5)

Other?

☐ Yes (go to question 3.6)

3.2. Provide details of the significant new information relating to the effects of the substance. (Include the date and some of the information.)

Further information?	☒ Yes	☐ No
Commercially sensitive information?	☐ Yes	☒ No

Regularly, the EPA identifies, or has brought to its attention, errors or inconsistencies in the classifications of substances set in approvals under the HSNO Act 1996. Additionally, new information frequently becomes available in the form of new study data and new or updated registration dossiers from other jurisdictions. The purpose of this application is to obtain grounds to reassess a number of approved substances where new information has been received.

Schedule 1 sets out the approved substances that have been identified as requiring changes, and provides the reasoning for those changes. This schedule also lists the approvals for mixtures containing these substances, in order to obtain grounds to reassess these substances as well.

The identified changes are a result of both internally and externally provided information, and relate to the classifications of the approved substances in this document.

3.3. Provide details of the information relating to the effects of the new substance (include the date and some of the information). The beneficial and adverse effects of the new substance should be compared with those of the substance.

Further information? ☐ Yes ☒ No

Commercially sensitive information? ☐ Yes ☒ No

3.4. Provide details of the significant change of use of the substance (include the former use and information on how this change has come about).

Further information? ☐ Yes ☒ No

Commercially sensitive information? ☐ Yes ☒ No

3.5. Provide details of the significant change in the quantity of the substance manufactured or imported.

Further information? ☐ Yes ☒ No

Commercially sensitive information? ☐ Yes ☒ No

3.6. Provide details of other reasons requesting a reassessment.

Further information? ☐ Yes ☒ No

Commercially sensitive information? ☐ Yes ☒ No

3.7. Provide any other information relevant to the request for reassessment.

Further information? ☐ Yes ☒ No

Commercially sensitive information? ☐ Yes ☒ No

4. Declaration

8 April 2020

Signature of applicant or person authorised on behalf of applicant

Date

Name: Dr Allan L Freeth

Schedule 1: Substances for reassessment

This schedule lists all the non-confidential substances which are proposed for reassessment under this application.

Current classifications and proposed classifications are given. The schedule also includes the justification for the proposed changes. Where classifications are proposed to be changed, the default controls are intended to be amended as appropriate for the new classifications.

Bold lettering indicates affected classifications.

Substances affected	Approval numbers	Current classification	Proposed classification	Justification for change	Other approvals potentially affected
1,3-dichloropropene CAS# 542-75-6	HSR001383	**3.1B**, 6.1C (I), 6.1C (O), 6.1C (D), 6.3A, 6.4A, 6.5B, 6.6B, 6.7B, 6.9B (I), 6.9B (O), 9.1A, 9.2D, 9.3B, 9.4B	**3.1C**, 6.1C (I), 6.1C (O), 6.1C (D), 6.3A, 6.4A, 6.5B, 6.6B, 6.7B, 6.9B (I), 6.9B (O), 9.1A, 9.2D, 9.3B, 9.4B	Documentation submitted to the EPA and information on the International Chemical Safety Card (ICSC) for 1,3-dichloropropene confirm the flashpoint for this substance is above 23 deg C and below 60 deg C (25 deg C stated on the ICSC card). The European Chemical Agency (ECHA) also classified the substance as Flam. Liq. 3, which corresponds to a flashpoint within the range of 23 deg C to 60 deg C. Based on this new information, the classification for this substance should change from 3.1B to 3.1C.	HSR001639 HSR001640 HSR100563 HSR101087 HSR101251 HSR101377
Chlorpropham CAS# 101-21-3	HSR002826	6.1E (O), 6.4A, 6.9B (O), **9.1A**, 9.2A	6.1E (O), 6.4A, 6.9B (O), **9.1B**, 9.2A	The EPA notes that the current 9.1A classification for chlorpropham is based on the E_bC_{50} (ie, the concentration at which 50% reduction of biomass is observed) from the *Navicula pelliculosa* algae study. The preferred observational endpoint for classification and risk assessment by the EPA is algal growth rate inhibition (E_rC_{50}) (the concentration at which a 50% inhibition of growth rate is observed). The E_bC_{50} is only used for classification if there are no E_rC_{50} values available. The EPA notes that there are E_rC_{50} values available from the recent EFSA review of chlorpropham (EFSA 2017). All of these values indicate that a 9.1B classification is appropriate for chlorpropham and the current harmonised Globally Harmonised System (GHS) classification in the European Union is “Aquatic Chronic 2” which is equivalent to a 9.1B classification. The EPA therefore considers that the classification of chlorpropham for aquatic ecotoxicity should be changed from a 9.1A to a 9.1B classification. Although chlorpropham is not bioaccumulative and is rapidly biodegradable, its classification cannot be downgraded because	HSR000637 HSR000651 HSR000823 HSR007885 HSR100992 HSR101364

				the chronic No Observed Effect Concentration (NOEC) is 0.32 mg/L for Zebra fish (*Brachydanio rerio)* (below the 1 mg/L threshold).	
Flumetsulam CAS# 98967-40-9	HSR003440	**6.4A**, 9.1A, 9.2A	9.1A, 9.2A	New data is available from the REACH registration dossier from Europe. In the dossier key study for eye irritation, flumetsulam was only associated with slight conjunctival redness and slight chemosis up to 24 hours after exposure, with no signs of irritation observed at 48 or 72 hours after exposure. We propose to remove the 6.4A classification for flumetsulam since it does not meet the threshold for classification for eye irritancy.	HSR100555 HSR100734 HSR100817 HSR100906 HSR101340 HSR101368
Flumioxazin CAS# 103361-09-7	HSR005387	**6.8A**, 9.1A	**6.8B**, **6.9B (O)**, 9.1A, **9.2A**	Classification changes for flumioxazin are proposed based on a hazard assessment conducted by the EPA in 2018 as part of application APP203429. In the studies reviewed, flumioxazin was shown to have an adverse impact on reproductive potential with reduced foetal survival post-partum at doses below those inducing maternal toxicity, and was shown to have teratogenic potential in rats. There is a convincing weight of evidence to conclude that flumioxazin is unlikely to present a reproductive hazard to humans and should not be classified 6.8A. A 6.8B classification for reproductive/developmental toxicity is however justified. Flumioxazin also demonstrated potential to cause anaemia and chronic nephropathy in rats after repeated exposures, as well as liver toxicity in mice and dogs (with less sensitivity), and should be classified as 6.9B (oral) for toxicity from repeated oral exposure. Data assessed by the EPA also showed that flumioxazin was very ecotoxic to non-target plants and should be classified 9.2A.	-

MCPA CAS# 94-74-6	HSR003327	**6.1D (D)**, **6.1D (I)**, 6.1D (O), **6.3B**, **6.9A (O)**, 8.3A, 9.1A, 9.2A, 9.3B	6.1D (O), **6.9B (O)**, 8.3A, 9.1A, 9.2A, 9.3B	Based on information from the US EPA (US EPA 2004) and EU (European Commission 2008) review reports, MCPA should not be classified for dermal or inhalation toxicity. The EU and US EPA review documents state that MCPA is not a skin irritant. It is considered appropriate to use the information in the review documents and not to classify MCPA as a skin irritant. The 6.9A (oral) classification of MCPA is based on a 1 year study in dogs in which adverse effects were found in the liver and kidney. However, the Joint Meeting on Pesticides Residues (JMPR) review concluded that the dog was an unsuitable surrogate for humans because of its relatively low renal capacity to excrete MCPA ion, leading to higher toxicity than in other species (JMPR 2012). A Lowest Observed Adverse Effect Level (LOAEL) of 35 mg/kg bw from a 90 day oral study in rats supports a classification of 6.9B (oral).	HSR000348 HSR000353 HSR000359 HSR000362 HSR000364 HSR000379 HSR000381 HSR000406 HSR000417 HSR000418 HSR001739 HSR100124 HSR100136 HSR100309 HSR100501 HSR100698 HSR100775 HSR100816 HSR100906
MCPA dimethylamine salt CAS# 2039-46-5	HSR003337	**6.1D (D)**, **6.1D (I)**, 6.1D (O), **6.3A**, **6.5B**, **6.8B**, **6.9A (O)**, **6.9A (I)**, 8.3A, **9.1D**, 9.2A, 9.3B	6.1D (O), **6.3B**, **6.9B (O)**, 8.3A, **9.1A**, 9.2A, 9.3B	Based on information from the US EPA (US EPA 2004) and EU (European Commission 2008) review reports, the MCPA dimethylamine (DMA) salt should not be classified for dermal or inhalation toxicity. The US EPA document states that the MCPA amine is a slight dermal irritant (Category III). The JMPR report (JMPR 2012) states that nil to slight skin irritation occurred in rabbits, depending on the formulation. Given that the JMPR and US EPA reports indicate	HSR000381 HSR000405 HSR002461 HSR100774 HSR100906 HSR101083

				that there are test data to support nil to slight skin irritation, it is proposed that the 6.3A classification is changed to 6.3B. Given that both the JMPR and US EPA documents state that MCPA DMA is not a skin sensitiser, it is proposed that the 6.5B classification is also removed. It is proposed that the 6.8B classification is removed on the basis of rat studies which showed developmental effects only occurring at maternally toxic doses. As it is known that this salt rapidly dissociates into the MCPA ion and dimethylammonium ion, information can be read across from the free acid. Rabbit and rat studies on MCPA showed no evidence of reproductive effects up to the highest tested dietary concentrations, supporting the removal of the 6.8B classification. MCPA DMA was classified 6.9A (oral) based on the classification for MCPA, and 6.9A (inhalation) based on the classification for methanamine. As it is proposed above to change the 6.9A (oral) classification of MCPA to 6.9B (oral), it is appropriate that this substance also be classified 6.9B (oral). Furthermore, the JMPR and US EPA documents state that no data are available on long-term toxicity by the inhalation route. Based on the available information, it is considered that the 6.9A (inhalation) classification should be removed from MCPA DMA. MCPA dimethylamine salt is highly toxic to aquatic plants (*Lemna gibba* EC50 = 0.17 mg/L). As per the user guide to threshholds and classification in the HSNO Act, the substance should be classified as 9.1A based on toxicity to aquatic plants. The change also aligns the aquatic toxicity classification with that of the MCPA free acid.	HSR101163 HSR101236 HSR101260 HSR101368

MCPA (Ethylhexyl ester) CAS# 29450-45-1	-	**6.1D (D)**, 6.1D (O), **6.1D (I), 6.4A**, **6.9A (O),** 9.1A, 9.2A	6.1D (O), **6.5B**, **6.9B (O)**, 9.1A, 9.2A, **9.3B**	Based on information from the US EPA (US EPA 2004), EU (European Commission 2008) review reports and REACH registration dossier, the MCPA ethylhexyl ester should not be classified for dermal or inhalation toxicity. The results of an OECD guideline 405 study assessing eye irritation conducted in 2008 submitted to ECHA under the REACH registration dossier indicated essentially no evidence of any eye irritation. We propose to remove the 6.4A classification. Based on data in the ECHA REACH registration dossier and the US EPA review report, MCPA ethylhexyl ester should be classified as a skin sensitizer 6.5B but not as a skin irritant.. As it is proposed above to change the 6.9A (oral) classification of MCPA to 6.9B (oral), it is appropriate that this substance also be classified 6.9B (oral). On the basis of expert judgement, the toxicity of the substances are associated with the MCPA portion of the salts and esters. The toxicity of the ester is predicted to be similar or higher than the MCPA free acid, therefore a 9.3B classification should be applied to MCPA Ethylhexyl ester.	HSR000360
MCPA, sodium salt CAS# 3653-48-3	-	**6.1D (D)**, 6.1D (O), **6.1D (I), 6.9A (O),** 9.2A, 9.3B	6.1D (O), **6.9B (O)**, **8.3A**, **9.1A**, 9.2A, 9.3B	Based on information from the US EPA (US EPA 2004) and EU (European Commission 2008) review reports, the MCPA sodium salt should not be classified for dermal or inhalation toxicity. As it is proposed above to change the 6.9A (oral) classification of MCPA to 6.9B (oral), it is appropriate that this substance also be classified 6.9B (oral). Based on information from the US EPA and the 8.3A classification for MCPA, we propose to add the 8.3A classification to this substance. In the EU, the recommendation is to classify all MCPA salts and esters as 9.1A (GHS Aquatic Acute 1). Given that the toxicity of	HSR000726 HSR101026

				the salts and esters are mainly attributed to the MCPA portion, and it has been demonstrated that a 9.1A classification should apply to other MCPA salts, we consider this classification appropriate for MCPA sodium salt.	
MCPA, potassium salt CAS# 5221-16-9	-	**6.1D (D)**, 6.1D (O), **6.1D (I), 6.9A (O),** 9.2A, 9.3B	6.1D (O), **6.9B (O)**, **8.3A**, **9.1A**, 9.2A, 9.3B	Based on a read across on information from the US EPA (US EPA 2004) and EU (European Commission 2008) review reports on MCPA sodium salt, the MCPA potassium salt should not be classified for dermal or inhalation toxicity. As it is proposed above to change the 6.9A (oral) classification of MCPA to 6.9B (oral), it is appropriate that this substance also be classified 6.9B (oral). Based on information from the US EPA and the 8.3A classification for MCPA, we propose to add the 8.3A classification to this substance. In the EU the recommendation is to classify all MCPA salts and esters as 9.1A (GHS Aquatic Acute 1). Given that the toxicity of the salts and esters are mainly attributed to the MCPA portion, and it has been demonstrated that a 9.1A classification should apply to other salts, we consider this classification appropriate.	HSR100909 HSC100133
MCPA-thioethyl CAS# 25319-90-8	HSR005152	**6.1D (D),** 6.1D (O)**, 6.1D (I), 9.3C**	6.1D (O)**, 9.1A, 9.2A, 9.3B**	According to the EU Classification, Labelling and Packaging Regulation report from 2016 (CLH report 2016), this compound should only be classified 6.1D (oral). It should not be classified for dermal toxicity as the LD_{50} is >5000 mg/kg, neither for inhalation toxicity as the LC_{50} was noted to be >5 mg/L. The 9.1A and 9.2A classifications of MCPA acid should be applied to MCPA salts based on a read across approach consistent with the US EPA bridging strategy adopted in the Reregistration Eligibility Decision (RED) for MCPA and associated salts (US EPA 2004). Given that the toxicity of the substances are associated	-

				with the MCPA portion of the salts and esters, the toxicity of the ester is predicted to be similar or higher than the MCPA free acid. A 9.3B classification should be applied based on read across. The lowest endpoint available for MCPA-thioethyl is >400 mg/kg bw which provides insufficient information to downgrade the classification.	
Metamitron CAS# 41394-05-2	HSR003442	6.1D (O), **6.1D (D)**, **6.1B (I)**, 9.1A, 9.2A, 9.3C	6.1D (O), **6.1D (I)**, 9.1A, 9.2A, 9.3C	Information is available from the EFSA Scientific Report 2008 for this substance (EFSA 2008). This substance has a LC_{50}=3.17 mg/L for inhalation in the key studies reviewed in the EFSA report and we therefore propose to change the 6.1B (inhalation) classification to 6.1D (inhalation). The dermal LD_{50} is > 5000 mg/kg bw and so does not trigger any classification for dermal toxicity. We propose to remove the 6.1D (D) classification.	HSR000535 HSR008044 HSR100524 HSR100598 HSR100753 HSR100882 HSR101136 HSR101145 HSR101154 HSR101178 HSR101186 HSR101235 HSR101295 HSR101339 HSR101345 HSR101361

Monensin CAS# 17090-79-8	HSR002865	**6.1A (O)**, 6.3B, 6.5B, 8.3A, 9.1A, 9.2B, 9.3A	**6.1B (O)**, 6.3B, 6.5B, 8.3A, 9.1A, 9.2B, 9.3A		-
Monensin sodium CAS# 22373-78-0	HSR003276	**6.1A (O)**, 6.3B, 6.5B, 8.3A, 9.1A, 9.2B, 9.3A	**6.1B (O)**, 6.3B, 6.5B, 8.3A, 9.1A, 9.2B, 9.3A	The species utilised in the key study supporting the previous classifications of monensin and monensin sodium is now considered inappropriate due to its known atypical sensitivity to this class of compounds. Furthermore, it is not a typical or validated species to use in assessing acute toxicity effects. Based on publicly available scientific literature (JECFA-Joint FAO/WHO Expert Committee on Food Additives 2009A and EMEA-European Medicines Agency 2007), the appropriate LD_{50} values for oral acute toxicity for this substance range between 22 and 96 mg/kg bw. Therefore, adopting the lowest appropriate LD_{50} value of 22 mg/kg bw for classification purposes, we propose to change the classification from 6.1A (O) to 6.1B (O) for both monensin and monensin sodium.	HSR000019 HSR000968 HSR002010 HSR002017 HSR002039 HSR002315 HSR002317 HSR002521 HSR007841 HSR007985 HSR100500 HSR100701 HSR101128
Narasin CAS# 55134-13-9	-	**6.1A (O)**, 6.9A (O), 8.3A, 9.1A, 9.2B, 9.3A	**6.1B (O)**, 6.9A (O), 8.3A, 9.1A, 9.2B, 9.3A	The species utilised in the key study supporting the previous classification of narasin is now considered inappropriate due to its known atypical sensitivity to this class of compounds. Furthermore, it is not a typical or validated species for use in assessing acute toxicity effects. Based on publicly available scientific literature (JECFA-Joint FAO/WHO Expert Committee on Food Additives 2009B), the LD_{50} for oral acute toxicity that must be used for this substance is 22 mg/kg bw. Therefore, we propose to change the classification from 6.1A (oral) to 6.1B (oral) for narasin.	HSR002021 HSR002035

Pymetrozine CAS# 123312-89-0	-	6.9B (O), 9.1C	6.9B (O), **6.7B**, 9.1C	New information is available for pymetrozine that supports classifying pymetrozine as a suspected human carcinogen, 6.7B. Both the European Union (CLH report 2017) and the US EPA (US EPA 2000) have identified that pymetrozine has carcinogenic properties. The EPA considers that this classification should apply to pymetrozine and all substances containing ≥ 0.1% pymetrozine.	HSR000412 HSR000413 HSR100290 HSR101205
Tea tree oil CAS# 68647-73-4	HSR003519	3.1C, 6.1D (O), 6.3A, 6.4A, 9.3C	3.1C, **6.1D (l)**, 6.1D (O), 6.3A, 6.4A, 9.3C	The current classification was assigned during the process of transfer to management under the HSNO Act, but a full data set was not reviewed during this process. The EPA reviewed the publicly available data on tea tree oil and proposes to add an acute toxicity 6.1D (inhalation) classification. Results of an LC_{50} study from the ECHA REACH registration dossier noted the combined (M/F) LC_{50} is 4.78 mg/L. This supports the new classification 6.1D (inhalation).	HSR002482 HSR002521 HSR002530 HSR002552 HSR100341 HSR100696 HSR100757 HSR101142
Thiodicarb CAS# 59669-26-0	HSR002882	6.1B (O), 6.1B (I), 6.1E (D), 6.4A, 6.9B (O), 9.1A, 9.3A	6.1B (O), 6.1B (I), 6.1E (D), 6.4A, 6.9B (O), 9.1A, 9.3A, **9.4A**	According to the EFSA scientific report (EFSA 2006), the LD_{50} (48 hour oral) is 0.153 ug of active ingredient (ai)/bee and the LD_{50} (48 hour contact) is 3.1 ug ai/bee. These values are consistent with the values available for a 375 g/L thiodicarb-containing formulated substance which are 0.547 ug formulation/bee (oral) and 4.643 ug formulation/bee (contact). This corresponds to a thiodicarb equivalent of 0.184 and 1.56 µg ai/bee, which is in the same order of magnitude as the reported toxicity of the pure active ingredient. The data support a 9.4A classification.	HSR000138 HSR000139 HSR000717 HSR000963 HSR007990 HSR101066
Trinexapac-ethyl CAS# 95266-40-3	-	6.1E (O), 9.1A, **9.2D**	6.1E (O), 9.1A, **9.3C**	Classification changes for trinexapac-ethyl are proposed based on a hazard assessment conducted by the EPA in 2019 as part of application APP203771. The substance is currently classified as 9.2D based on data from the UK 1995 Pesticides Safety Directorate. The studies supporting the previous classification have a study duration of greater than 14 days so do not adhere to current international test guidelines.	HSR000802 HSR100067 HSR100269 HSR100371 HSR100710 HSR100680

				Consequently, the EPA considers that no existing data supports the soil ecotoxicity classification of trinexapac-ethyl. New data provided in APP203771 showed the substance was harmful to terrestrial vertebrates. Based on the acute toxicity to zebra finch (*Taeniopygia guttata*, acute oral LD_{50} = 1684 mg/kg bw), the substance should be classified as a 9.3C.	HSR101219 HSR101220

Other approval potentially affected by the changes mentioned in the table above: HSR100010

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